

ISPE: Pharma Industry Outlook



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Linking Past ISPE Drivers...to Today

- **The industry's perfect storm - declining revenue, patent cliffs, low R&D...**
 - Lead industry to reduce cost and improve supply chain efficiency

The Past ...

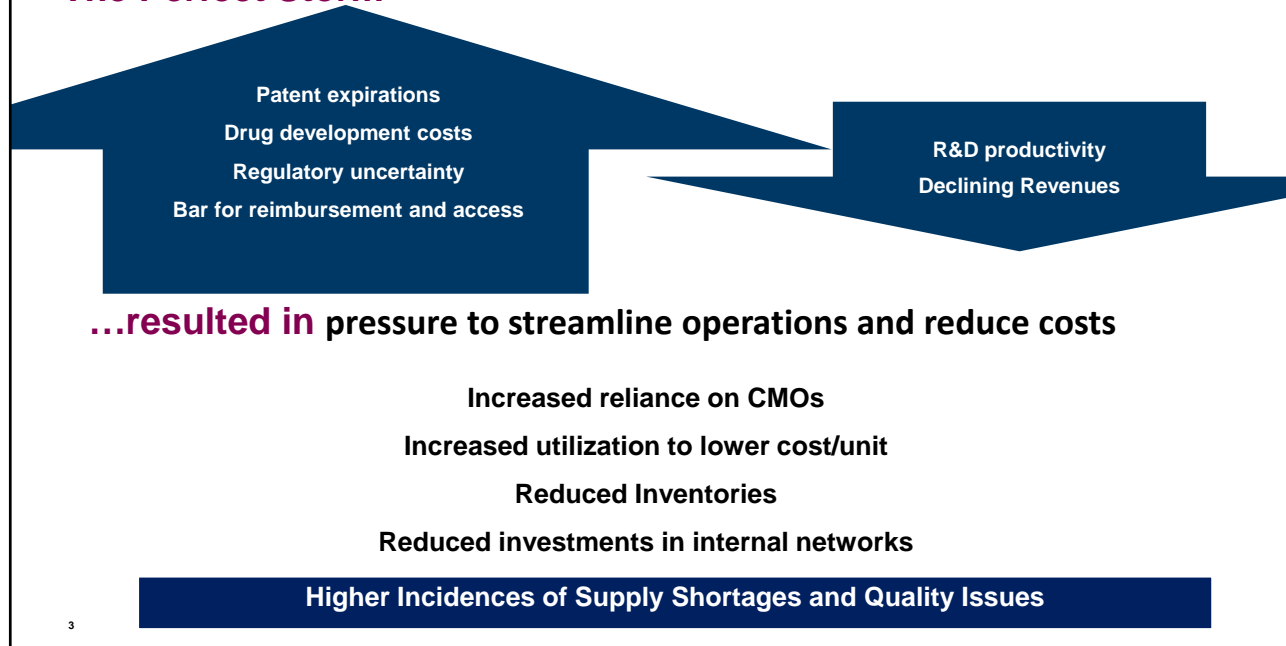
- **Did we get the balance right?**
 - Quality versus cost tradeoffs
 - Supply versus cost tradeoffs
 - Consolidation to reduce costs (essential to industry valuation), but it increased supply risks

Today...

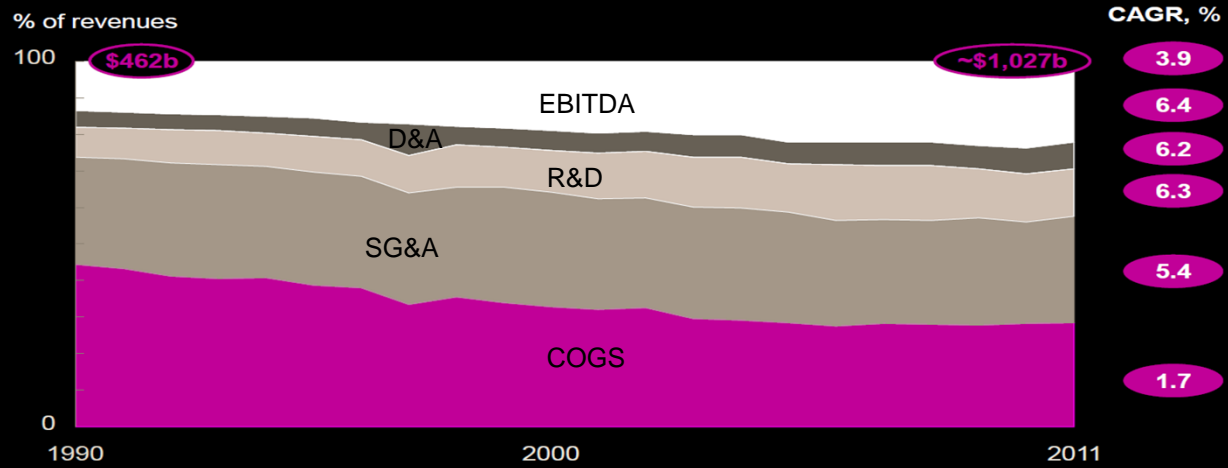
- **Pipelines are robust and accelerating**
- **The supply network - facilities, sites, and suppliers are lean and strained**

**How Do We Know That We Have a Robust Supply Chain
and Understand its Risks?**

The Perfect Storm



Response from Industry (Great Performance by Supply Chain)... Reduce COGM to Preserve Earnings



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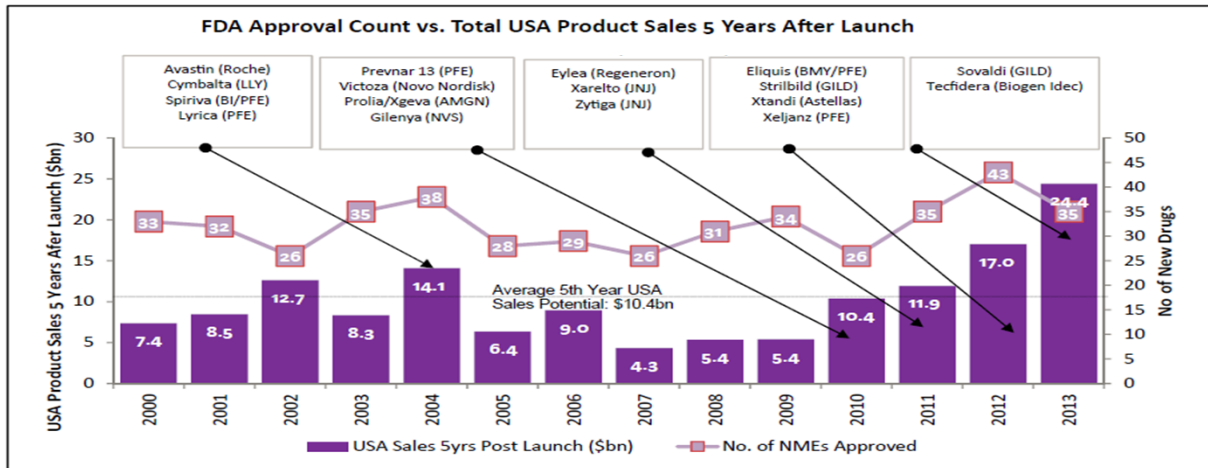
Source: McKinsey and Company, October 13, 2014 ISPE Presentation

Industry Trend:
Suddenly R&D Hits Growth Spurt
New BLAs Submitted at an Historic Rate

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2013 - Good Year for Drug Approvals

Nine of the top ten forecast to reach >1\$B sales in US five-years post launch

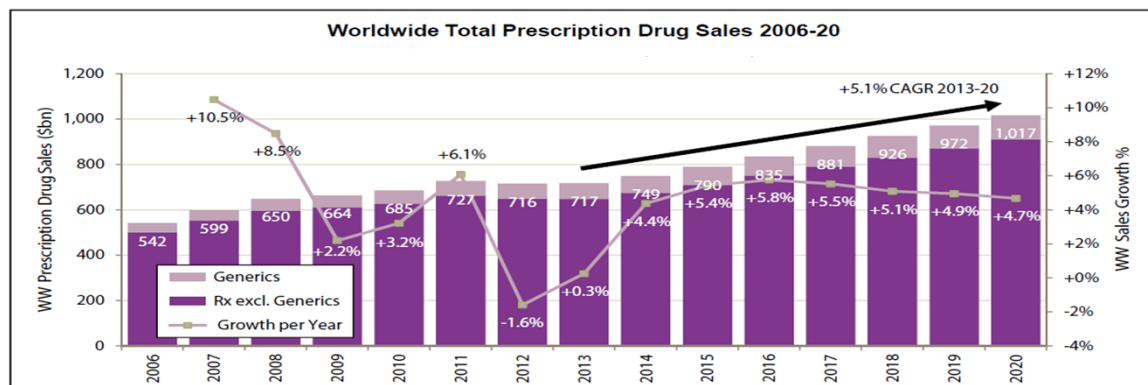


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Source: Evaluate Pharma, June 2014

>\$1 Trillion Dollars of Worldwide Rx Sales by 2020

Return to growth after 2012 contraction

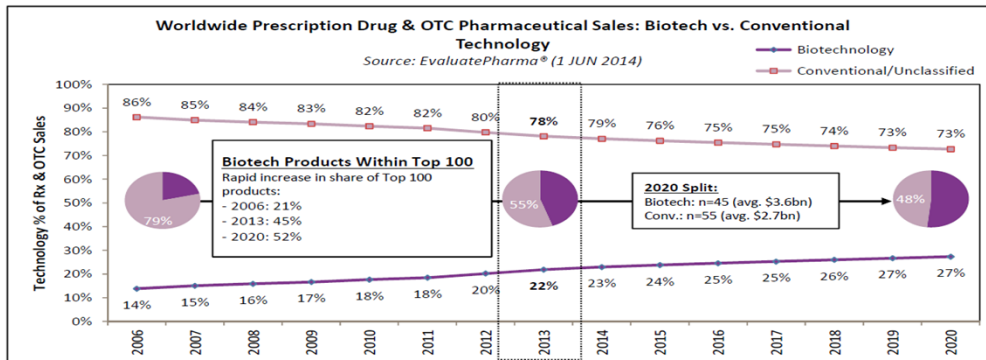


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Source: Evaluate Pharma, June 2014

Clear Growth Within the Large Molecule/ Biologics Space

% Bio sales within top 100 products expected to increase to 52%

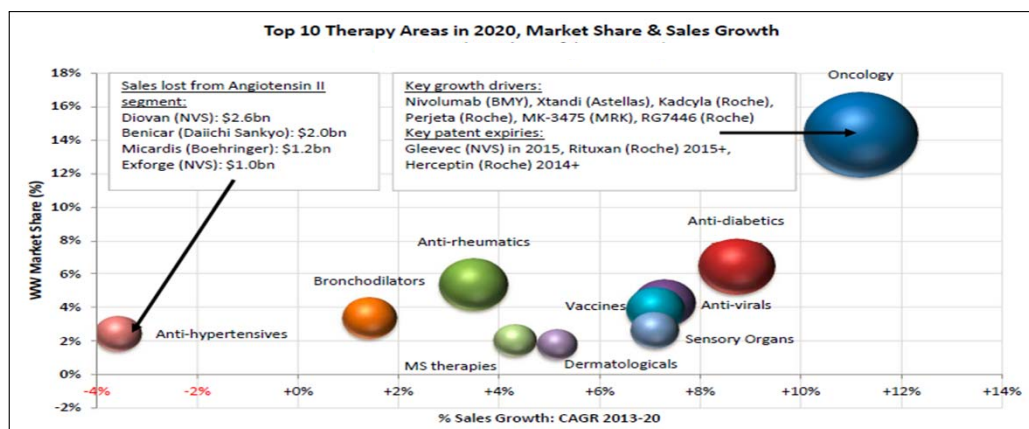


Biologics Sales
14% in 2006 to
27% in 2020

Source: Evaluate Pharma, June 2014

Oncology Has Largest and Fastest Growth ...11% Growth Annually

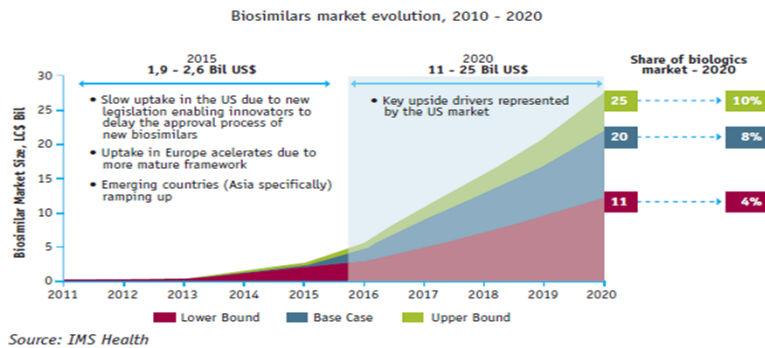
Driven by new class of anti-cancer products targeting the PD-1/ PD-L1 pathway



Source: Evaluate Pharma, June 2014

Biosimilar Market of \$25B by 2020 Will Absorb Significant Capacity Too

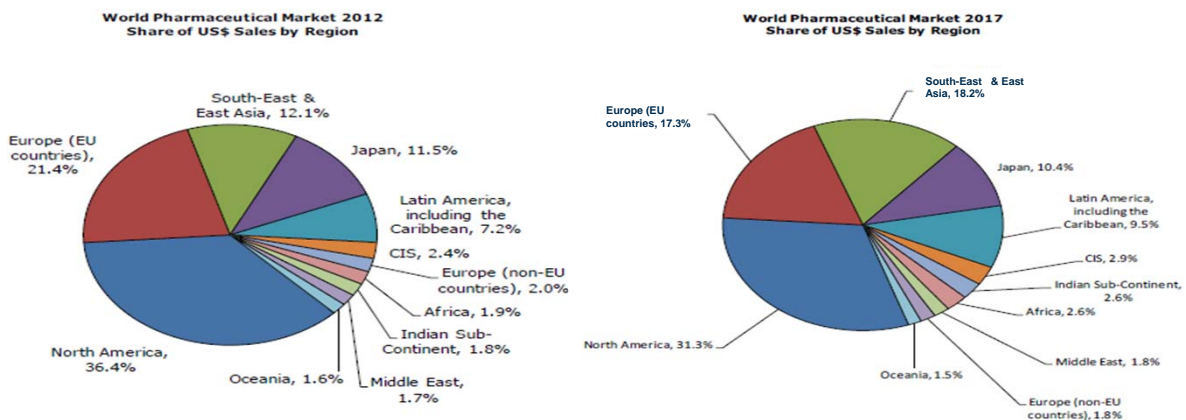
FIGURE 5: US WILL REPRESENT THE CORNERSTONE OF THE BIOSIMILARS MARKET IN THE LONG RUN, WITH AN UPSIDE POTENTIAL OF UP TO 25 BIL US\$ IN 2020



Biosimilars are also expected to grow the overall market increasing the need for capacity

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Emerging Markets Grow From 30% in 2012 to 40% of Global Rx Sales by 2017

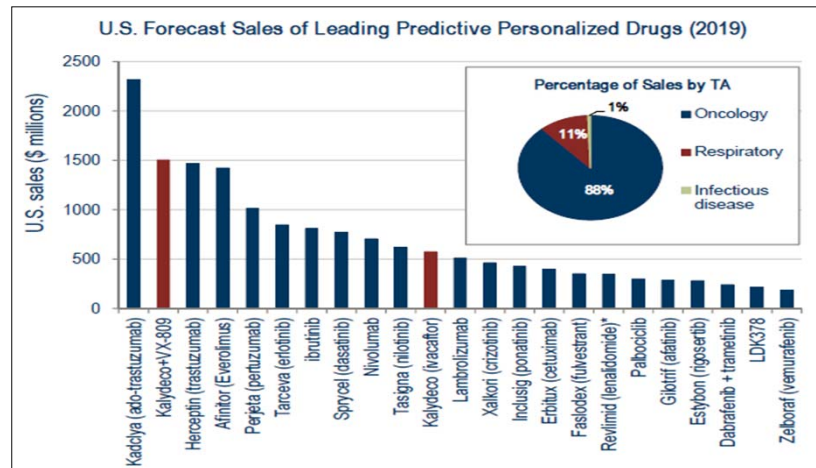


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Source: IMS Market Prognosis, Global 2013-2017, V1.0

US Market for Predictive Personalized Drugs is Expected to Double from 2013 to 2019

Oncology represents largest % of drugs with predictive CDx device or assay



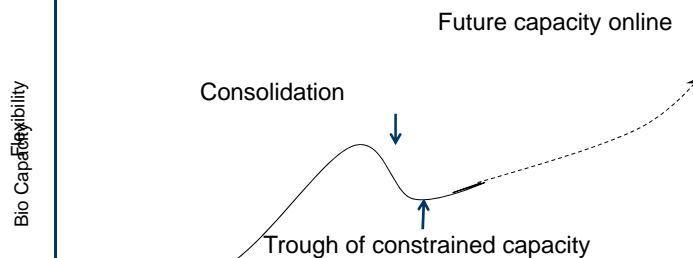
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Source: 2013 DR/ Decision Resources LLC

Yet...

We Are Now At Our Lowest Point of Capacity Agility and Resilience

Pinched!
Limited capacity to support new growth

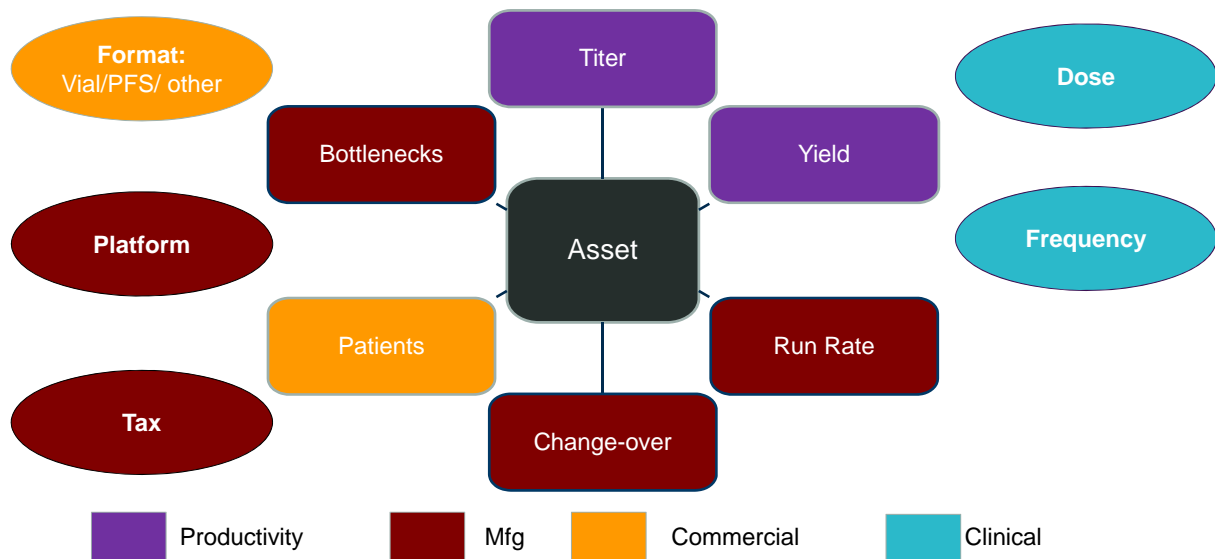


**17 bio facilities being added now...
On-line in time?**

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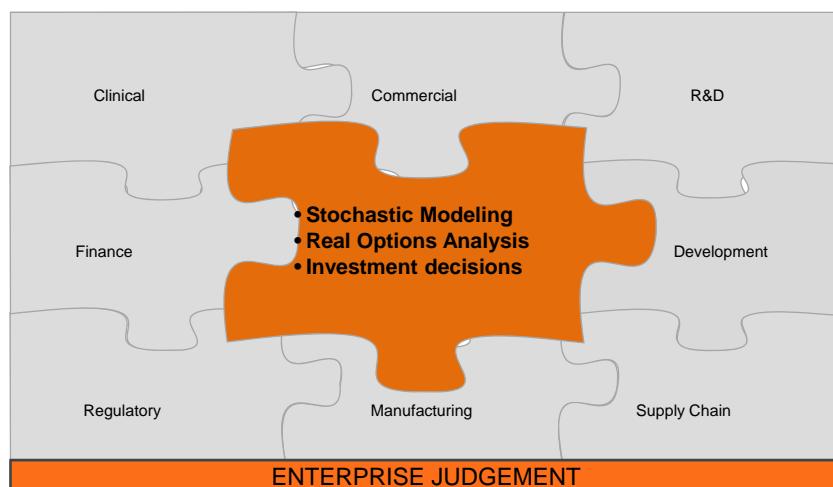
Source: Adapted from Gartner Hype Cycle

Planning for Growth- Broad Range of Uncertainty



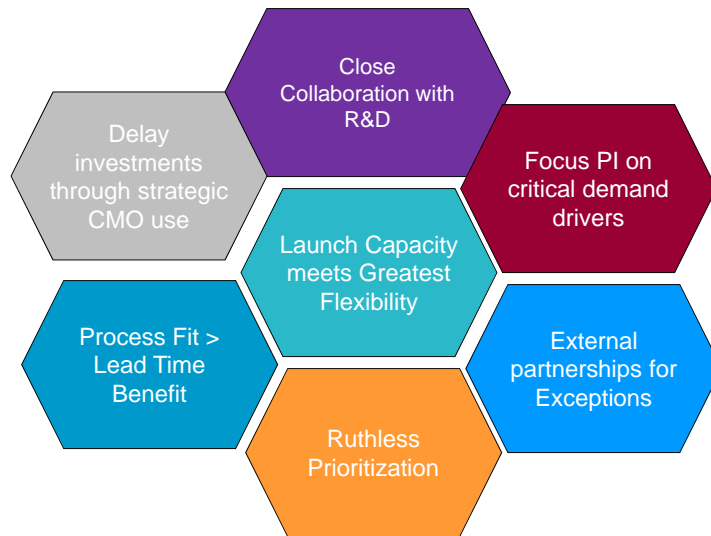
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What is Needed: Tying Together Information Across Diverse Groups to Create Functional Interoperability



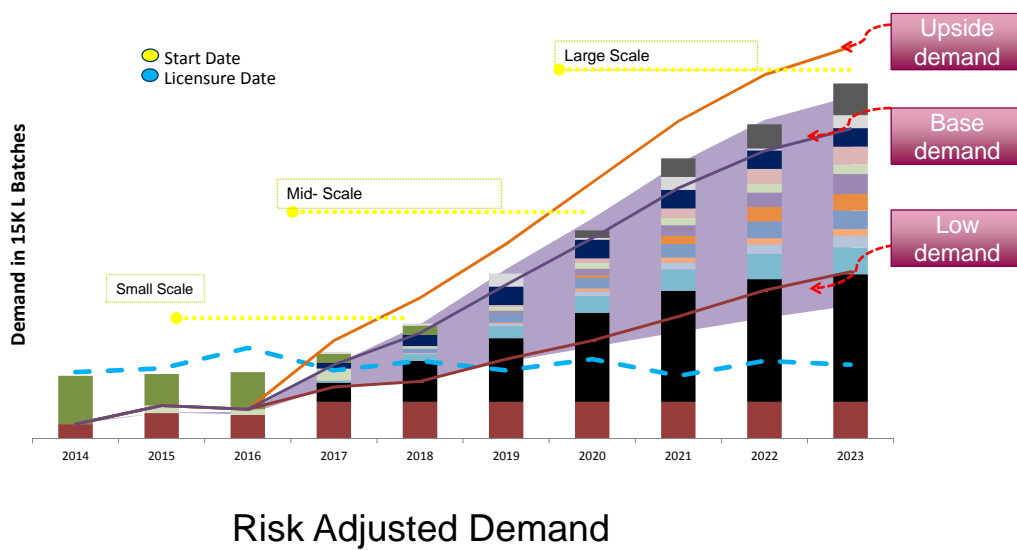
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Strategic Implications



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To What Level of Demand Would You Build? And By When?



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What Does All This Mean?

- **Depends on whether you are in Small Molecule versus Bio!**
- **Small Molecule**
 - Growth focused upon emerging market
 - Pipelines showing promise for some but others still 4 to 5 years away
 - New pipeline may drive some re-investment in API
- **Bio/Large Molecule**
 - Very strong pipelines nearing fruition
 - 20+ large scale plants under construction
 - Bulk DS capacity very constrained 2016-2021
 - CMO's sold out
 - DP CMO capacity can be at risk : Quality
- **Resources**
- **Both Small and Bio/Large Molecule**
 - Primary Care → Specialty Care
 - High Value / Low Volume
 - Further Small Molecule footprint consolidations in Western markets

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Our Vision for ISPE

- **Our history, our founding, our growth has always been tied to deliver of value to our Firms and Members in the Manufacturing Space**
 - Engineering: Support of new facilities
 - Future technical needs
 - Manufacturing: Especially the development and start-up of new facilities
 - Regulatory Affairs: New facility licenses or license to operate
- **It is important to understand that our focus on Regulatory Affairs is not tied to detailed technical content where that content is not directly related to our primary mission**
- **If our firms do not see value in ISPE membership, current economics will restrict membership**
- **Equally, if our members do not see personal or career value in membership, time constraints will restrict membership**

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Our Vision for ISPE

- **Collectively across the full spectrum of our industry, we are now facing a growth stage**
 - But not in our traditional areas of expectation
- **In our traditional products space Emerging Markets (China, Southern Hemisphere) are large growth segment**
 - Some companies looking at double digit growth in China
 - Southern Hemisphere
 - Japan
- **Pipelines in both small and large molecules maturing for many firms**
 - With a vengeance!
 - Fast track, Break-through Therapies are driving huge accelerations in timeline

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Questions??

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