



# Business Development Fundamentals

Finance Concepts in Licensing



Biotechnology  
Industry  
Organization



# Business Development Fundamentals

## FINANCE CONCEPTS IN LICENSING

### Valuation Methodology

*John Selig, Woodside Capital Partners*

[john.selig@woodsidecap.com](mailto:john.selig@woodsidecap.com)

### **Building a Business Development Model**

*Philippe Nore, MiNDERA*

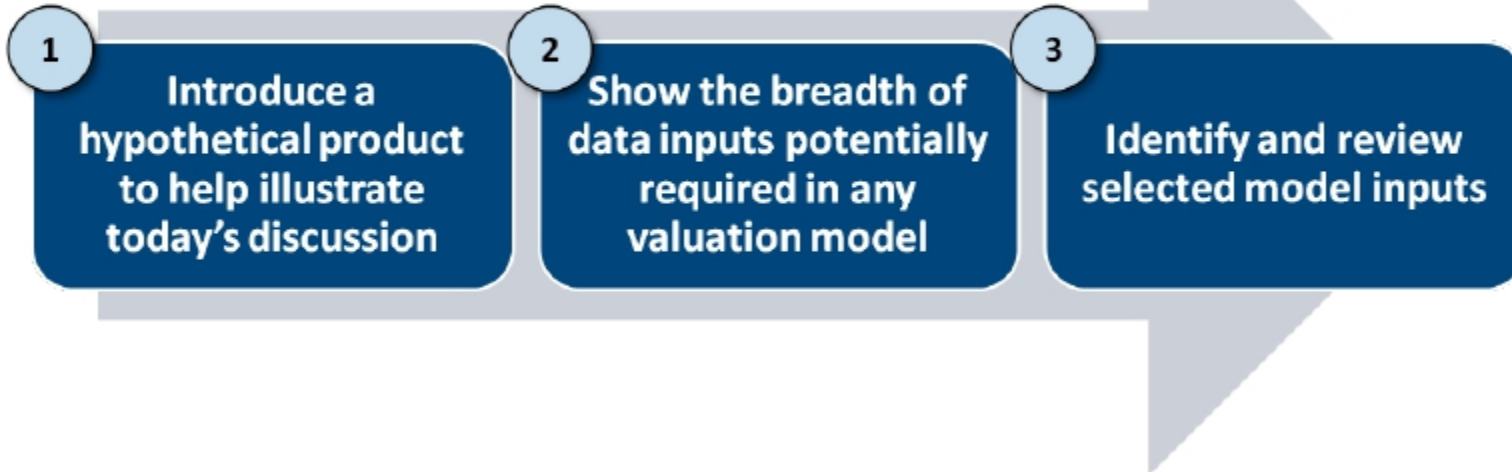
*Materials developed by Campbell Alliance*

[pnore@minderadx.com](mailto:pnore@minderadx.com)



# Business Development Fundamentals

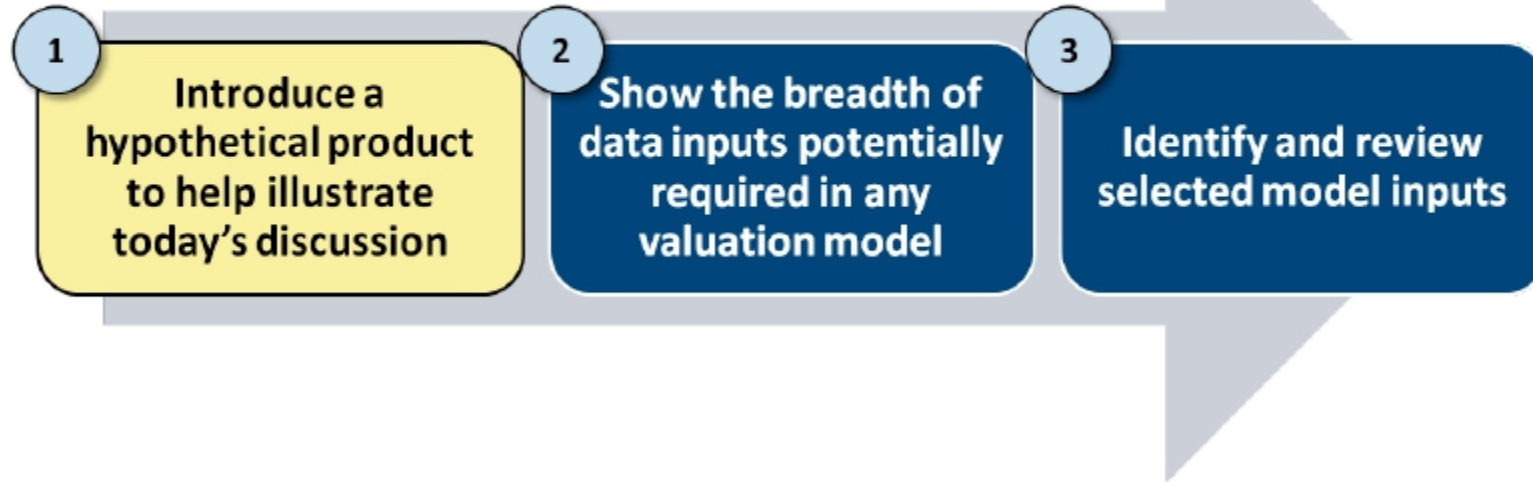
The next section of today's discussion will be to arm you with knowledge about the key data sources to use when building valuation models and to alert you to common mistakes that can occur along the way.





# Business Development Fundamentals

We will first provide you with the details of a hypothetical product that will help guide today's discussion.





# Business Development Fundamentals

**As we think about the key inputs to building a valuation model and the data sources used to generate those inputs, it will be helpful to reference a hypothetical product.**

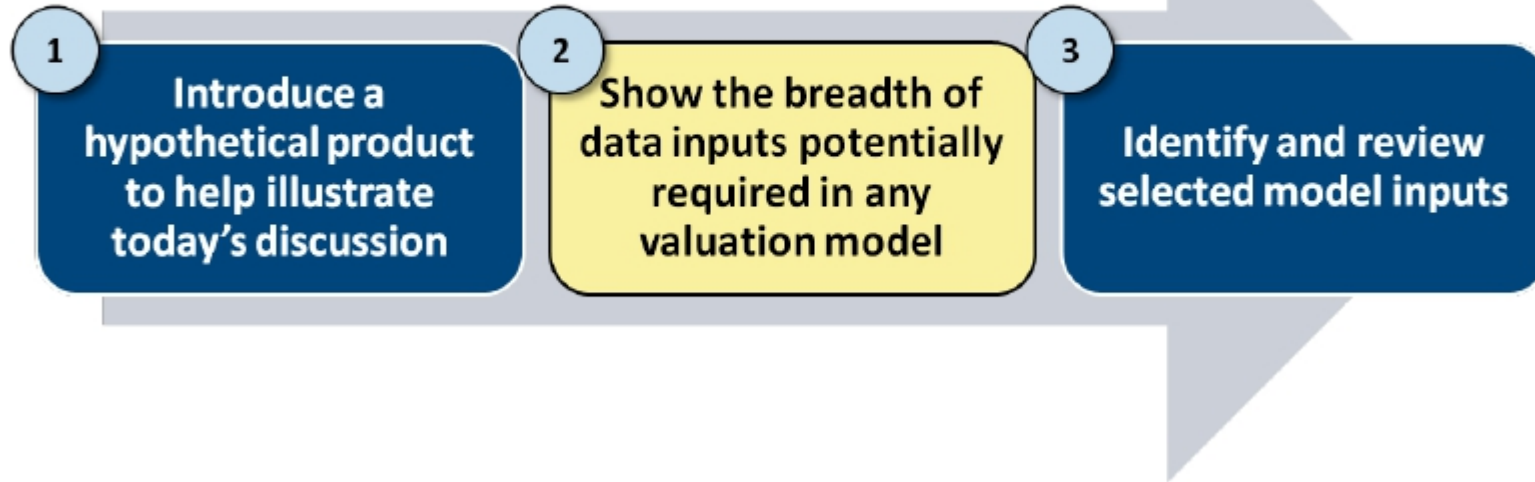
- Our hypothetical product, “Zaxxon,” is a molecule currently in development for moderate to severe Crohn’s disease.
- It has the potential to be a very effective medication, but it comes with some side effects that we can assume will relegate it to always be a later-line therapy.
- We expect this product to enter phase III trials in October 2015.
- For the sake of simplicity we will imagine that we are only interested in the potential value of this product in the US.
- The drug is expected to be prescribed almost exclusively by specialists (gastroenterologists).
- Patent expiration for Zaxxon is expected to occur in late 2025.





# Business Development Fundamentals

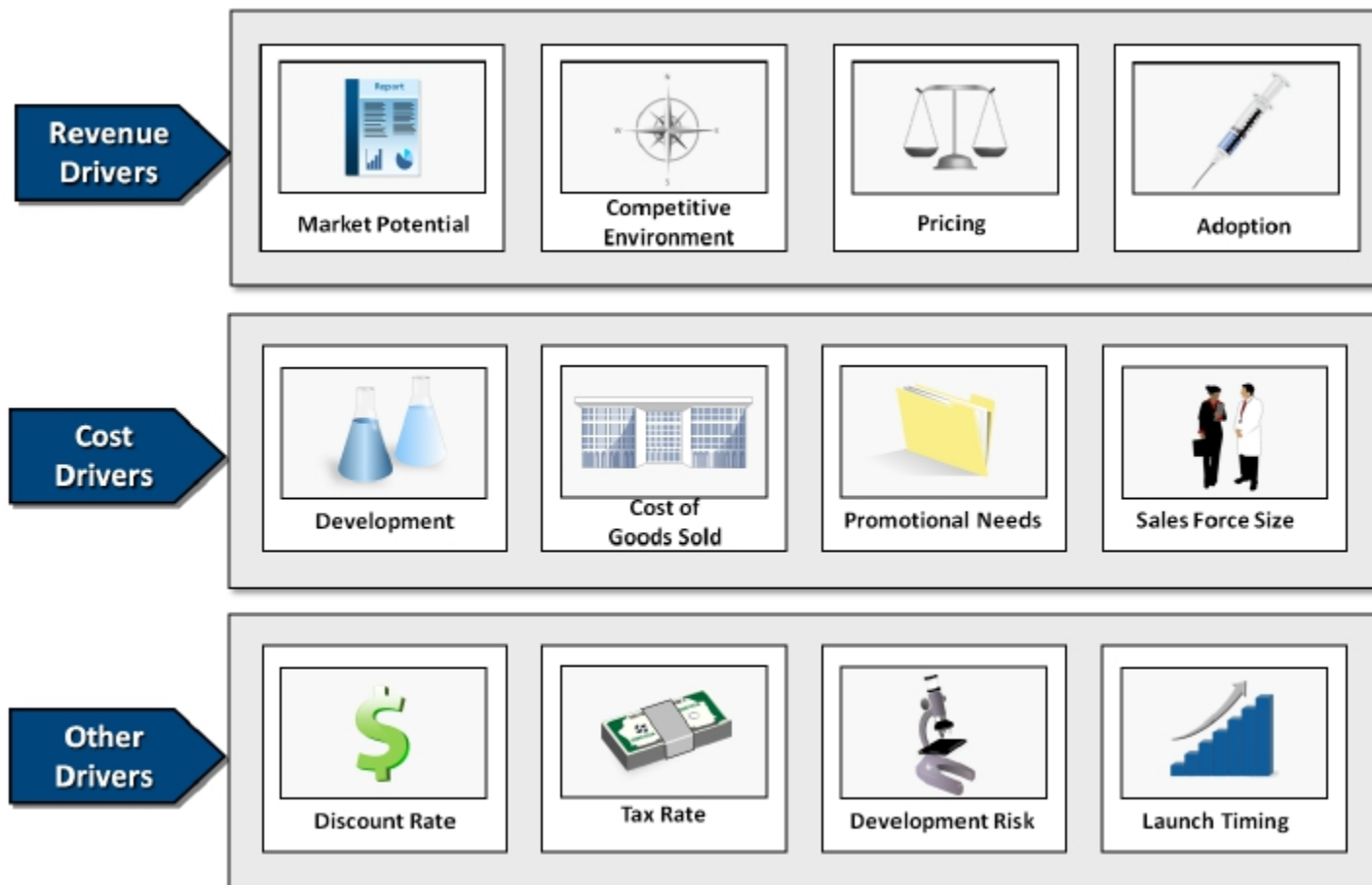
Building a valuation model requires you to make assumptions for a number of different forecast drivers.





# Business Development Fundamentals

Model inputs can be divided into three segments: revenue, cost, and other, which account for inputs that are neither revenue nor cost drivers.







# Business Development Fundamentals

When developing valuation models, it is important to remember that the forecast estimate is only as good as the assumptions that go into it. Significant time must be invested in identifying appropriate data sources that can support valid forecast assumptions.

## Revenue Inputs

- Patient flow
- Product adoption
- Price of therapy
- Reimbursement
- Payer access
- Length of therapy
- Number of episodes per year

## Cost Inputs

- Development
- Sales force
- Pre-launch marketing
- Post-launch marketing
- Costs of goods sold
- Rebates/discounts
- NDA application
- Milestone payments

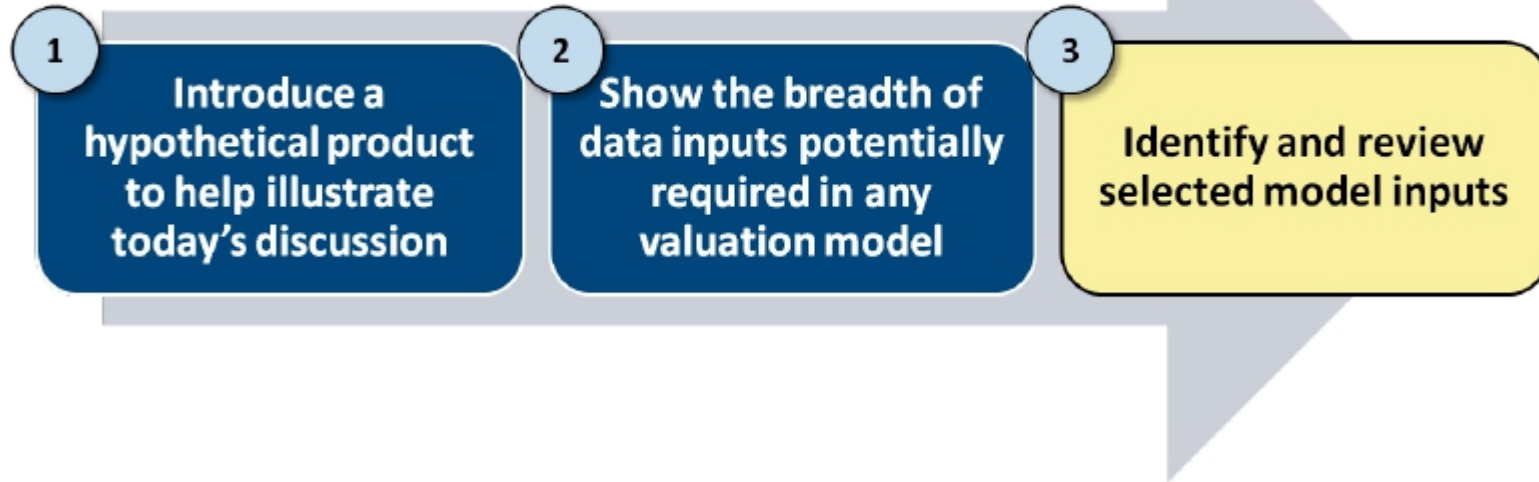
## Other Inputs

- Discount rate
- Tax rate
- Development risk
- Launch timing



# Business Development Fundamentals

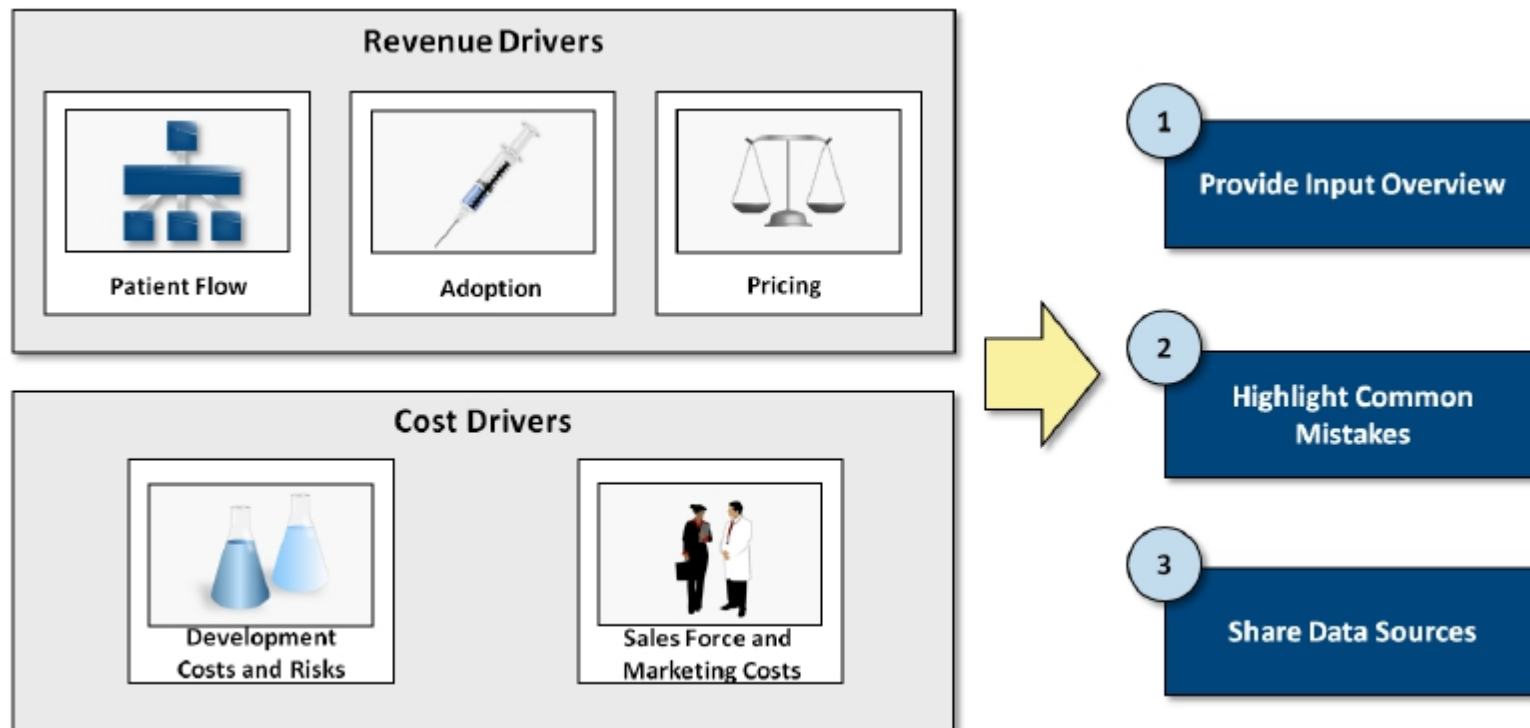
Our remaining time will be focused on reviewing several key model inputs.





# Business Development Fundamentals

Due to our limited time we have focused our discussion on a few important inputs that go into a valuation model. For each, we will provide an overview, highlight mistakes commonly made with the assumption, and share helpful data sources.



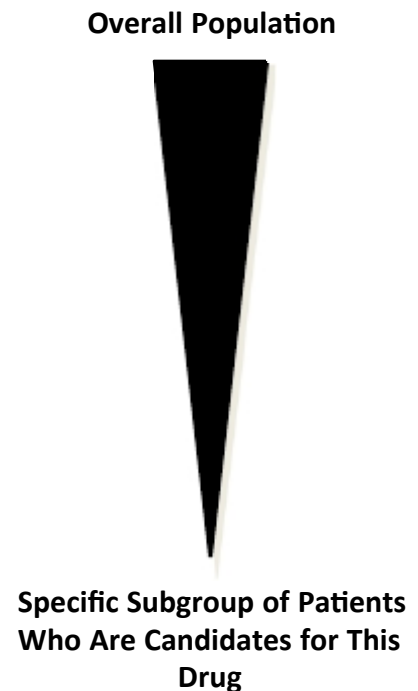




# Business Development Fundamentals

A starting point for understanding the patient flow is often the US census population data. From there, we then segment the relevant patient population based on primary and secondary research.

Population	Total Population in US	300M
Prevalence Rate	Crohn's Prevalence (.17%)	520K
Segmentation by Disease Severity	<i>Moderate to Severe Crohn's Population (60%)</i>	312K
Diagnosed and Treated Rate	<i>Diagnosed and Treated Moderate to Severe Crohn's Population (90%)</i>	281K
Segmentation by Line of Therapy	<i>Moderate to Severe Crohn's Prevalence Not on 1<sup>st</sup>-Line Therapy (80%)</i>	225K





# Business Development Fundamentals

**Using potentially biased sources and not pinpointing the appropriate patient population can overestimate Zaxxon's product valuation.**

Patient Flow Component	Common Mistake	Instead You Should...
<b>Prevalence</b>	Using only figures cited in the press, by patient advocacy groups, or industry participants	<ul style="list-style-type: none"><li>▪ Combine prevalence estimates from a number of sources.</li><li>▪ Consider the potential incentives and biases of particular sources.</li><li>▪ Segment the patient universe according to Zaxxon's product profile.</li></ul>
<b>Segmentation by Disease Severity</b>	Including patients whose disease severity does not match Zaxxon's profile	
<b>Diagnosed and Treated Rate</b>	Including all patients with a condition, not just those whose condition warrants treatment by a physician	
<b>Segmentation by Line of Therapy</b>	Including patients whose treatment status does not match Zaxxon's profile	



# Business Development Fundamentals

There are a number of sources that can be consulted when constructing a patient flow. Ideally, each assumption will be verified through multiple sources.

Secondary Research			Primary Research With Appropriate Stakeholders
Free and Publicly Available (Easy-to-use, but be mindful of source quality)	Syndicated Data (One-time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
<ul style="list-style-type: none"><li>• National Institute of Health website [<i>prevalence</i>]</li><li>• World Health Organization website [<i>prevalence</i>]</li><li>• Journal articles [<i>prevalence, segmentation, diagnosed and treated rate</i>]</li><li>• Patient advocacy websites [<i>prevalence</i>]</li><li>• SEC filings and press releases of competitors [<i>prevalence</i>]</li><li>• NHANES (CDC) [<i>prevalence</i>]</li><li>• SEER database (NIH) [<i>oncology prevalence</i>]</li><li>• National Hospital Discharge Survey (CDC) [<i>prevalence</i>]</li><li>• US Renal Data System (ESRD)</li><li>• International Agency for Research on Cancer [<i>international cancer prevalence</i>]</li></ul>	<p>Many may cover some or all dimensions of the patient flow. It is important here to check the source behind the source and to cross-reference inputs across multiple sources.</p> <ul style="list-style-type: none"><li>• Datamonitor</li><li>• Business Insights</li><li>• Decision Resources</li><li>• Analyst reports</li><li>• Kantar Health (oncology)</li><li>• Some journal articles</li></ul>	<p>Script data for competitive products can help you refine and validate all dimensions of the patient flow.</p> <ul style="list-style-type: none"><li>• IMS Health</li><li>• Truven Health Analytics</li></ul>	<p>Primary research with physicians should be used to validate findings from secondary sources when possible.</p>

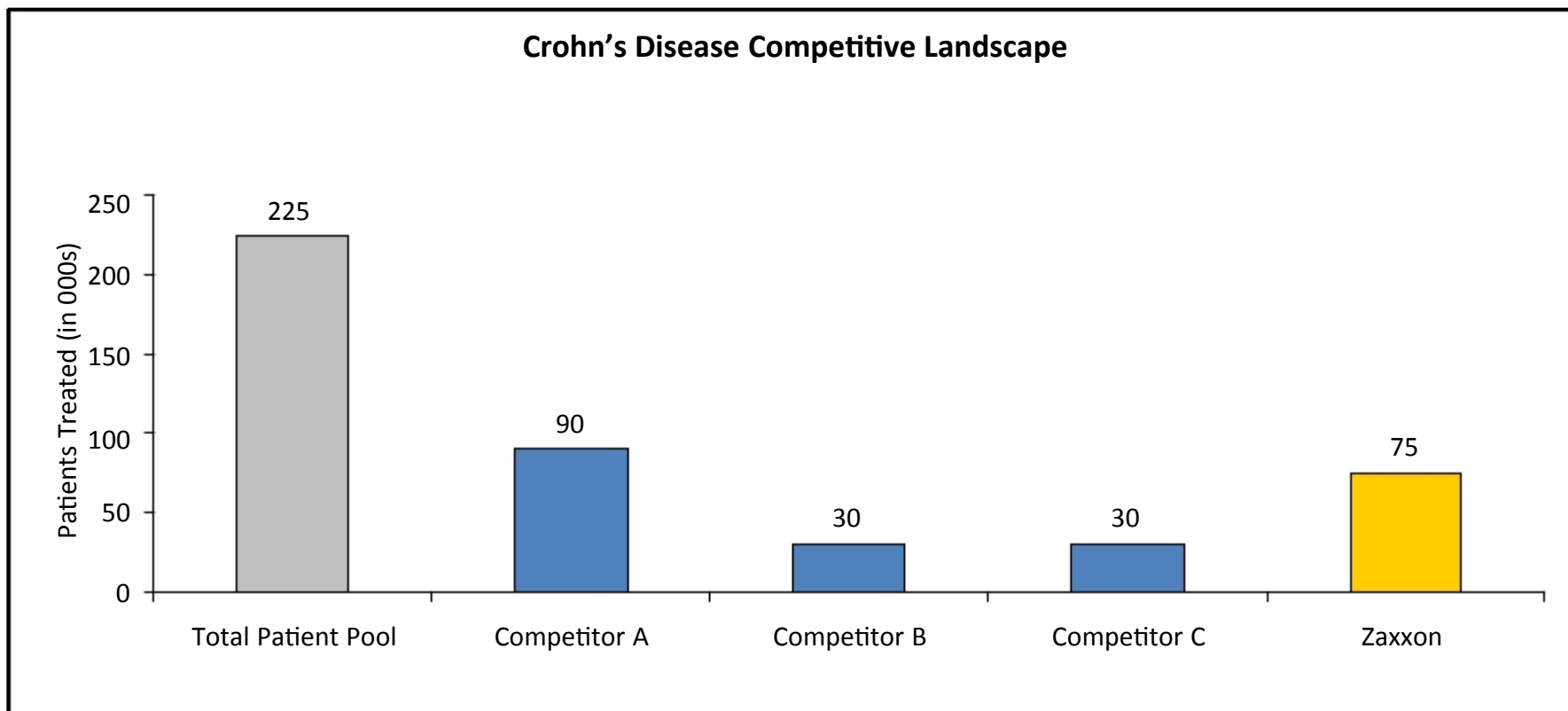






# Business Development Fundamentals

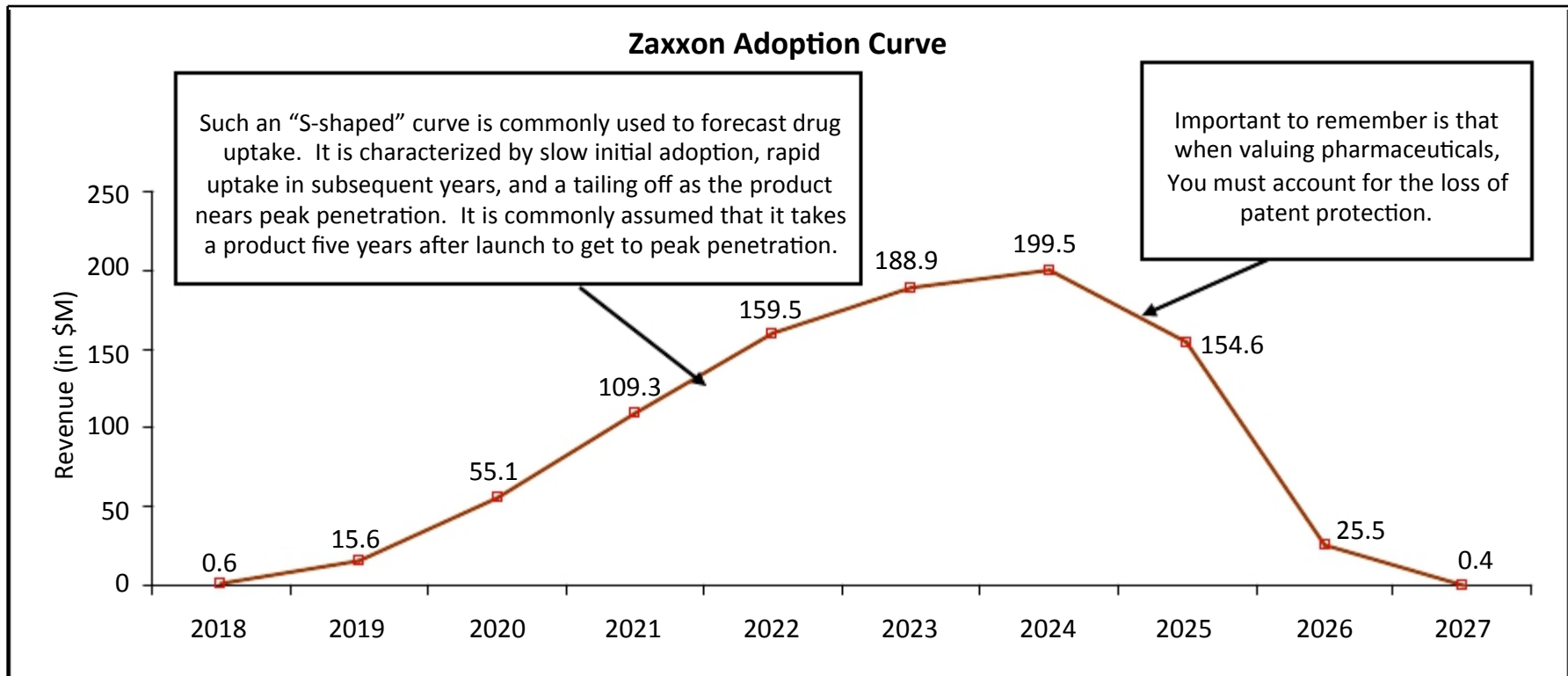
After identifying the total potential patient population, we need to estimate the number of patients for whom physicians will prescribe Zaxxon.





# Business Development Fundamentals

We must also assume an uptake curve for the adoption of Zaxxon. In this example we assume a five-year sigmoid curve.





# Business Development Fundamentals

Even with primary market research with prescribing physicians, there are a number of common mistakes that can dramatically alter product valuation.

Common Mistake	Instead You Should...
<b>Ignoring compliance</b>	Do not forget to account for lost patients. A percentage of patients will experience insufficient efficacy and/or troublesome side effects with Zaxxon just as they do with other therapies.
<b>Using an unrealistic product profile in market research</b>	Share with physicians a target profile based on Zaxxon's clinical data. Overestimating or underestimating Zaxxon's efficacy, safety, and/or convenience can result in a misrepresentation of the drug's value.
<b>Not considering future competitors when assessing the future market for Zaxxon</b>	When forecasting the future market for Zaxxon, remember to account for future entrants. In physician market research ask physicians about their potential use of Zaxxon in light of current and future competitors.
<b>Unrealistic product adoption timeline</b>	Base Zaxxon's uptake curve on the unmet need and competitive environment of the market you are forecasting.



# Business Development Fundamentals

**Estimates for the adoption rate should be grounded in primary market research with prescribing physicians but can be validated through secondary research.**

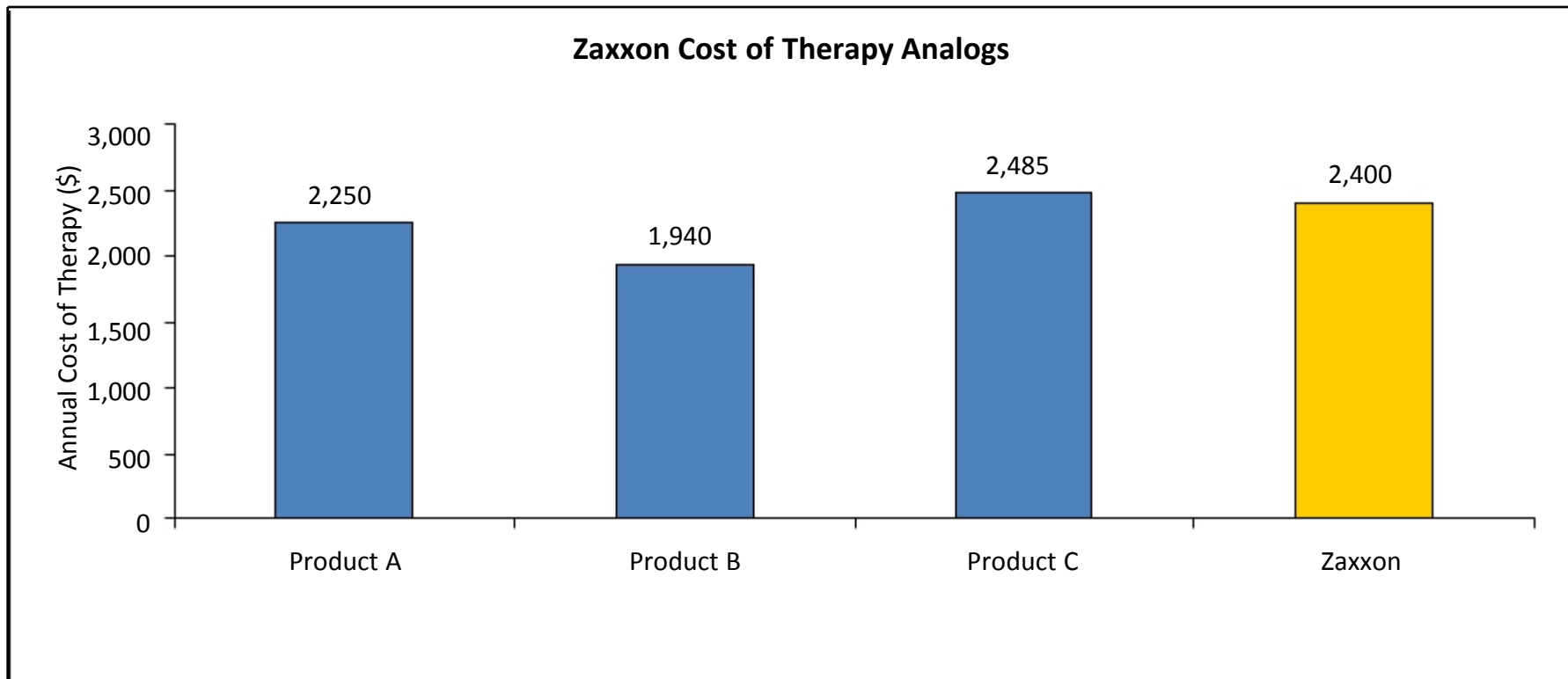
<i>Secondary Research</i>			
<b>Free and Publicly Available (Easy to use but be mindful of source quality)</b>	<b>Syndicated Data (One time purchases or subscriptions)</b>	<b>Data Service Companies (High quality but potentially expensive)</b>	<b>Primary Research with Appropriate Stakeholders</b>
<ul style="list-style-type: none"><li>▪ SEC filings and press releases of competitors may provide historical and current sales of competitive products</li><li>▪ If primary research is not feasible, an assessment of the competitive landscape and a comparison of competitive products against Zaxxon can be a starting point to estimating an adoption rate for Zaxxon</li><li>▪ Some analyst reports</li><li>▪ FDA Orange Book [patent life]</li></ul>	<p>Analyst and industry reports can lay out the current competitive environment for Crohn's disease, which can help you profile competitive products along with Zaxxon in your primary market research. Sources include:</p> <ul style="list-style-type: none"><li>▪ Datamonitor</li><li>▪ Decision Resources</li><li>▪ BCC Research</li><li>▪ Arrowhead Publishers</li><li>▪ Visiongain Intelligence</li><li>▪ Business Insights</li></ul>	<p>Data companies, including Truven Health Analytics and IMS, can provide historical sales trends on analog products that could enable you to construct adoption curves specific to Zaxxon.</p>	<p>Estimates for an adoption rate for Zaxxon should be generated through market research with appropriate physicians. Sharing Zaxxon's product profile with physicians can give an early sense for their likely adoption once Zaxxon is launched.</p>





# Business Development Fundamentals

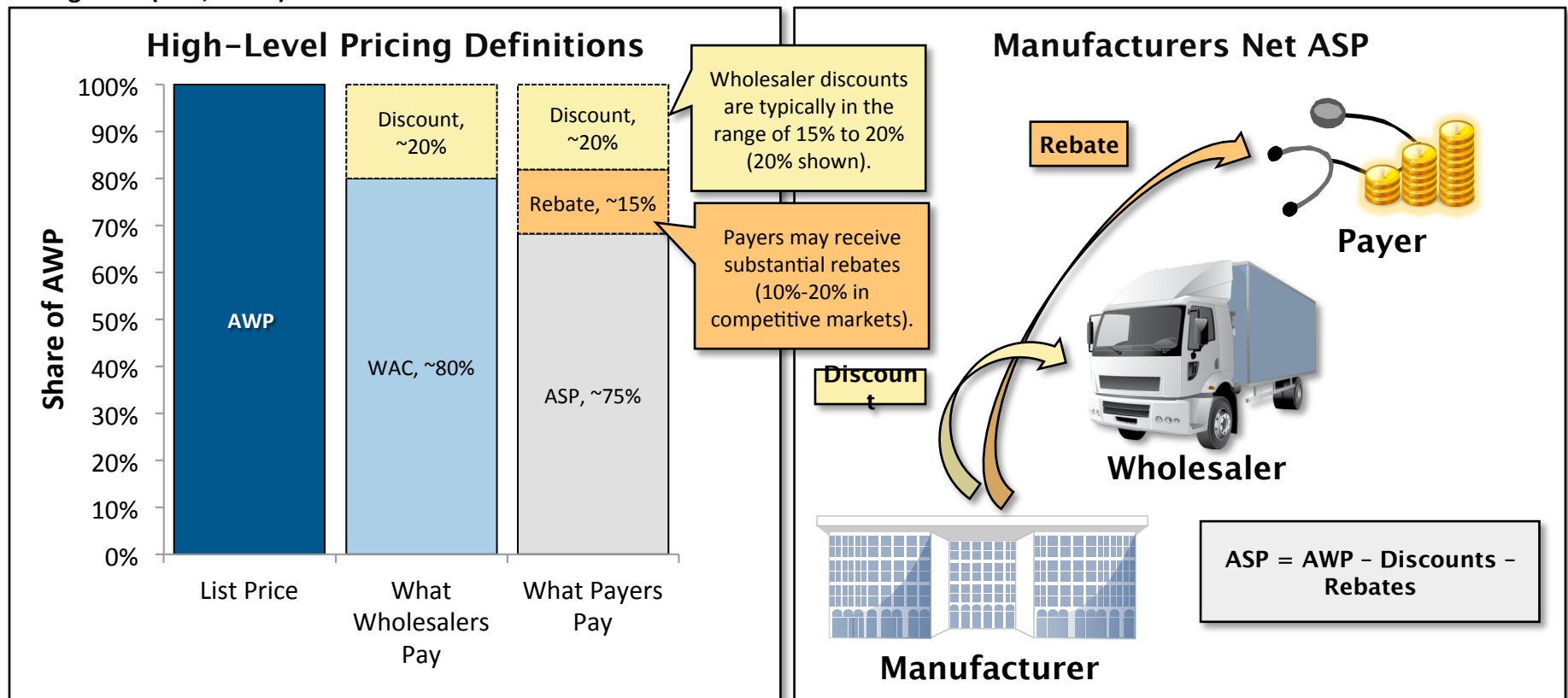
Looking at the annual treatment costs of analog therapies is a good starting point.





# Business Development Fundamentals

We need to know the price of a drug if we are to estimate its revenue. Be aware that “price” is a simple word with multiple meanings. Price may be expressed in terms of average wholesale price (AWP; “list”), wholesale acquisition cost (WAC; “wholesale”), and Average Selling Price (ASP; “net”).



We need to know ASP for the financial models. CMS (<https://www.cms.gov/McrPartBDrugAvgSalesPrice/>) now publishes ASP for drugs sold in the US.

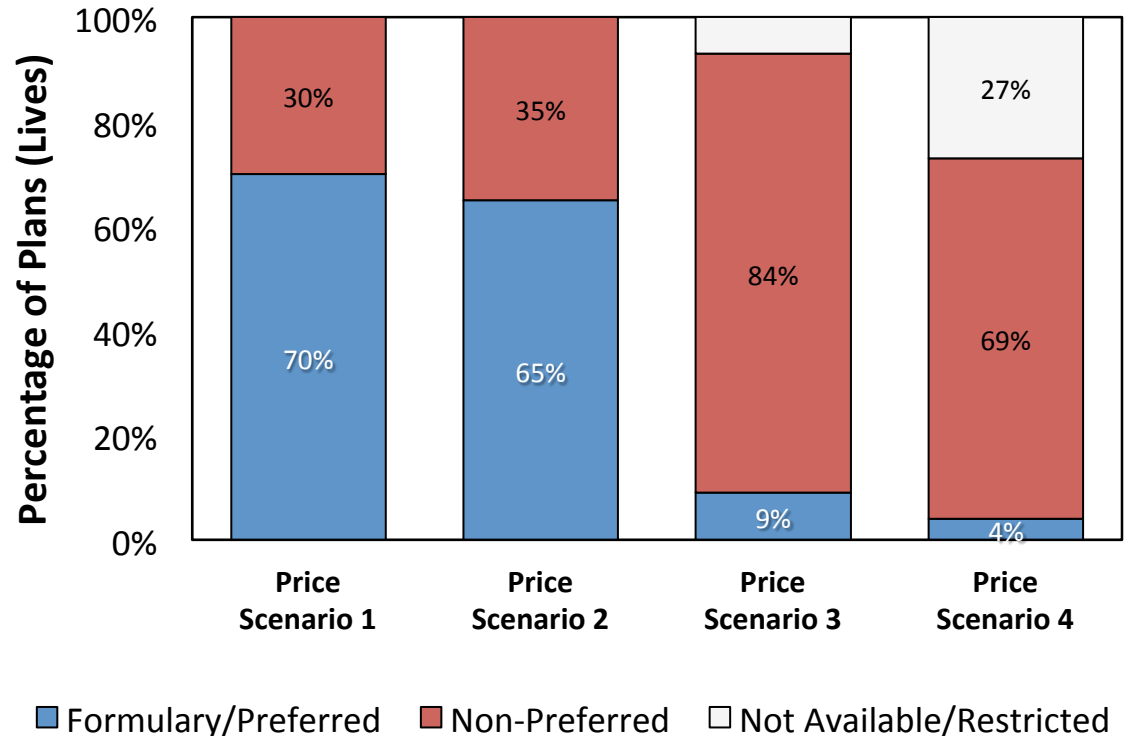


# Business Development Fundamentals

Pricing and Market Access Insights can be developed through interviews with key formulary decision makers who will enable you to assess the high-level relationship between price and formulary access.

- Key perspectives to test with payers:
  - Market access landscape
  - Access and restrictions at different price points and product profiles
  - Product adoption across different access scenarios
- By covering a few targeted pricing scenarios (portraying multiple market conditions), we can derive the high-level tradeoffs in price and access.
  - A relatively small number of plans cover the majority of managed care lives.
  - Greater sample sizes would require including either extremely small plans or stakeholders without true formulary decision-making authority.

### Estimated Impact of Net Price on Formulary Access







# Business Development Fundamentals

**Using inappropriate product analogs, ignoring price rebates, and not taking into account the influence of generics are all common mistakes in estimating price.**

<b>Common Mistake</b>	<b>Instead You Should...</b>
<b>Using the wrong analogs</b>	Make sure you identify appropriate analogs based on similar efficacy, safety, and method of administration.
<b>Ignoring rebates</b>	Account for potential rebates in the sales price of your drug.
<b>Not paying attention to the generic status of competitive products</b>	Research the remaining patent life of competitive products. If one or more products go generic during your forecast period, it could have a dramatic impact on your pricing power.



# Business Development Fundamentals

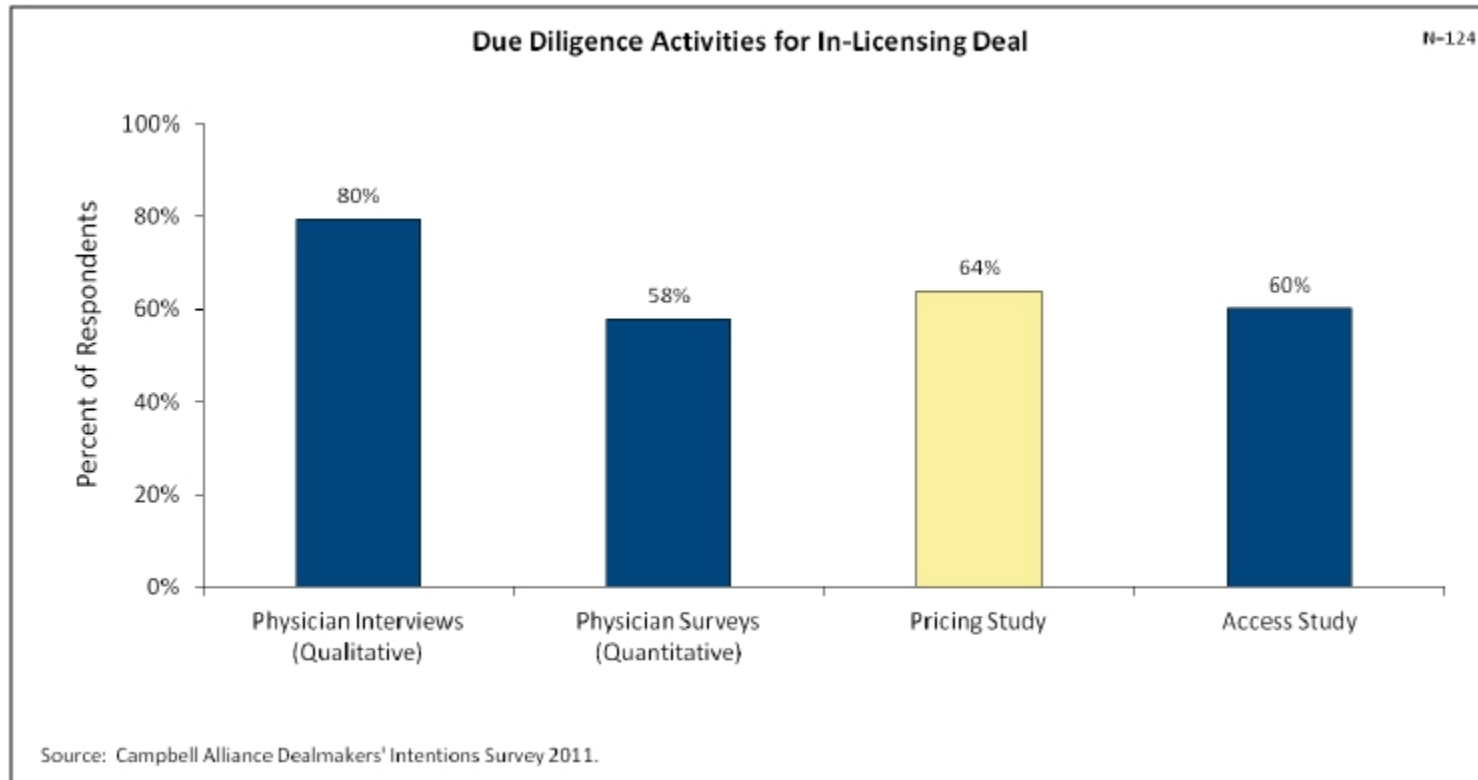
There are a number of potential sources to use to identify potential analog products for pricing and to find the prices for those analog products.

<i>Secondary Research</i>			
Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	Primary Research with Appropriate Stakeholders
<ul style="list-style-type: none"><li>▪ Mail order prescription websites</li><li>▪ Center for Medicare and Medicaid Services (CMS) – ASP Database</li></ul>	<ul style="list-style-type: none"><li>▪ FDB First Databank</li><li>▪ Red Book (IMS Health)</li><li>▪ Epocrates.com (formulary data)</li><li>▪ Medispan (formulary data)</li></ul> <p><i>Syndicated publishers with pricing focused materials:</i></p> <ul style="list-style-type: none"><li>▪ Decision Resources</li><li>▪ Visiongain Intelligence</li></ul>	<ul style="list-style-type: none"><li>▪ Medi-Span – Price Rx® / Wolters Kluwer – Can provide current and historic pricing information by product</li></ul>	Estimates for pricing and market access assumptions for Zaxxon should be generated through market research with appropriate formulary decision makers within payers (Regional/ National Managed Care Organizations, Pharmacy Benefit Administrators, Medicare, Medicaid, etc.) . Sharing Zaxxon’s product profile with payers can give an early sense for their likely access restrictions at various price levels.



# Business Development Fundamentals

Based on the Dealmakers' Intention Survey, pricing analysis in addition to physician analysis is becoming more of the norm when evaluating in-licensing opportunities.





# Business Development Fundamentals

## Example of a bad revenue analysis from a Wall Street Analyst

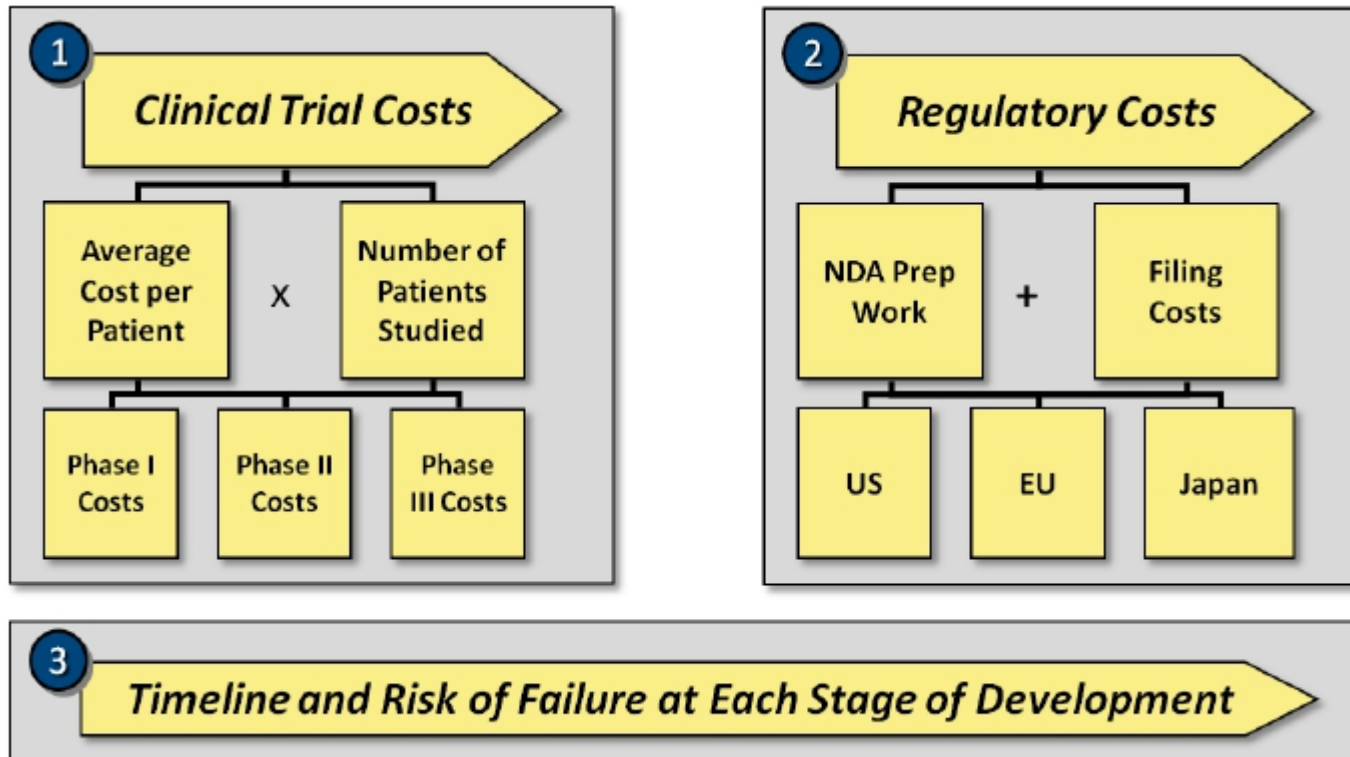
<b>US Market</b>	2012	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<i>(All figures in thousands except prices)</i>											
<b># Patients eligible for treatment</b>	3000										
% Diagnosed and treated	20%										
<b>#Patients actually treated</b>	600	654	713	777	847	923	1,006	1,097	1,196	1,303	1,420
<i>Growth %</i>	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%	9%
<b>% Market Share</b>		0%	3%	6%	9%	12%	15%	15%	15%	15%	15%
# Patients treated		2	21	47	76	111	151	165	179	195	213
<b>Cost per treatment (6 months)</b>		\$2,887	\$2,974	\$3,063	\$3,155	\$3,250	\$3,347	\$3,447	\$3,551	\$3,657	\$3,767
<i>Price Increase</i>			3%	3%	3%	3%	3%	3%	3%	3%	3%
Cost for one-year treatment		\$2,887	\$2,974	\$3,063	\$3,155	\$3,250	\$3,347	\$3,447	\$3,551	\$3,657	\$3,767
<b>Total U.S. products sales</b>		\$5,774	\$63,601	\$142,800	\$240,491	\$360,038	\$505,193	\$567,113	\$636,803	\$714,835	\$802,607
<i>Growth YoY</i>			1002%	125%	68%	50%	40%	12%	12%	12%	12%





# Business Development Fundamentals

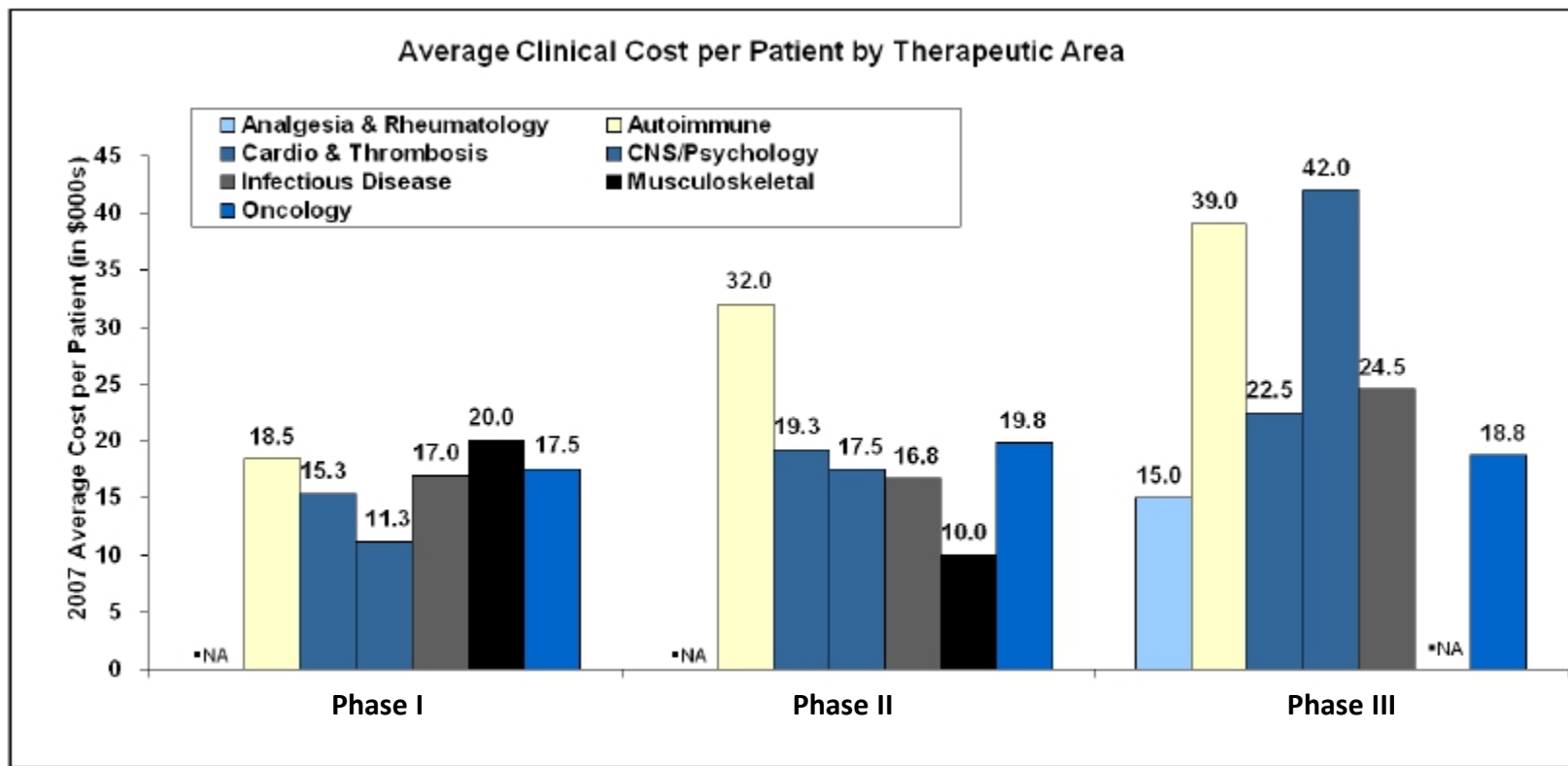
There is no substitute for a detailed, line-by-line forecast of clinical trial costs. However, when we lack a detailed forecast, we can use an estimation approach to forecast development costs.





# Business Development Fundamentals

To estimate clinical costs, it is important to consider the therapeutic area of interest, the number of trials necessary, and the anticipated length of each trial.

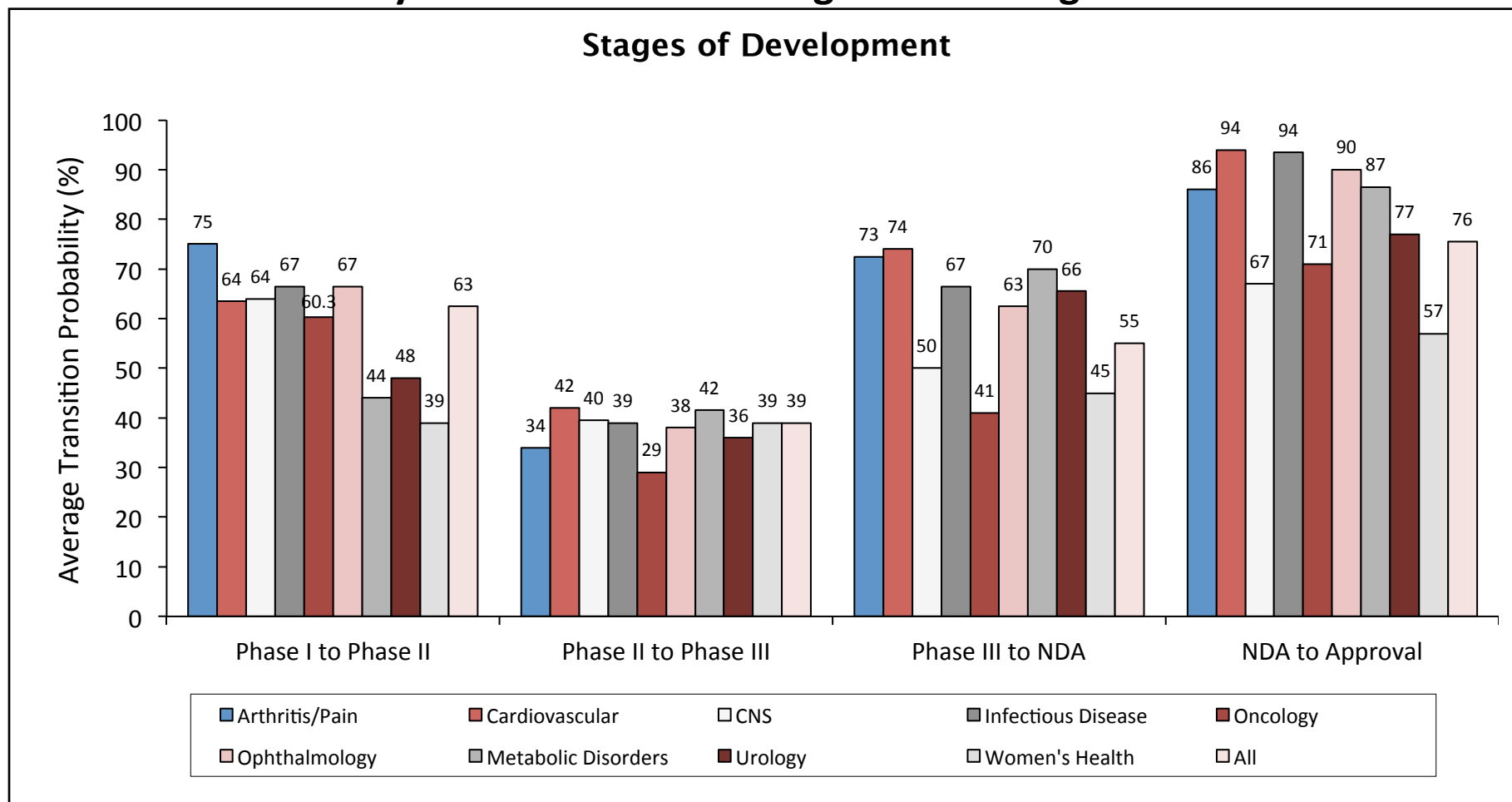


Source: Statistics on Drug Development. Costs/Complexity. Cited in Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2008/2009.



# Business Development Fundamentals

Clinical success is by no means a sure thing. Forecasting clinical



Source: Kola I, Landis J. Can the pharmaceutical industry reduce attrition rates? *Nat Rev Drug Disc.* 2004;3:711-715.





# Business Development Fundamentals

**Not properly accounting for development costs and risks can dramatically affect your valuation model as these occur in the early years of the forecast where valuation is most sensitive.**

<b>Common Mistake</b>	<b>Instead You Should...</b>
<b>Failing to account for development risk</b>	In your model you need to account for the scenario where the drug fails overall, eliminating all subsequent cash inflows and outflows.
<b>Not accounting for potential trial failures, especially in areas with high placebo response rates</b>	Failed trials still cost money. Account for the possibility that your drug may need additional trials to account for failures by examining the trial history of competitive products.
<b>Using unrealistic development timelines</b>	The timing of cash flows is important in a valuation model, particularly in the early years. Be sure to assume a reasonable timeline, including for regulatory approval, when building a valuation model.



# Business Development Fundamentals

There are several sources that may be used to help estimate development costs.

Factor	Secondary Research	
	Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)
Estimating average cost per patient	<ul style="list-style-type: none"><li>▪ Internal company data</li></ul>	<ul style="list-style-type: none"><li>▪ Paraxel's Pharmaceutical R&amp;D Statistical Sourcebook (provides data by phase and by therapeutic class)</li><li>▪ Frost &amp; Sullivan</li><li>▪ Datamonitor</li><li>▪ Kalorama Information</li><li>▪ Business Insights</li><li>▪ Center Watch</li></ul>
Estimating number of patients in trials	<ul style="list-style-type: none"><li>▪ Internal company data</li><li>▪ NIH</li><li>▪ FDA Center for Drug Evaluation and Research</li><li>▪ Clinicalstudyresults.org</li><li>▪ Clinicaltrials.gov</li></ul>	
Estimating development risk	<ul style="list-style-type: none"><li>▪ Internal company data</li><li>▪ NIH</li><li>▪ FDA Center for Drug Evaluation and Research</li></ul>	



# Business Development Fundamentals

The more customized to your situation the better, but below are some general industry data that you may consider using in the absence of anything else.

Factor	Secondary Research	
	Free and Publicly Available (Easy-to-use but be mindful of source quality)	Syndicated Data (One-time purchases or subscriptions)
Estimating average cost per patient	<ul style="list-style-type: none"><li>Internal company data</li></ul>	<ul style="list-style-type: none"><li>Paraxel's</li></ul>
Estimating number of patients in trials	<ul style="list-style-type: none"><li>Internal company data</li><li>NIH</li><li>FDA Center for Drug Evaluation and Research</li><li>Clinicalstudyresults.org</li><li>Clinicaltrials.gov</li></ul>	<ul style="list-style-type: none"><li>Statistical Sourcebook (provides data by phase and by therapeutic class)</li><li>Frost &amp; Sullivan</li><li>Datamonitor</li><li>Kalorama Information</li><li>Business Insights</li><li>Center Watch</li></ul>
Estimating development risk	<ul style="list-style-type: none"><li>Internal company data</li><li>NIH</li><li>FDA Center for Drug Evaluation and Research</li></ul>	

According to the NIH and FDA (as cited on the Mayo Clinic website), the following are estimates for trial sizes:  
P1 = 20-80  
P2 = 100-300  
P3 = 1000-3000





# Business Development Fundamentals

It is important to first understand the concept of “deciling.” In sales force forecasts, a prescribing universe is often broken down into deciles based on prescribing levels.

Top Prescribers of CNS Market

Market Decile	Number of Prescribers	Cum. # of Prescribers	Cum. % of Prescribers	Cum. % of TRx
10	3,517	3,517	0.5%	10.0%
9	6,437	9,954	1.5%	20.0%
8	8,890	18,844	2.9%	30.0%
7	11,245	30,089	4.7%	40.0%
6	13,864	43,953	6.8%	50.0%
5	17,141	61,094	9.5%	60.0%
4	21,863	82,957	12.8%	70.0%
3	30,136	113,093	17.5%	80.0%
2	50,445	163,538	25.3%	90.0%
1	482,539	646,077	100.0%	100.0%

Composition of Top Prescribers

Market Decile	Number of Prescribers	Psych	PCP
10	3,517	2,845	425
9	6,437	2,992	2,879
8	8,890	2,321	5,705
7	11,245	2,051	7,920
6	13,864	2,011	9,983
5	17,141	2,129	12,152
4	21,863	2,626	14,493
Total	82,957	16,975	53,557



# Business Development Fundamentals

A “reach and frequency” model can be used to estimate sales force costs.

A	Item	Value
	Details per Day	4
	Selling Days per Year	211
	Details per Year per Rep	844
	Cost per Year per Rep	\$200K

	Audience	US Gastroenterologists	Total
B	Number of Specialists	11,864	11,864
C	Frequency of Details	15 for deciles 9-10; 10 for deciles 6-8	
	Total Details	71,184	71,184
D	Share of Cost to Product	100%	100%
E	Required Reps	84	84
	Total Detailing Cost	\$16.8M	\$16.8M

Expected cost of field force

- A Determined the typical fully-loaded field-force costs by market (and/or specialty) based on industry benchmarks
- B Determined number of relevant specialists by market to be targeted for Zaxxon
- C Determined the reach (i.e., *How many deciles to target?*) and frequency (i.e., *How often to target these deciles?*) based on internal company decisions
- D Allocated share of detail to Zaxxon (based on expected positioning within detail call)
- E Calculated the number of required reps and total detailing costs for Zaxxon



# Business Development Fundamentals

There are a number of common mistakes that can be made across the different variables that go into a “reach and frequency” model.

Common Mistake	Instead You Should...
<b>Not allocating the sales force costs across multiple products</b>	If the sales force will be detailing multiple products to the same physicians, the sales force cost should be split accordingly.
<b>Not using fully-loaded costs to estimate the cost of a salesperson</b>	In addition to base salary and bonus, you must account for benefits. A rule of thumb is 2x salary and bonus to arrive at a “fully-loaded” cost.
<b>Accounting for all physicians within a prescribing universe when forecasting sales costs</b>	Typical sales efforts focus only on the top few prescribing deciles to get the highest return on investment. Include only those target physicians who are believed to be sales targets.



# Business Development Fundamentals

There are several sources that can be consulted when building a “reach and frequency” model to estimate sales force costs.

Factor	Secondary Research			Primary Research with Appropriate Stakeholders
	Free and Publicly Available (Easy to use but be mindful of source quality)	Syndicated Data (One time purchases or subscriptions)	Data Service Companies (High quality but potentially expensive)	
<b>A</b> Determining fully-loaded field-force costs	<ul style="list-style-type: none"><li>Internet research (salary.com)</li><li>\$150K-\$250K is often used as fully-loaded cost</li></ul>	<ul style="list-style-type: none"><li>Cutting Edge Information</li></ul>		Potentially validate data through primary research
<b>B</b> Determining number of relevant specialists to be targeted	<ul style="list-style-type: none"><li>AMA website</li></ul>	<ul style="list-style-type: none"><li>OECD website (provides European data)</li></ul>		
<b>C</b> Determine reach and frequency	<ul style="list-style-type: none"><li>Internal assumption</li></ul>	<ul style="list-style-type: none"><li>Cutting Edge Information</li></ul>	<ul style="list-style-type: none"><li>Verispan can provide data on sales force size</li></ul>	Potentially validate data through primary research
<b>D</b> Allocate share of detail to Zaxxon	<ul style="list-style-type: none"><li>Internal assumption</li></ul>			





# Business Development Fundamentals

## Assessing other marketing costs and taking into account new trends is also critical

- Increasing number of physicians restrict access to sales reps
- Reliance on eDetailing and digital marketing is increasing – Need to budget for this
- Direct to consumer advertising can be very effective but is very expensive: make sure it is part of your forecast if it is going to be used

Product	Company	2014 DTC Spend
Cialis	Eli Lilly	\$248M
Lyrica	Pfizer	\$227M
Eliquis	BMS/Pfizer	\$219M
Viagra	Pfizer	\$211M
Humira	AbbVie	\$203M
Latuda	Sunovion	\$179M
Xeljanz	Pfizer	\$161M
Celebrex	Pfizer	\$119M
Abilify	BMS	\$108M
Chantix	Pfizer	\$103M

Source: MM&M DTC Report



# Business Development Fundamentals

## Example of a bad NPV analysis from a Wall Street Analyst

### NPV Model

*All figures in thousands (except per share figures)*

Year	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Product sales	\$5,774	\$63,601	\$142,800	\$240,491	\$360,038	\$505,193	\$567,113	\$636,803	\$714,835	\$802,607
Operating expenses (75% of sales)	\$4,331	\$47,701	\$107,100	\$180,368	\$270,029	\$378,895	\$425,334	\$477,602	\$536,126	\$601,955
Net income (25% profit margin)	\$1,444	\$15,900	\$35,700	\$60,123	\$90,010	\$126,298	\$141,778	\$159,201	\$178,709	\$200,652
Net income*Likelihood of Success (80%) = E/	\$1,155	\$12,720	\$28,560	\$48,098	\$72,008	\$101,039	\$113,423	\$127,361	\$142,967	\$160,521
NPV of EAT	\$377,536									
Cash by 2Q13E	\$26,000									
Total NPV	\$403,536									
NPV/Share	\$4.50									



# Business Development Fundamentals

## Modeling Best Practices

*As we close today's presentation, there are a few important modeling best practices to discuss.*

### Managerial Recommendations

- Make sure you understand the market environment
- Don't overcomplicate the risk assessment (more on this on the next page)
- Compare the results of your model with current products and recent deals.

### Modeling Recommendations

- Use a standardized model template—starting from a blank spreadsheet for each new model is time-consuming and increases the potential for calculation errors
- Avoid hard coding values in formulas
- Use standardized formatting conventions that clearly differentiate user input from model calculations
- Create a page in your model to provide references for important inputs
- Create a dashboard with key inputs and outputs for sensitivity analysis, Data Table function in Excel is a simple way to do sensitivity analysis



# Business Development Fundamentals

End