Approaches to Financial Valuation of Biopharmaceutical Assets: Select Case Studies

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This presentation is designed to introduce and review various strategies used to construct financial valuations. The outlined content is pertinent to assets in the life sciences industry that require well-vetted assumptions and appropriate risk adjustments. The insights we share herein are based on completed projects for several of our biopharmaceuticals clients. The content is not intended to support or refute specific valuation approaches or methodologies described by other industry professionals.

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Background

Introduction

THE PURPOSE OF CONSTRUCTING A FINANCIAL VALUATION

Financial valuations estimate the monetary value of an asset, portfolio, or company at a specified point in time

Valuations are used to guide life science companies through key business decisions including:

- Prioritization of a company's own portfolio
- Strategic planning ahead of clinical, commercial, or strategic events that may impact a company's value
- External transaction events including divesture, fundraising events, licensing deals, and M&A

Multiple stakeholders within the life sciences industry rely on financial valuations

Potential Valuation Applications

Internal use

Company executives may need to determine if an investment is beneficial under certain market conditions by estimating the necessary investment and time needed to advance an asset or portfolio

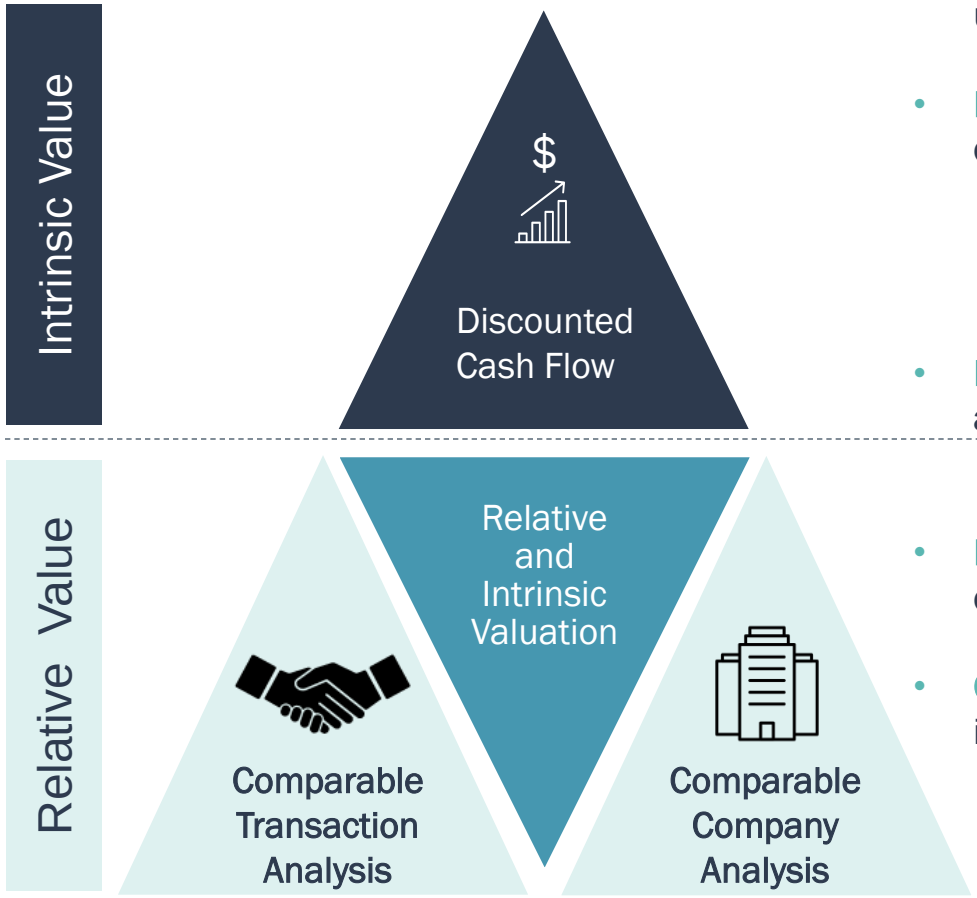
Business development teams estimate the necessary investment and time needed to advance an asset or portfolio and to determine if such an investment is likely to be beneficial under certain market conditions

Third party assessment

Investment banks calculate a transaction value most beneficial for all parties involved in a deal, or construct a fairness opinion for a client to determine whether a proposed price is appropriate

Consulting organizations assist clients' business development teams or new product planning functions in preparation for a transaction, or to assist in prioritizing their portfolios

To construct a valuation model three methods are frequently used to calculate the intrinsic and relative monetary value of a company or an asset



Valuation Methodologies

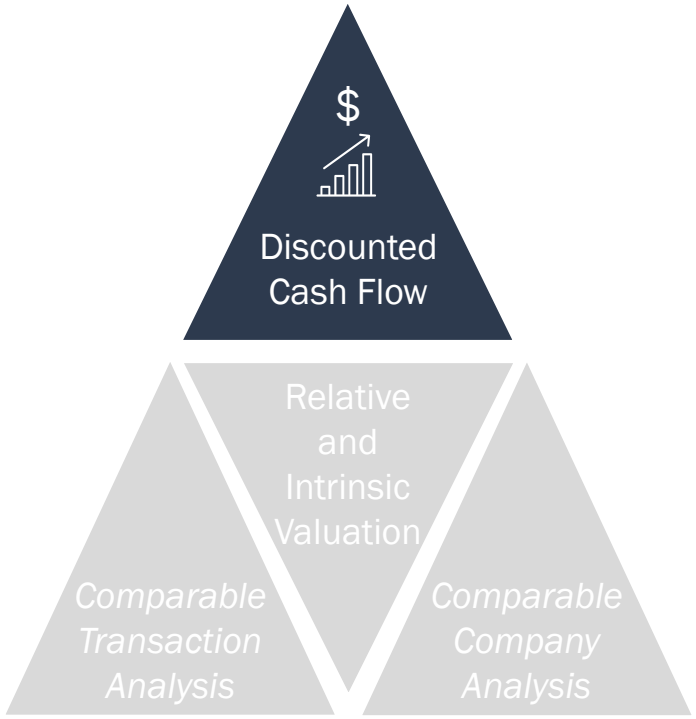
- Intrinsic value is the actual value of a company or an asset based on the estimated underlying value of the asset(s), and is calculated using a DCF model
- Discounted Cash Flow (DCF) models the revenues and expenses of an opportunity that can be used to compute the present day value of future cash flows
  - In the life sciences industry a DCF is typically risk adjusted for clinical and regulatory hurdles that need to be overcome for an asset to begin generating revenues
- Net Present Value (NPV) is the difference between the present value of cash inflows and cash outflows commonly over the duration of an opportunity's market exclusivity

- Relative value is driven by comparable transaction analysis and/or a comparable company analysis, both which complement and support a DCF model
- Comparable analyses apply a multiple to the target opportunity to determine its value in certain market conditions. The multiple is determined by:
  - Transactions that occurred in similar market conditions
  - Companies with similar business models, strategies, or focus therapeutic areas

Each valuation methodology has its advantages and shortcomings

	Advantages	Shortcomings
 **Discounted Cash Flow**	• Derives intrinsic value • Not as sensitive to public markets or economic conditions	• Very sensitive to the assumptions – modifications can drastically change the DCF, which needs to be constantly updated as expectations evolve • Particularly sensitive to future-looking assumptions, which are more pronounced for earlier-stage assets
 **Comparable Transaction Analysis**	• Informs probable exit strategy for assets across their clinical development path	• Timing of transaction and market conditions may impact accuracy and applicability of multiple used • Analog transactions made under similar market conditions may be challenging to find
 **Comparable Company Analysis**	• May provide insights into competitive space for assets across the clinical development path	• Heavily influenced by market or industry dynamics

A DCF model requires a revenue forecast, clinical development path requirements, and other assumptions that drive cash flows



Elements of a Discounted Cash Flow

1 Revenue Forecast

- Forecasts the commercial success of a product after regulatory approval
- Accounts for all related dynamics within the evolving commercial environment that will impact that success, including:
  - Addressable market (e.g. epidemiology or prescription volumes)
  - Price
  - Market share
  - Competition on the market, or in development to predict market share
  - Reimbursement
- Must be supported by well-vetted assumptions, which can be derived from primary or secondary market research

2 Expense Requirements

- Clinical development path requirements (e.g., timing and associated costs)
- Regulatory filing costs
- Commercialization expenses
- Costs for adding additional indications to asset development
- Estimates of the company's overhead

3 Other Cash Flows

- Includes depreciation, amortization and working capital that must be included to capture the impact these cash flows have on the asset's intrinsic value

A discounted cash flow (DCF) model incorporates three financial categories to calculate annual cash flows

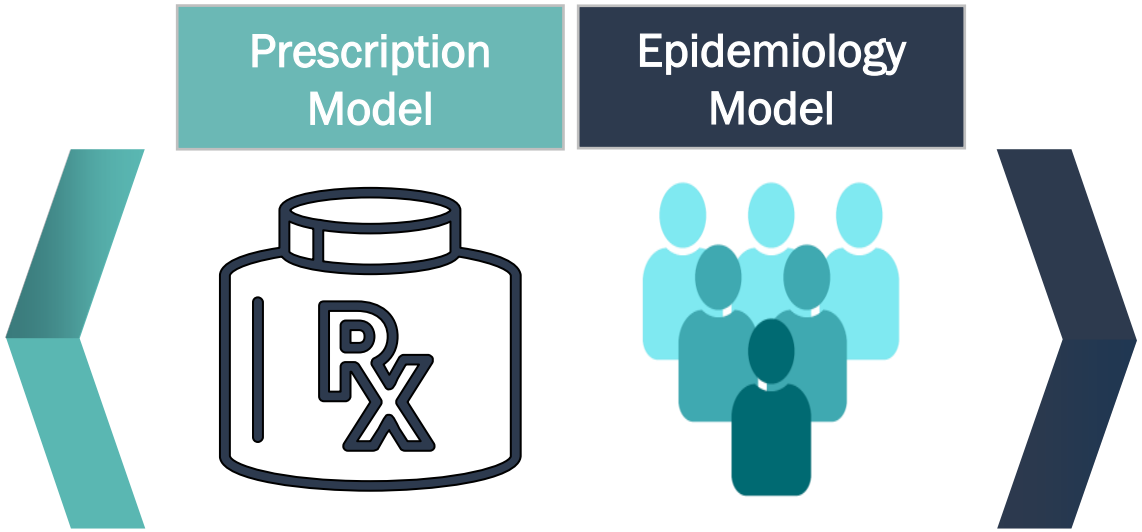
Revenues	−	Expenses	−	Other Cash Flows**	=	Annual Cash Flow
Total TRx's (prescription model) *OR* *Total Patients (epi model)* *X* *Dosing Schedule* *X* *Price* *X* *Penetration of Patient Population* *X* *Market Share Based on Competitors* = *Gross Revenue* *X* *Gross to Net Discount* = *Net Sales*		*COGS* + *R&D Expenses* + *SG&A Expenses* = *Operating Expense**		*Capital Expenditures* + / - *Change in Working Capital* + / - *Capital Loss Carry Over* + / - *Taxes* + / - *Depreciation and Amortization*		↓ Risk Adjustment at Each Stage of Development ↓ Add Terminal Value ↓ Enterprise Value

TRx = Prescriptions
*Normally the Operating Expense does NOT include COGS. However, COGS is an expense related to operations
**For the purpose of this presentation, we will not be reviewing or applying "Other Cash Flows" because these are different for each valuation

To estimate revenue potential two bottom-up approaches are commonly used. Different factors must be considered when determining which approach is most optimal

Preferred method when considering therapies in mature markets with extensive units data for existing treatment options

- Can readily identify the size of the addressable market due to the historic performance of previously approved products
- Able to distinguish the performance of approved therapies based on product characteristics, such as molecule type, route of administration, biological mechanism (etc.) using historical data
- Product proxies can be the primary source of market share assumptions due to the historic performance of select products



Typically more favorable when estimating the performance of a novel product that will disrupt the market, or is the first product approved for a disease or patient segment

- Ability to apply and adjust multiple epidemiology parameters to target or add patient subpopulations to the target patient population
- Utilizes detailed assumptions supported by primary or secondary market research to reflect how a product may be adopted in specific patient populations
- Can allow for assumptions reflecting possible changes to variables, such as diagnosis, treatment, or compliance rates

Prescription- and epidemiology-based models incorporate several different components that are used to drive revenue forecasts

Components of a Revenue Potential Model

Basis of estimates	Prescription Model	Epidemiology Model	Basis of estimates
1 • Unit script data over time • Data may be segmented by brands vs. generics, formulation, physician specialty, marketing channels, etc.	Total TRx's and Growth Rates	Patient Prevalence and Incidence	1 • Incidence and prevalence of disease; associated growth rates • Size of relevant patient segments
	Product Share	Target Patient Segment	
2 • Adoption curves that occur as 1st/2nd/3rd/etc. order of entry for comparable products • Peak penetration based on unmet need and clinical differentiation	Adoption Rate (years to peak)	Diagnosis Rate	2 • Competing products and timing of launches of future competitors • Ability to meet unmet need and level of differentiation
	Price	Penetration within Population	
3 • Price optimization analysis (e.g. price/demand curves, cost/volume curve)	Product Revenue (Gross)	Product Market Share	3 • Delivery dosing schedule • Impact on rates of diagnosis, treatment, compliance and response to therapy
		Dosing Schedule	
		Response & Compliance Rates	
		TRx Price	4 • Price estimates based on pricing and reimbursement landscape and estimate of added benefit to clinicians, payers and other stakeholders
		Product Revenue (Gross)	

The degree of impact of certain variables, such as R&D expenses and probability of success, will differ when modeling clinical stage assets as compared to commercial stage assets

	Clinical Stage Asset	Commercial Stage Asset
Cash Flows	• Negative during the years of clinical development • Positive when the asset is launched as a marketed product, assuming commercialization is successful	• If profitable, cash flows are immediately positive • Free cash flows will not be impacted by any clinical or regulatory probability of success (POS) rate for the previously approved indication
R&D vs. SG&A expenses	• During development phase company will experience large R&D expenses and moderate SG&A expenses • Once approved, R&D shrinks and SG&A increases, due to commercial, sales and marketing costs	• R&D will be low, unless asset is in development for additional indications or requires post-approval studies • SG&A expenses will be higher in early years in comparison to a clinical stage asset, due to the existing commercial resources
Market Share & Penetration	• Consider competitors and unmet clinical need • Comparison with other competitors currently in the pipeline • Timing of product introductions	• Adjusted to account for the potential launches of competitors • Accounts for maturity of the adoption curve in the life-cycle of the product
Probability of Success	• Will reflect an annual clinical probability of success adjustment for the technical and regulatory risks associated with the asset's advancement through clinical development	• The approved indication will not require risk-adjustment, assuming there aren't any additional regulatory requirements

Risk adjusting free cash flows is industry specific. It is predominantly used in the life sciences due to the number of clinical hurdles assets must overcome to reach the market

Risk Adjusted Cash Flow*

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Free Cash Flows	($10)	($30)		($50)		($5)	$75mm
Phase of Development Progression	Phase 1	Phase 2		Phase 3		NDA/BLA	Approval
	Phase Success 64.5%	Cumulative POS 64.5%	Phase Success 32.4%	Cumulative POS 20.9%	Phase Success 60.1%	Cumulative POS 12.6%	Phase Success 83.2%	Cumulative POS 10.4%	Cumulative POS 10.4%
Risk Adjusted Free Cash Flows	($6.5)	($6.3)		($6.3)		($0.5)	$7.8mm

Phase Progression	Industry Average Phase Probability of Success (POS)
Phase 1 to 2	64.5%
Phase 2 to 3	32.4%
Phase 3 to NDA/BLA	60.1%
NDA/BLA to Approval	83.2%

Source: Hay, Michael, et al. "Clinical development success rates for investigational drugs." Nature biotechnology 32.1 (2014): 40-51.

*The values presented herein are for illustration purposes only and do not represent a real case scenario

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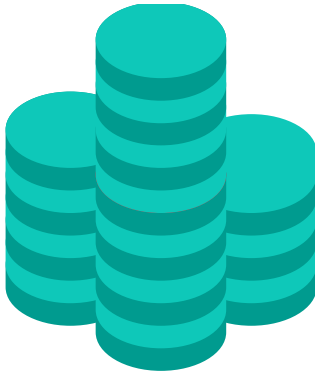
Annual cash flow is risk adjusted for each phase of clinical development and then combined with the terminal value to determine the enterprise value

Determining the Enterprise Value

Annual Cash Flow

- Free cash flows calculate the NPV over a defined forecast period
- Products in earlier stages of development generate negative annual cash flows due to R&D expenses and corporate overhead
- Upon regulatory approval annual cash flows increase and generate profit



Risk Adjustment at Each Stage of Development

- Annual cash flows are risk adjusted for each phase of clinical development and assigned a POS value
- When products advances to Phase 3 the cumulative POS of Phase 1, 2, & 3 is applied to the respective year

Add Terminal Value

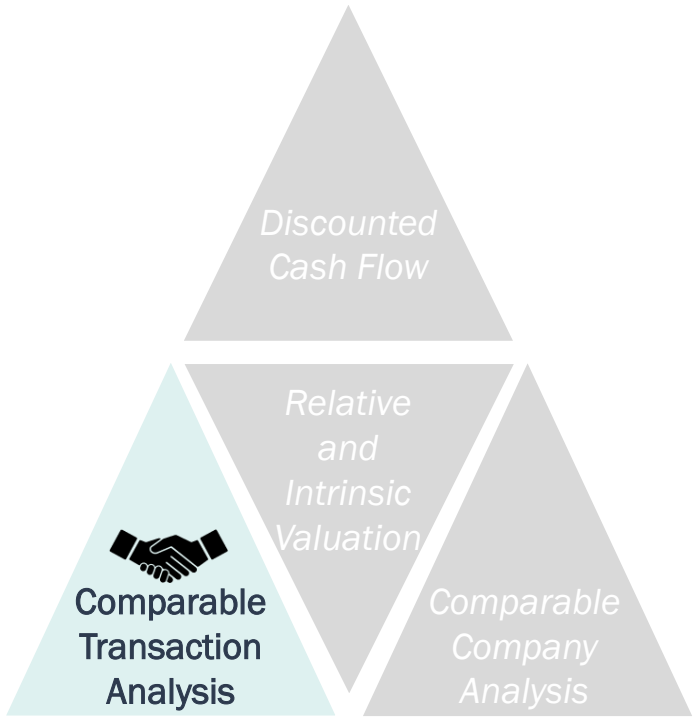
- Terminal value is the present day value of an asset beyond the forecasted years captured in the DCF model, often during an asset's exclusivity period
- Terminal value of a pharmaceutical or biotech asset usually represent a small portion of the assets' total intrinsic value due to generic erosion

Enterprise Value

- Enterprise value is calculated after combining the risk-adjusted NPV and terminal value
- This value is not impacted by public market conditions and is exclusively driven by the assumptions applied in the DCF model

A comparable transaction analysis defines the value of a company based on precedent transactions that have occurred under similar market conditions

Comparable Transaction Analysis Methodology



1 Identification of benchmark transactions

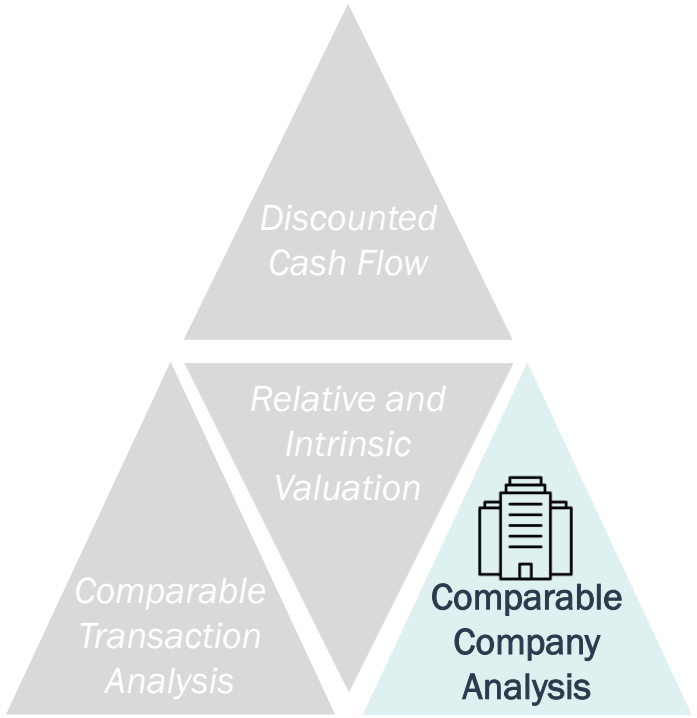
- Highlights transactions with similar characteristics to the target asset (e.g. therapeutic area, level of differentiation, market size)
- Ideally, transactions are recent, occurring in the last 3-5 years, in an effort to reflect similar market conditions
- Reflects a range of premiums buyers have applied
- The precedent transaction does not need to have closed to use it as a comparable, because that transaction may have not materialized for other reasons unrelated to the value or purchase price

2 Calculate multiple after evaluating several transactions

- May be the average, median, or quartile transaction amount
- This helps to define the relative value of the company based on the transaction activity in the market
- A few multiples to derive from the precedent transaction analysis include revenue, earnings before interest, taxes, depreciation and amortization (EBITDA), and Earnings before interest and taxes (EBIT)/Enterprise value (EV) multiple

The comparable company analysis, also referred to as trading comps, compares and contrasts existing financial ratios of similar public companies with a target company in the same space

Comparable Company Methodology



1 Identification of company analogs

- Private companies can be used in the comparable company analysis; however, it's more feasible to use public companies because of the amount of financial information that is easily accessible
- Selection depends on the similarities between the comparable companies and the target company, such as business mix, revenue base (size), geographical presence, profitability, and market growth

2 Calculate multiple after evaluating multiple peer companies

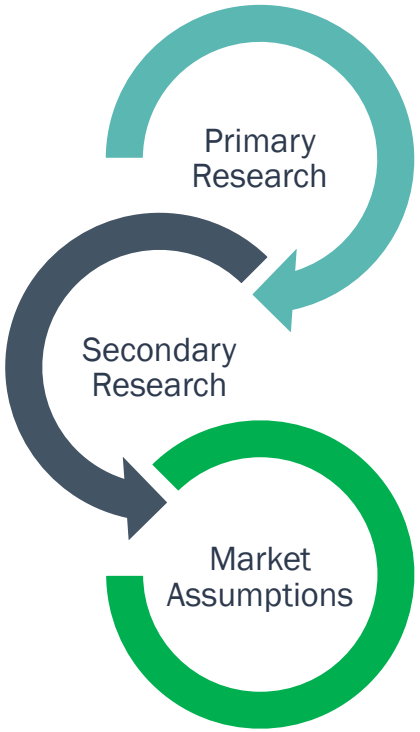
- Trading and performance multiples are derived from the selected peer group of companies
- These ratios and multiples are used as a measurement to determine whether the target company is over- or under-valued
- Multiple is applied to effectively reflect the relative value based on the state of the economy and public markets
- Important ratios to identify and include in the analysis are:
  - Price/earnings (P/E)
  - EV/EBITDA
  - Price to Sales
  - EV to sales

Every assumption in a valuation must be supported by objective, well-sourced data, which can be derived from primary and/or secondary market research

Research Methodologies

Secondary research is the main driver for historical benchmarking and provides the baseline quantitative assumptions

- Various sources may be used to complement and validate primary research, including:
  - Peer-reviewed journals or conference proceedings and abstracts
  - Pipeline, clinical trial, or prescription/sales databases
  - Industry or financial analyst reports
  - Patient advocacy groups materials
- Identifying proxies for an opportunity is key to driving baseline assumptions and may include:
  - Previous assets in a similar therapeutic area, market size, or specialty focus
  - Therapies with comparable level of clinical differentiation and/or order of market entry



Primary research is a robust method used to test or identify a product's value proposition and can drive forward-looking quantitative estimates

- Key stakeholders may be interviewed, including academic and community-based clinicians, KOLs, payers, hospital administrators, etc.
- One on one qualitative interviews can help understand the treatment paradigm, identify current patient segmentation and patient journey, unmet needs, and strength of current and emerging competitors
- Surveys among a large stakeholder sample can help drive quantitative assumptions
- A target product profile (TPP) may be used to test the potential of an opportunity, including:
  - Identification of relevant patient segments
  - Reaction to product attributes and value propositions
  - Strength of preclinical or clinical data
  - Ability to meet unmet needs
  - Adoption drivers and barriers

Case Study 1

Product opportunity assessment resulting in a revenue forecast

Key Highlights:

- Use of TPP to inform market assumptions
- Epidemiology-based revenue model

Product opportunity assessment resulting in a revenue forecast

Project Background and Objectives

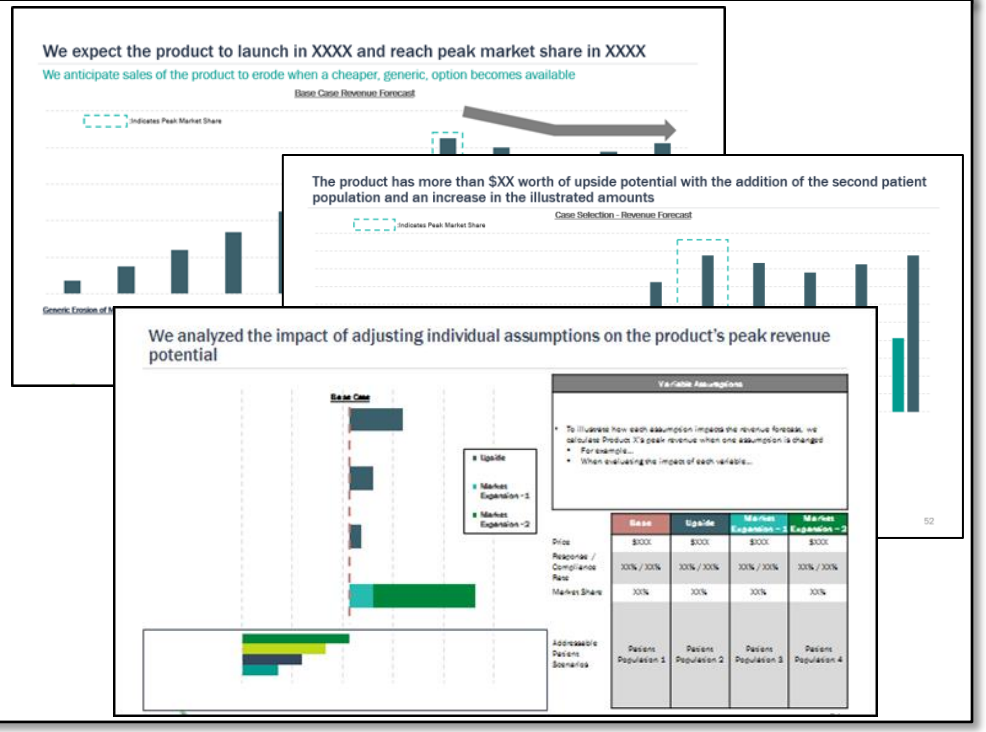
- Bluestar BioAdvisors (Bluestar) was approached by a pharmaceutical company to evaluate the U.S. market opportunity for an early stage agent for the treatment of a chronic pulmonary condition
- The analysis focused on an assessment of patient segmentation, unmet needs, the likely adoption of the product (using a TPP for stakeholder interviews), and the evolving competitive landscape

Key Activities

- In-depth U.S. stakeholder interviews were conducted to discuss treatment dynamics, unmet needs, and solicit feedback on a TPP
  - 20+ interviews with PCPs and specialists
  - 4 payer interviews
- Constructed a revenue forecast with adjustable metrics to understand sensitivities of our assumptions. Adjustable variables included:
  - Patient segment
  - Market share
  - Launch timing
  - Response rate

Key Output

- Assessed how the product would be adopted across relevant patient segments in the future treatment landscape
- Created an Excel-based peak revenue forecast for internal use with variable assumption toggles
- Supported the revenue forecast with assumptions driven from primary and secondary research
- Created a presentation summarizing the revenue forecast, as well as key market drivers



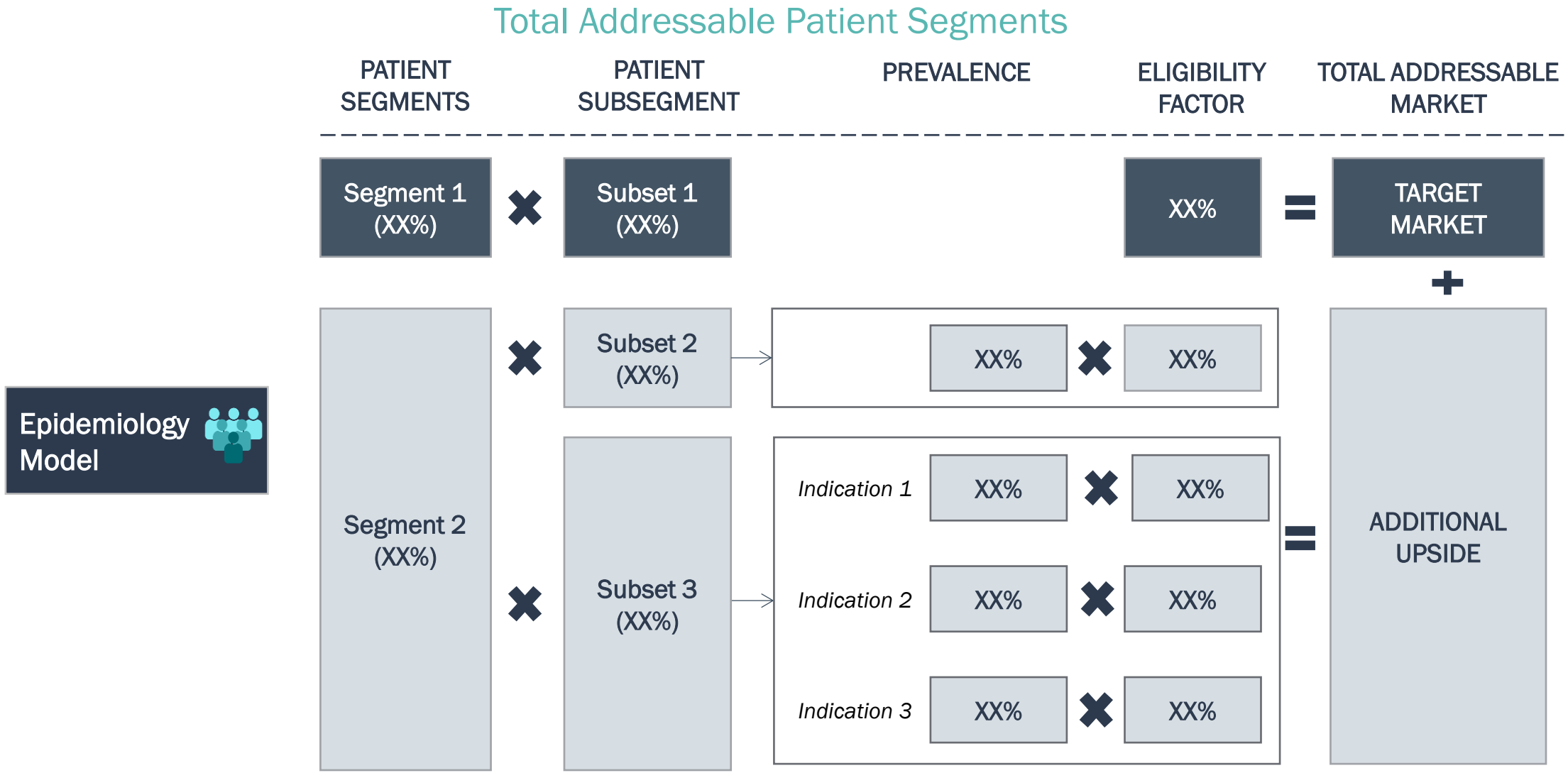
We used a TPP to understand the benefits and shortcomings of our client's product, Product X, and how its profile compares to its main competitor - Product Y

PRODUCT X TPP			
Indication	Chronic Pulmonary condition		
Overall Rationale	• _____ receptors are expressed by… • Targeting _____ receptors for the condition has been validated based on… • Product X has the potential to provide…		
MOA	A receptor antagonist		
Treatment Approach	Chronic use in patients as a monotherapy		
Dosing	• XX mg PO BID		
Preclinical Data To Date	*Head to head data against Product Y competitor*		*Safety Data*
	• Reduced tolerability issue • Dose-dependent efficacy demonstrated in animal models	<u>Superior Potency and Selectivity</u> • 1 log more potent than the competing Product Y • 3 log more selective for A receptor	• No genotoxicity • No clinical signs in monkey • Vomiting seen in dog at higher doses
Anticipated Clinical Efficacy	*Comparable efficacy to Product Y demonstrated in Phase 2 studies*		
Anticipated Clinical Safety (AEs)	*Superior to Product Y; benchmark data for which is shown below* • *~__% of patients reported side effect 1* • *~__% of patients reported side effect 2* • ~__% of patients reported side effect 3 • ~__% discontinuation due to AEs, most of which were related to side effect 1, 2 or 3		

The TPP informed multiple assumptions in the revenue forecast, including:

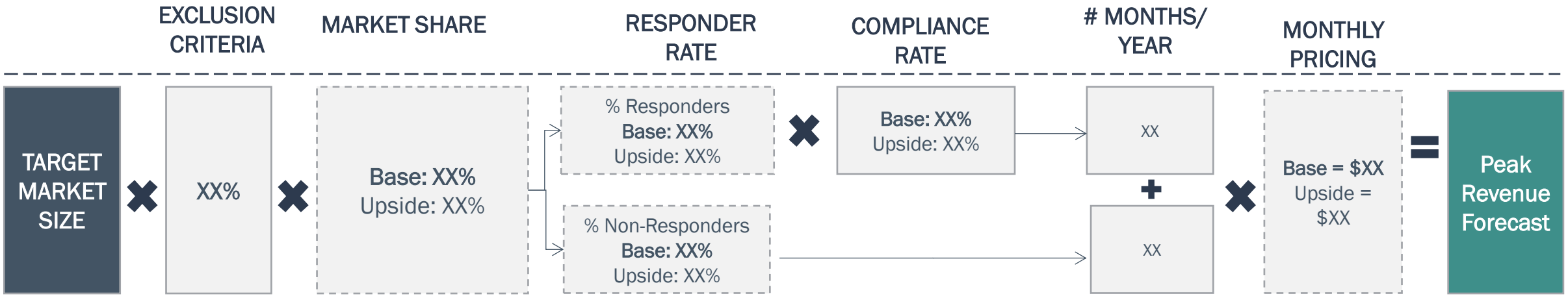
- **Key patient segments to target and expected penetration** within each, based on patient eligibility and degree of clinical benefit expected with Product X
- **Market share expectations** from physician interviews and the clinical data requirements relative to competing Product Y, needed for base, high, low share scenarios
- **Pricing expectations** from payers, based on demonstrated clinical benefit and tier placement of comparable product analogs

Based on the specific patient inclusion criteria, addressable patient populations and market penetration were calculated; additional patient segments were also considered as an upside



To calculate the product's peak revenue we developed assumptions for a range of variables based on product proxies, secondary literature, and stakeholder feedback

Peak Revenue Forecast



Upside/ Downside scenarios

Excludes patient segment Y

Base:
- Assumes competition takes share

Upside:
- Assumes that there is less competition

Base:
- Represents patients with >XX% response to therapy

Upside:
- Represents patients with >XX% response to therapy

- XX% represents average
- XX% is seen with other types of patients

Changes in assumptions regarding duration of therapy for various patient segments

Dotted Boxes indicate assumptions that can be toggled in the model

Case Study 2

Prescription-based valuation model with a terminal value for one asset in two indications

Key Highlights:

- Comparable analysis to determine market share
- Prescription-based revenue build
- Methods to determine terminal value

Prescription-based valuation model with a terminal value for one asset in two indications

Project Background and Objectives

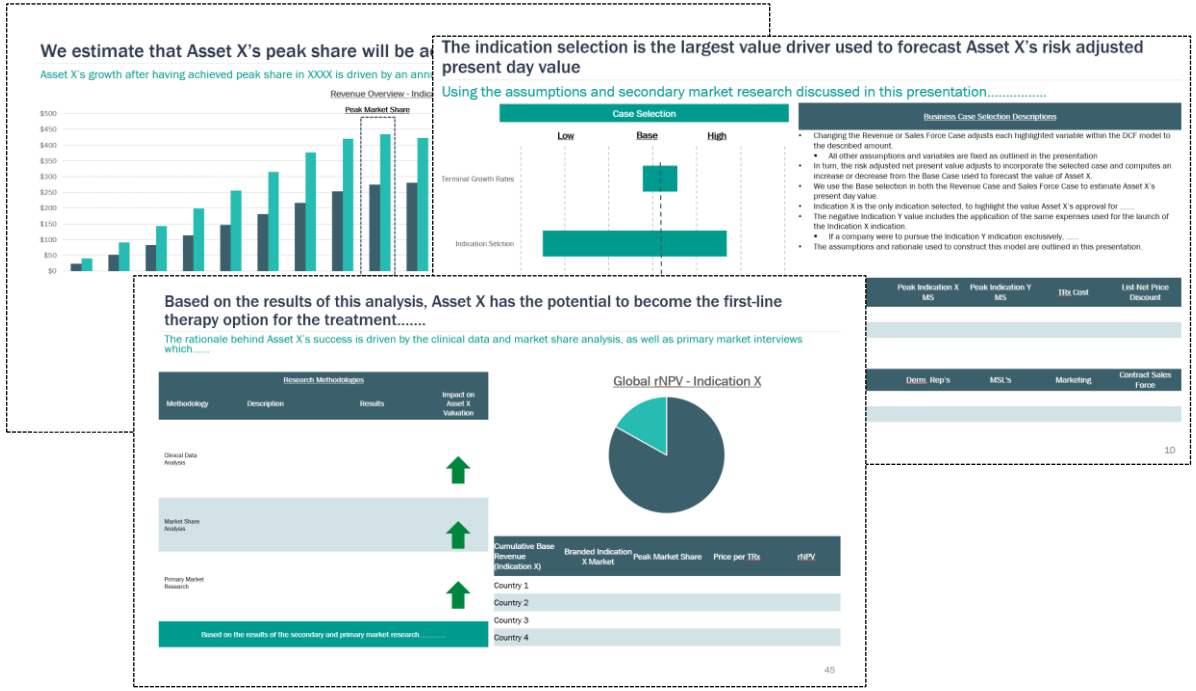
- Bluestar was approached by a small pharmaceutical company seeking an objective valuation analysis using a DCF and comparable transaction analysis method
- Using secondary and primary market research, U.S. and EU5 DCF models were constructed that calculated the NPV and rNPV of the novel reformulation in two similar dermatological indications
- A comparable transaction analysis was also constructed to identify the relative value of the opportunity

Key Activities

- DCF Model Construction
  - Created a revenue forecast for two target indications
  - Outlined the clinical development path and annual expenses
  - Estimated the necessary sales force to commercialize in the U.S. & EU5
- Used U.S. prescription data of comparable approved products to determine the market share of each approved treatment option; identified which products achieved the most market share, based on product attributes and other market dynamics
- Conducted focused interviews with a handful of U.S.-based specialists

Key Output

- Created three different revenue scenarios, which were used to calculated the rNPV range
- Identified which expenses shifted the rNPV
- Calculated the increase in intrinsic value for the asset as it advances through clinical development
- Determined the asset's relative value, as well as terminal value



Based on our client's product profile (Product X), which exhibits superior efficacy, we concluded that the product could be used as an earlier stage therapy and capture significant share against the top competitors for both indications

Product X Market Share

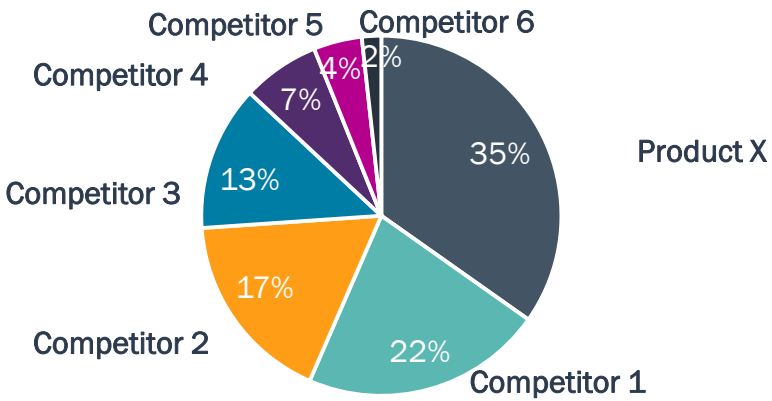
US Script Data | Clinical benefit relative to competitors

Product	TRx	TRx %	Primary Efficacy Endpoint	Secondary Efficacy Point Endpoint	Qualitative Feedback on Product X and competitors
Product X	--	--	XX%	Superior by x%	Qualitative Feedback X
Competitor 1	XX	53%	XX%	XX%	Qualitative Feedback 1
Competitor 2	XX	33%	XX%	XX%	Qualitative Feedback 2
Competitor 3	XX	20%	XX%	XX%	Qualitative Feedback 3
Competitor 4	XX	11%	XX%	XX%	Qualitative Feedback 4
Competitor 5	XX	7%	XX%	XX%	Qualitative Feedback 5
Competitor 6	XX	2%	XX%	XX%	Qualitative Feedback 6

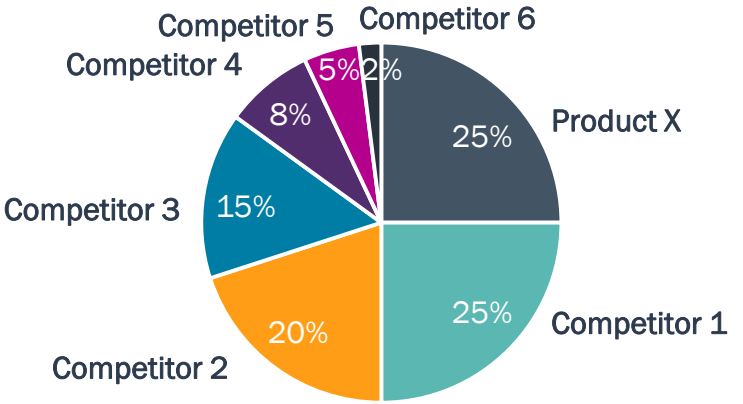
Relative market share was based on both the primary and secondary research:

- Clinical trial results and historical script data of current competitors
- Physician feedback on efficacy of Product X compared to competitors and potential line of therapy for which it could be introduced

Estimated Market Share of Product X in Indication 1



Estimated Market Share of Product X in Indication 2



We constructed a prescription-based model to forecast the impact Product X will have on the treatment of both dermatological indications

Prescription Model Revenue Build and DCF model

Prescription Model	Dermatological Indication 1	Dermatological Indication 2
Total TRx's and Growth Rates	6M Scripts	1.5M Scripts
	-2% Growth Rate	
Peak Product Share	35% Peak Market Share	25% Peak Market Share
Adoption Rate (Years to peak market share)	8 years to peak	
Price	$425/year	
	5% annual growth rate	

The following assumptions were used to support the DCF model and to calculate the terminal growth rate

Assumption	Rate
COGS	$20 per sold unit
Clinical Development Costs	$40M for completion of Phase 2b-Market

Clinical Development Timeline	• Indication 1 & 2
	  • Completion of Phase 2 trials
	  • Completion of Phase 3 trials
	  • Time for NDA Filing
	  • Expected Product Launch

G&A Expense	5% of Net Sales
	  • 70& salary and personnel
	  • 90% for general overhead costs

Promotion & Marketing Expense	15% of Net Sales
Taxes	35%
Probability of Success Rates	Phase 1: A%; Phase 2: B%; Phase 3: C%; Approval: D%
Discount Rate	X%
Terminal Growth Rate	-32%

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Terminal value is the value of a company's expected free cash flow beyond the period forecasted in a DCF model

Methods to Calculate Terminate Value

Terminal Value Application

- After capturing the patent exclusivity period in a DCF model, a perpetual growth model is used to estimate the terminal value of the product
- Usually when valuing a biopharma asset the terminal value captures a small portion of the product's intrinsic value due to generic erosion

1

Exit Multiple Method Overview

- The exit multiple approach assumes that the business will be valued on a market multiple basis at the end of a specific year
- This method is heavily impacted by the performance of the market
- Multiples are usually identified by conducting a comparable company or transaction analysis
  - These analyses focus on numerous companies and completed transactions to calculate specific financial multiples (revenue, EBITDA, EBIT, etc.)
  - Users must identify comparable examples that share similar characteristics with the target asset
- A value is typically determined as a multiple of EBIT or EBITDA
- These multiples vary based on the company, industry, and other economic conditions

2

Perpetual Growth Model

- Applies one terminal growth rate to the last risk adjusted free cash flows captured in the DCF model
  - This is used in place of estimating the annual revenues and expenses the product will generate beyond the time period captured in the DCF
- The method assumes that the product's growth will continue at a stable rate until the product ceases to exist
- Compared to the exit multiple approach, the perpetual growth method does not incorporate external market trends (i.e. financial multiples)
- For this project, we applied a negative growth rate, which represents the assumption that the product will ultimately dissolve
- The terminal value accounts for a minority of the total rNPV versus the amount of value captured in the market exclusivity period

Case Study 3

Epidemiology-based valuation model supported by primary and secondary market research and precedent transactions analysis

Key Highlights:

- Payer feedback informing insurance coverage and pricing assumptions
- Precedent transaction analysis providing relative value of a target opportunity
- NPV analysis informing strategic decisions

Epidemiology-based valuation model supported by primary and secondary market research and precedent transactions analysis

Project Background and Objectives

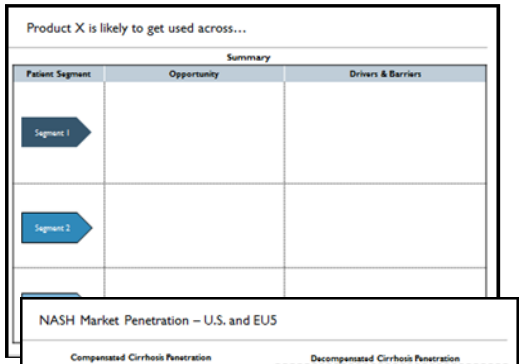
- Bluestar was engaged by a life science investment bank on behalf of their client to evaluate the market opportunity for a novel agent to treat NASH and develop a global revenue forecast, as well as NPV in key geographies
- The analysis focused on the assessment of market unmet needs, the likely adoption of the product based on a TPP, and the evolving competitive landscape

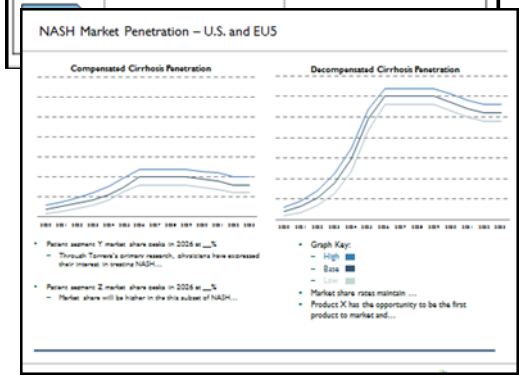
Key Activities

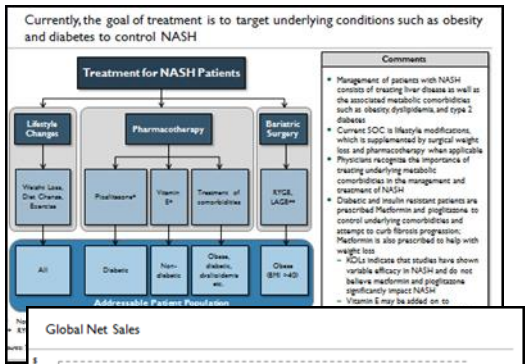
- Extensive secondary research included
  - Peer-reviewed literature
  - Drug pipeline and clinical trial databases
  - Company literature and financial reports
  - Market reports
- In-depth stakeholder interviews in the U.S. and EU5 to discuss treatment dynamics, unmet needs, and to solicit feedback on a TPP
  - Interviews with gastroenterologists/hepatologists
  - Payer interviews (U.S. only)

Key Output

- Assessed how the product would be adopted in the future treatment landscape
- Created a product valuation supported by market analysis
  - Identified the addressable patient population and key drivers/barriers to adoption based on market feedback
  - Evaluated pricing considerations
  - Developed assumptions and rationale for commercial efforts in the U.S. and EU5
- Analysis was used to support various strategic opportunities the client was considering







Part of the primary market research efforts focused on payers, as we sought feedback on cost of therapy, reimbursement, and factors that would influence coverage decisions

Primary Market Research Example

Reaction to TPP in Indication #1

- **Payers felt the TPP for Indication #1 was very impressive**
  - The endpoints for the indication were clinically significant, as ideally the product should show a reduction in hospitalizations
  - There were no safety concerns
- **Payers are well aware of the high cost associated with treating these patients as they advance in severity, due to the lack of optimal treatment options to modify the course of the disease**
  - However, payers felt that should the improvement described in the product profile be demonstrated, the product could be priced like a specialized product, in excess of $XX
- **Payers anticipate that the product will require prior authorization**

Reaction to TPP in Indication #2

- **Payers had more questions about the TPP in Indication #2, including:**
  - Long-term improvement the product would have on patients
  - Better understanding of which patients would benefit the most from treatment
- **Being that this population would likely be on drug for many years, payers acknowledged that they are likely to be more sensitive to price in this indication**
  - Payers discussed prior authorizations, re-authorizations, and specialty tiers as likely

OVERALL PAYERS FELT THERE WAS A GREATER CHANCE FOR PREMIUM PRICING AND LESS RESTRICTIVE FORMULARY STATUS IN INDICATION #1

By analyzing precedent transactions that had similar characteristics to the product being assessed, the relative value of the target opportunity was estimated

Precedent Transaction Analysis

Date	Licensor	Licensee(s)	Asset Name	Phase	Deal Territory	Upfront	Total Milestone	Total Deal Value	Royalty Notes	Therapeutic Area	Target Indication
2016	Licensor 1	Licensee 1	Asset 1	2	Japan	$XX	$XX	$XX	The licensor will receive double-digit royalties based on net sales	Therapeutic Area 1	Indication 1
2015	Licensor 2	Licensee 2	Asset 2	2B	China, Hong Kong, and Macau	$XX	$XX	$XX	The licensor will receive royalties of 10% if the licensee succeeds in bringing the product to market the deal territories	Therapeutic Area 2	Indication 2
2015	Licensor 3	Licensee 3	Asset 3	3	China, Hong Kong, Macau, and Taiwan	$XX	$XX	$XX	The licensee has agreed to pay royalties on net sales of the product at a rate in the teens	Therapeutic Area 3	Indication 3
2015	Licensor 4	Licensee 4	Asset 4	2A	Global; Excluding Japan, Korea, Taiwan, China & Latin America	$XX	$XX	$XX	Royalties under the license agreement are due on net sales in the territory during the term of the agreement	Therapeutic Area 4	Indication 4
2014	Licensor 5	Licensee 5	Asset 5	2/3	Japan and Other Select Countries Throughout Asia (Undisclosed)	$XX	$XX	$XX	Undisclosed	Therapeutic Area 5	Indication 5
2014	Licensor 6	Licensee 6	Asset 6	2A	Global; Excluding North America and Japan	$XX	$XX	$XX	The licensor will receive royalties on net sales of the product from the licensee	Therapeutic Area 6	Indication 6
2014	Licensor 7	Licensee 7	Asset 7	3	USA	$XX	$XX	$XX	Undisclosed	Therapeutic Area 7	Indication 7
2014	Licensor 8	Licensee 8	Asset 8	2B	Global; Excluding US & Japan	$XX	$XX	$XX	The licensor will receive royalties on future sales	Therapeutic Area 8	Indication 8
First Quartile						$XX	$XX	$XX			
Median						**$XX**	**$XX**	**$XX**			
Mean						**$XX**	**$XX**	**$XX**			
Third Quartile						$XX	$XX	$XX			

- The illustrated transactions were selected based on the similarities each product had to our client's product, including:
  - Relevance to the therapeutic area
  - Ongoing development of each product in Phases 2-3
  - The agreements listed focused on a specific region or country (to distinguish such an analysis from purely global licensing transactions)
- Based on the selected transactions, we believe our client can seek to receive an upfront, total milestone, and total deal value within the median to mean range

After completing the DCF model, the present day value was calculated for each potential strategic transaction in which the client would or wouldn't retain commercial responsibilities

	Strategic Option	Key Components	Pros/Cons	rNPV of Strategic Option
External Commercial Focus	**Regional Licensing Transactions** License individual country or regional rights to separate companies	▪ Comprehensive process to identify the best partner for each region ▪ Tailor licensing deal to partner and regional characteristics ▪ Typical deal involves upfront payment, milestone payments, and royalties	▪ Pros: Select best partner for each region; no impact on other regions should partner terminate agreement; receive upfront cash payments ▪ Cons: Time consuming negotiation process; must work closely with numerous partners	▪ Region 1: $XX ▪ Region 2: $XX ▪ Region 3: $XX ▪ Region 4: $XX Cumulative Value $XX
	Global Divestiture Divest the global rights of the product through a sale or out-licensing agreement	▪ Select one strategic partner with a global presence ▪ Benefit of working with one partner; risk of a potential negative outcome if partner terminates deal	▪ Pros: Collaboration with only one partner; proper selection of a global partner ensures that product will be sold worldwide; receive one upfront payment ▪ Cons: High impact if partner terminates; partner may not have strong commercial presence in all regions	▪ Cumulative Value: $XX
Internal Commercial Focus	**Affiliate Commercialization** Use a subsidiary of the ownership company to distribute the product	▪ This option exists in markets where the company has an existing affiliate equipped with a sales force ▪ The company may choose to pursue this strategy in certain markets while out-licensing the product in other markets	▪ Pros: Maintain all operations in-house; easier communication for planning and implementation; steady cash flow stream ▪ Cons: Affiliates may not have strong presence in certain regions; not able to leverage strengths of a partner	▪ Region 1: $XX ▪ Region 2: $XX ▪ Region 3: $XX ▪ Region 4: $XX Cumulative Value $XX
	Strike a Co-Promotion Agreement Execute an out-licensing agreement with co-promotion stipulations	▪ Partner with a company who has an established sales force within the PCP and Specialty physician setting the product is developed to treat ▪ The company is responsible for a portion of the sales and marketing expenses	▪ Pros: Potential to partner with an established sales force; increased share of voice; share expenditure with partner ▪ Cons: Must share revenues; overlap may not be resource efficient	▪ Region 1: $XX ▪ Region 2: $XX ▪ Region 3: $XX ▪ Region 4: $XX *Assuming 50/50 split Cumulative Value $XX

The NPV analysis provided our client with a better understanding on the implications for each strategic option, particularly around commercial considerations

Case Study 4

Transaction preparation supported by a valuation

Key Highlights:

- Non-binding term sheet summary
- Using rNPV of term sheets to inform deal decisions

Transaction preparation supported by a valuation

Project Background and Objectives

- Bluestar, in collaboration with a life science investment bank, assisted a small pharmaceutical company in a sell-side mandate where the objective was to divest its early stage gastrointestinal (GI) program to a strategic life sciences partner
- Advising activities included marketing the opportunity to parties with an existing GI portfolio, sharing the advantages of the novel GI portfolio, and assisting the client in obtaining the ideal qualitative and quantitative terms from a strategic partner

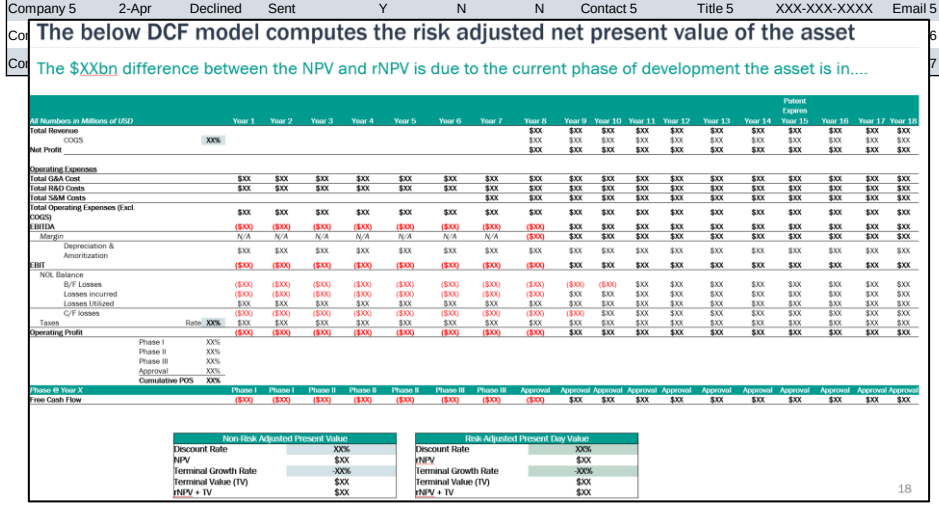
Key Activities

- Authored and edited non-confidential information memoranda that were shared with executives at each potential bidding party. Memoranda included:
  - Opportunity teaser
  - Non-confidential deck
  - Clinical trial data summary
- Constructed an independent valuation and transaction models that calculated the rNPV based on the quantitative terms proposed in the non-binding term sheet (NBTS)

Key Output

- Captured the interaction of each team member by creating a communication database
- Conducted >10 in-depth discussions with potential bidders to gauge their interest in the opportunity
- Created a DCF model calculating the global NPV of the opportunity
- Created a transaction model, which calculated the NPV each party would retain based on the terms in the final contract

Company	Contact Date	Response	Non-Conf materials	CDA	Conf Call	Data Room	Point of Contact	Title	Phone Number	Email
Company 1	2-Apr	Declined	Declined	Y	N	N	Contact 1	Title 1	XXX-XXX-XXXX	Email 1
Company 2	22-Apr	Declined	Sent	Y	Y	Y	Contact 2	Title 2	XXX-XXX-XXXX	Email 2
Company 3	21-Apr	Declined	Sent	Y	Y	Y	Contact 3	Title 3	XXX-XXX-XXXX	Email 3
Company 4	21-Apr	Sent Reminder	Sent	Y	Y	Y	Contact 4	Title 4	XXX-XXX-XXXX	Email 4
Company 5	2-Apr	Declined	Sent	Y	N	N	Contact 5	Title 5	XXX-XXX-XXXX	Email 5



After receiving competitive bids an information memorandum was prepared highlighting the quantitative terms captured in each NBTS

All Amounts in $mm	NBTS #1		NBTS #2
Milestone Payments	Indication 1	Indication 2	Lead Product
Upfront	$XX Cash		$XX Cash $XX Equity
Phase 1	–	–	$XX
Phase 2	$XX	–	$XX
Phase 3	$XX	$XX	$XX
Regulatory Filings	$XX / $XX / $XX	$XX / $XX / $XX	–
Regulatory Approval	$XX / $XX / $XX	$XX / $XX / $XX	$XX / $XX / $XX
Total Deal Compensation	**$XX**		**$XX**

	NBTS #1	NBTS #2
Sales Milestones @ $SM1 / $SM2 / $SM3 / $S4M / $SM5	$XX / $XX / $XX / $XX / $XX	$XX / $XX / $XX / $XX / $XX
Royalties Tranches $R1 / $R2 / $R3 /$R4 / $R5	XX% / XX% / XX% / XX% / XX%	XX% / XX% / XX% / XX% / XX%

Comments on NBTS #1

- In addition to the clinical and commercial milestone payments the company has also included a transaction payment
- If there is a change in control to the product the transaction payment clause will award the licensor a portion of the total transaction amount
- The amount of transaction payment the licensor will receive is based on the timing of the product's development:
  - XX% prior to the completion of Phase 2B
  - XX% on or after Phase 3

Comments on NBTS #2

- There are minimal discrepancies between the current NBTS and the previously submitted NBTS
- Additionally, the licensee has included clinical milestone and royalty payments for the development of an additional indication
  - $XXmm
  - XX% royalty if net sales ≥ $XXmm
  - XX% royalty if net sales < $XXmm

rNPV Split
• The rNPV split of each NBTS is (Licensor% / Partner %): ▪ NBTS #1: XX% / XX% ▪ NBTS #2: XX% / XX%

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Utilizing the calculations from the DCF model, the present day value the licensor and licensee would receive was calculated based on the terms of each NBTS

NBTS Description	Total rNPV of Each NBTS
NBTS #1	$XX
NBTS #1 Version 2	$XX
NBTS #2	$XX
NBTS #2 Version 2	$XX

Value Retained by Licensor	Value Retained by Licensor
$XX	XX%
$XX	XX%
$XX	XX%
$XX	XX%

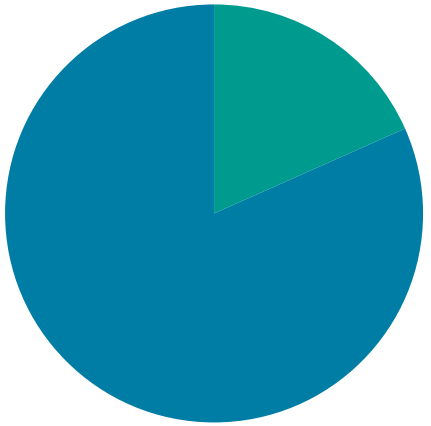
Value Allocated to Licensee	Value Allocated to Licensee
$XX	XX%
$XX	XX%
$XX	XX%
$XX	XX%

NBTS Description	Royalties					Sales Milestones			
	$R1	$R2	$R3	$R4	$R5	$SM1	$SM2	$SM3	$SM4
NBTS #1	X%	X%	X%	X%	X%	$XX	$XX	$XX	$XX
NBTS #1 Version 2	X%	X%	X%	X%	X%	$XX	$XX	$XX	$XX
NBTS #2	X%	X%	X%	X%	X%	$XX	$XX	$XX	$XX
NBTS #2 Version 2	X%	X%	X%	X%	X%	$XX	$XX	$XX	$XX

General Observations

- NBTS #2 Version 2 is not substantially different from NBTS #2 Version 1 that was submitted previously
- Financially, the only difference is an increase of $XXmm
- Qualitatively, the licensee denied three of the clients requests
- Each request was related to the development of the product and non-compete clauses that satisfied our clients expectations

rNPV Split of NBTS #2 Version 2



Key Takeaways and Introduction to Bluestar BioAdvisors

Key Takeaways

- Financial valuations inform business development decisions when preparing for a transaction or to assist in prioritizing asset portfolios
- Valuation methodologies consist of DCF, which serves as the basis of rNPV construction, as well as comparable transactions and comparable companies analyses
- rNPV remains the preferred method of financial valuation that sets the stage for a common ground in negotiations across biopharmaceutical organizations
- Construction of a financial model can serve as the basis of a transaction model, which calculates the NPV each party would retain based on the terms of non-binding terms sheet and, ultimately, the contract
- Every assumption in a valuation must be supported by objective, well-sourced data, which can be derived from primary and/or secondary market research. The saying “garbage in/garbage out” rings especially true when applying assumptions to a model
- Epidemiology- or prescription-based models can be constructed to derive revenue potential of clinical-stage or commercial products; various factors need to be considered when determining which approach is optimal in a given situation
- Although most rNPVs are typically calculated based on a 10-year discounted cash flow or the life of the exclusivity period, terminal value provides additional insight into a product’s “perpetual” value
- Comparable transaction and company analyses are used to validate valuations by using real-world examples and by trying to account for the impact of product, company, and market conditions

About Bluestar BioAdvisors

- Bluestar BioAdvisors LLC is a boutique, client-centered consulting firm that services companies in the life sciences industry.
- We assist clients in answering key strategic questions about asset value, positioning, and future market potential.
- We also serve as an independent, objective advisor, guiding our clients through the critical decision-making points of portfolio planning and business development activities.
- Our clients range from startups to major multinationals. They may be seeking to:
  - Better understand how to optimally develop and position products to meet the needs of the market
  - Gain an independent perspective on how to prioritize investments or develop product/therapeutic area strategies
  - Obtain assistance with identifying and characterizing new licensing or acquisition opportunities
- Our services focus on market and product assessments, commercial diligence, forecasting/NPV analysis, product positioning, competitive landscape analysis, asset search and evaluation, and therapeutic area/indication prioritization and strategy.

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