XYZ Biotech: A Fictional Business Development Case Utilizing Quantitative Tools to Evaluate a New Antibody-Drug-Conjugate Opportunity for Metastatic Breast Cancer

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Multiple considerations must be evaluated with a new acquisition or license in biopharmaceutical business development. This case utilizes a fictional company, XYZ Biotech, to illustrate the quantitative considerations in evaluating an antibody-drug combination product in the metastatic breast cancer (mBC) space. The steps shown in this case also include the development of a market model to define the potential size of the market opportunity, a weighted benefit pricing model to evaluate the present price, and a net present value model to estimate projections from the product. The case also engages multiple qualitative considerations as part of the discussion section. It concludes by offering several nuanced questions at the end to stimulate discussion around the analysis, probe additional considerations needed for a business case, and analyze what other elements or issues would drive a decision. In the appendix is a short case summary of key facts for participants to develop solutions and share in class before reviewing the case narrative.

Keywords: bottom-up analysis, Compounded Annual Growth Rate (CAGR), discount rate, Free cash flow (FCF), market sizing, market model, Net Present Value (NPV), pricing model

INTRODUCTION

Biopharmaceutical business development managers commonly encounter difficulty deciding whether a potential new innovative product is worth acquiring from a potential partner. These individuals must weigh the value of its need compared to existing alternatives (if any), its acceptance, and differentiation (influence) in the industry, and strategically plan for an impact on its market share, amongst other economic changes (Austin, 2016). The challenge is evaluating the acquisition's future potential and impact on the

company's value (Austin, 2016). This effort involves engaging in financial analysis as part of the due diligence required to assess the opportunity to acquire a pharmaceutical asset.

For new ventures, the stages of maturity are viewed to establish different strategies to engage, create, value, and develop revenue or resource opportunities (Austin, 2016). The three stages of maturity are project, product, and platform (York et al., 2022). For projects, ventures can partner through project collaborations via research to fit their assets within another firm's value chain (York et al., 2022). They also may license the asset or gain an early-stage corporate venture, but this would be a low valuation (York et al., 2022). For products, licensing and alliances are strategies to pursue partnerships, and revenue can be generated through out-licensing medicinal chemistry assets early in the process (York et al., 2022). Depending on the product development stage, this licensing will involve more valuation and commitment (York et al., 2022). Products may also present merger and acquisition opportunities with complementary firms and offerings (York et al., 2022). Lastly, platforms represent a more mature entity using technology, products, established leadership, and personnel for growth (York et al., 2022).

This case imagines that one is a business development manager at XYZ Biotech (XYZ), a fictional oncology biopharmaceutical company. The year of this assessment is 2013. Based on the current unmet needs in the metastatic breast cancer (mBC) space for human epidermal growth factor receptor 2 (HER2) positive patients and the company's desire to expand its pipeline, XYZ's business development team is examining an opportunity to acquire an antibody-drug conjugate (ADC) treatment. As the business development manager, one must engage in a "due diligence" effort, which involves both quantitative and qualitative analysis to make a "go" or "no go" recommendation.

So, how should this manager proceed in this business development decision? This case proceeds through several quantitative steps to inform the overall business analysis, which involves market size, growth rate, price-to-value, and net present value assessments. These elements guide the flow of the case and the ultimate decision for this proposal. The case closes by probing the audience to make the final recommendation from the manager's perspective, using supportive evidence from the case's fact pattern. The discussion and probing questions facilitate further analysis and discourse regarding considerations that could influence the final recommendation on this presented asset opportunity.

BACKGROUND

Metastatic Breast Cancer

The first step in acquiring a drug used in a certain disease state is developing a strong understanding of the current therapeutic landscape. Therefore, it is important to understand the epidemiology, up-to-date treatment guidelines, and ADCs currently on the market in the mBC therapeutic area for this case. Breast cancer is the second leading cause of cancer-related death in women (Centers for Disease Control and Prevention, 2023). Thirty percent of all new female cancers yearly are breast cancer diagnoses (SEER, 2023). The American Cancer Society estimates that in the United States, by 2023, there will be about 297,790 new invasive cases, 55,720 new ductal carcinomas in situ cases, and 43,700 deaths from breast cancer (American Cancer Society, 2023). Death in this patient population has decreased only by one percent from 2013 to 2018 (American Cancer Society, 2023).

On the contrary, incidence rates have increased by 0.5% annually (American Cancer Society, 2023). The median age of a breast cancer diagnosis is 62, alluding to the fact that this disease mainly occurs in middle-aged and older women (American Cancer Society, 2023). Black women experience the highest death rate, whereas Asian/Pacific Islanders have the lowest (American Cancer Society, 2023). More than 3.8 million breast cancer survivors are currently in the United States, and some patients are still being treated (American Cancer Society, 2023).

According to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), treatment options in patients with breast cancer vary depending on the type of breast cancer (i.e., TNBC [triple negative breast cancer], ER+ [estrogen receptor], HER2-, HER2+, etc.) (NCCN, 2023). Surgery, chemotherapy, hormonal therapies, targeted therapies, and radiation are some treatments offered to these patients (NCCN, 2023).

At the time of this case assessment (2013), the standard treatments included HERCEPTIN®, generic taxane, PERJETA®, TYKERB®, AND XELODA® (NCCN, 2013). For treatment naïve patients, the following combinations are used: HERCEPTIN® + generic taxane, HERCEPTIN® + PERJETA®, and HERCEPTIN® + PERJETA® + generic taxane (NCCN, 2013). For recurrent patients, HERCEPTIN® + generic taxane, HERCEPTIN® + TYKERB®, HERCEPTIN® + PERJETA®, and TYKERB® + XELODA® are more commonly used combinations (NCCN, 2013).

In this case, the fictional company seeks to acquire an ADC, an example of targeted therapy, as previously discussed. An ADC is a monoclonal antibody that delivers highly potent chemotherapy agents to kill cancer cells. They bind to specific proteins or receptors on the cancer cells and can kill them with the potential for reduced damage to neighboring cells (NCI, 2023). The number of diagnoses and death rates in the mBC population shows that there are still unmet needs that must be addressed, such as disease control, prolonged intervals of therapy, and adverse events due to treatments. The unmet need involves identifying and developing treatment regimens with improved tolerability that increase patient quality of life, reduce patient burden, and maximize economic value.

XYZ Biotech

In this fictional case study, XYZ is a global biotechnology company developed in 2010 that values scientific excellence and innovation. The mission of this company is to work with urgency, develop medicines for severe diseases, and impact the lives of patients living with mBC. XYZ is a small company of approximately one hundred employees who bring diverse perspectives and skills from various previous pharmaceutical companies. The executive leadership team is also composed of members from varying educational backgrounds and areas of work. All XYZ employees work together with the same common goal: finding a cure for breast cancer. XYZ is dedicated to hiring employees who exemplify the core values of integrity, diversity, authenticity, and innovative thinking in the work they do every day.

XYZ has one product in its pipeline, and this asset is currently in phase 2 of clinical development. XYZ is awaiting results from the phase 2 study to determine if the company will proceed with a phase 3 trial. XYZ hopes to invest 55% of its earnings in research and development in the upcoming year. Additionally, the company is now interested in joining the novel ADC space for patients with mBC.

Business Case

It is important to evaluate an opportunity before pursuing it. No decision should be made at the business level without weighing the potential consequences that could occur. Do the benefits outweigh the risks? Will the business development strategy stimulate the company's growth and add value to its pipeline, or will it be a sunk cost? In the pharmaceutical industry, mergers and acquisitions allow companies to access new research while conducting less of their own. Mergers and acquisitions are when companies or assets are consolidated through financial transactions (DePamphilis, 2001). These transactions can be mergers, acquisitions, consolidations, tender offers, purchase of assets, and management acquisitions (DePamphilis, 2001). Although "mergers" and "acquisitions" are used interchangeably, a merger combines two firms, while an acquisition is when one company purchases another outright (Danzon et al., 2007). In the instance of companies using mergers and acquisitions to obtain access to new research while conducting less of their own, the investment of traditional chemically synthesized drugs produced lower financial returns, leading traditional and larger pharmaceutical companies to lean on investing in smaller companies with pipelines that contain complicated and costly biologics (Danzon et al., 2007; Opler et al., 2014).

This business development opportunity aims to understand the importance of identifying therapeutic area unmet needs, evaluating revenue potential, and assessing the value a product can add to an existing portfolio before confirming the product's acquisition (Opler et al., 2014). Given many variables, the quantitative side of this business case involves the following considerations. First, one must consider the potential market opportunity for this combination product before confirming the acquisition. Next, the case shifts to discuss how to evaluate revenue potential properly. One must determine if the present price of the product looking to be acquired is appropriate or if it may need to be adjusted based on the clinical benefit score of the product. Lastly, the net present value (NPV) estimates the value a product can add to an existing

portfolio. Free cash flow (FCF) estimates revenues from the five-year income statement proforma, potential market share, proposed acquisition price, and prevailing cost of capital would influence the NPV analysis. By the end of the case, the goal is to explain whether the mBC market is attractive if the product is based on market size, price, and NPV.

MARKET SIZING AND MODELING

When investigating market opportunities, the first step is to conduct secondary market research to estimate product revenue trajectory (Austin, 2016). Secondary market research involves pulling data from the National Cancer Institute (NCI) SEER program (2013) (SEER, 2023); the NCCN Guidelines®, Breast Cancer Guidelines (2013) (NCCN, 2013); IMS (now IQVIA) sales of breast cancer drugs (IMS, 2013); Genentech information on competing products such as HERCEPTIN® (Genentech, 2013a) AND PERJETA® (Genentech, 2013b), and Redbook pricing information (Thompson, 2013).

In examining the data from NCI SEER and NCCN Guidelines, there are two sources of mBC patients found who are HER+: naïve (previously undiagnosed) patients and recurrent (previously treated) patients (NCCN, 2013; SEER, 2023). The number of new naïve patients annually is 3,000, and the number of new recurrent patients annually is 14,000 (NCCN, 2013; SEER, 2023).

The next part of the research examines the NCI treatment protocols and NCCN Guidelines for treatment options (NCCN, 2013; NCI, 2013). The individual agents used include HERCEPTIN® (HER), generic taxane (TAX), PERJETA® (PER), TYKERB® (TYK), and XELODA® (X) (NCCN, 2013; NCI, 2013). Examining the NCCN Guidelines for breast cancer IQVIA data, the treatment protocols for naïve and recurrent use (and percentage of the time) are found (NCCN, 2013). For naïve patients, these include HER+TAX (20%), HER+PER (30%), and HER+PER+TAX (50%) (NCCN, 2013). For recurrent breast cancer, the treatment protocols include HER+TAX (30%), HER+TYK (10%), HER+PER (10%), and TYK+X (50%) (NCCN, 2013).

Finally, the analysis needs information gathered from IMS Health (now IQVIA after IMS Health merged with Quintiles in 2016) to learn about the number of units used annually in a patient for each drug based on an average patient weighing 70 kg with a 1.6 M^2 body surface area (IMS, 2013). The annual use of each treatment's stock-keeping unit (SKU) is as follows: HER (12), TAX (12), PER (12), TYK (8.4), and X (9.8) (IMS, 2013). From the Redbook (Thompson, 2013), wholesale acquisition cost (WAC) per unit of each drug's SKU is obtained: HER ($3,310.47), TAX ($2360), PER ($4,075.66), TYK ($4,693.59), and X ($3834.26).

This market research serves to identify whether the targeted market has a large universe of potential customers, apparent future user growth, and the opportunity to attract active users. The market size and unmet needs and gaps are identified to determine whether the market is attractive to enter.

In this case, one creates an Excel model with drug pricing and a bottom-up construct of the total mBC market, including two segments, naïve and recurrent. A bottom-up analysis estimates potential sales to determine a total concluding profit (Opler et al., 2014). This construct starts at ground level and uses data, considerations, and strategic planning to predict a company's performance if a new product is acquired (Opler et al., 2014). Treatment value is estimated by calculating the yearly costs of mBC regimens using the WAC for each treatment and annual use data (SKU) (Table 1). This analysis uses the annual cost per regimen, the estimated market share based on the time in the market (pulled from IMS (IQVIA) 2013 sales of breast cancer drugs), and the number of patients to calculate the value of each market segment (Table 2).

TABLE 1*
ESTIMATED YEARLY COSTS OF INDIVIDUAL AGENTS

	SKU Units in 12 Mons Based Upon SKU Content	Cost WAC	Cost/Year
HERCEPTIN®	12	$3,310.47	$39,725.64
Generic TAXANE®	12	$2,360.00	$28,320.00
PERJETA®	12	$4,075.66	$48,907.92
TYKERB®	8.4	$4,693.59	$39,426.16
XELODA®	9.8	$3,834.26	$37,575.75

*Annual costs based on WAC/SKU, published dosing, 70 kg weight, 1.6 m2 BSA, published regiments, and number of treatments/SKU
WAC: wholesale acquisition cost; BSA: body surface area; SKU: stock-keeping unit
IMS, 2013; THOMPSON, 2013

The bottom-up analysis estimated a market size of around $296 million (M) for naive HER2+ mBC patients and $1.05 billion (B) for recurrent HER2+ mBC patients (Table 2). Typically, market sizes close to $1.3-1.5 B are worth investigating (Austin, 2016; Opler et al., 2014; York et al., 2022).

TABLE 2
ESTIMATED MARKET SIZE* FOR NAÏVE AND RECURRENT DISEASE

	WAC	%	MBC Patients	Est Patients	Est Cost WAC
Naive					
HERCEPTIN®+ TAX	$68,045.64	0.2	3000	600	$40,827,354.00
HERCEPTIN®+ PERJETA®	$88,633.56	0.3	3000	900	$79,770,204.00
HERCEPTIN®+ PERJETA+ TAX	$116,953.56	0.5	3000	1500	$175,430,340.00
Segment Total					**$296,027,928.00**
Recurrent					
HERCEPTIN®+ TAX	$68,045.64	0.3	14000	4200	285,791,688.00
HERCEPTIN®+ TYKERB®	$79,151.80	0.1	14000	1400	110,812,514.40
HERCEPTIN®+ PERJETA®	$88,633.56	0.1	14000	1400	124,086,984.00
TYKERB®+ XELODA®	$77,001.90	0.5	14000	7000	539,013,328.00
Segment Total					**$1,059,704,514.40**

*Annual $ based upon individual annual costs from Table 1, recurrent from adjuvant, and estimate market share based on time in the market.
TAX: Generic Taxane
IMS, 2013; NCCN, 2013; THOMPSON, 2013

Pricing Analysis Using the Price/Benefit Model

Furthermore, the next step, in this case, is to evaluate whether the current market price of the drug is reasonable or if the market price should be modified based on several factors, such as clinical benefit, survival, and competitor pricing. A weighted benefit pricing model is created to assess the clinical benefit of therapy concerning its cost. Such a model is built to create an environment where the marginal costs of a drug asset are equal to the marginal benefits the drug provides. It can allow for more realistic pricing (Kesner & Walters, 2005). This model will help standardize all current treatment options.

To create the model, one must first decide which variable to use to compare to the current cost of treatment. In oncology, overall survival is the gold-standard clinical endpoint typically used since cancer treatments aim to extend a patient's life (Ha et al., 2022). Given the long-term nature of this endpoint, it can be valuable in assessing the impact of a drug on a disease, especially in early-stage cancers. As this case focuses on mBC, clinical benefit is a translation of the impact of the treatment regimen on overall survival within the pricing model.

After determining the variables for this pricing model, the next step is to understand how to reconcile the two market segments, naïve and recurrent, to create one pricing model for the entire disease state. One approach is to create a ratio for each regimen based on the clinical benefit and the market share. This approach allows one to create a weighted benefit of a regimen based on its relative market size (Table 3).

TABLE 3
WEIGHT BENEFIT SCORE MODEL

Naïve	**Survival**	**CBS**	**Price**	
HERCEPTIN®+ TAX	13	2	$ 5,670.47	
HERCEPTIN®+ PERJETA®	14	2.5	$ 7,386.13	
HERCEPTIN®+ PERJETA® + TAX	15	3	$ 9,746.13	
Recurrent	**Survival**	**CBS**		
HERCEPTIN®+ TAX	12	1	$ 5,670.47	
HERCEPTIN®+ TYKERB®	13	2	$ 8,004.06	
HERCEPTIN®+ PERJETA®	13	2	$ 7,386.13	
TYKERB® + XELODA®	12	1	$ 8,527.84	
Composite	**Naive CBS**	**Recurrent CBS**	**Weighted CBS**	**Price**
HERCEPTIN®+ Generic Taxane	2	1	1.125	$ 5,670.47
HERCEPTIN®+ PERJETA®	2.5	2	2.20	$ 7,386.13
HERCEPTIN®+ PERJETA® +	3		3	$ 9,746.13
HERCEPTIN®+ TYKERB®		2	2	$ 8,004.06
TYKERB® + XELODA®		1	1	$ 8,527.84

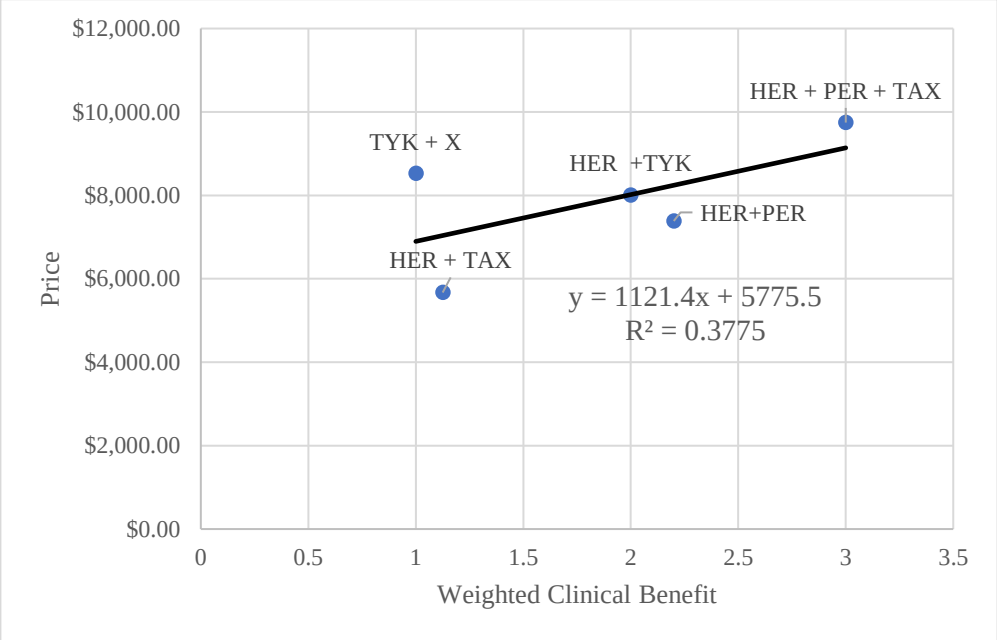
CBS: Clinical Benefit Score; TAX: Generic Taxane

The final step in creating a weighted benefit pricing model is to plot the relationship between weighted clinical benefit and the price of the existing regimens on the market. Plotting the weighted clinical benefit

against the price allows one to understand the relationship between the two variables in the existing marketplace. It helps determine how to price the new potential asset (Figure 1). One strategy used to understand the relationship between the variables is to plot a regression line to understand the correlation between points on a scatter plot. Lines of regression are valuable tools used to determine the strength and direction of a relationship. This tool allows one to make predictions for forecasting and helps to understand further how variable a data set is.

Regarding this case, the five therapies on this market were plotted using their weighted clinical benefit and price. The ensuing equation for the line of regression was y=1121.4x + 5775.5. This equation was then used to predict XYZ's drug price. This drug can be priced at $11,382.50 by using this equation to reflect its relative benefit compared to its competitors currently on the market.

FIGURE 1
WEIGHTED PRICE BENEFIT MODEL WITH LINE OF REGRESSION



HER: HERCEPTIN®, TAX: Generic Taxane, PER: PERJETA®, TYK: TYKERB®, X: XELODA®

NET PRESENT VALUE

Income Statement and Free Cash Flow

The price of a drug is only one component to consider when assessing whether acquiring an asset is a substantial investment for a company. The viability of one's potential acquisition depends on the future financial strength of the asset. To further understand this investment, one must create an income statement to assess generated revenue and, ultimately, FCF, a critical measure of a company's cash flow health and profitability (Na, 2018). To calculate the revenue, one must understand the variables required. At a minimum, revenue is calculated by multiplying the number of units sold by the unit's selling price.

In this case, one is given the number of patients in this market segment and the market share of the asset over the first five years on the market; however, the number of units sold was not given. Assumptions based on the oncology market space were used to calculate the yearly number of units sold. It is assumed that each patient would receive one drug unit per treatment cycle, and one treatment cycle would last one month, meaning each patient would receive 12 units annually.

To calculate the number of units sold annually, one needs to multiply the number of patients by the estimated market share. Then, one must multiply this figure by the estimated number of units (12 units)

annually per patient. One then multiplies this figure by the new price of the drug, $11,382.50, to generate the yearly revenue potential of this potential asset. As seen in Table 4, the above-described process led to an approximate revenue of $232.2M in XYZ's first year on the market. This revenue estimate does not include the expenses required to conduct business, so one must next calculate FCF.

FCF's definition is net operating income before depreciation expenses, tax expenses, interest expenses, and stock dividends, scaled by net sales (Na, 2018). The cost of goods sold (COGS) and indirect expenses required to do business are assumed to be 30% of XYZ's potential revenues for this asset. As seen in Table 5, revenue was multiplied by 30% to generate an estimated $69.6M in FCF for the first year on the market. FCF provides a clearer picture of an asset's annual profitability, as it accounts for business expenses. However, it does not provide a complete picture since future money is worth less than money in the present.

TABLE 4
NET PRESENT VALUE ANALYSIS

Year	**0**	**1**	**2**	**3**	**4**	**5**	**6**
Market Share	0	0	10%	25%	35%	40%	45%
Patients (#)	0	0	1,700	4,250	5,950	6,800	7,650
Treatment Periods (#)	0	0	12	12	12	12	12
Revenue	0	0	$232,203,000.00	$580,507,500.00	$812,710,500.00	$928,812,000.00	$1,044,913,500.00
Free Cash Flow*	$0.00	$0.00	$69,660,900.00	$174,152,250.00	$243,813,150.00	$278,643,600.00	$313,474,050.00
Discounted Free Cash Flow†	**-**	**-**	**$55,533,242.98**	**$123,958,131.66**	**$154,947,664.58**	**$158,109,861.81**	**$158,815,709.41**
Initial Investment	-$1,500,000,000						
NPV	-$848,635,389.55						

*30% †R=12%

Calculating the NPV

To assess the viability of XYZ's investment, one must calculate the present value of future cash flows, which is best calculated by understanding an initial investment's net present value (NPV). The next step in assessing the value of this product is determining whether the acquisition of this product would provide a favorable NPV. The NPV calculates the current value of a future stream of payments. Calculating NPV addresses the need to account for the time-dependent value of money (Hopkinson, 2017). The NPV can be negative or positive. A negative NPV would result in a net loss for the company; therefore, the investment would most likely not be considered, and the project would be rejected. A positive NPV indicates that the investment will exceed the anticipated costs and be worthwhile for the company. A positive NPV will support the statement that the investment in this product will be profitable for the company, and the project should be considered for approval (Hopkinson, 2017).

XYZ is considering acquiring $1.5B for this product that completed phase 3. To create the NPV model for this case, we will assume that FDA approval will occur and allow the product to be on the market two years from the date of the acquisition. FCF from this product would be 30% of revenues, estimated revenues from the market model, estimated share for each year with product in the market, and projected price. The discount rate (r) is 12%, and the NPV period to assess would be five years from product launch, meaning the model would consider seven years total. Share estimates from the market model for years 1 through 5 on the market, years 2-6 from the current time, would be 10%, 25%, 35%, 40%, and 45% of the mBC market.

FCF for this product is calculated as 30% of yearly revenues before calculating discounted FCF. Discounted FCF is calculated as follows: (free cash flow)/ $(1 + r)^{year}$. In this case, r (the discount rate), reflected as the weighted cost of capital, would be 12% (Opler et al., 2014; York et al., 2022). The year would vary based on the product's length. The NPV is then calculated by adding the discounted FCF amounts for each year the product is on the market and deducting that from the original investment of $1.5B (Woo et al., 2019). The resultant NPV for this case is -$848,635,389.55. The negative NPV supports the statement that the investment in this product would not be an attractive investment for the company (Woo et al., 2019).

DISCUSSION

This case study addresses the question- "What quantitative considerations are needed for evaluating a business development opportunity?"- which drives the examination of steps and considerations that need addressing to determine if the investment opportunity for XYZ is worth pursuing.

Evaluating an acquisition is complex. The first key driver of success is evaluating the potential market demand by understanding the current size and anticipated growth. When conducting a bottom-up analysis, one would assess the market size based on secondary market research by evaluating current lines of therapy, WAC, and the potential market share of current therapies. While this effort serves as a baseline process for assessing the market size, one must consider that not all patients will be treated according to guideline recommendations and that market shares may change when the prospective asset reaches the market in two years.

Interestingly, the model only considered one year of therapy based on mBC mortality rates within that period. With improved treatment options, some patients might live longer than a year and receive more therapy. To address this issue, one could perform a scenario analysis with assumptions for treatment survivors beyond a year. Ideally, one would need to define the assumption up front, supported by literature, and provide a percentage for each segment's (naïve and recurrent) population that might spill over into year two. Such consideration would need to be added to the current patient pool estimates. Also, one would need to estimate the duration of the survival. For example, if 10% of the recurrent population survives beyond a year, then this population would consider adding 1,400 patients to the 14,000 figure to account for the growth. However, when learning that the survival period might only be three months, this figure must be divided by four to account for the shorter treatment period (3 months vs. 12 months).

Additionally, evaluating the growth rate of a market is essential to understand when determining whether there is potential for long-term growth in this space. Given the crowded market, the growth rate would need to reach double digits for one's investment to have a strong potential for long-term returns. A lower growth rate may be acceptable for a market with fewer players competing for a share. In this case, the market opportunity is deemed unattractive given the small size and low potential for growth.

This analysis might also benefit from a compounded annual growth rate (CAGR) of the market calculated to confirm growth in the naïve and recurrent mBC markets and estimate growth potential. A CAGR considers the annual rate of return required for an investment or market (Milne, 1969; Saylor Academy, 2023; van Genuchten & Hatton, 2012). A CAGR considers the initial and ending values and compounding over time (Ha et al., 2022; Milne, 1969; van Genuchten & Hatton, 2012). It can be used to measure and compare past market growth, or in this case, project growth (Ha et al., 2022; Milne, 1969; Saylor Academy, 2023; van Genuchten & Hatton, 2012).

An additional factor to consider is setting a reasonable price for the asset, which is representative of its relative benefit compared to the market price but also representative of the relative benefit of the asset. Creating a weighted benefit pricing model is one approach to score treatments and weigh them against one another to determine the relationship between the benefit and price of currently marketed products. However, this model utilizes the WAC or the list price. This figure does not account for discounts and rebates, which the average selling price (ASP) incorporates to provide a more accurate representation of the price in the marketplace. Understanding how to score benefits dependent on the type of market and needs of the stakeholders is imperative to creating a strong model. One must assess the current unmet needs

in the market and develop a marker of success relevant to stakeholders to drive business. Entering a crowded market limits the ability to freely price a drug based on perceived benefit as one's price is now tied and compared to competitors. Entering a market as a first asset or with a novel mechanism of action allows one to freely price an asset based on assumed clinical benefit.

Throughout this case, one must consider the potential for events that might affect the business negatively. This review involves conducting a risk analysis. This effort aims to determine whether a project should be undertaken depending on risks and risk reduction. A quantitative and qualitative analysis assesses risk in a proposal (Galway, 2004; York et al., 2022). This case qualifies as a quantitative risk analysis because numeral values are used to assess the risk of this proposal (Galway, 2004). Furthermore, cash flow is another concept to consider when analyzing this product's investment. There are a few different types of cash flow, but for this business case, it is important to calculate FCF. This financial metric measures the after-tax operational funds produced by the proposed project without considering the source of debt and equity in financing (Tham & Velez-Pareja, 2019). Throughout this process, this statement measure should be available to all stakeholders. This statement measures the project or firm's expected operating benefits and costs, which must be considered before investing (Keating & Keating, 2017).

Another consideration is the discount rate. In pharmaceutical industry project proposals, discount rates generally range from 10% to 14% (Opler et al., 2014). However, these can vary based on current market conditions and relative risk based on the asset's or company's maturity or stage (Opler et al., 2014). The present value of future costs must be discounted and subtracted from the present value of future benefits that have also been discounted (Keating & Keating, 2017). This calculation determines the net benefits. The appropriate discount rate must be chosen for future costs and benefits and interpreted theoretically based on the time preference for present versus future expenditure (Boni, 2020; Hopkinson, 2017; Opler et al., 2014; Woo et al., 2019).

Finally, one must address an acquisition's overall financial impact on a company, especially with a large upfront cost. It is essential to evaluate the NPV analysis to evaluate this impact. NPV is based on the understanding that current dollars are worth more than future dollars. Hence, a company must conduct thorough due diligence to support such a significant business decision. Such diligence requires understanding the impact of the investment on a company balance sheet with forecasts based on potential market share and growth, product price, COGS, and assumptions on medicine utilization. Minor changes in these assumptions can lead to drastic changes in investment viability, rendering understanding the assumptions imperative.

This case chose baseline assumptions in an ideal market; however, one must understand that these assumptions may have added complexity based on additional variables such as a patient dying, incomplete or partial response to therapy, switching therapies, or transitions to end-of-life care. These variables profoundly impact revenue forecasts and downstream effects on FCF and, ultimately, the NPV assessment. One must, therefore, find the right balance between an initial investment cost, market size, potential market share, expenses required to conduct business, and the opportunity cost of the investment capital. This assessment is critical to the business case and allows senior management to compare investment projects. In the case of XYZ, a reduced initial investment price could create a scenario with an NPV of 0 and serve as a counteroffer. An initial investment of $651,364,610.45 would create an NPV of 0. This data and a comparison of similar assets may serve as the rationale for a counteroffer to negotiate a stronger deal for XYZ. A negative NPV generally signals that the asset for venture investment fails to provide a viable financial case to move forward after accounting for discounted future cash flows versus the initial investment alone. However, in some cases, managers might still decide to move forward with such investments based on business considerations. For example, a harmful NPV acquisition may be considered if it allows the company to explore additional market segments, enter a new therapeutic area, access a unique technology or technology platform to reinforce its pipeline or minimize the threat of external competition. Although not captured in the financial analysis, such acquisitions may serve as strategic building blocks for a company's long-term vision.

Finally, beyond the quantitative considerations, one should consider additional qualitative elements. The most notable is the leadership and the integrated team, driving change in both organizations and

aligning the cultures (Austin, 2016; Boni, 2020). Organizational fit is important when creating a business or deciding between two businesses. Essential to fit is that the parties involved in making the decision have built a relationship of trust and respect for one another (Austin, 2016; Boni, 2020). A collaborative partnership is vital when making complex business decisions (Boni, 2020). Common vision and fit implies that the partners and their respective shareholders mutually agree to pursue together and ultimately to achieve - thereby creating value to be shared (Boni, 2020). These are the broad leadership topics to keep in mind as a partnership is contemplated, consummated, and launched: 1) leadership of the integrated team itself; 2) driving change in both organizations; and 3) meshing or aligning cultures (Boni, 2020). Furthermore, one needs to consider the team's capabilities and diverse backgrounds (not just scientific but business), representing its absorptive capacity for learning, growing, and execution (Spinelli et al., 2014; York et al., 2022). A more seasoned team with industry and startup capabilities and experience working together will bring such a capacity, which may lend well to effectively transitioning the asset to the acquiring company to maximize the commercial opportunity (Boni, 2012; Boni, 2019).

CLOSING CONSIDERATIONS FOR FURTHER DISCUSSION

Thus, given the underlying fact pattern and ensuing discussion involving the quantitative considerations in this case, let us return to this case's original charge. Imagine the research done by the business development manager involved in evaluating this opportunity. What would this individual's recommendation be? What facts from this case would support one's position for a "go" or "no go" decision, and if a "go" decision is made, would this be to acquire or license this product?

In addition to these core questions, the business development team might ponder several other critical considerations influencing the XYZ's ultimate decision. These additional queries allow for further analysis and discourse on evaluating a new asset opportunity:

1) What additional assumptions would you make about an asset when considering an acquisition?
2) What market conditions should be present to create a favorable environment for an investment opportunity?
3) What nuances should be considered in the market model for mBC? What about the pricing model?
4) What qualitative considerations should be considered in creating the business case?
5) How do unmet needs, competitive assessment, acquired company management capabilities, and strategic fit in the assessment?
6) How would one compare the asset to competitor products to determine an ideal price?
7) What modifications to the NPV model need to occur to result in a favorable investment opportunity? How do certain variables impact the overall assessment?
8) If the NPV was not favorable, at what acquisition price of the asset would the NPV be attractive? How would one find that figure using a "what if" analysis?

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APPENDIX

The case with key facts should be assigned for students to work on quantitatively before reviewing the article. Once completed, the review of the article and discussion of its decision points and questions can occur after working with the case outputs. Following this flow will enhance the learning experience.

Metastatic Breast Cancer Treatment Market Model and Pricing Benefit Case
You are a new business development manager at XYZ Biotech. Your vice president is examining an opportunity to acquire an antibody-drug combination product. This product's lead market opportunity would be breast cancer, particularly metastatic disease.

Assignment 1: Your vice president has asked you to develop a market model to define the market opportunity in the metastatic breast cancer (mBC) space with interest in patients who are HER2+.
You start investigating the market opportunity by conducting secondary market research. This effort involves pulling data from (1) the National Cancer Institute SEER program (2013); the National Comprehensive Cancer Network (NCCN) Breast Cancer Guidelines (2013); (3) IMS Sales of breast cancer drugs (2013); (4) Genentech information on competing products such as HERCEPTIN® and PERJETA® (2013), and (5) Redbook pricing information.

In examining the data from NCI SEER, NCCN, and Genentech, you learn that there are two sources of mBC patients who are HER+: (1) naïve (previously undiagnosed) patients and (2) recurrent (previously treated) patients. The number of new naïve patients on an annual basis is 3000, and the number of new recurrent patients on an annual basis is 14,000.

The next part of your research involves looking at the NCI treatment protocols and NCCN guidelines for treatment. You learn that the individual agents used include HERCEPTIN® (HER), generic taxane (TAX), PERJETA® (PER), TYKERB® (TYK), and XELODA® (X). Examining the guidelines and IMS data, you learn about the treatment protocols for naïve and recurrent use (and percentage of the time). For naïve patients, these include: (1) HER+TAX (20%), (2) HER+PER (30%), and (3) HER+PER+TAX (50%). For recurrent, the treatment protocols include (1) HER+TAX (30%), (2) HER+TYK (10%), (3) HER+PER (10%), and (4) TYK+X (50%).

Finally, you gather information from IMS to learn about the number of units used annually in a patient for each drug based on an average patient of 70 kg, 1.6 M2 body surface area. You learn the annual use of SKUs: (1) HER (12), (2) TAX (12), (3) PER (12), (4) TYK (8.4), and (5) X (9.8). From the Redbook you obtain about the wholesale acquisition cost (WAC) per unit each drug SKU: (1) HER ($3310.47), (2) TAX ($2360), (3) PER ($4075.66), (4) TYK ($4693.59), and X ($3834.26).

Deliverable: With these data, you will need to construct an Excel model that includes drug pricing and provides a bottom-up construct of the total mBC market that includes the two segments (naïve and recurrent). Explain why this market is attractive or not.

Assignment 2: Your vice president would like to get a feel for the pricing of this product. Presently the company marketing the product, prices it with a cost at a wholesale acquisition cost (WAC), or list price, of $8,000 per administration. You consult with your medical affairs and health economic colleagues to get a sense of what the survival duration is with each treatment regimen and how to assign a benefit score. For naïve patients, months of extended survival in months are as follows: (1) HER+TAX (13), (2) HER+PER (14), and HER+PER+TAX (15). For recurrent, the treatment protocols include HER+TAX (12), HER+TYK (13), HER+PER (13), and TYK+X (12).

You learn that the drug you are considering displays extended survival in recurrent patients by 18 months. The clinical benefit scores for each (1) HER+TAX (2), (2) HER+PER (2.5), and HER+PER+TAX (3). For recurrent, the treatment protocols include HER+TAX (1), HER+TYK (2), HER+PER (2), and TYK+X (1). The translating benefit with your drug is 5.

Deliverable: Your assignment is to construct a weighted benefit pricing model using pricing and clinical benefit data. You are to recommend whether the present price of the product to acquire is appropriate or that you could increase (or decrease) the price and why.

Assignment 3: Your management wishes to know whether the acquisition of this product would provide a favorable Net Present Value (NPV). Currently, the firm is considering an acquisition price of this product that completed phase 3 at $1.5 billion.

Deliverable: Use the following assumptions to create an NVP model: 1) FDA approval and ability to be on the market in two years from the acquisition of this product; 2) Free cash flow from this product would be 30% of revenues; 3) estimate revenues from your market model, estimated share for each year in the market, and projected price; 3) the discount rate (r) is 12%; 4) the NVP period to assess would be five years from product launch, meaning that your model would consider seven years total; and 3) Share estimate from your market model for years 1-5 on the market (years 2-7 from now) is 10%, 25%, 35%, 40%, and 45% of the MBC market. Present your findings. Is it positive or negative? If negative, at what price would the NVP end up at zero.