

# How to Approach Asset Valuation in Pharma & Biotech:

## Putting a price tag on emerging therapies



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# Introduction

Pharma and biotech companies are innovation drivers at the frontlines of research and development. To fund and support this promising science, there is a great need for partnerships and mergers and acquisitions (M&A) to drive the growth/pipeline of the industry. For these collaborative relationships to occur, understanding the value of a company's underlying assets is of the utmost importance.

Since Trinity's founding, multiple pharma and biotech clients have relied on its expertise in forecast and valuing assets. These engagements have grown both in amount and in deal value following recent venture investment trends in the life sciences space. Between 2012 and 2017, both total investments and average investments per financing event have increased by ~20% per year.<sup>1</sup>

Companies with no launched products or even pre-clinical assets have sought our expertise to help them recognize the potential behind their innovative research. Armed with this knowledge, they can either better understand their own value and come to partnership discussions from a position of strength or use this information to help maximize funding. For companies in these situations, being in control of the story is essential. With this white paper, we briefly look at the valuation of pharma and biotech assets and explore some of the specific nuances involved.

<sup>1</sup>Brown et al., Pharma, Biotech & Medtech 2017 in Review, Evaluate, February 2018



# Common Valuation Methodologies

There are a number of ways to value an asset in the life sciences space, with many additional nuances to consider. The selection of one method over another is often influenced by a number of factors: an asset's stage of development (e.g., clinical vs commercial), the sources and information at hand to carry out the valuation (e.g., details of business sources and expense mapping such as clinical trial costs), as well as the purpose for the valuation (e.g., internal assessment versus M&A analysis).

For many other industries, utilizing a net present value (NPV) analysis is the standard practice. These are then often supported by an analysis of financial metrics and ratios (e.g., Price/Earnings, multiples on EBITDA, etc.).

However, given that risky assets (often with only future potential revenue) are the predominant value drivers in the life sciences space, an alternative valuation approach is recommended. For these assets, we recommend using two different techniques. First, we risk-adjust discounted cash flow streams (rNPV) to account for an asset's probability of being approved by the FDA and entering the market. Second, for the riskiest assets (e.g., those in the earliest stages of clinical development) where a credible forecast cannot be made, Trinity looks to comparable asset deals that have recently occurred in the marketplace to develop a benchmark for an asset's value.

These valuation approaches are detailed below:<sup>2, 3, 4</sup>

**Financial Multiples/Ratios:** This method anchors value to a marketplace benchmark based upon select financial metrics. Commonly used metrics include sales (price/sales ratio), book (price/book ratio), earnings (price/earnings ratio), and earnings growth (price/earnings growth ratio). This method is considered more appropriate for more established public companies given the heavy reliance on 'price.' While this method is quick and easy, it does not adequately reflect asset-specific nuances.

**Net Present Value (NPV):** NPV measures and discounts future free cash flows to calculate the present value of an asset. This is a robust way of estimating the attractiveness of an investment opportunity; however, this method is more appropriate and reliable for commercial companies with more predictable cash flows.

<sup>2</sup> Koller, T., Goedhart, M., & Wessels, D. (2015). *Valuation: Measuring and Managing the Value of Companies*, 6th edition. John Wiley & Sons.

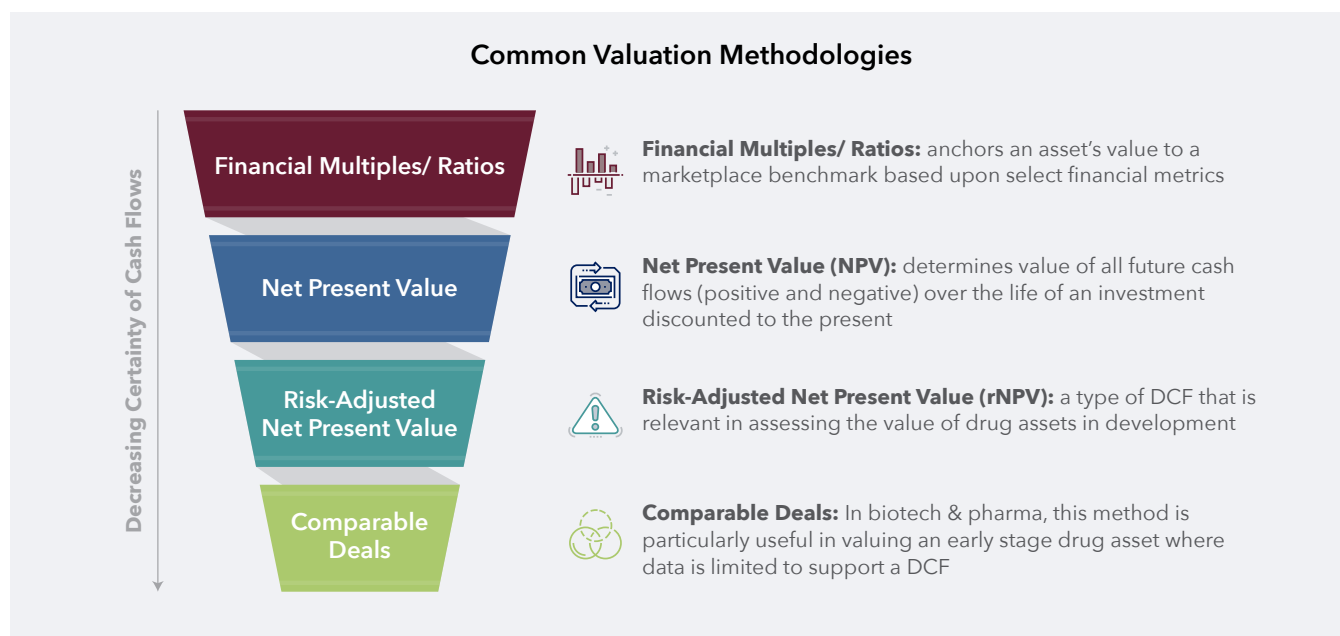
<sup>3</sup> Stephen Edward, *Discounted Cash Flow Valuation: Advantages & Pitfalls*.

<sup>4</sup> Suozzo et al., *Valuation Multiples: A primer*, UBS Warburg, November 2001.



**Risk-adjusted net present value (rNPV):** rNPV further accounts for risk associated with an asset's cash flows. This method is particularly relevant in assessing the value of drug assets in development given their inherent risk. This method factors in product probability of success at each stage of clinical development and regulatory approval.

**Comparable Deals:** This is another relative-method of valuation where previous comparable market transactions (e.g., asset sales and partnerships) are used as a benchmark for asset value. In pharma and biotech, this method is particularly useful in valuing an early stage drug asset — such as preclinical assets — where data is limited to support a more robust rNPV. While early stage assets may only contribute nominal value, these assets may be of particular interest to a potential partner and a valuation will lack credibility if these assets are not appropriately considered. However, it is always challenging to find truly comparable transactions.



**Figure 1: Common Valuation Methodologies**

# Asset Valuation Best Practices

Valuations are entirely dependent on the approach and, as such, can result in dramatically different outcomes depending on the specific methodology. Therefore, for any asset valuation, it is important to have a sound and validated approach that:

- 1. Is unbiased, objective, and data-driven**
- 2. Relies on an assumption-driven forecast and valuation model (leveraging both primary and secondary market research)**
- 3. Does not over-complicate the analysis so parties are able to negotiate practically**

The best practice is to first identify and understand the opportunity and rNPV for each individual asset. While we also assess the book value of a company's balance sheet (e.g., cash on hand, real estate, land, outstanding debt, intellectual property, etc.), we spend much of our time and scrutiny assessing our client's most important components - the drugs themselves. The standard of value used in our valuations is fair market value.<sup>5</sup>

While our valuation work attributes a value to an asset, an additional perspective to consider is that of the potential acquirer or partner (e.g., how do they perceive value and what are they willing to pay for it). There are a number of factors that influence this willingness to pay: potential synergies with the target asset, a more bullish forecast, the broader health of the economy, etc. Therefore, it is important that we validate the outputs of our rNPV findings with a comparable deals analysis to better understand the value of assets in the current market environment. We feel that the learnings from this analysis are an important validation step of our work against the real-world evidence to attribute a "real value" to an asset.

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<sup>5</sup>Fair market value is the price, in cash or equivalent, that a buyer could reasonably be expected to pay, and a seller could reasonably be expected to accept, if a business were exposed for sale on the open market for a reasonable period of time, with both buyer and seller being in possession of the pertinent facts and neither being under any compulsion to act.



## Key Valuation Considerations

Within the rNPV valuation framework, there are a number of key factors that must be considered, including an asset's net income (sales) potential, stage of development, probability of success, nature (single molecule vs platform), among many others. These considerations are critical to comprehensively capture the asset-specific nuances and accurately reflect value.

### Net Income

In every valuation at Trinity, net income is informed by an individualized asset-specific forecast grounded on very specific and well-sourced assumptions. First, we conduct an in-depth secondary research analysis using a diversity of publicly available and Trinity-owned sources to understand the market and identify key hypotheses and assumptions. Second, we conduct primary market research by engaging key stakeholders—including physicians, patients, payers, and key opinion leaders—to both pressure test our hypothesis as well as obtain insight into the current market, unmet needs, and most importantly, the value proposition and market positioning of the asset.

### Stage of development

Valuation of early stage and late stage assets differs not only by the assumptions that feed into the model but also by the confidence of the final output value. In addition to the lack of clinical trial data on safety and efficacy, early stage assets often lack information around expense mapping, source of business and market opportunity. As a result, there is a greater range in values assigned to these assets, an indication of low confidence. In contrast, there is a narrower range in values assigned to the later stage assets due to richness of data rendering ability to project net income with higher confidence.

### Probability of Success

For clinical assets, the stage of development informs the risk profile for the asset and the probability of entering the market.<sup>6</sup> Earlier stage assets, compared to late stage assets, have a lower probability of success of entering the market and are thus inherently riskier. For example, a phase I asset (across all diseases and indications) has a ~10% likelihood of being approved by the FDA and entering the market compared to a ~50% likelihood for a phase III asset. Even within a given phase, success rates are highly variable. A phase I asset in oncology has a much lower likelihood of success compared to a phase I asset in the infectious diseases space (~5% vs ~20%, respectively). Similarly, even within oncology, variability exists as evidenced by a higher likelihood of approval for a phase I asset in renal cell cancer compared to that in non-small cell lung carcinoma (~6% vs ~18%, respectively).

<sup>6</sup> Hay, Michael, et al. "Clinical Development Success Rates 2006 – 2015." *Bio* (2016).



An asset's therapeutic class, chemical structure, or mechanism of action is another consideration that impacts the probability of success. For example, biologics – large, complex molecules produced using recombinant DNA technology – have a higher likelihood of success compared to new molecule entities (NME). Similarly, therapies with biomarkers have a higher probability of success compared to those without. This is primarily due to biomarkers' ability to easily identify a target patient population; as a result, the FDA may designate faster tracks for assets with biomarkers on their roads to approval.

## Molecule asset vs platform asset

An asset's overall value can differ greatly based on whether it is a targeted single molecule or a platform. Because a platform asset generally has utility in more than one indication/patient type, its value reflects the additive value of multiple potential drug approvals. As a result, platform assets will have a much higher 'upside' value compared to a single molecule asset. An example of a hypothetical platform asset is an antibody-drug conjugate product that can target different diseases by slight alteration of the product, either on the antibody end or the drug end.



Figure 2: Key Valuation Considerations

# Trinity Case Study

## Client Situation

Our client was a US-based oncology biopharma company and was looking for an independent valuation of its oncology portfolio that consisted of 10 pipeline assets at different stages of development for numerous cancer types.

## Trinity Approach

Trinity applied a "sum of parts" valuation approach. In this approach, we assessed the rNPV of each asset separately to accurately capture asset specific nuances and therefore, the likelihood of success and associated risks. Due to scarcity of robust clinical and market prediction data, Trinity exclusively used a comparable analysis methodology to value preclinical assets. Comparables were also used to validate the rNPV outputs of all other assets (phase I and beyond). Trinity's valuation approach consisted of 3 key steps:

### Phase I: Assumptions Gathering and Model Design

Trinity conducted a thorough secondary research analysis to understand all assets, parse out market opportunities, and gather key assumptions. Because assumptions such as the stage of development, indication, and biomarker index separated one asset from the other, they were thoroughly vetted to ensure accuracy and precision of the forecast. A summary of those assumptions that formed the crux of the forecast are shown in the table below:

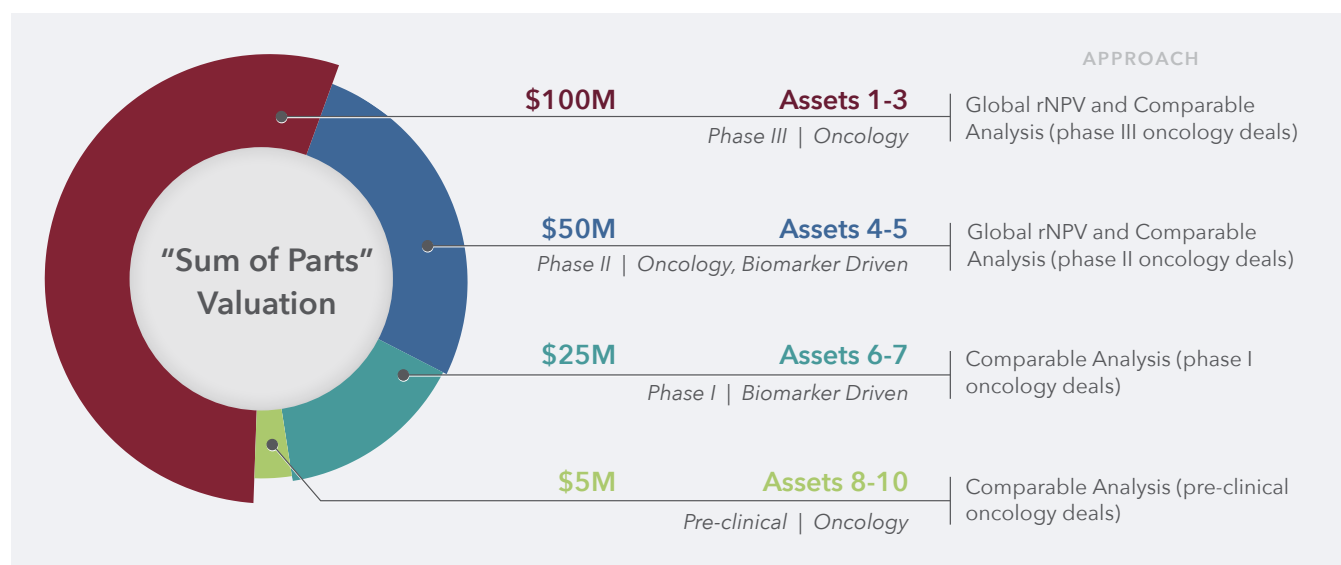


Figure 3: "Sum of Parts" Valuation (Illustrative value output)





## Phase II: Primary Market Research

Trinity interviewed 10 key opinion leaders (KOLs) to both better understand the markets (and the level of disease unmet needs) as well as receive unbiased expert reactions to the client assets, including their likelihood to prescribe. This research also helped us determine where (e.g., specific patient types) and how (e.g., line of therapy) each asset would be used to inform each asset valuation.

## Phase III: Forecast & Valuation Report Development

Trinity leveraged phase I and phase II outputs to create a valuation report grounded on comparable deals and a custom-built revenue forecast.

## Outcome & Implications

Trinity provided a comprehensive valuation report for the client's oncology portfolio. The report captured asset-specific nuances and highlighted key strengths and weakness of each asset to inform the client's current and future business decisions. The report underwent expert and legal scrutiny by the client and was received well.

## Client Situation

### Overview



US based oncology biopharma was looking for an independent valuation of its oncology portfolio

### Portfolio

10

pipeline assets at different stages of development for numerous cancer types

## Trinity Approach

Trinity applied a "sum of parts" valuation approach. In this approach, the rNPV of each asset was assessed separately to accurately capture asset specific nuances and therefore, the likelihood of success and associated risks. Trinity used comparable methodology to value early stage (Preclinical to Phase II) assets and to validate the rNPV outputs in the case of late stage assets (Phase III and beyond).

Trinity's valuation approach consisted of 3 key steps:

## Valuation: 3 Key Steps



### Phase I: Secondary Research

Trinity conducted a thorough secondary analysis to understand all assets and their opportunities and gather key assumptions



### Phase II: Primary Market Research

Trinity interviewed 10 Key Opinion Leaders (KOLs) to assess unmet needs and receive unbiased expert reactions to the client assets including their likelihood to prescribe

Research helped corroborate major findings of the secondary research



### Phase III: Forecast & Valuation Development

Trinity leveraged phase I and phase II outputs to create a valuation report grounded on comparable deals and a custom-built revenue forecast

Following key assumptions were incorporated into the forecast to customize each asset valuation:

1. **Clinical Probability of Success (PoS)**
2. **Indication**
3. **Biomarker Index**

## Outcomes & Implications

Trinity provided a comprehensive valuation report for client' oncology portfolio

The report captured asset-specific nuances and highlighted key strengths and weakness of each asset to inform client's current and future business decisions

Figure 4: Trinity Case Study



# Conclusion and Next Steps

For all of our clients, the results of our valuation work are important drivers of decision-making. This valuation work helps our clients realize the potential behind their innovative assets. Our clients use this knowledge for several reasons: to understand a company's overall value, to come to a partnership discussion with another entity, or to maximize funding for further development.

Some real-world examples of how Trinity has supported clients with valuation work in the past include:

**Mergers and Acquisitions:** Valuation of a startup pharma's oncology therapy platform led to a recent acquisition of the company by a larger pharma in a transaction greater than \$1B. The platform asset was part of a phase I/II study in several oncology indications.

**Fundraising:** Valuation of a startup pharma's pre-clinical portfolio of oncologic agents helped internal stakeholders both better understand the value of the assets as well as prepare for future fundraising efforts to support further product R&D.

**IPO Planning:** Valuation of late stage biopharma's lead clinical assets to help prepare the company to go public. These findings were incorporated into the registration document required by the stock exchange for the company to go public.

**Litigation Support:** Valuation of a biopharma's pipeline assets, the specific value of which were in question as part of a legal suit. These findings were summarized as part of an expert witness report that ultimately underwent legal scrutiny.

Therefore, a valuation is a critical first step in a company's effort to maximize an asset's value and to advance business interests.

Interested in better understanding our innovative approach to forecasting and valuation? Please reach out to [hsanchez@trinitypartners.com](mailto:hsanchez@trinitypartners.com) and [acombs@trinitypartners.com](mailto:acombs@trinitypartners.com) to learn more about these services, as well as the other types of support that we provide for our clients.

