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WHITE PAPER

Valuing an Early-Stage Asset in Pharma and Biotech

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June 2022

In 2018, Trinity Life Sciences published a white paper titled, *How to Approach Asset Valuation in Pharma & Biotech: Putting a price tag on emerging therapies.* At the time, pharma and biotech firms were seeing venture investment growth of ~20% per year. This trend has only accelerated alongside the value of co-developments, partnerships, joint ventures, licensing agreements and other deals nearly doubling from 2019 to 2020.[1] Quantifying the value of underlying assets throughout the clinical development process remains vital to ensuring continued collaboration in pharma and biotech.

Since first publishing in 2018, Trinity has continued to be at the forefront of valuing next-generation therapeutics such as CAR-T platforms, T-Cell Engagers, and Gene Therapy. Trinity feels strongly that in order for companies to succeed in bringing these complex therapies to market a new approach is needed in understanding and evaluating the commercial model. Such insights empower and enable companies to take control of their financial future by having a deeper sense of their value to maximize funding. In this white paper, we explore the increased nuance required to develop a pre-clinical valuation in a small-cap firm.

How to Approach Asset Valuation in Pharma & Biotech: Putting a Price Tag on Emerging Therapies

Trinity's Asset Valuation in Pharma & Biotech paper explored several common valuation methodologies. It suggests that in established and publicly traded companies, valuation can be conducted using conventional ratios such as sales (price/sales ratio), book (price/book), earnings (price/earnings ratio) and earnings growth (price/earnings growth ratio) or a net present value (NPV) analysis. The NPV approach discounts future free cash flows to determine the present value of an asset or company. Risk-adjusted net present value (rNPV) and comparable deals, however, are more appropriate methodologies for valuing pharma and biotech assets, due to the associated risks of developing a drug. In a rNPV, cash flows are further discounted by the probability of success of the asset being approved. Comparable deals derive asset value through relevant market transactions and are more applicable to preclinical assets that lack a clear probability of success. It is this area of asset valuation that we will cover in greater detail in this paper.

[1] Cancherini, L, Lydon, J, Santos da Silva, J, Zemp, A. "What's ahead for biotech: Another wave or low tide?" McKinsey & Company, 30 April 2021. https://www.mckinsey.com/industries/life-sciences/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide

Forecast and NPV

A comparable deals methodology has historically offered the most efficient way at arriving at a valuation due to the increased uncertainty of preclinical assets and their typically small cap companies. We begin by examining structural barriers to developing a NPV with a small cap, early-stage company. Understanding future free cash flows begins with an understanding of revenue.

Future free cash flows begins with an understanding of revenue. The forecast takes the total universe of patients and concludes with achievable patients in a given year. This can be viewed as a funnel that starts with diagnosed prevalence (the total number of patients) or incidence (the total number of newly diagnosed patients) and is filtered by a variety of different considerations such as mutation rate, risk-factor status, or treatment sequencing among others. To reach revenue, other considerations such as duration of therapy (most relevant in oncology) and adherence are factored into the addressable patient population before inclusion of price and its gross-to-net based on insurance reimbursement. While a bevy of benchmarks and primary and secondary research considerations are incorporated into the forecast, we will focus in greater detail on the next step of the valuation process – accounting for expenses.

After revenue is determined, the various expenses must be accounted for including the cost of goods sold (COGS), research and development (R&D), and selling, general, and administrative expenses (SG&A). COGS and R&D are reached through clinical development plans and manufacturing metrics; however, SG&A is more complex in a preclinical company. This is due to the increased difficulty in sourcing analogs. Company 10-Ks readily report the data but are often inclusive of numerous assets both commercial and clinical, inhibiting the ability to parse the single SG&A spend of an asset at various timepoints. Similarly, single-asset preclinical and clinical companies may report SG&A at one point but ultimately begin developing other assets or get acquired by a larger firm. This then describes the difficulty of identifying the longitudinal SG&A of one asset across therapeutic areas.

Trinity's Launch Spend & Performance database compiles granular company financials and consensus forecasts to more accurately project SG&A before, during, and after-launch across a range of therapeutic areas, specifically for first launch companies. This enables us to isolate the costs for commercializing a single asset. As sales force is generally scaled immediately before launch to increase patient and physician mindshare, selling spend is crucial to identifying what amounts to a successful launch strategy. Thus, the Launch Spend & Performance database not only provides insights on SG&A spend, but also enables sensitivities that inform how toggling spend impacts launch performance and the subsequent valuation.

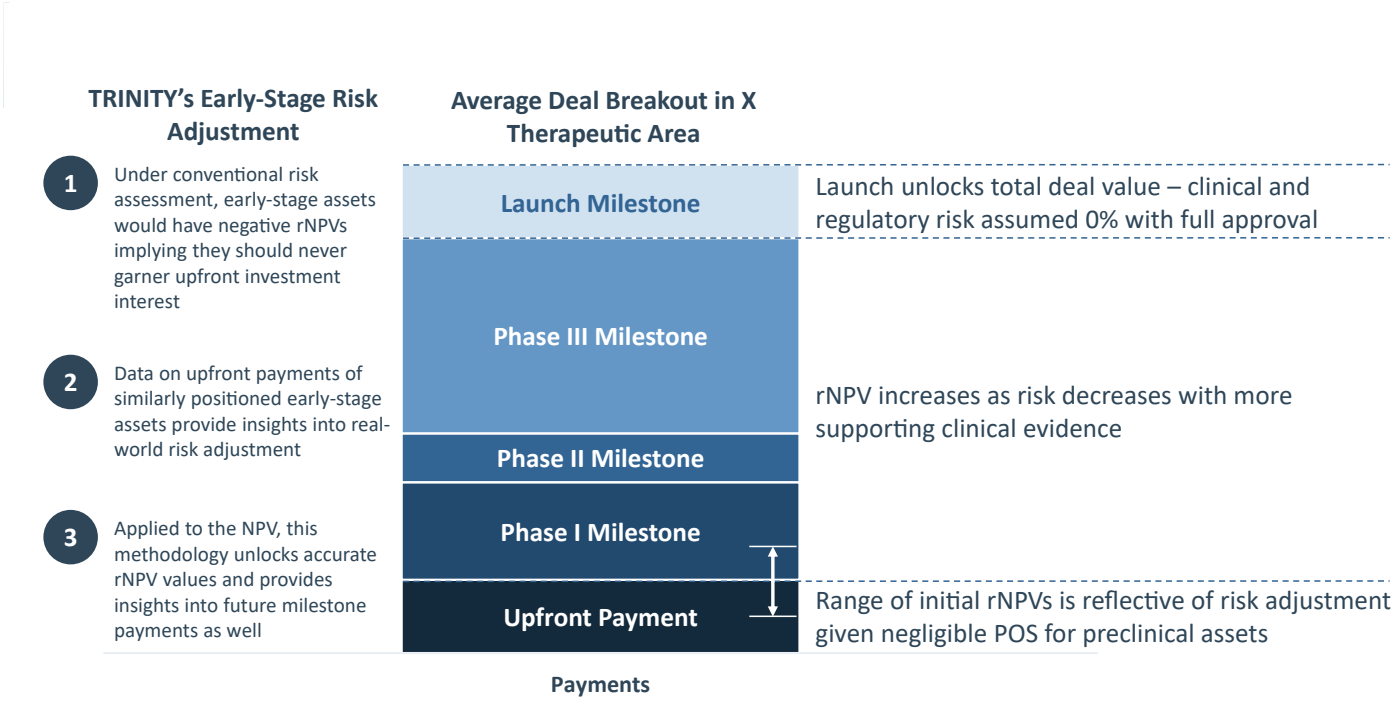
Separately, TGaS Advisors, a division of Trinity, is a proprietary benchmarking platform that aggregates metrics such as functional spend and sales force FTE. The platform features a roster of large, emerging, and pre-commercial life science companies, allowing for a targeted, cohort-level view. Further, companies in the member network not only submit quantitative data points but also qualitative ones. When viewing aggregate emerging oncology data for example, we can provide the needed context sourced directly from high-ranking leadership at those respective companies. Thus, triangulating the Launch Spend and Performance database as well as the TGaS benchmarking insights allows for precise, targeted metrics for developing a more accurate and dynamic NPV perspective.

Risk Adjustment

Once the NPV is finalized, the next step in the valuation process is to account for the risk inherent to a drug reaching approval. Clinical trials provide a standardized way to evaluate risk at various timepoints in the regulatory process as we can deduce a probability of success (POS) for a Phase I asset, for example, based on the percent of trials in a therapeutic that progress from Phase I to Phase II, Phase II to Phase III, and Phase III to approval. While POS increases with each stage in the process, the stakes of failure also increase due to the sunk costs of the prior phases. To mitigate risk in pharma and biotech acquisitions, deals are often structured with an upfront payment followed by milestone payments set to clinical achievement. These payments reflect the stepwise increase in value as the probability of overall success increases with each successful trial.

Risk adjustment for preclinical assets is challenging because it lacks the centralized oversight necessary for data aggregation that the FDA/NIH provides with clinical trials. Further, all preclinical trials also have the additional risk that a Phase I asset bears which amounts to an already low POS. If we were to risk adjust any NPV based purely on POS for preclinical assets, the result would likely be so low as to be not commercially viable. Despite this apparent lack of risk adjusted value, however, a preclinical asset clearly has some level of inherent worth. Even at the height of uncertainty surrounding COVID19, there were still twelve licensing deals valued at over one billion USD for discovery/preclinical assets in 2020. Upfront payment on these deals ranged from 30 – 100 million USD.[2] This range, for assets at a similar stage and class, reflects the relative risk of an early asset investment with limited data.

To provide a risk-adjusted, market reflective NPV in the preclinical setting, Trinity has developed a database of recent deals. Milestone payments occur only after the milestone is successfully reached and thus mitigate risk. Total deal value then is analogous to the NPV when structured in this manner and as such, the upfront payment would be indicative of the rNPV. Rather than a pure POS adjustment, the ratio of the upfront payment to the total deal value can be seen as suitable risk adjustment rooted in comparable deals. The nuance between assets is still maintained under this methodology as the proportionality of the deal and not merely its size is what is being applied.



[2] Hardison, S. "Oncology dealmaking in 2020." Biopharma Dealmakers, Nature. 01 March 2021. https://www.nature.com/articles/d43747-021-00024-y

Client Situation

Our client was a U.S.-based oncology biopharma company and was looking for an independent valuation of its lead preclinical CAR-T asset.

Trinity Approach

Trinity applied the upfront payments rNPV valuation approach. In this approach, we began with a forecast that accounted for the likely positioning of a novel CAR-T given expectations of current and future entrants. Due to the client's request for a rapid turnaround, we sourced future patient share based on benchmarks and analyst projections without primary market research. We then assessed the latest deal terms of preclinical CAR-T therapies to accurately capture the nuances of the paradigm shifting technology that still accounted for the risk of the asset. Overall Trinity's valuation approach consisted of three steps.

Phase I — Assumptions Gathering and Forecast Development

Trinity conducted a thorough secondary research competitive intelligence assessment that examined the future of hematology-oncology at the therapeutic class level as well as at the CAR-T product level. An industry standard order of entry curve was developed based on the number of risk-adjusted pipeline competitors. Since analysts rarely project revenues for pre-clinical assets, order-of-entry share and revenue insights were compared against analyst projections for similar assets further in development.

Phase II — Valuation Development

Trinity applied the revenue streams from the forecast into a valuation framework. We incorporated the client's clinical development plan and manufacturing capabilities for projecting R&D spend and COGS. Further, Trinity utilized the Launch Spend & Performance database to ensure a tailored SG&A view that would optimize launch planning. The base case for the NPV was finalized and upside and downside sensitivities around class penetration were included given launch was still in the distant future.

Phase III — Risk Adjustment

Trinity examined recent pre-clinical CAR-T deals and the ratios of upfront payment to milestone payments. The median upfront payment ratio was applied to the NPV to achieve risk-adjustment and then compared against the raw upfront payment values to ensure a feasible CAR-T valuation grounded on comparable deals and a custom-built revenue forecast.

Outcome and Implications

Trinity provided a comprehensive valuation report for the client's lead CAR-T asset. The report captured asset specific nuance and highlighted key strengths and weakness of the asset to inform the client's current and future business decisions. The report underwent expert legal scrutiny and extensive pressure testing by the client. The methodology was deemed both sound and innovative and the valuation was seen as exemplary.

Conclusion and Next Steps

For all of our clients, the results of our valuation work are important drivers of decision-making. The SG&A and risk-adjustment methodological nuance helps our clients realize the true potential behind their innovative assets with even greater precision. 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.

Our clients seek and trust Trinity in valuation work because of our:

- Extensive forecasting experience that spans countless years across all life science settings
- Precision from our Launch Spend and Performance and TGAS databases
- In-depth knowledge with over 75 PhDs with decades of industry experience who guide on clinical feasibility and scientific reasons to believe
- Robust in-house pressure testing that utilizes a deal history database to provide real-world context

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

- **Mergers and Acquisitions / Business Development & Licensing:** Valuation of a startup biotech's cell therapy platform led to a recent acquisition of the company by a larger pharma in a transaction greater than one billion USD. The lead asset on the platform was a preclinical asset about to enter a Phase I trial

- **Litigation Support:** Valuation of biotech CAR-T platform's potential lost value to delays as part of a disagreement with the development partner. Two valuations were conducted to represent two launch sequences with the differences reflecting the client damages. The lead asset was a preclinical CAR-T platform in heme-onc

- **Fundraising Efforts:** An early-stage biopharma sought a valuation of its lead asset and associated diagnostic across a few hematological oncology indications and development of an investor presentation to support Series C fundraising discussions

- **Partnering:** An early-stage CAR-T developer sought to develop a global valuation across three indications, to serve as basis for partner discussions for later stage development and commercialization; Trinity conducted KOL interviews in US, EU, and China to inform utilization

- **Go/No-Go Stage-Gate Development Decisions:** A large pharmaceutical company needed support in developing multi-scenario NPV models for three metabolic assets in development to help inform decision to proceed to late-stage development with one asset

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

Authors

Jason Karas | Principal, Strategic Advisory

Jason joined Trinity in September 2019. He has significant expertise in helping develop and execute growth strategies for biopharmaceutical companies, from portfolio management (e.g. business development strategies, therapy area expansion, R&D prioritization, and investment decisions) to clinical development strategy support (e.g. using real-world data to identify right patient segments, pipeline and competitive analysis) to commercialization (e.g. opportunity assessment and launch strategy). Jason brings over decade of corporate and product valuation experience in the life sciences spanning his time at Accenture M&A Strategy group, IQVIA's Portfolio Strategy & Transactions team, now at Trinity, leading several global valuations across a range of technologies and therapeutic areas.

Jason graduated from University of California, Los Angeles. with a degree in biology and international economics, followed by an M.Sc. in Decision Sciences from The London School of Economics and Political Science, and an MBA in Entrepreneurial Studies from London Business School.

Utkrisht (UT) Yadav | Associate Principal, Strategic Advisory

UT is part of Trinity's Strategic Advisory group. Since joining Trinity in 2019, UT has worked with global biopharmaceutical companies and emerging biopharma on projects including corporate and growth strategy, commercial opportunity assessments including forecasts and valuations, portfolio strategy, new product launch strategy, and brand and lifecycle growth strategy. One of UT's primary focus is helping our clients to decide how to invest in both internal and external development opportunities, and shape broader franchise and portfolio strategy, by developing robust forecasts and valuations grounded in deep market insights and benchmarks. His experience is spread across several therapeutic areas including, oncology, rare diseases, CNS/psychiatry, hematology, and immunology, and women's health. Prior to Trinity, UT was part of Life Sciences Commercial Strategy practice at Deloitte in New York and Chicago.

UT has a strong research experience in tissue engineering and regenerative medicine and has a Masters of Science in Biomedical Engineering from Carnegie Mellon University.

Herman Sanchez | Senior Partner, Strategic Advisory

Herman Sanchez has worked for over twenty years in the healthcare industry in academia conducting clinical trial research and design, and in strategic management consulting to pharmaceutical, medical device, and biotech companies. Herman joined Trinity at the beginning of 2006. While at Trinity his work has focused on commercialization strategy, business development assessment, and strategic product planning. Prior to joining Trinity, he worked as a Senior Associate at Boston Healthcare with device and pharmaceutical clients on product entry strategy, business development and reimbursement strategy. In his work consulting for pharmaceutical/biotech and medical device companies he has covered a number of disease/therapeutic areas including diagnostics, cardiovascular disease, vision care, diabetes, hepatitis C, alcohol abuse/dependence, oncology, Alzheimer's disease, orthopedics, wound care, and renal disease. He has been published in peer-reviewed publications on topics such as suicidal ideation, minority patient recruiting, alcohol use/abuse and depression/anxiety treatment. Herman holds an undergraduate degree from Harvard University and an MBA from the Tuck School of Business at Dartmouth.

About Trinity

Trinity Life Sciences is a trusted strategic commercialization partner, providing evidence-based solutions for the life sciences. With 25 years of experience, Trinity is revolutionizing the commercial model by providing exceptional levels of service, powerful tools and data-driven insights. Trinity's range of products and solutions includes industry-leading benchmarking solutions, powered by TGaS Advisors. To learn more about how Trinity is elevating life sciences and driving evidence to action, visit trinitylifesciences.com.

For more information, please contact us at info@trinitylifesciences.com.