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Thought Leadership

Intrinsic Value of an Early-Stage Pharmaceutical Asset

Increasing confidence in valuation
With discrete discount aggregation method

Foster Rosenblatt

Intrinsic Value of an Early-Stage Pharmaceutical Asset

INCREASING CONFIDENCE IN VALUATION WITH DISCRETE DISCOUNT AGGREGATION METHOD

Background

Finding the true intrinsic value of an early stage pharmaceutical asset is difficult and most often done poorly even by seasoned professionals. At this early point in product development, risk adjustments to future cash flows are overly sensitive, future attributes of the product are unknown and characteristics of the future market are uncertain.

Often, investors try to account for such risk by using an unsubstantiated "rule of thumb" high discount rate. However, as per Roger Ibbotson, a leading expert on cost of capital, the discount rate is a function of the investment rather than the investor. This indicates that using the acquirers' or the acquirees' cost of capital is erroneous. Therefore, to accurately value cash flows in a transaction, each asset must be discounted at a rate to reflect the unique risks associated with the asset's expected cash flow.

The vast majority of life sciences investors use standardized discount rates that represent "historical" norms and do not accurately reflect the current unique attributes of an asset. Thus, there is a randomness introduced into the valuation process that undermines the rationality of the negotiation process between buyer and seller. The consequences are that investors never accurately calculate the true intrinsic value of the asset and/or a good deal is lost because an appropriate purchase price is never agreed.

The Solution

There is methodology that can solve this problem and empirically derive the most appropriate discount rate for an early stage pharmaceutical asset by accounting for both known risks and unknown risks to an expected cash flow. Through a number of work steps that have to be informed by scientific, clinical, regulatory and commercial inputs, a multi-stage risk adjustment is made on the free cash flow ("FCF") to derive a risk-adjusted FCF ("rFCF"). Therefore, the net present value ("NPV") is calculated using the riskless borrowing rate. Then, the implied risk-adjusted cost of capital is back-calculated.

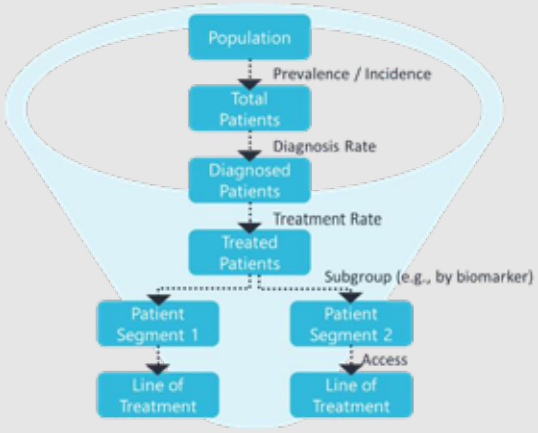
Net Revenue Forecast

A valuation for an early pipeline product begins with an accurate forecast of the top-line revenue. Differing forecast approaches should be selected depending on the market condition in which the asset is expected to compete. These include the following:

- **Mature Market** (e.g., hypercholesteremia, anxiety disorder): Demand-based forecast using industry demand data such as prescription audit data and integrated unit audit data
- **New Market or Market Segment** (e.g., rare diseases and niche oncology): Epidemiology-based forecast using either prevalence or incidence data
    - **Prevalence:** chronic conditions; assumes continuous treatment
    - **Incidence:** acute conditions; needs to account for progression, mortality, and cure/remission

Whether or not demand data or epidemiology data is the starting point of the sales forecast, both data sets have to be converted to eligible treated patients by recognizing each asset's unique properties (e.g., study design & pricing).

Defining Target Market



The target market is not just a function of the clinical trial design (i.e., inclusion & exclusion criteria). It is also a function of the price & formulary placement.

Once an eligible patient pool is determined, demand for the asset needs to be assessed by applying a patient share to the eligible patient pool. Patient share can be explored through primary market research with physicians and patients. Patient share can also be estimated through analog research analyses where the asset's future share is modeled after drugs with similar product characteristics (e.g., order of entry, efficacy, and safety) that were launched in similar market condition (e.g., therapeutic area, size of the market, number of branded and generic competitors). If budget and timing allow, triangulation of both primary and secondary approaches should be considered.

The annual number of patients needs to be transformed into units. The treatment regimen (i.e., duration of treatment and number of units per treatment) is applied and then factored down to account for patient persistence and compliance. Patient persistence and compliance estimates are often available in primary publications, and they can be obtained by analyzing longitudinal claims data. Lastly, the units need to be adjusted to account for inventory.

The final step is applying the list price and gross-to-net discount (also known as a revenue reduction factor). The list price multiplied by units provides the gross revenue that needs to be factored down to account for distributor allowance, managed care contract, co-payment rebate and any other assistance programs. The pricing and gross-to-net discount should be informed through primary market research as well as analog analyses.

Free Cash Flow Forecast

Estimating FCF requires an experienced expert to anticipate all the development and operating costs that are specific to the asset. In years past, this was done with analogs or generally applied guidelines. Those days are past. This step must be completed uniquely for each asset based on the specific product attributes and future market characteristics. These are the major buckets to consider (not an exhaustive list):

- **Development Costs:** The cost of a clinical trial will be directly correlated with the therapeutic area and the size of the target population. Selecting appropriate analogs based on similar target patient populations is an appropriate way to estimate the clinical trial costs.
- **COGS:** If actual API manufacturing costs are not available, COGS should be estimated based on the product's attributes. For example, a biological product (e.g., monoclonal antibody) will cost significantly more than a chemical product. Whether or not a device is associated with the product (e.g., injector) should also be considered.
- **Sales Force Costs:** Achieving the target share of voice in the market is critical in achieving the net sales forecast. The number of physician details, which translates to number of sales reps required, will depend on the type of product. For specialty products, targeting decile 1-4 prescribers could be enough. However, for primary care products, the manufacturer may require targeting decile 1-8 prescribers. Therefore, the sales force will be significantly more expensive.
- **Direct-to-Consumer Costs:** In the case that a product demand will be driven by the patient, or for other special circumstances, DTC costs should be determined. This cost will be higher for patient-driven products compared to treatment decisions that are dominated by physicians or payers.
- **Medical Costs:** The size of the target prescriber population, as well as the addressable patient pool, will determine the size of the medical team. For example, the number of pharmacovigilance cases will be higher for primary care products. The costs will also depend on whether a special program such as a risk evaluation mitigation strategy ("REMS") is required.

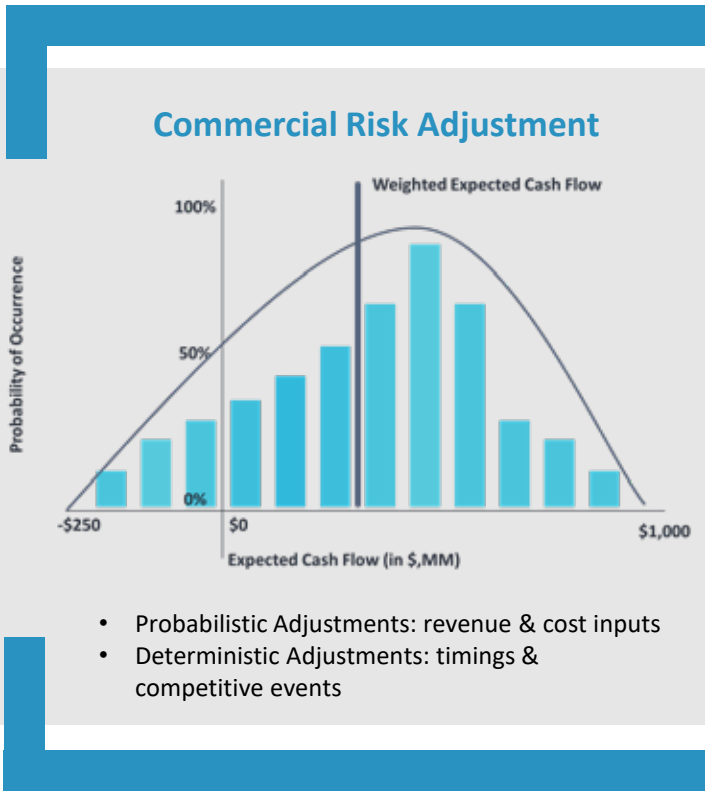
After accounting for all of the costs, earnings (defined as EBITDA) are calculated for each year going forward.

EBITDA is transformed into FCF for the asset by adjusting for tax, depreciation & amortization, capital expenditure, and net change in net working capital. For a pharmaceutical product valuation, terminal value that assumes perpetual FCF is not appropriate because of critical events such as loss exclusivity exist. Therefore, either a multi-stage terminal value model is needed, or a FCF forecast should be extended out until end of exclusivity.

Risk Adjustments

The definition of risk, in the context of asset valuation, is the degree of uncertainty in achieving future expected cash flow in terms of timing and amount. There are two types of known risks associated with a clinical asset: commercial risks and technical risks. FCFs need to be factored to account for both types of risk.

Commercial risk can also be thought of as variances of the FCF forecast of the asset. Multiple FCFs should be built and then weighted to arrive at a weighted expected FCF to account for the commercial risk. Weight adjustments can be done by using both probabilistic and deterministic approaches.



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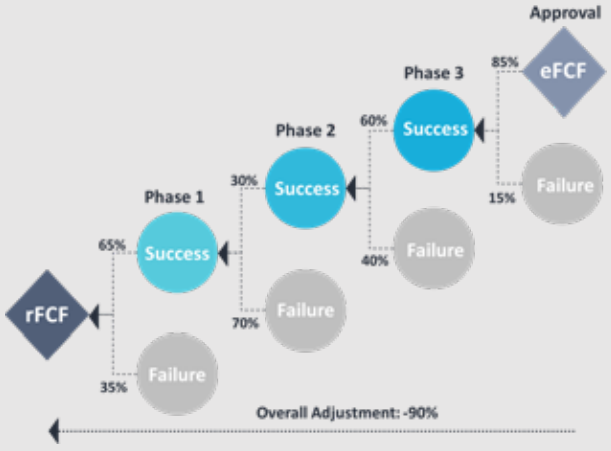
- **Probabilistic Adjustment:** If data is available, Monte Carlo simulation should be used on the key inputs to the net revenue and free cash flow forecast (e.g., epidemiology, market share, price, and costs). However, data is not often readily available to run a Monte Carlo simulation (e.g., distribution data). In such cases, creating Base-Case, Worse-Case and Best-Case scenarios could produce similar results as running Monte Carlo simulation using Betapert or Triangle distribution.
- **Deterministic Adjustment:** Scenarios created using a deterministic approach should be used to model the competitive impact from the launch of other pipeline assets. Deterministic adjustment is more appropriate than probabilistic adjustment because the competitive impact of future products is also subjected to the probability of their successful launch. For example, a competitor in phase 2 clinical development only has a 15-20% chance of reaching the market.

Technical Risk Adjustment



- Revenue: adjusted by the cumulative PoS of all clinical stages
- Cost: adjusted based on development stage

FCF also needs to be factored to account for the probability of success of clinical development and regulatory approval (i.e., the technical risks). Two common adjustments:

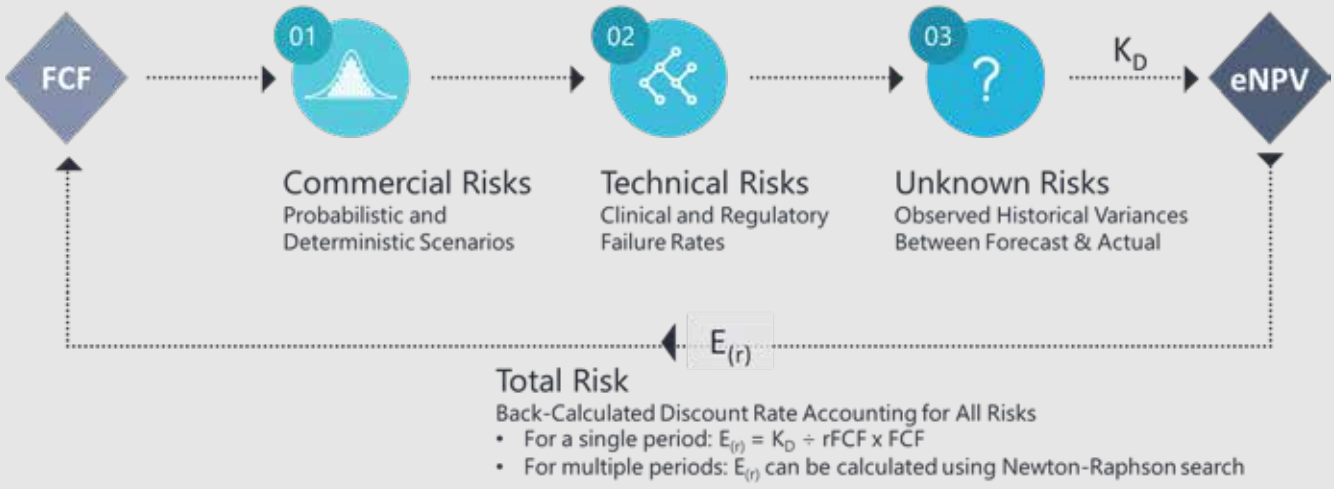
- **Revenue Adjustment:** Net revenue is factored by the cumulative probability of success ("PoS") rate of passing all stages of development. For example, if a phase 2 asset is forecast to have a net revenue of $100M, then the product of PoS of phase 2, phase 3, and NDA needs to be applied to the net revenue.
- **Cost Adjustment:** The probability of incurring costs needs to be factored depending on the timing of the costs. For example, the cost to conduct a phase 2 clinical trial is factored by the PoS of passing phase 1, and the cost to conduct phase 3 clinical trial is factored by the product of the PoS of phases 1 and 2.

These two types of risk adjustments account for the known risks associated with the FCF used for valuation. However, early pharmaceutical assets also have unknown risks that are not accounted for in the commercial and clinical risk adjustments described above. These unknown risks are illustrated by the historical variances between forecasts done during clinical development and the realization of actual sales. It was observed, not surprisingly, that the variance is the highest for forecasts done during phase 1 clinical trial and the lowest for forecasts done after products were launched. Therefore, a final risk adjustment needs to be done. These unknown risks can be accounted for using the certainty-equivalent approach by subtracting the cash-risk premium for the expected cash flow or adjusting the risk-less rate. The risk-adjusted FCF is then used in discount cash flow valuation to derive the intrinsic value of the asset.

Valuation

Discount cash flow ("DCF") valuation method is commonly used in the valuation of a clinical asset. However, it is often used incorrectly. The two main types of errors include the use of an unfounded discount rate and/or applying a discount rate to an incorrect cash flow.

Discrete Discount Aggregation Method



Legend: K_D: Average Industry Cost of Debt; $E_{(r)}$: Expected Cost of Capital (includes risk premium)
FCF: most probable free-cash-flow; rFCF: risk-adjusted free-cash-flow

- **Discount Rate:** The discount rate should be a function of the investment rather than the investor. However, identifying the correct discount rate is difficult. Often, most analysts use an unsubstantiated high discount rate to account for the various types of risk associated with an early-stage clinical asset. Existing models (e.g., Capital Asset Pricing Model or Fama-French model) do not necessarily capture the risk associated with clinical assets. These models also only work for publicly traded companies that inherently have lower risk compared to an undiversified single asset. Therefore, investors often increase the derived rate to account for asset-specific risk, but such an approach is subjective and drives the discount rate to an arbitrary, desired rate that renders previous analyses pointless.
- **Cash Flow:** Accounting for different types of risk can be accomplished either through adjusting the FCF or increasing the discount rate. However, it cannot be both, which often happens during a financial transaction. If risked-adjusted FCF is used as the basis of DCF valuation, then the cost of debt (close to the risk-free rate) should be used. If unadjusted (most probable) FCF is used as the basis of DCF valuation, then risk-adjusted cost of capital should be applied.

There are advantages and disadvantages to each of these approaches. Applying a "risk-adjusted" discount rate to an undiscounted FCF is straight forward and easier to understand. With this approach, if the NPV is zero, the rate of return is the discount rate used. Applying the cost of debt to a risk-adjusted cash flow provides transparency to the risks that were taken into consideration and helps investors understand how a valuation can change as the asset moves through the development pathway. However, with the second approach it is not easy to see or derive the actual rate of return.

The recommended approach is to use risk-adjusted FCF and unadjusted cost of debt in determining the valuation of a clinical asset. It is also necessary to calculate back what the implied risk-adjusted discount rate is if the unadjusted FCF was used. This can be achieved with the following formula:

$$\sum_{t=1}^{\infty} \frac{rFCF_t}{(1+K_D)^t} = \sum_{t=1}^{\infty} \frac{FCF_t}{(1+E_{(r)})^t}$$

- rFCF: risk-adjusted FCF (includes commercial, technical risks, unknown risks)
- FCF: unadjusted FCF (excludes risks)
- K_D: average industry cost of debt
- $E_{(r)}$: implied discount rate for unadjusted FCF

For illustrative purpose, $E_{(r)}$ for a single period can be calculated using $E_{(r)} = (K_D \div rFCF) \times FCF$. However, because the cash flow is in a time series, $E_{(r)}$ is solved using Newton-Raphson Search. The solved Re is a discount rate that incorporates all the commercial, technical, and unknown risks, and it needs be communicated to facilitate financial transactions.

Lastly, it is also important, and sometimes more important in a financial transaction, to determine the market value of the asset. The market value of the asset can be determined using comparable valuation methodology. Valuation using the comparable approach assesses the cost of capital coming from the marketplace, which is the pool of investors pricing the risk of a particular asset. This provides the basis of the consensus expected rate of return that an asset needs to provide in order to attract capital to an asset.

In Conclusion

Finding the true intrinsic value of an early stage pharmaceutical asset is complex, and traditional methods are not serving the current needs of investors. Fortunately, application of techniques such as discrete discount aggregation creates a more transparent and accurate approach to de-risk transactions and rationalize capital markets. One caveat is that an in-depth understanding of the industry is needed to apply these methods.

Case Study

Business Situation

A private equity firm wanted to understand the commercial opportunity and fair value of a clinical asset that was in phase 2 clinical development for a neurology indication.

Approach & Methodology

F|R forecast the FCFs using an epidemiology-based approach. The various revenue & cost inputs were informed by secondary and primary market research & analysis. F|R determined the intrinsic value and implied risk-adjusted discount rate using Discrete Discount Aggregation ("DDA") Method.

Business Outcomes

$,MM	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
FCF	($25.0)	($50.0)	($150.0)	$200.0	$400.0	$600.0	$800.0	$1,000.0	$1,000.0	$1,000.0	$1,000.0
rFCF	($25.0)	($15.0)	($27.0)	$17.9	$35.8	$53.7	$71.6	$89.5	$89.5	$89.5	$89.5

Risk Adjusted NPV:

$$\text{eNPV} = \sum_{t=1}^{10} \frac{rFCF_t}{(1+K_D)^t}$$

$$\text{eNPV} = \sum_{t=1}^{10} \frac{rFCF_t}{(1+4\%)^t}$$

eNPV = **$340M**

Implied Discount Rate:

$$\sum_{t=1}^{10} \frac{FCF_t}{(1+E_{(r)})^t} = \text{eNPV}$$

$$\sum_{t=1}^{10} \frac{FCF_t}{(1+E_{(r)})^t} = \$340M$$

$E_{(r)}$ = **48%**

F|R determined the asset has a fair value of $340M using the "DDA" method. F|R also back-calculated the implied risk-adjusted discount rate, which was 48%. F|R facilitated and expedited the transaction by communicating to the seller how the asset's unique risks were accounted.

In this case, the back-calculated discount rate was higher than the client's standard discount rate, which meant the client would have over-valuated the asset.