



GUEST ARTICLE

CONGRESS MUST ACCOUNT FOR HIGHER COST OF BIOPHARMA STARTUPS



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“Limiting the exclusivity on biologic innovations is likely to intensify the current downward pressure on venture returns and drive them further below the asset class cost of capital.”



REUTERS

One of the most important advocacy efforts that life sciences investors have undertaken in the last several years is educating members of Congress and the Administration about both the unique benefits and challenging dynamics of venture investing.

It is critical that lawmakers and regulators understand the drivers of the early stage life sciences industry so that their policies will not upset the risk/reward equation that motivates investment in innovation.

One such example is the current discussion regarding a **Food and Drug Administration** pathway to approve follow-on biologics. Policy makers are trying to determine the appropriate balance between innovation and competition by setting a proper period of exclusivity for innovators after a new biologic is brought to market. This exclusivity period is a critical element of the investment decision, as it guarantees a revenue stream if and when the product becomes successful. It is one of the prime motivators for venture investors and institutional investors to fund new biopharma startups.

If the exclusivity period is shortened, it will lower the potential return on investment in the company to below the cost of capital (CoC) or hurdle rate for venture investors and over time reduce the flow of capital to this segment of the asset class. But what is that cost of capital? Unfortunately, to date, Congress has been using data from large public companies, not private early stage startups where a substantial and

growing share of biopharmaceutical innovations take place, to determine this rate. This faulty analysis is problematic because it sets the cost of capital at 10%, much lower than where venture investors know it to be.

To demonstrate this reality, the **National Venture Capital Association** commissioned professors **Iain Cockburn** of **Boston University** and **Josh Lerner** of **Harvard University** to derive the cost of capital for early stage biotechnology companies. The following is a redacted summary from their work, which found the cost of capital for these startups to be in excess of 20 percent.

Cost of Capital

The formula to derive the CoC combines (1) the time value of money and (2) the risk of not getting your money back. For large diversified companies with established products, markets and cash flows, the CoC is in the 7% to 12% range. For smaller companies facing significant business and technology risk, the CoC is much higher to compensate for the additional risk.

Corporate finance theory has long used the Capital Asset Pricing Model (CAPM) to measure the cost of capital.

Cost of Capital = Risk Free Rate + β x risk premium

Risk Free Rate = Treasury Notes = 4%

β = a company specific measure of risk

– For the average mature company, $\beta = 1$

– For riskier companies, $\beta > 1$

– For very risky companies, $\beta > 2$

Risk Premium = payment to equity investors to take on fixed risk = 5% to 7%

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Illustrative Costs of Capital

	Risk free rate		β		Equity risk premium		WACC/Cost of Capital
Risk-free (e.g. Treasury bonds)	4%	+	0.0			=	4%
Mature, diversified firm	4%	+	1.0	x	7%	=	11%
Mid-cap biotech company	4%	+	1.5	x	7%	=	14.5%
Small-cap, early stage biotech company	4%	+	2.0	x	7%	=	18%
Venture investment in biotech	4%	+	2.5	x	7%	=	21.5%

Note: Assumes no debt

Published studies show β for publicly traded small cap biotechs is around 1.5-2.0 (Barra Betas, Ibbotson Beta Book, Golec & Vernon, 2007, DiMasi & Grabowski, 2007). For all venture β is around 2 (Driessen_Lin_Phalippou, 2007; Woodward, 2005), likely higher for biotech investments

Biopharma startups have several inherent challenges that contribute to a higher Beta and Risk premium, including (1) a very long time to market (10++ years), (2) excessive levels of risk (fewer than 1% of drug candidates will make it to market), (3) large amounts of capital needed to move technologies forward, and (4) uncertain exit opportunities through IPO or acquisition.

The CoC for biopharma startups (21.5%) constitutes the hurdle rate of return for institutional investors to continue to invest in biopharma venture capital funds. It is nearly twice the hurdle rate for a mature and diversified company (11%) and nearly 50% higher than the hurdle rate of a mid-cap biopharma company (14.5%). (See table: *Illustrative Costs of Capital*.)

CoC vs. Early Stage Returns

Historically venture-backed returns for biopharma investments have been difficult to measure, since they are privately reported, highly variable over time, have many losses offset by a few large gains, and focus on larger funds vs. individual investments. However, there are benchmarks that suggest that all venture capital returns vary

Cumulative Venture Returns

1 year	3 years	5 years	10 years	20 years
-16.6	4.0%	6.3%	15.4%	17%

Note: Returns are net to investors. Data are for all VC stages and over various time horizons ending 12/31/08. Source: Thomson Reuters

widely over various time periods and firm by firm.

According to **Cambridge Associates Inc.**, the realized rate of return (IRR) on 1,606 biopharma companies that were acquired, went public or failed from 1986-2008 was 25.7% gross, corresponding to 20.7% net to investors. These above-average returns in biopharma, compared to all venture capital, reflect above-average risk in this sector.

In fact, 44% of the 1,606 deals resulted in a full or partial loss. These losses were offset by a few substantial successes. However, when analyzing the total IRR for all 2,829 biopharma companies in the same time frame, including unrealized investments, the rate was 15.7% net to investors—below institutional investors hurdle rate of return.

Downward Pressure

The last biopharma IPO class from late 2003 to late 2007 has been disappointing, as buy-siders started to anticipate growing regulatory challenges and kept raising the risk discount rate in the sector. This poor exit environment has put downward pressure on VC performance in the past few years, and the recent financial crisis has added an additional toll on almost every aspect of the investment ecosystem.

The IPO window has been closed for the past year; the lack of IPOs has, in turn, weakened the M&A market, as large corporate buyers are biding their time and waiting for valuations to fall further before bidding on potential targets. Added regula-

tory and policy pressure can only further impact the biopharmaceutical ecosystem. These dynamics threaten the long-term performance of biopharma venture firms and of their portfolio companies in the next several years.

Limiting the exclusivity on biologic innovations is likely to intensify the current downward pressure on venture returns and drive them further below the asset class cost of capital. The current exit environment is almost entirely driven by M&A and depends on large biopharma companies placing the right economic value on innovative programs from the venture-backed companies. Reducing that value through lesser protection will impact direct investment in innovation; biologics are particularly vulnerable to a shorter data exclusivity period as patents do not bring the same level of protection than for small molecules.

It is readily acknowledged that the U.S. biopharma industry was created from successive waves of biopharma founded and nurtured by venture capitalists during that last 20 years. More than 50% of molecules that go into human trials originate or are acquired from these startup companies. They are a “keystone species” in the ecosystem that contributes to the quality of care and to the technological leadership of the United States.

These startups face more than enough risks with their long investment cycle, technology uncertainty, capital intensity and regulatory hurdles. This is why it is critical to support the appropriate level of economic value for these products through a thoughtful level of protection and incentive for innovation. Biopharmaceuticals represent only 10% of total health care costs in this country and it may be more important to support innovation in medical discovery than in other less strategic yet more costly sectors.

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