Biotechnology Innovation Organization
1201 New York Ave., NW
Suite 1300
Washington, DC, 20005
202-962-9200

Biotechnology Innovation Organization
Statement for the Record
U.S. House Committee on Financial Services Subcommittee on Capital Markets
A Roadmap for Growth: Reforms to Encourage Capital Formation and Investment Opportunities for All Americans
April 23, 2023

Introduction

BIO is the world's largest life sciences trade association representing nearly 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative biotechnology products that will help to solve some of society's most pressing challenges, such as managing the environmental and health risks of climate change, sustainably growing nutritious food, improving animal health, enabling manufacturing processes that reduce waste and minimize water use, and advancing the health of our families.

BIO appreciates the opportunity to present these comments to the Committee as it considers reforms to encourage capital formation and investment opportunities for all Americans.

There is a pressing need for reforms that support entrepreneurs, protect investors, and ensure the continued economic dynamism that has catapulted the United States into its current position as the global leader in innovation.

The Importance of Capital Formation in the Life Sciences

The American bioeconomy is a testament to the benefits of free and fair capital markets that allow for entrepreneurial risk-taking. Our capital markets are a key reason why the United States remains the global leader in life sciences research and in the translation of scientific discovery into therapeutics, diagnostics, and cures.

BIO urges the Committee to build on this success with carefully targeted reforms that promote greater access to capital while protecting investors, promoting transparency, and preserving market integrity.

Global competition in the "biotechnology revolution" is accelerating as nations continuously learn from and adapt to American-born innovation, which includes not only our novel ideas and technologies but also dynamic new business models and policies.

The work of biomedical R&D carries with it a very high risk for early investors. A recent study by MIT found that oncology programs have a 3.4% chance of resulting in an FDA approved product,[1] yet billions of dollars of private and public capital from exchanges are invested every year to find treatments and bring them to the patients who need them.

No other investment carries with it such a low rate of success. These low probabilities of success, significant sums of money, and decade-long timelines required to create a new biomedical product has led to the development of a highly specialized ecosystem to price, transfer, and absorb these entrepreneurial risks.[2] These investments require an efficient capital market ecosystem.

It is no coincidence that the country with the most robust capital formation ecosystem also happens to be the country that produces the most groundbreaking medicines. In fact, the United States produces more new medicines than the rest of the world combined. Our markets are also larger than those of the next nine largest financial markets combined.[3]

In short, robust capital formation yields a robust innovation economy. If we intend to continue being the world's leader in biotechnology innovation, we must enhance our capital formation policies to maintain our competitive advantage.

Private Markets

All innovation journeys begin in the private market. Angel investors provide entrepreneurs with those first dollars needed to take the gigantic leap from the lab to commercialization, which takes more than a decade, billions of dollars, and a high risk of failure.

Angel and venture investors serve a critical function that public markets cannot. They not only provide capital but also invaluable advice, mentorship, and a network that is leveraged to take innovations to the next step. We need more angels, not fewer. We need more dynamic and liquid private markets, not more constrained private markets.

Private capital differs most significantly from public capital in that they have specialized expertise and a higher tolerance for extreme uncertainty and a longer investment horizon. They can invest in a company that is not expected to generate revenues for a decade—as is the case

[1] Lo et al, "Estimation of clinical trial success rates and related parameters," Biostatistics (2018)
[2] https://www.nature.com/articles/s41587-021-00876-w
[3] https://data.worldbank.org/indicator/CM.MKT.LCAP.CD?locations=US

across the biotech ecosystem—and not feel pressured to sell. In fact, the opposite holds true. They invest more time and resources to develop the team and mature the enterprise.

These investors know that biotechnology companies consume cash at a ferocious rate, and they expect the majority of their dollars to go towards scientific progress. These early investors know each portfolio company intimately, and they care about nurturing the growth of the company and its leaders.

BIO supports the "Equal Opportunity for All Investors Act of 2023," which would have the Securities and Exchange Commission establish an examination to qualify an individual as an accredited investor and no longer limit the definition to a wealth criterion.

Across the bioeconomy, private capital tends to be patient capital. It allows for mistakes, for growth, and for the maturity of entrepreneurs from scientists to corporate leaders. All of this is crucial for first-time founders and those seeking to change the world by bending the arc of disease.

However, fundraising is not a binary decision between public or private capital, but rather a continuum where regulatory burdens should grow in tandem with access to the larger pools of capital needed to advance clinical trials.

Both private and public markets are accessed based on company specific needs for financing. After a certain point in the lifecycle of a biotech company, the costs associated with running clinical trials exceed the capital base of private markets and, therefore, entrepreneurs must then take the leap into the largest pool of capital on the planet: U.S. stock exchanges.

Public Markets

It is no secret that fewer companies now pursue an IPO and become public. There are several reasons for that, including the significant increase in costs associated with being a public company. These funds are diverted from a small biotech's core mission of R&D and clinical development, which is the main reason investors fund our members.

Instead, small biotechs must spend a growing percentage of their limited capital raise on regulatory filings and paperwork, quarterly reporting when our cadence of news is more sporadic, and on ancillary services required of public companies, such as those dedicated to ensuring the enterprise and its officers, engage appropriately with non-specialized investors for the first time, and navigating the legal risks that follow volatile periods of stock performance.

BIO urges Congress to adopt rules that reflect the differences between public and private markets in a targeted manner that protects investors, preserves the integrity of markets, and facilities robust capital formation.

The JOBS Act of 2012 (P.L. 112-106), is an example of a successful targeted approach. It ushered in a new era of dynamic capital formation for the biotechnology industry. It represented a recognition by Congress that regulations must fit the purpose for which they were designed and not impose costly burdens that do not benefit markets or investors. We believe that Congress should build on this success and resist the calls to add additional and unnecessary reporting requirements to public markets, Board directorships, and related expenses, both direct and indirect, dedicated to matters that are not material to our business and will not aid investors in making informed decisions.

These are additional costs that threaten to divert scarce funds from science to compliance and require innovators to raise new funds from public markets at a time when these markets are especially tight. Ultimately, the costs to the system are increasingly dedicated to reporting rather than delivering on our promise to change the course of rare diseases. The challenge for policymakers is to ensure that any additional regulatory costs yield substantive benefits for market integrity and investor protection.

A critical bottleneck is that public market regulation is once again becoming a one-size-fits-all, which makes being a public company much more burdensome for smaller businesses. Recent proposed rules by the SEC notably did not fully consider the impact of these new rules on small businesses, as noted by the Small Business Administration's Small Business Advocate.[4]

It is important to recall at this point that despite being public companies, early-stage small biotechs lack an approved product and have no recurring revenues to fund daily operations. They are entirely dependent on capital markets to finance their work.

As is the case with private markets, small biotechs raise money from investors (this time from public equity investors in initial public offerings and follow-on issuances) and enter into partnerships with pharmaceutical companies to advance clinical trials which can cost in the hundreds of millions of dollars. In essence, the biotechnology industry has a fixed pool of money that must be budgeted across years of operating until the next need to raise more money for the next clinical trial.

[4] https://www.sec.gov/comments/s7-10-22/s71022-20131758-302192.pdf

The difference from private markets is that the cost of capital is significantly higher and the cost of being a public company consumes ever greater amounts of budget from one year to the next. This is an especially salient point in context of the last few years, when the industry experienced significant volatility in response to COVID, which was followed by the current multi-year decline.

For context, the entire sector saw speculative inflows as the response to COVID attracted public monies even if companies were not responding to the pandemic but were rather developing cancer therapeutics or treatments for rare diseases.

This epic market swing increased share prices and forced companies to exit the emerging growth company, or EGC, exemption and forced them to comply with new regulatory filing requirements despite the fact that their stock prices collapsed shortly after breaching the thresholds. This loss of EGC status in many cases had nothing to do with the fundamentals of these companies, but with overall market conditions.

For context, this is one of the main reasons most small biotechs lose the emerging growth company exemption of the JOBS Act, which shields them from spending significant sums of money on reporting that investors have not requested but regulation requires. Public market fluctuations often cause biotechs to cross public float thresholds that trigger additional reporting requirements. This trigger event is not based on company fundamentals, such as finally having product revenues. This is like having a tax system that is based on the number of years working instead of income.

Providing more flexibility to the emerging growth company definition would be a significant help to small companies. Extending the exemption by five years and raising the public float thresholds maintain the spirit of the JOBS Act and will help companies better absorb new regulations. This is especially relevant to the biotechnology sector where R&D timelines can run for a decade or longer.

BIO believes that Congress can build on the past success of the JOBS Act with narrowly targeted changes to the law.

BIO supports the "Helping Startups Continue to Grow Act," which would create a longer runway for young, pre-revenue companies to maintain their Emerging Growth Company status as it would align the exemption length with product cycle timelines.

BIO also supports a draft proposal by Senator Ted Budd (R-NC) to increase reporting thresholds by updating the decades-old public float thresholds that define emerging growth companies. One option is to bring these thresholds in line with actual markets is to adjust the public float thresholds by the amount the equity market has grown since 2012, when the JOBS Act was enacted.

According to the World Federation of Exchanges, the U.S. equity market grew from $18.7 trillion at the end of 2012, when the JOBS Act was enacted, to $40.7 trillion in 2020.[5] Markets have doubled since 2012, which would bring the EGC public float threshold just under the limit that investors already use to define a small company's market capitalization, which is $2 billion. It is time for the SEC to raise the thresholds to be in line with how markets have grown since the legislation became law.

Conclusion

BIO supports transparent and reliable capital markets, both private and public, that allow companies to efficiently "graduate" or transition across funding structures while minimizing overlap in reporting and disclosure burdens. Disclosures and reporting obligations should scale as a company matures and generate revenues.

Small tweaks can mean a big difference for emerging biotechnology entrepreneurs who continue to face a tidal wave of challenges, especially in the current bear market in public equities that have left IPO on-ramps and follow-on issuances shuttered.

We must learn from the past and avoid costly errors that threaten to sacrifice what has been built over the last 80 years. We should not institute rules and regulations that will only concentrate capital further and raise the cost of entrepreneurship to the point that we box out the innovative small businesses that account for the lion's share of innovation in this dynamic industry. Rather, Congress should build upon the successful implementation of the bipartisan JOBS Act of 2012 and take further bipartisan action to help smaller companies grow.

Thank you for this opportunity to present BIO's views.

Nick Shipley
Chief Advocacy Officer
Biotechnology Innovation Organization

[5] https://data.worldbank.org/indicator/CM.MKT.LCAP.CD?locations=US