Biotechnology Innovation Organization

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President & CEO

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The Honorable Mike Crapo
Chairman
Committee on Banking, Housing, and Urban Affairs
United States Senate
239 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Sherrod Brown
Ranking Member
Committee on Banking, Housing, and Urban Affairs
United States Senate
713 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Crapo and Ranking Member Brown:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit to the Senate Banking Committee legislative proposals designed to increase economic growth, stimulate job creation, and support America's 21st century innovation economy. We are hopeful that the Committee will consider these suggestions and ultimately pass legislation to ensure that America's capital markets are able to support the capital formation necessary to finance the years of research and clinical trials necessary to bring a life-saving medicine to patients.

Since the JOBS Act was signed into law five years ago, 212 emerging biotech companies have used provisions in the law to go public. The ability of growing businesses to access the public markets, as supported by the JOBS Act, is of paramount importance to biotechnology innovation because investment capital is the lifeblood of scientific advancement. It costs over $1 billion to develop a single life-saving treatment, and most companies spend more than a decade in the lab before their first therapy is approved.

The many JOBS Act success stories in the biotech industry are attributable to the one-two punch at the core of the law: First, it allows small companies enhanced access to investors, increasing the capital raising potential of an offering. It then provides them with targeted relief from costly regulatory burdens, decreasing the amount of capital diverted from research. This combination is critical for biotech innovators and has increased the viability of the public market for growing companies looking to fund their capital-intensive development programs.

Given the strong impact that the JOBS Act has had on biotech capital formation, BIO is encouraged that the Banking Committee is considering ways to continue to support the growth of small public companies. The 212 newly public biotech emerging growth companies (EGCs) benefitted greatly from the IPO On-Ramp, but they now face the day-to-day challenges of being a public company. BIO appreciates the Committee's ongoing work to build on the success of the JOBS Act, and we offer the following policy solutions designed to ensure that emerging biotechs can continue to access innovation capital on the public market:

- BIO supports extending the JOBS Act's SOX Section 404(b) exemption for an additional five years for former EGCs that maintain a public float below $700 million and average annual revenues below $50 million, as proposed by the Fostering Innovation Act.

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- BIO supports enhanced short selling transparency, complementary to the existing disclosures required of long investors, in order to shine a light on manipulative trading behaviors that disincentivize long-term investment in innovation.

- BIO supports instituting SEC oversight of proxy advisory firms in order to foster accountability, transparency, responsiveness, and competition in the proxy advisory firm industry, as proposed by the Corporate Governance Reform and Transparency Act.

- BIO supports broadening the SEC's small business classifications (which define smaller reporting companies and non-accelerated filers) to encompass growing innovators with a public float below $250 million or annual revenues below $100 million, a targeted expansion from the existing $75 million public float cap.

- BIO supports making XBRL compliance optional for EGCs and certain low-revenue issuers while the SEC studies how to improve the disclosure mechanism, as proposed by the Small Company Disclosure Simplification Act.

BIO believes that these targeted reforms would enhance the capital formation ecosystem, reduce regulatory burdens, and incentivize funding for the next generation of breakthrough medicines; attached you will find details outlining each proposal and its impact on biotechnology innovation.

We look forward to working with you to build on the success of the JOBS Act, enhance capital formation, and spur scientific advancement at biotech small businesses across the country.

Sincerely,

James C. Greenwood
President and CEO

The Fostering Innovation Act:
Extending the IPO On-Ramp for Pre-Revenue Innovators

The most direct policy impact of the JOBS Act has been the five-year exemption from Section 404(b) of Sarbanes-Oxley (SOX). Section 404(b) requires an external auditor's attestation of a company's internal financial controls that provides little-to-no insight into the health of an emerging biotech company – but is very costly for a pre-revenue innovator to comply with, making the JOBS Act exemption extremely valuable.

Biotech investors demand information about the growth-stage companies in which they invest – and spend countless hours learning as much as they can about the company's science, the diseases it is treating, the patient population, the FDA approval pathway, and myriad other variables that will determine the company's ultimate success or failure. The testing-the-waters process created by the JOBS Act has been so successful for the biotech industry because it allows companies a platform to disseminate *more* and *more detailed* information to potential investors. But the information that these investors want and need does not align with what is required by SOX – and yet virtually all biotechs are subject to this one-size-fits-all mandate that can cost them over $1 million per year once their EGC exemption expires.

Despite these important savings for which biotechs are eligible during their first five years on the public market, it remains the case that the biotech development timeline is a decades-long affair. Most biotechs that went public under the JOBS Act will still be in the lab and the clinic at the dawn of year 6 on the market – still reliant on investor capital to fund their research, but facing a full-blown compliance burden identical to that faced by commercial leaders and multinational corporations.

To address this upcoming capital diversion from science to compliance, Reps. Kyrsten Sinema (D-AZ) and Trey Hollingsworth (R-IN) have introduced the Fostering Innovation Act (H.R. 1965) in the House of Representatives. The bill was also introduced in the House in the 114th Congress, where it received strong, bipartisan approval in the Financial Services Committee and passed the full House by voice vote. It would extend the JOBS Act's SOX 404(b) exemption for certain small companies beyond the existing five-year expiration date. This important legislation recognizes that a company that maintains the characteristics of an EGC but has been on the market beyond the five-year EGC window is still very much an emerging company.

The Fostering Innovation Act would apply to former EGCs that have been public for longer than five years but maintain a public float below $700 million and average annual revenues below $50 million. These small businesses would benefit from an extended SOX 404(b) exemption for years 6 through 10 after their IPO. The additional five years of cost-savings would have the same impact as the first five years – emerging companies would be able to spend investor capital on growing their business. In the biotech industry, that means small business innovators can remain laser-focused on the search for breakthrough medicines.

If a company eclipses $50 million in average annual revenues, its full SOX 404(b) compliance obligations would kick in. The Fostering Innovation Act does not grant a carte blanche exemption – it is targeted specifically at pre-revenue companies, because revenue is the key indicator of company size, and of the ability to pay for expensive compliance obligations like Sarbanes-Oxley. Maintaining the JOBS Act's public float test of $700 million while drastically lowering the revenue test from $1 billion to $50 million limits the Fostering Innovation Act to a specific universe of truly small companies – instituting a company

classification regime for years 6 through 10 post-IPO that accurately reflects the nature of small businesses while also supporting their growth.

Under current law, small, pre-revenue companies are often required to file the same reports as revenue-generating, profitable multinational corporations. Under the Fostering Innovation Act, these emerging companies would save millions of dollars that can be utilized to fund groundbreaking R&D and life-saving medical research.

Short Selling Transparency:
Preventing market manipulation

The unique business model of groundbreaking innovation leaves emerging biotechs particularly vulnerable to stock manipulation via abusive short selling strategies. Biotech companies depend on the public market for the capital necessary to fund late-stage clinical trials. However, the high-stakes nature of their research, their often-thinly-traded stocks, the limited publicly available information about ongoing trials, and their dependence on a small portfolio of products or product candidates can be exploited by short sellers who prioritize short-term profits over the long-term health of patients. Abusive short trading strategies harm growing companies and disincentivize long-term investment in innovation.

BIO acknowledges that appropriate shorting can support the stable, liquid markets that fuel the growth of emerging biotech innovators. However, we strongly believe that the current lack of transparency related to short positions is enabling trading behaviors that unfairly harm growing companies, long-term investors, and, most importantly, patients. Emerging biotechs face a consistent and significant risk of manipulation by short sellers, who are protected by the lack of disclosure required of short positions.

Specifically, growing innovators face campaigns mounted by manipulative short investors who spread online rumors about small biotech companies, or publish false or misleading data about clinical trials or marketed therapies, in order to drive down their stock price. The end goal of this manipulation is to generate a quick profit for short sellers at the expense of the long investors who support life-saving innovation. Recently, a new strategy has emerged wherein hedge fund managers take a short position in a biotech company's stock and then immediately file a series of spurious patent challenges through the Patent Office's *inter partes* review (IPR) process, initiating a stock drop that, again, benefits short sellers but harms long-term innovation.

Company management has a fiduciary duty to protect shareholders, but the lack of transparency around short positions makes it exceedingly difficult to police short manipulation effectively. This consistent risk of manipulation, and the lack of information available that would allow companies to combat it, disincentivizes the long investment necessary to fund the decade-long, billion-dollar biotech development pathway.

BIO believes that increased short transparency, designed to complement the existing long disclosure regime, would shine a light on manipulative behaviors, allow market participants to make informed trading decisions, and ensure equitable rules for all types of investments. Specifically, we would support required disclosures of investors taking significant short positions, modeled after the beneficial ownership disclosure obligations in SEC Regulations 13D and 13G.

The current disclosure regime for long positions exists to provide information regarding persons that may have potential influence over, or control of, an issuer. Investors taking short positions, on the other hand, face no public disclosure requirement, despite the significant influence they exert on issuers. Their power stems not from voting rights, but rather from the ability to spread rumors and engage in manipulative trading behaviors that harm growing companies and disincentivize long-term investment in 21st century innovation and job creation – yet there is not a parallel disclosure regime for the reporting of short positions.

Notably, BIO supports a short disclosure regime that is *complementary*, rather than identical, to the existing long disclosure requirements. The long disclosure trigger in Regulation 13D (5% of a class of an equity security) is unlikely to capture short manipulation for the simple reason that few short sellers take a large enough short position to cross the 5% threshold – yet still find it easy to manipulate a company's stock even if they are short far less than 5%. BIO would support either a lower disclosure trigger or a standard based on a different metric than outstanding shares (for example, trading volume could be a more appropriate measure given that the depressive effect of short sales on a stock price is largely a function of the volume and frequency of short transactions relative to the overall securities transaction volume).

Issuers, investors, and patients are all impacted by the current lack of short transparency. A commonsense disclosure regime for short positions would shine a light on manipulative practices while giving investors and companies the information they need to make informed market decisions.

The Corporate Governance Reform and Transparency Act: Regulating proxy advisory firms

Proxy advisory firms often have outsized influence on the decision-making processes of emerging companies and their shareholders. The firms' impact has grown in recent years, with their rise to prominence largely coinciding with the rise in institutional ownership of American stocks. Institutional investors' reliance on proxy firms, combined with an overall rise in shareholder activism, has dramatically increased the firms' ability to influence proxy votes and company decisions. Recent studies have shown that a firm's recommendation can swing the shareholder vote by as much as 25%.

Despite their significant influence on emerging companies, proxy advisory firms (the universe of which is functionally limited to just two firms) generally refuse to engage in a productive or transparent dialogue with smaller issuers, instead relying on one-size-fits-all recommendations that do not take into account a company's or its shareholders' unique circumstances. Furthermore, the conflicts of interest inherent in the business models of those firms which engage in business consulting in addition to providing proxy recommendations raise serious concerns.

For growing biotech companies, these issues are particularly acute. Biotech small businesses operate in a unique industry that values a strong relationship with investors, yet they often are held to standards that are not applicable to their company and forced to engage in proxy fights over issues that do not add value for shareholders. When a proxy firm issues a recommendation that is not applicable to an emerging biotech and remains unwilling to consider alternative approaches or methodologies, it can harm a company's relationship with its shareholders and distract management from the core business of the company. Even in instances where a proxy firm has not yet made a recommendation, their influence is felt in boardrooms across the industry as companies strive to structure their corporate policies to satisfy the firms rather than in the company's best interests.

BIO believes that proxy advisory firms should be more transparent and open to input in their recommendation-setting process, particularly when issues uniquely impact small businesses; furthermore, we support requiring proxy firms to include an issuer's dissenting opinion in their final report in instances where a company and a firm reach different conclusions on a given recommendation. We also believe that the firms with conflicted business models should be required to avoid potential conflicts of interest.

In the 114th Congress, Rep. Sean Duffy (R-WI) and former Rep. John Carney (D-DE) introduced the Corporate Governance Reform and Transparency Act, which would provide for SEC oversight of proxy advisory firms. The bill is designed to foster accountability, transparency, responsiveness, and competition in the proxy advisory firm industry. By ensuring that firms have adequate resources to provide accurate recommendations on emerging companies as well as processes in place engage in a dialogue with smaller issuers, the legislation would make it more likely that a firm's recommendation is relevant to a company's business model. Further, the bill's regulation of conflicts of interest would ensure that the proxy firms are actually acting in the best interests of shareholders.

BIO strongly supports the Corporate Governance Reform and Transparency Act, which last year was approved by the House Financial Services Committee on a bipartisan 41-18 vote. Passage of legislation to regulate proxy firms would be a welcome change from a status quo that forces companies to contort themselves to satisfy proxy advisors rather than making decisions in the best interests of the company and its shareholders.

SRC & Non-Accelerated Filer Reform:
Creating commonsense company classifications

Under current SEC rules, companies qualify as both a smaller reporting company (SRC) and a non-accelerated filer if their public float falls below $75 million. By providing growing businesses with scaled disclosure opportunities, these issuer categorizations allow for important cost savings that decrease the amount of innovation capital diverted from the lab. SRCs benefit from scaled obligations under Regulation S-K and Regulation S-X, while non-accelerated filers are exempt from SOX 404(b) compliance.

BIO believes that the current $75 million public float cap is too low. Emerging biotechs need significant innovation capital to fund their research, and they are valued highly by investors for their future potential – but they can ill afford expensive compliance burdens even if their public float exceeds $75 million, which often happens. BIO supports reforms to the SEC's company classifications so that any small business with a public float below $250 million or annual revenues below $100 million would be considered both an SRC and a non-accelerated filer. Similar reforms have been endorsed by the SEC Advisory Committee on Small and Emerging Companies and the SEC Government-Business Forum on Small Business Capital Formation.

Last summer, the SEC issued a proposed rule that would increase the public float cap for SRCs, but not non-accelerated filers, to $250 million. This proposal is an important first step, but BIO strongly believes that the SRC and non-accelerated filer definitions should be consistent at $250 million in public float. Additionally, we believe that revenue is a more appropriate arbiter of company size (and, importantly, of a company's ability to pay for expensive compliance burdens), so a revenue-only test should be added to both definitions as an alternative to the existing public float standard.

Reforming the SRC and non-accelerated filer classifications, and including revenue as a component in that determination, would represent a dramatic change in emerging innovators' ability to access capital on the public market and to put that capital to work developing medicines for patients in need.

The Small Company Disclosure Simplification Act: Reforming XBRL

Public companies are required to provide their financial statements in an interactive data format using eXtensible Business Reporting Language (XBRL). XBRL "tags" certain data points in an issuer's filing statement and exports them in a standardized layout. The ostensible goal of XBRL is to make financial data comparable across issuers, but it falls prey to the one-size-fits-all approach that inflicts so many reporting requirements. The data that is supposedly comparable is heavily weighted toward traditional metrics that might be useful to an investor evaluating profitable multinational corporations – but that provide little to no insight into the health of an emerging, pre-revenue biotech. Investors largely realize this shortcoming of XBRL and thus do not utilize XBRL reports to evaluate emerging companies. Yet every single public company faces an identical XBRL compliance requirement.

In addition to failing to provide useful information for investors, XBRL reporting is very costly for resource-constrained small businesses. XBRL is actually its own computing language – one that requires specific expertise outside the bounds of traditional financial or accounting training. Companies need experts in the XBRL language to properly file the appropriate reports, so small issuers turn to external contractors to complete their XBRL filings. The cost of an external XBRL contractor is significant for an emerging company, reducing the capital available for more vital functions like research and development.

In the 114th Congress, former Rep. Robert Hurt (R-VA) introduced the Small Company Disclosure Simplification Act, which was approved by the Financial Services Committee and the full House on a bipartisan basis. The bill would broaden the IPO On-Ramp created by the JOBS Act by making the XBRL compliance requirement optional for EGCs. It would also institute a temporary XBRL exemption for low-revenue companies while the SEC studies how to improve the compliance mechanism.

The cost burden of XBRL, and therefore the amount of capital diverted from R&D, is significant, and the targeted reforms included in the Small Company Disclosure Simplification Act would free growing companies from a costly regulatory burden that does more harm than good.