Written testimony of the

**Biotechnology Industry Organization**

Submitted to the United States Senate Committee on Banking, Housing, and Urban Affairs Subcommittee on Securities, Insurance, and Investment

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**Capital Formation and Reducing Small Business Burdens**

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**Executive Summary**

- The Biotechnology Industry Organization (BIO) represents more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states. The vast majority of BIO members are pre-revenue small businesses.

- More than 140 biotech companies have undertaken a public offering as emerging growth companies (EGCs) under the JOBS Act, a dramatic change from the constricted IPO environment prior to the law's enactment.

- A healthy public market is key to funding the search for next-generation medicines. BIO supports policies that increase the flow of capital to innovative small businesses and decrease capital diversions from the lab to unnecessary compliance burdens.

- **BIO supports the Fostering Innovation Act**, which would add a revenue test to the SEC’s filing status classifications under Rule 12b-2 and provide important regulatory relief for emerging biotechs.

- **BIO supports the Small Company Disclosure Simplification Act**, which would exempt EGCs and certain low-revenue issuers from the costly XBRL reporting requirement.

- **BIO supports legislation to require the SEC to finalize its proposed rule implementing the new Regulation A+ pathway created by the JOBS Act**. BIO also supports the SEC’s proposed qualified purchaser definition, which would set a single national standard of review for Regulation A+ offerings.

- **BIO supports the Disclosure Modernization and Simplification Act**, which would direct the SEC to review and revise Regulation S-K to reduce the regulatory burden on smaller issuers and eliminate duplicative, outdated, and unnecessary compliance requirements.

- **BIO supports the Encouraging Employee Ownership Act**, which would reduce the disclosure burden on firms that offer stock options to their employees.

- **BIO supports the Improving Access to Capital for Emerging Growth Companies Act**, which would broaden the impact of the JOBS Act’s IPO On-Ramp.

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Testimony of the Biotechnology Industry Organization

Chairman Crapo, Ranking Member Warner, and Members of the Subcommittee, the Biotechnology Industry Organization (BIO) applauds you for convening today’s hearing and for continuing your efforts to support capital formation and minimize regulatory burdens for America’s small businesses.

BIO represents more than 1,100 innovative biotechnology companies, the vast majority of which are of growth-stage innovators. A typical biotech company has fewer than 50 employees (most of whom are scientists) and is dedicating vast sums of investment capital to the decades-long, billion-dollar R&D pathway intrinsic to groundbreaking medical advancement. These small businesses operate without the benefit of product revenue to fund their work, so they place a high value on policies that incentivize investment in innovation and prioritize resource efficiency. Any policy that increases the flow of innovation capital to emerging companies could lead to funding for a new life-saving medicine – while any policy that diverts capital to unnecessary and costly regulatory burdens could lead to the same treatment being left on the laboratory shelf.

The Jumpstart Our Business Startups (JOBS) Act, for which BIO was a strong advocate, was a perfect balance of capital formation incentives and right-sized regulations. This important law allows enhanced access to investors, increasing the capital potential of a public offering, and then reduces the regulatory burden on emerging growth companies, decreasing the amount of capital diverted from R&D. This one-two punch is critical for biotech innovators and has increased the viability of the public market for growth-stage businesses looking to fund their capital-intensive development programs.

In the three years since the JOBS Act was signed into law, there have been more than 140 IPOs in the biotech industry. For comparison, the three years prior to the JOBS Act saw fewer than 40 biotech IPOs. Further, the JOBS Act has allowed many companies to go public earlier in their development timeline. The last three years have seen 24 IPOs by biotechs in the earliest stages of research (pre-clinical R&D and Phase I clinical trials), compared to just one pre-clinical IPO in the five years before the JOBS Act. Biotech investment is riskiest at the earlier stages of development – only 1 in 10,000 compounds discovered will lead to an FDA-approved drug – but early-stage innovation is critical to the health of the biotech industry and to patients waiting for breakthrough treatments and cures. The JOBS Act has allowed younger companies to access public financing, driving capital to early-stage research that holds the potential to unlock the secrets of Alzheimer’s, HIV/AIDS, cancer, and other devastating diseases. It is clear that smart policymaking can have an impact on the capital formation ecosystem for innovative companies, and BIO thanks the Subcommittee for once again taking steps to support the growth of America’s small businesses.

Reducing Small Business Burdens

The Disclosure Modernization and Simplification Act

One bill being considered by the Subcommittee, the Disclosure Modernization and Simplification Act, provides a valuable way of looking at America’s current reporting regime for public companies. This legislation would direct the SEC to review and revise Regulation S-K to reduce the regulatory burden on smaller issuers and to eliminate compliance requirements that are duplicative, overlapping, outdated, or unnecessary. This commonsense directive takes aim at the pervasive one-size-fits-all nature of much of the public company reporting regime. By directing the SEC to specifically emphasize a flexible
approach that scales or eliminates burdensome disclosures, this bill would slow the damaging diversion of capital from science to compliance that many of these rules represent.

The spirit of this legislation should guide how Congress and the SEC approach all regulatory requirements for smaller issuers. Forcing small businesses to file the same reports as multinational corporations represents a significant cost burden that can stymie the growth of an early-stage innovator – without providing additional benefits to investors. The Disclosure Modernization and Simplification Act specifically requires the SEC to ensure that all companies, large and small, continue to provide “all material information” to investors – a standard that BIO strongly supports. For emerging biotechs, an informed investor is a good one. In fact, 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 always align with what is required by the SEC. Investors find value in biotech companies by understanding scientific milestones and clinical trial progress – not financial disclosures that simply show a decade-plus of R&D expenses. And yet small, pre-revenue biotechs are often required to file the same reports as revenue-generating, profitable corporate behemoths. Other industries surely face their own unique circumstances, and many small businesses across all sectors of the economy endure the cost burdens of overregulation – yet a blanket one-size-fits-all approach prevails.

The Fostering Innovation Act

Take, for example, SEC Rule 12b-2, which divides companies by size to determine many of their compliance obligations. The Rule splits issuers into three buckets by public float: (1) companies with a public float below $75 million (non-accelerated filers), (2) those with a public float between $75 million and $700 million (accelerated filers), and (3) companies whose public float exceeds $700 million (large accelerated filers). If we apply the spirit of the Disclosure Modification and Simplification Act to Rule 12b-2, we must ask ourselves what a pre-revenue biotech company with a public float of $400 million truly has in common with a $400 million widget-maker. The biotech is highly valued because it is working toward a groundbreaking treatment that may, years from now, save millions of lives. The widget-maker, on the other hand, is highly valued because it is manufacturing millions of widgets today. These two companies have little in common beyond their valuations, yet are bound by the same disclosure regime.

BIO urges Congress and the SEC to take a discerning look at any and all regulations that govern public company disclosures, with the goal of achieving a commonsense, right-sized regulatory environment. Specific to Rule 12b-2, BIO supports adding a revenue component to the non-accelerated filer definition. By defining an issuer with annual product revenues below $100 million as a non-accelerated filer, a reformed Rule 12b-2 with a revenue test would more accurately reflect the nature of small public companies. BIO also believes that the $75 million public float ceiling for non-accelerated filers is out of date and should be increased to $250 million. These important reforms were included in the Fostering Innovation Act, which was approved by the House Financial Services Committee in the 113th Congress.

Reforming the non-accelerated filer definition could have a dramatic impact on emerging biotechs. Rule 12b-2 governs numerous regulatory requirements, including compliance with Section 404(b) of Sarbanes-Oxley (SOX), from which non-accelerated filers are exempt. SOX Section 404(b) represents a significant cost burden for a pre-revenue company, costing up to $1 million annually – a large sum that comes directly from investment dollars.
intended for research yet does not provide much protection to investors. Congress has already recognized that compliance with Section 404(b) is overly burdensome for small businesses by providing an exemption for EGCs in the JOBS Act. BIO urges Congress to take additional steps away from the one-size-fits-all compliance regime – to which EGCs will revert at the end of the five-year on-ramp – and instill permanent, commonsense filing status classifications that take revenue into account. Such a change would further open the public market to biotech capital formation, allowing companies to grow and attract investors without fear of subjecting themselves to a costly compliance burden.

The Encouraging Employee Ownership Act & the Improving Access to Capital for Emerging Growth Companies Act

BIO applauds the Subcommittee for considering additional legislation that applies the framework of the Disclosure Modernization and Simplification Act to other rules and regulations. For example, the Encouraging Employee Ownership Act would reform SEC Rule 701 to allow a wider pool of companies to effectively compensate their employees. By reducing the disclosure burden on firms that offer stock options to their employees, the bill would support a valuable compensation practice that allows small businesses to hire the most highly skilled workers. BIO supports an effective disclosure regime that preserves the ability of innovative biotechs to attract talented workers and compensate them competitively without incurring additional compliance burdens.

Similarly, the Subcommittee is considering the Improving Access to Capital for Emerging Growth Companies Act, which would make technical changes to the IPO On-Ramp in the JOBS Act to ensure it is working as effectively as possible for a wide range of growing businesses. BIO commends the Subcommittee for taking these initial steps toward disclosure effectiveness, and urges it to continue its important work.

Support for an effective disclosure regime is widespread and bipartisan. The Disclosure Modernization and Simplification Act passed the House Financial Services Committee in the 113th Congress by a vote of 59-0. The Improving Access to Capital for Emerging Growth Companies Act was approved 56-0. Both bills were included, along with the Encouraging Employee Ownership Act, in the Promoting Job Creation and Reducing Small Business Burdens Act – which passed the full House of Representatives last September by a bipartisan vote of 320-102.

The Small Company Disclosure Simplification Act

Also included in this bipartisan package was the Small Company Disclosure Simplification Act, which had passed out of the House Financial Services Committee by a 51-5 vote. This important bill would broaden the IPO On-Ramp created by the JOBS Act by exempting EGCs from the requirement to provide financial statements in the eXtensible Business Reporting Language (XBRL) interactive data format. 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 problem 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.

Along with the EGC exemption from XBRL reporting, the Small Company Disclosure Simplification Act would also institute a temporary exemption for low-revenue companies while the SEC studies how to improve the compliance mechanism. Here again we see the importance of reviewing and reforming one-size-fits-all regulatory requirements. BIO urges the Subcommittee to continue down the path it has laid for itself and include a reexamination of the XBRL regime alongside the other cost-cutting proposals it is considering.

BIO is proud to support the Disclosure Modernization and Simplification Act, the Encouraging Employee Ownership Act, and the Improving Access to Capital for Emerging Growth Companies Act. We appreciate the steps the Subcommittee is taking toward an effective disclosure regime, and we are hopeful that Members on both sides of the aisle will continue to support right-sized regulations that provide important information to investors without creating a costly capital diversion that could slow the growth of small business innovators.

**Capital Formation**

*Regulation A+*

In addition to the important disclosure effectiveness legislation the Subcommittee is considering, it also has before it a bill that would give the SEC a deadline to finalize the reforms to Regulation A mandated by the JOBS Act. BIO was a strong supporter of Title IV of the JOBS Act, which directed the SEC to create a Regulation A pathway for offerings of up to $50 million. However, emerging biotechs have been prevented from utilizing this new avenue to capital because the SEC has not yet finalized its rule implementing the required changes.

The SEC proposed a rule authorizing Regulation A+ offerings of up to $50 million in December of 2013. BIO believes that the increased offering limit of $50 million – a significant change from the $5 million limit under the existing Regulation A exemption – will provide a valuable fundraising option for capital-intensive biotech companies. The relative ease of conducting a Regulation A+ offering is extremely important to growing biotechs given their need to efficiently use investment capital, and the increased offering limit will better reflect the reality that groundbreaking research is a costly endeavor.

BIO provided comment on the proposed rule, applauding the SEC for taking steps to implement the new Regulation A+ pathway and largely praising its proposal. In particular, BIO’s comment letter provided strong support for the SEC’s proposed qualified purchaser definition, which would effectively set a national standard of review for Regulation A+ offerings and avoid costly state-specific roadblocks for emerging biotechs considering such an offering.

BIO strongly believes that Regulation A+ cannot function without a national review standard. The SEC’s proposing release notes that “the cost of state securities law
compliance...would discourage market participants from using the new exemption” – and BIO emphatically agrees. Given that the goal of the JOBS Act was to increase capital availability, requiring issuers to spend dollars to “analyze and comply with separate registration or qualification requirements, or to identify and comply with applicable exemptions, in each state in which they intend to offer or sell securities” would undercut the very intent of the law.

Instead, BIO supports a single national standard of review for Regulation A+ offerings. Though some stakeholders have proposed a coordinated review program that purports to streamline the review process, BIO still believes that a national standard is the only way for issuers to avoid the barrage of conflicting, state-specific requirements that would accompany an obligation to comply with divergent securities law in all 50 states.

BIO thanks the Subcommittee for considering legislation that would give the SEC a deadline to act on Congress’s Regulation A+ mandate. We share the Subcommittee’s sense of urgency, and join our voice to what is now a very loud chorus urging the SEC to finalize its rule. Further, we implore the SEC to maintain the qualified purchaser definition that it itself proposed, providing certainty to issuers and opening up an avenue to capital formation for a wide swath of early-stage companies.

Additional Reforms

BIO is encouraged that the Subcommittee is taking a proactive stance in encouraging the SEC to finalize its Regulation A+ rulemaking. We welcome efforts to support capital formation at growing companies, and hope to work with the Subcommittee to enact additional reforms that will bolster the fundraising potential of emerging biotechs.

For example, BIO supports efforts to expand the mission of the SEC Office of Small Business Policy to include an emphasis on capital formation. Currently, the only responsibility of the Office is to hold the annual Government-Business Forum on Small Business Capital Formation. BIO is an annual participant in the Forum, but we believe that the Office is wasting its potential by having such a singular focus. There are bright minds and hard workers staffing the Office – perhaps, at Congress’s direction, they could undertake new efforts, in conjunction with the business community, to incentivize capital formation, create an effective disclosure regime, and support the growth of small public companies.

Similarly, BIO believes that the Public Company Accounting Oversight Board (PCAOB) would benefit from an expanded voice from small businesses in its decision-making process. The Board already benefits from the expertise of the investment community via its Investor Advisory Group; BIO believes that emerging companies similarly have insights to offer, especially given the impact that the PCAOB’s regulations have on small businesses. BIO would welcome enhanced dialogue between the business community and the PCAOB – perhaps via a small business ombudsman – in an effort to ensure that investors’ capital is spent effectively.

BIO also supports specific regulatory changes that the Subcommittee should consider as it continues to seek ways to sustain small business capital formation. In addition to the reforms to SEC Rule 12b-2 and the XBRL compliance regime mentioned above, we believe that emerging growth companies should be able to use forward incorporation by reference on Form S-1. We believe that Form S-3 should be available to issuers after 6 months on the public market rather than the full year currently required. We believe that the Well-Known Seasoned Issuer (WKSI) definition should be expanded so that more companies can
take advantage of shelf offerings. The universe of policy options is broad, and we look forward to working with the Subcommittee as it engages on these important issues.

**Conclusion**

The extraordinary success of the JOBS Act in the biotech industry means that the work of the Subcommittee has taken on increased import for emerging biotech companies. The search for capital in our industry is always ongoing – it does not end at the IPO. As such, BIO strongly supports efforts by Congress and the SEC to enhance the capital formation ecosystem and incentivize funding for the next generation of breakthrough medicines.

In addition to capital formation, BIO’s member companies put a high value on capital efficiency. Every dollar spent on unnecessary regulatory burdens is an investor dollar diverted from the lab. The decades-long development timeline associated with groundbreaking science means that most small biotechs will still be pre-revenue (and thus dependent entirely on investment capital) when their five-year JOBS Act on-ramp expires. For many innovators, the dawn of year six on the public market will bring with it a new, costly compliance burden. BIO believes that a move away from the existing one-size-fits-all regulatory regime will support the growth of these companies beyond the IPO On-Ramp, incentivizing scientific advancement and sustaining small innovative businesses as they continue their efforts to bring life-saving treatments to patients who desperately need them.