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On behalf of the Biotechnology Industry Organization

Before the United States House of Representatives Committee on Financial Services, Subcommittee on Capital Markets and Government Sponsored Enterprises

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Legislative Proposals to Improve the U.S. Capital Markets

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Executive Summary

- GlycoMimetics is a clinical-stage biotechnology company based in Rockville, Maryland. The Biotechnology Industry Organization (BIO) represents GlycoMimetics and more than 1,100 other innovative biotech companies, the vast majority of which are pre-revenue small businesses.

- GlycoMimetics undertook a successful IPO in January 2014 using key provisions in the Jumpstart Our Business Startups (JOBS) Act. More than 180 biotech companies have gone public 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 innovative, next-generation medicines and maintaining the U.S. as a global leader in 21st century industries like biotechnology. BIO supports policies that *increase* the flow of capital to innovative small businesses and *decrease* capital diversions from the lab to unnecessary compliance burdens.

- It can take more than a decade and cost more than $2 billion to bring a single biotech therapy to patients in need. Biotech research is funded almost entirely by investment capital because emerging biotechs operate without any product revenue.

- BIO supports the Fostering Innovation Act, which would extend the JOBS Act's Sarbanes-Oxley (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.

- BIO supports the SEC Small Business Advocate Act (H.R. 3784), which would create an Office of the Small Business Advocate at the SEC and grant emerging companies an important voice in the SEC's rulemaking process.

- BIO supports the Small Business Capital Formation Enhancement Act, which would require the SEC to take action on recommendations made by the SEC Government-Business Forum on Small Business Capital Formation.

- BIO supports the HALOS Act, which would support small businesses and their investors during the Regulation D, Rule 506(b) offering process.

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Testimony of Brian Hahn

Good morning Chairman Garrett, Ranking Member Maloney, and Members of the Subcommittee. My name is Brian Hahn, and I am the Chief Financial Officer at GlycoMimetics, Inc., a clinical-stage biotechnology company located in Rockville, Maryland. GlycoMimetics is a small business with 40 employees, all of whom are dedicated to our search for next generation medicines.

Our lead product candidate is a treatment for patients undergoing acute crises caused by sickle cell disease. These critical events are extremely painful and hard to treat beyond simple palliative care, but we hope to address sickle cell crises more effectively by ending the crisis more quickly, avoiding opioid painkiller use, and reducing a patient's hospital stay. We are also conducting Phase 1/2 clinical trials for a treatment that has the potential to increase the ability of chemotherapy to kill cancer cells in patients suffering from acute myeloid leukemia (AML). We expect to expand that candidate's testing in 2016 to treat patients with multiple myeloma as well. These medical advances – all of which have been developed in-house by the dedicated scientists at GlycoMimetics – would dramatically improve the quality of life for patients and their families.

The research we are undertaking at GlycoMimetics is mirrored across the biotech industry. Biotech companies are engaged daily in the search for the next generation of cures and treatments, and our colleagues across the country share GlycoMimetics's passion for developing life-changing medicines for patients in need. The Biotechnology Industry Organization (BIO) represents over 1,100 innovative biotech companies, including GlycoMimetics, in all 50 states. The vast majority of these companies are emerging, pre-revenue businesses working in the lab to move life-saving science forward. I serve as the Co-Chair of BIO's Finance and Tax Committee, a group of finance professionals dedicated to ensuring a policy environment that supports the capital formation necessary to fund our industry's vital research.

Policies that encourage capital formation are of paramount importance to growing biotechs, because investment capital is the lifeblood of scientific advancement. It costs over $2 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. During this long development process, virtually every dollar spent by an emerging biotech comes directly from investors. Expenses ranging from buy-in-bulk beakers to $150 million clinical trials are all funded by investment capital because biotechs remain pre-revenue through their entire time in the lab and the clinic.

Early-stage innovators do not have the luxury of funding their product development through sales revenue. Instead, the groundbreaking research that leads to a company's first product is funded by a series of financing rounds from angel investors, venture capitalists, large pharmaceutical companies, and, eventually, public market investors. The capital burden of a pivotal clinical trial – which can require hundreds of patients in the clinic to meet the stringent safety and efficacy standards necessary to ensure patient care – often necessitates an IPO to fund this critical stage of the research process.

GlycoMimetics undertook an IPO in January 2014, raising $64 million to fund the next phase of our research. Our IPO was supported by the Jumpstart Our Business Startups (JOBS) Act, a game-changing reform of the public offering process that offers a scaled compliance regime for companies through the fifth anniversary of their IPO. Prior to the passage of the JOBS Act, the recession had severely curtailed biotech financing – more than 100 public biotechs closed their doors, venture financing dried up, and small companies had few

options to fund their research. Since 2012, we have seen a sea change on the market. Numerous biotechs have capitalized on the success of the JOBS Act, using its provisions to enhance their IPO and secure capital for advanced research and costly clinical trials. To date, the JOBS Act has supported over 180 biotech IPOs – a dramatic surge that highlights the impact of effective policymaking on the capital formation ecosystem.

Because pre-revenue small businesses utilize only investment dollars to fund their work, they place a high value on policies like the JOBS Act 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 JOBS Act represents a significant move away from costly one-size-fits-all regulations. This important law allows emerging growth companies (EGCs) to have enhanced access to investors via testing-the-waters meetings, increasing the likelihood that an offering will be successful. It then takes the vital step of reducing the regulatory burden on EGCs, ensuring that the capital raised in an offering is not subsequently diverted from R&D and company growth. 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. I applaud the Subcommittee for considering legislation that would build on the success of the JOBS Act and support a regulatory environment that prioritizes capital formation and resource efficiency at growing companies.

Disclosure Effectiveness and the Fostering Innovation Act

Sarbanes-Oxley Section 404(b)

One key reason that the JOBS Act has been so effective for emerging biotechs like GlycoMimetics is its emphasis on appropriately tailored regulatory burdens. One-size-fits-all compliance requirements have a uniquely damaging impact on biotech companies. These regulatory burdens do not meet their intended purposes because they require the reporting of information that is irrelevant to our business model. For pre-revenue small businesses, the significant time and fiscal burdens divert critical capital from science to compliance. This problem is exacerbated by the fact the SEC has a very narrow definition of what constitutes a small company, meaning that any scaling of regulatory burdens reaches only the lowest-valued of issuers.

Emerging biotechs are the very definition of a small business. At GlycoMimetics, we have just 40 employees, and 31 of them are directly involved in the research and development supporting our product candidates. Our income statement shows capital flowing directly from investors to the lab. And yet the SEC does not consider us "small" because our public float – a measure of investors' predictions about our growth potential and future value, not our current size – exceeds the SEC's arbitrary $75 million cap. This $75 million ceiling defines the SEC's smaller reporting company (SRC) and non-accelerated filer universe. These growing businesses rightly receive certain regulatory allowances and exemptions, but the current definition is extremely limited, and thus fails to capture a broad swath of small public companies that would benefit from a move away from one-size-fits-all regulations.

The most damaging aspect of the SEC's approach to company classification is the diversion of capital from science to compliance dictated by Sarbanes-Oxley (SOX) Section 404(b). 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 extremely costly for a pre-revenue innovator to comply with. Non-accelerated filers are exempt from Section 404(b), which means that all companies with a public float above $75 million must comply. An SEC study published in 2011 found that SOX Section 404(b) compliance can cost over $1 million annually, a staggering sum for a pre-revenue small business.

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 a hundred 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 companies are subject to this one-size-fits-all mandate that can cost them over $1 million per year.

Congress took the important step of exempting EGCs from Section 404(b) compliance in the JOBS Act, and GlycoMimetics has benefitted from being able to spend dollars on R&D and job creation that otherwise would have been earmarked for SOX compliance. The IPO On-Ramp is a welcome five-year window wherein the securities laws see GlycoMimetics as the small company that we truly are. However, it remains the case that the biotech development timeline is a decades-long affair. It is extremely likely that GlycoMimetics will still be in the lab and the clinic when our EGC clock expires – which is to say that we will still not be generating product revenue. Our audit fees increased by roughly $400,000 after our IPO due to the existing regulatory environment for public companies, and we expect our SOX 404(b) compliance obligations alone to further increase costs by more than $350,000 annually starting in year 6 post-IPO. Those valuable funds could cover clinical costs for a more than a dozen patients, but our innovation capital will instead be spent on unnecessary reporting burdens.

Most biotechs that went public under the JOBS Act will find themselves in the same predicament 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.

The Fostering Innovation Act

Reps. Kyrsten Sinema and Michael Fitzpatrick have introduced the Fostering Innovation Act, which would extend the JOBS Act's SOX 404(b) exemption for certain small companies beyond the existing five-year expiration date. This important bill 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 – growing 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 will save millions of dollars that can be utilized to fund the groundbreaking R&D and life-saving medical research. BIO and I strongly support this vital legislation, and I want to thank Reps. Sinema and Fitzpatrick for taking this important step to support capital formation and company growth at America's pre-revenue businesses.

Fulfilling the SEC's Mission to Facilitate Capital Formation

BIO and I appreciate the steps the Subcommittee is taking to support the SEC's mission of facilitating capital formation while maintaining efficient markets and protecting investors. The SEC has the ability to be a key facilitator of capital formation, and its expertise can be brought to bear in designing policies that support company growth, reduce one-size-fits-all compliance costs, and enhance the capital formation potential of the public markets. The Subcommittee is considering legislation today that would encourage the SEC to support small business capital formation and ensure that the concerns of growing companies remain at the forefront of the SEC's decision-making process.

H.R. 3784, the SEC Small Business Advocate Act

The SEC Small Business Advocate Act (H.R. 3784), sponsored by Reps. John Carney, Sean Duffy, Ander Crenshaw, and Mike Quigley, would establish an Office of the Small Business Advocate at the SEC. The Small Business Advocate would serve as a partner to the existing Investor Advocate, giving small businesses an independent voice at the SEC and helping the SEC to understand the impact of regulatory burdens on growing companies as it considers new compliance requirements.

Involving small businesses in the regulatory process would ensure that the SEC considers the effect that its rules have on growing companies across the country. As I have mentioned, overly burdensome compliance requirements have an inordinate impact on small businesses, and the Small Business Advocate would be charged with helping the SEC move away from one-size-fits-all rules. The Small Business Advocate could also be a source of new policy ideas that would incentivize and support capital formation. Proactive regulations and programs designed to drive investment to growing innovators would fulfill the SEC's mission to facilitate capital formation.

The proposed Office would also organize and support the SEC Advisory Committee on Small & Emerging Companies and the SEC Government-Business Forum on Small Business Capital Formation. These two groups convene private sector stakeholders to formulate policy recommendations that would support small business growth. BIO has long supported the work of these groups, both of which endorsed the policy ideas that eventually became the JOBS Act. Bringing the Advisory Committee and the Government-Business Forum under the auspices of the new Office of the Small Business Advocate would create an exciting hub for

policy formulation to support the capital needs of growing businesses powering the American economy.

BIO and I believe that the proposed Office of the Small Business Advocate would improve the regulatory regime for growing companies by giving them a strong voice at the SEC. The regulations and policy decisions made by the SEC have a significant impact on emerging businesses, and regulators' choices impact the entire capital formation ecosystem. Ensuring that the SEC enacts policies that support the growth of innovative job creators will build on the success of the JOBS Act and further enhance the role that public capital plays in the search for groundbreaking discoveries and lifesaving medicines.

The Small Business Capital Formation Enhancement Act

The SEC Government-Business Forum on Small Business Capital Formation is an important venue for the business community to impact the policy development process in Washington. The Forum, which has convened annually since 1982, provides an opportunity for small businesses to recommend policy changes to the SEC that would reduce regulatory burdens and enhance capital formation.

Historically, the Forum has been adept at suggesting policies that have a real impact on growing companies. For instance, every title of the JOBS Act can trace its origins to the Forum. The Forum's 2011 report includes recommendations on the IPO On-Ramp, Regulation A+, Regulation D, crowdfunding, and Section 12(g) that would eventually pass Congress as the JOBS Act in March 2012. Put simply, small businesses understand their own regulatory environment, and are uniquely equipped to advise the SEC on how it could be reformed to enhance capital formation.

However, despite the fact that most Forum recommendations could be adopted by the SEC through its standard rule proposal process, the SEC is often reluctant to act. The JOBS Act's Regulation A+ and Regulation D proposals were, in one form or another, included in the Forum report for more than a decade before Congress stepped in and made a change. There are myriad examples of Congress recognizing the value of the Forum's recommendations even when the SEC does not. Just in this Congress, the Subcommittee has considered legislation inspired by the Forum that would exempt growing businesses from XBRL compliance (H.R. 1965, the Small Company Disclosure Simplification Act), increase the viability of Form S-3 for small companies (H.R. 2357, the Accelerating Access to Capital Act), and allow forward incorporation by reference on Form S-1 (H.R. 1723, the Small Company Simple Registration Act). Specific to today's hearing, the Forum has for years recommended expanding the small company exemption from SOX Section 404(b) compliance (as in the Fostering Innovation Act).

Congress clearly recognizes the Forum's value, and Rep. Bruce Poliquin has introduced the Small Business Capital Formation Enhancement Act to encourage the SEC to take steps to implement the Forum's recommendations on its own. Under the Small Business Capital Formation Enhancement Act, the SEC would be required to review the recommendations made by the Forum. For each recommendation, the SEC would have to provide an assessment of the policy proposed and subsequently disclose what action, if any, it intends to take with respect to the Forum's findings.

This legislation will encourage the SEC to act on the Forum's recommendations – with the goal of stimulating small business capital formation. This would better ensure that the SEC implements tailored policies that place appropriate emphasis on the capital needs of small businesses. If the SEC decides against taking up a policy change recommended by the

Forum, its assessment and input would enhance the dialogue around the Forum's recommendations, allowing participants to take the SEC's feedback into account in subsequent years, or offering Congress a chance to step in and craft legislation that combines the best of the Forum's and the SEC's policy preferences.

The Small Business Capital Formation Enhancement Act would enhance the role of the SEC Government-Business Forum on Small Business Capital Formation in the policymaking process, and, if it is enacted, BIO and I believe it would lead to smart regulations that support emerging company growth.

Rule 506 of Regulation D

BIO was a strong supporter of Title II of the JOBS Act, which removed the prohibition on general solicitation for offerings to accredited investors conducted under Rule 506 of SEC Regulation D. I support continued efforts to ensure that the Rule 506 offering process is structured appropriately so that it has the strongest possible impact on small business capital formation.

The HALOS Act

The JOBS Act directed the SEC to lift the ban on general solicitation for offerings conducted under Rule 506, provided that issuers take reasonable steps to verify that all purchasers in an offering are accredited. The SEC created Rule 506(c) to implement this reform while maintaining the "old" Regulation D as Rule 506(b), which does not allow general solicitation but also does not impose verification procedures on investors. These dual offering pathways provide valuable flexibility for investors, but there has been some confusion for small companies considering a traditional Rule 506(b) offering that do not want to inadvertently violate the new Rule 506(c) rules.

The Helping Angels Lead Our Startups (HALOS) Act, sponsored by Reps. Steve Chabot, Kyrsten Sinema, Robert Hurt, and Mark Takai, would clarify that presentations made at "demo days" or other government-, non-profit-, or angel-sponsored events would not violate the general solicitation prohibition in Rule 506(b). This change would remove roadblocks for investors and reduce confusion for companies deciding between Rule 506(b) and Rule 506(c) offerings.

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 and I strongly support efforts by the Subcommittee to enhance the capital formation ecosystem, reduce regulatory burdens, and incentivize funding for the next generation of breakthrough medicines.

The most damaging facet of a one-size-fits-all regulatory regime for the biotech industry is the diversion of investment funds from science to compliance in the absence of product revenue. Biotech small businesses place a high value on capital efficiency, so I applaud the Subcommittee for considering legislation today that would reduce compliance costs for small businesses while also supporting capital formation.

Legislation like the Fostering Innovation Act will ensure that growing companies have the opportunity to be successful on the public market without being forced to siphon off

innovation capital to spend on costly compliance burdens that do not inform emerging biotech investors. The SEC Small Business Advocate Act and the Small Business Capital Formation Enhancement Act would put in place processes to implement similar policies that stimulate public capital formation. BIO and I believe that these important reforms will support the growth of emerging innovators 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.

I am thankful that Congress was able to pass the JOBS Act three and a half years ago, which supported GlycoMimetics's public offering, and I am hopeful that it will be able to enact further legislation – like the bills being considered today – that could support the search for breakthrough treatments at the next generation of emerging growth biotechs. I appreciate your dedication to these vital issues, and I look forward to supporting your work in any way I can.