Brian Hahn

Chief Financial Officer, GlycoMimetics, Inc.

On behalf of the Biotechnology Industry Organization

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Subcommittee on Capital Markets and Government Sponsored Enterprises

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Legislative Proposals to Enhance Capital Formation for Small and Emerging Growth Companies

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Executive Summary

- GlycoMimetics is a clinical-stage biotechnology company based in Gaithersburg, Maryland. BIO represents GlycoMimetics and more than 1,100 innovative biotech companies, academic institutions, state biotechnology centers, and related organizations in all 50 states.

- GlycoMimetics undertook a successful IPO in January 2014 using key provisions in the JOBS Act. Nearly 80 biotech companies have taken advantage of the JOBS Act to go public, and many more are on file with the SEC.

- GlycoMimetics and many biotech EGCs have benefited from the testing-the-waters, confidential filing, and regulatory relief provisions in the JOBS Act. This important law allows enhanced access to investors, increasing the capital potential of an offering, and then institutes a relaxed regulatory burden, decreasing the amount of capital diverted from R&D.

- A healthy public market is vital to the success of the biotech industry. BIO supports targeted market reforms that will decrease the cost of capital and increase the capital formation potential for emerging biotech companies trading on the public market.

- BIO supports the Fostering Innovation Act (H.R. 2629), which would amend the filing status classifications in SEC Rule 12b-2 to classify companies with a public float below $250 million or revenues below $100 million as non-accelerated filers.

- BIO supports targeted reforms that enhance capital formation for small companies, including:
  - Reforms to SEC Rule 144A to enhance secondary market liquidity for private offerings, including those conducted under SEC Regulation D and Regulation A,
  - SEC review of Regulation S-K to reduce duplication and small company costs,
  - Amendments to SEC Rule 701 to allow growing innovators to attract and compensate employees competitively,
  - An expansion of the WKSI definition to increase access to effective shelf offerings,
  - An EGC and non-accelerated filer exemption from conflict minerals reporting,
  - Forward incorporation by reference on Form S-1, and
  - Expanded eligibility for Form S-3 to encompass a greater pool of small companies.

BIO Contact: Charles H. Fritts
cfritts@bio.org
(202) 962-6690

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, a small, publicly traded biotechnology company in Gaithersburg, Maryland. GlycoMimetics has 30 employees, all of whom are dedicated to our search for next generation medicines. Our lead product is designed to treat 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 are hopeful that our research will lead to a better path forward for patients and their families. In order to fund the next stage of our research, GlycoMimetics raised $64.4 million through an IPO in January – the first public offering of 2014.

I am also a member of the Finance and Tax Committee at the Biotechnology Industry Organization (BIO). BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. Because of the unique capital needs of biotech research – it can take more than a decade and upwards of $1 billion to bring a single product to patients – a strong public market that supports capital formation is vital to the success of our industry.

A late-stage clinical trial can cost upwards of $200 million, a sum that is difficult to raise with just private investors. The public market has a broader capital reach, and growing biotechs often turn to an IPO to fund the expensive Phase III trials required for FDA approval. As such, the Jumpstart Our Business Startups (JOBS) Act, designed to increase capital availability for emerging growth companies (EGCs) entering the market, was tremendously important for the growth of small biotechs like GlycoMimetics. The JOBS Act was signed into law two years ago by President Obama, and in that time it has stimulated nearly 80 biotech IPOs. For comparison, the two years prior to the JOBS Act saw just over 30 IPOs in our industry. This important law allows enhanced access to investors, increasing the capital potential of an offering, and then institutes a relaxed regulatory burden, decreasing the amount of capital diverted from research. This one-two punch is critical for biotech innovators and has increased the viability of the public market for a growing company looking to fund its capital-intensive development program.

I have spent most of the past 15 years in biotech start-ups, and I am extremely optimistic about the potential that companies like GlycoMimetics have to develop medicines that change and save lives and, while doing so, create jobs and stimulate the American economy. The recent market for biotech offerings in the wake of the JOBS Act has sped this progress by providing innovation capital for breakthrough R&D being conducted at small businesses across the country. During my time in the biotech industry, I have seen growing companies struggle to access public capital because the policy environment did not support capital formation on the public market, so I am thankful that Congress passed the JOBS Act two years ago and is considering legislation to further improve its efficacy.

The JOBS Act and the Biotech Industry

In 2003, I was part of the management team that took Advancis Pharmaceutical public. Advancis was a small biotech company developing treatments for infectious disease, and our IPO raised $60 million to fund a Phase II clinical trial and to expand our pre-clinical pipeline. We had only 40 employees and no product revenue, and all of our energy was focused on staffing up and enrolling patients to complete our Phase II trial. But 2003 was well before the JOBS Act instituted the IPO On-Ramp for emerging growth companies. From Day 1 on the market, Advancis was hit with a full-blown public reporting burden. We faced

the same compliance requirements as the rest of our IPO brethren from 2003, including Colonial Bank, Tempur-Pedic, and Orbitz – you may have heard of them.

Shortly after our IPO, we tripled our finance and accounting staff, going from a small shop with just two employees to a seven-person team. For a company with just 40 total employees, this was a significant jump. More importantly, five new hires in the finance department meant that Advancis missed out on hiring five scientists who would have furthered our research. Even with our staff expansion, we were nearly overwhelmed by public company reporting. Compliance with Sarbanes-Oxley (SOX), which had passed Congress the summer before our IPO, became my full-time job.

For growing biotech companies, overly burdensome regulatory standards present a unique challenge. Because these R&D-focused innovators do not fund the billion-dollar biotech research process through product revenue, they depend almost entirely on external investors for innovation capital. These investors stress the importance of resource efficiency, because spending capital on compliance diverts funds from the lab and could delay drug development. Investors looking for a return, companies advancing their science, and patients waiting for treatment – all parties involved are united in the need for capital efficiency in the name of scientific progress. As such, costly regulations that divert capital from science to compliance can stifle capital formation, slow company growth, and ultimately harm patients and their families.

Unfortunately, in 2003 Advancis was still subject to a one-size-fits-all regulatory regime. When GlycoMimetics went public a decade later, the regulatory environment had changed dramatically. The JOBS Act has led to a sea change in how growing biotechs approach the public market. Title I of the law creates the IPO On-Ramp, instituting a commonsense compliance burden for emerging growth companies.

During the IPO process, the ability to conduct testing-the-waters meetings and increase our dialogue with potential investors was a game-changer. More than half of our testing-the-waters meetings eventually resulted in the investor participating in the IPO, and across the board we saw substantially increased investor awareness of our company and interest in the offering. Biotech companies like GlycoMimetics have complicated technology, an opaque regulatory pathway, and a complex commercial story – and the additional time with investors gave us time to clarify questions about these aspects of our business in a more robust way that would not have been possible in a traditional half-hour roadshow meeting. For GlycoMimetics specifically, we were able to get to know several investors that we had not previously met, and they ended up being among the largest of the new investors in our IPO.

The confidential filing provision in Title I of the JOBS Act played a similarly influential role in our offering. We tested the waters while on file confidentially, conducting investor meetings out of the glare of the media spotlight and avoiding heightened scrutiny that could have placed an undue expectations burden on the company or our potential investors. The confidential filing period led to a more productive dialogue with the SEC and allowed us to wait for the right market conditions before going forward with our IPO.

Now that GlycoMimetics is a publicly traded company, we benefit from the five-year transition period onto the market that comes with being an EGC. The most notable allowance during these five years is the exemption from compliance with Section 404(b) of SOX. Section 404(b) requires an expensive external attestation of a public company's internal controls, to be disclosed to investors on an annual basis. However, the true value of a biotech company is found in scientific milestones and clinical trial advancement toward

FDA approvals rather than financial disclosures of losses incurred during protracted development terms. The business model of biotechnology is simple – we take in millions, if not billions, of dollars to fund our research and often do not earn a single penny in product revenue for more than a decade. Our science is the key to our business, and it is the most important thing for investors to understand. In the biotech industry, an informed investor is a good one. However, the information that these investors want and need does not always align with what is required by SOX.

At GlycoMimetics, we strive to keep our investors informed of our progress, but wasting their valuable capital on government red tape instead of spending it on innovation and advancement does not serve their needs nor those of the patients who are waiting for our therapies. As such, the five-year EGC on-ramp and corresponding SOX exemption will have an important impact on growing biotechs like ours. We will remain pre-revenue through the entirety of the EGC time horizon, so the cost savings from this allowance will be vital to our progress. SOX compliance would require us to take dollars from investors and divert them to reporting that investors do not want or need, so without that burden we will be able to focus exclusively on advancing our research and moving our clinical trials forward in order to find cures and treatments for devastating diseases.

H.R. 2629, the Fostering Innovation Act

The transition period onto the market is extraordinarily impactful for emerging growth companies in the biotech industry, and GlycoMimetics and the rest of the nearly 80 biotech EGCs are already benefiting from that JOBS Act allowance. But 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 in five years – which is to say that we will still not be generating product revenue. Biotech companies that went IPO shortly after the JOBS Act was signed are approaching the halfway point of their EGC exemptions, and most of them are similarly far from having a product on the market.

When the EGC clock runs out, they will still be reliant on investor capital to fund their research, and they will be in the same predicament in which I found myself in 2003 – facing a full-blown compliance burden identical to that faced by commercial leaders and multinational corporations. As I have mentioned, biotechs retain a simple corporate structure through most of their development timeline. They may grow from 15 scientists in a lab to 50 scientists in lab, but the core essence of the business model is a capital-intensive, laser-focused drive toward medical advancement. Yet the dawn of Year 6 on the market will bring with it a new diversion of capital from science to compliance for these pre-revenue innovators.

Rep. Michael Fitzpatrick has introduced legislation that would better reflect the reality that emerging, pre-revenue companies face on the public market. His bill, the Fostering Innovation Act (H.R. 2629), would provide the SEC with more accurate company classifications in order to institute a commonsense regulatory burden for small businesses and innovative job creators outside of the EGC on-ramp.

Rep. Fitzpatrick's bill would amend the accelerated filer definition under SEC Rule 12b-2. Currently, the term "accelerated filer" encompasses any and all companies with a public float between $75 million and $700 million. This wide swath of businesses is far too broad as it currently exists, and ensnares growing businesses by lumping them in with mature, profit-generating companies. Accelerated filers are subject to an enhanced regulatory burden compared to non-accelerated filers (companies with a public float below $75

million), including, but not limited to, compliance with Section 404(b) of SOX, from which non-accelerated filers are exempt.

This problem is particularly acute in the biotech industry because of the high costs of biotech research. After GlycoMimetics's $46 million IPO, our stock has done well on the market and our public float is currently about $300 million. But we still have only 30 employees, one facility, and no product revenue – hardly the picture of a complex corporation. The Fostering Innovation Act recognizes this reality for many highly valued, low-revenue companies by taking the important step of adding a revenue test to the accelerated filer definition. Under the bill, any company with annual revenues below $100 million would not be considered an accelerated filer, and would thus be classified as non-accelerated unless their public float topped $700 million, pushing them into large accelerated filer status.

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. Instead of dreading the expiration of the EGC on-ramp, small companies can continue to focus their attention and capital on growth, research, and development. As I have mentioned, the most damaging facet of SOX for the biotech industry has been the diversion of investment funds from science to compliance in the absence of product revenue. By taking revenue into account when determining a company's compliance burden, the Fostering Innovation Act would more accurately classify companies and provide important regulatory relief for small businesses.

H.R. 2629 would also amend the public float ceiling for non-accelerated filers. Despite their simple corporate structure and lack of product revenue, many biotechs have a relatively high public float. Thus, they find themselves grouped with the accelerated filers and obliged to comply with the numerous regulatory burdens attendant to that definition, including SOX. By defining companies with a public float below $250 million as non-accelerated filers (a change from the existing $75 million standard), the Fostering Innovation Act would update Rule 12b-2 and provide a more accurate picture of the market for companies and regulators alike.

The Fostering Innovation Act would narrow the universe of accelerated filers to those with a public float between $250 million and $700 million with revenues above $100 million. The companies below these thresholds would benefit from being treated by the SEC as the small companies that they truly are. Complying with non-accelerated filer standards rather than those required of accelerated filers would provide tremendous relief for these growing businesses. The exemption from SOX Section 404(b) alone would save innovative start-ups millions of dollars. Additionally, non-accelerated filers have a relaxed timeline for their quarterly disclosures because their small size and lack of a large compliance department make the filings more onerous – attributes shared by biotech companies currently in the accelerated filer bucket. Non-accelerated filers also enjoy certain allowances within those filings, including exemptions from Compensation Discussion and Analysis (CD&A) reporting, the elimination of certain disclosures about market risk and other risk factors, and exclusions for some financial data. These changes would allow small biotech companies to focus on their mission of delivering cures and treatments to patients who need them rather than time-consuming and costly reporting.

Capital Markets Enhancement

As I have mentioned, a viable public market is vital for the health of the biotech industry – and, of course, the health of the patients waiting on the treatments being developed – both

because it allows companies to raise enough capital to fund expensive research and expand their pipeline and because it can give small businesses leverage in M&A negotiations with larger pharmaceutical partners. I am pleased that Congress has taken steps to follow the success of the JOBS Act and further improve market conditions for emerging businesses.

Recently, the Financial Services Committee approved two pieces of legislation that I believe will stimulate capital formation for innovative research. The Small Company Disclosure Simplification Act (H.R. 4164), introduced by Reps. Robert Hurt and Terri Sewell, would provide an exemption for growing companies from the costly requirement to file financial statements using eXtensible Business Reporting Language (XBRL). The Small Cap Liquidity Reform Act (H.R. 3448), introduced by Reps. Sean Duffy and John Carney, would also stimulate capital formation by providing small businesses with tick size flexibility through a pilot program designed to relieve them from the one-size-fits-all trading standard imposed by decimalization. I applaud the Committee for taking these important steps toward a public market that better supports funding for vital research.

I am also encouraged that the Subcommittee is considering today a package of legislation to further enhance the capital formation potential of the markets. Congressional support of the market is key to financing the search for breakthrough cures and treatments.

Rep. Ann Wagner has circulated a bill that would increase the pool of companies eligible to use Form S-3 to register for an offering. Form S-3 is the most simplified SEC registration form, and utilizing it to conduct an offering contributes to the cost-savings goals of emerging companies. Additionally, the Form allows forward incorporation by reference so that certain data automatically updates when new quarterly or annual reports are filed (Forms 10-Q and 10-K), giving companies flexibility when conducting an offering on a delayed or continuous basis. Rep. Wagner's legislation would expand Form S-3 eligibility by allowing public companies not currently listed on a national exchange to file the Form. It would also remove the capital limit for offerings conducted using Form S-3, eliminating the existing cap that limits offerings to a third of an issuer's public float. These expansions to Form S-3 eligibility would increase small companies' access to public funds in an efficient and cost-effective manner that will stimulate capital formation.

Rep. Wagner's legislation is complemented by a bill offered by Rep. Kevin McCarthy that would expand the Well-Known Seasoned Issuer (WKSI) definition. The primary benefit of being a WKSI is that any Form S-3 filed by a WKSI is automatically effective and not subject to SEC review. This streamlined process grants flexibility to WKSIs, eliminates delays, and allows them to conduct offerings "off the shelf" with greater efficacy. Because WKSIs are only required to pay the SEC a filing fee when the shelf offering actually commences (rather than at the time of filing the S-3, as is the case for non-WKSIs), they save capital and only incur a cost burden when they decide to go forward with an offering. Currently, WKSI eligibility is limited to companies with a public float above $700 million. Rep. McCarthy's bill would lower that threshold, allowing companies to qualify as WKSIs if they have a public float above $250 million. For a growing biotech company, this would give important flexibility in the timing of a secondary offering, allowing the company to prepare and register the offering in advance, and make the offering at the moment market conditions are best. Allowing more issuers to qualify as WKSIs and therefore conduct effective shelf offerings will expand the capital formation potential of Form S-3 and provide a valuable avenue to innovation funding on the public market.

There are a number of other important reforms being considered today. Rep. Wagner's bill would, in addition to allowing more companies to use Form S-3, extend eligibility for forward incorporation by reference (currently limited to issuers filing Form S-3) to issuers

filing Form S-1. Also, I understand Rep. Gary Miller is working on a bill that would exempt EGCs and non-accelerated filers from conflict minerals reporting, which could relieve growing companies from a costly and confusing burden.

Chairman Garrett's Disclosure Modernization and Simplification Act would direct the SEC to review the compliance regime under Regulation S-K in order to reduce and eliminate duplicative or outdated reporting requirements. Regulation S-K governs all of a company's annual filings, so its reach has a significant capital impact on pre-revenue issuers. This welcome initiative would instruct the SEC to study and institute commonsense rules for smaller issuers and EGCs, allowing for scalability and a move away from one-size-fits-all burdens.

Rep. Randy Hultgren's legislation to amend SEC Rule 701 would reduce the disclosure burden for companies that offer stock options to their employees, a valuable compensation practice that allows small businesses to hire the most highly skilled workers. BIO was supportive of the private shareholder limit reforms in Title V of the JOBS Act; specifically, the exemption from the shareholder count for employees compensated with stock options gives small companies room to grow. Rep. Hultgren's legislation is a welcome follow-on to this provision, preserving the ability for innovative biotechs to attract talented workers and compensate them competitively without incurring additional compliance burdens.

For private offerings, Rep. Mick Mulvaney would improve on the expansion of SEC Regulation D in the JOBS Act by shortening the holding period for restricted securities from 6 months to 3 months, improving the secondary market liquidity of these shares. BIO strongly supported Title II of the JOBS Act, which lifted the ban on general solicitation for Regulation D offerings, and I believe that improving the tradability of shares purchased under the Regulation D exemption will ensure that these offerings have the trading environment they need in order to be viable capital-raising tools.

I am encouraged that the Financial Services Committee remains committed to continuing its work to improve the capital formation ecosystem for small and emerging companies, and I am proud to support its efforts.

Conclusion

Emerging, pre-revenue biotech companies depend on investment capital to support the search for next-generation medicines, and many turn to the public markets to find investors and fund research. We have seen the clear appetite for capital formation on the public market in the wake of the JOBS Act – and GlycoMimetics was a clear beneficiary of that law. The rise in biotech IPOs in the last two years has unambiguously shown that public fundraising is fundamental in the search for groundbreaking medical advancements.

If Congress wants to build on the success of the JOBS Act and further increase capital availability for breakthrough research, it should take steps to ensure that the public market remains accessible for emerging businesses. If these smaller issuers have increased access to investors and are not forced to siphon off innovation capital to spend on costly compliance burdens, they will be able to fund R&D and create jobs across the country. A public market that supports capital formation for growing companies will stimulate the American economy and, in the biotech industry, support research that will change the lives of patients and their families.