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On behalf of the Biotechnology Innovation Organization

Before the Joint Economic Committee of the United States Congress
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Hearing on the Innovation Economy, Entrepreneurship, and Barriers to Capital Access

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Executive Summary

GlycoMimetics is a clinical-stage biotechnology company based in Rockville, Maryland. The Biotechnology Innovation Organization (BIO) represents GlycoMimetics and 1,000 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. In the six years since the JOBS Act became law, 276 biotech companies have gone public as emerging growth companies (EGCs).

- GlycoMimetics will lose its status as an EGC in January 2019, five years after our IPO. As a result, we will immediately be subject to onerous auditor attestation requirements set forth in Section 404(b) of the Sarbanes-Oxley (SOX) Act, despite being years away from having a product on the market

- GlycoMimetics, like many other biotechnology companies, has a high valuation thanks to the promise of its technology and investor confidence in our future. However, we are currently locked out of several valuable tax breaks due to our future potential. Simple changes to existing provisions of the tax code could promote innovation by allowing us to invest more in our R&D—and ultimately get our treatments to patients faster.

- BIO fully supports policies that build on the success of the JOBS Act, FDASIA's "breakthrough therapies" designation, as well as policies that provide tax relief and strengthen patent protections. Together, these policies would increase the flow of capital to innovative small businesses, decrease capital diversions from the lab to unnecessary compliance burdens, and support companies once they are public.

- These policies include:

    - Expanding the current smaller-company exemptions from Sarbanes-Oxley Section 404(b) auditor attestation requirements by passing the "Fostering Innovation Act" (H.R. 1645/S.2126/S.488), which would extend the JOBS Act exemption for EGCs for an additional five years;

- Reforming Section 382 of the tax code to encourage investment in high growth, pre-revenue companies, while maintaining the current anti-abuse provisions;

- Simplifying and expanding Section 1202 of the tax code to exempt gains on investments in Qualified Small Business Stock (QSBS) to encourage investment in innovative breakthroughs;

- Broadening the criteria to enable more innovative startups to benefit from the payroll R&D credit in Section 41 of the Tax Code; and

- Strengthening patent protections through enactment of the STRONGER Patents Act, which would improve biotech companies' abilities to attract investors who recognize the potential of our innovations.

Testimony

Good morning Chairman Paulsen, Ranking Member Heinrich, and Members of the Joint Economic Committee. My name is Rachel King, and I am the co-Founder and Chief Executive Officer of GlycoMimetics, Inc., a 50-employee public biotech company based in Rockville, Maryland. I also serve on the Board of Directors for the Biotechnology Innovation Organization (BIO), which represents GlycoMimetics and over 1,000 other growth-stage biotechs that are driving the search for the next generation of cures and breakthrough medicines. I am pleased to be testifying in front of Representative Delaney, in whose district GlycoMimetics is based, as well as Representative Comstock, whose district is also part of the local biotech healthcare cluster, the BioHealth Capital Region. It is my privilege to be here today to discuss policies that will help small growth companies like biotechs access the capital necessary to fund the next innovative breakthrough to address disease, hunger or pollution.

Private emerging companies working on innovative therapeutics are highly dependent on access to capital.[1] More than 95% of these companies are in the R&D process without an FDA-approved product on the market. It costs over $2.6 billion to develop a single life-saving treatment[2], 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 generally remain pre-revenue through their entire time in the lab and the clinic. In short, investment capital is the lifeblood of scientific advancement.

Early-stage biotech 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

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[1] BIO Industry Analysis, "Emerging Therapeutic Company Investment and Deal Trends," 2018, http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.69712784.1270809009.1528142129-1736185180.1496688333.

[2] BIO, "The Biotechnology Ecosystem: By the Numbers," https://www.bio.org/toolkit/infographics/biotechnology-ecosystem-numbers.

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. Additional follow-on offerings through public markets can provide timely access to capital after key clinical or regulatory milestones.

Licensing also provides a significant source of funding for emerging companies, and often entails sharing development expertise and technical resources with a larger company.[3] In 2017, roughly 43% of emerging company programs are partnered with other companies, demonstrating the importance of licensing and collaborations in the biopharmaceutical industry.[4] Each of these financing pathways—venture financing, IPOs, follow-on offerings, and licensing partnerships—are vital to translate novel drug candidates into approved medical products for patients. The policies championed by Congress to improve capital formation and encourage innovation through regulatory relief, tax incentives, and restored patent protections have a meaningful and very tangible impact on emerging biotech companies' abilities to access each of these pathways and attract the long-term investment necessary to bring the next innovative cure to the market.

To that end, BIO supports policies that facilitate small innovators' access to capital. As described below, Congress plays a critical role in enacting policies that help small companies attract capital and minimize its diversion from the lab to unnecessary compliance burdens.

Success of the JOBS Act

Since pre-revenue small businesses like GlycoMimetics utilize only investment dollars to fund our work, we place a high value on policies like the JOBS Act that induce investment in innovation and prioritize resource efficiency. Any policy that increases the flow of 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 taking longer to get to patients, or worse, left on the laboratory shelf.

Enacted in 2012, the JOBS Act has been an unqualified success, enhancing capital formation and allowing companies to focus on science rather than compliance. In the six years since the JOBS Act became law, 276 biotech companies have gone public as emerging growth companies (EGCs). As a result, emerging growth biotech companies have raised 22.5 billion dollars through IPOs that paved the path for them to develop 27 novel drugs that have garnered FDA approval. The IPO onramp and regulatory relief provisions in the JOBS Act certainly helped facilitate GlycoMimetics's IPO in January 2014. However, without action by Congress, once GlycoMimetics loses its JOBS Act provisions in January 2019, we will immediately be forced to spend additional hundreds of thousands of dollars per year on regulatory requirements related to increased financial reporting.

As companies like mine face the end of the JOBS Act on-ramp at the five-year mark, legislation currently before Congress that would extend this on ramp would be extremely

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[3] BIO Industry Analysis, "Emerging Therapeutic Company Investment and Deal Trends," 2018, http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf?_ga=2.69712784.1270809009.1528142129-1736185180.1496688333.

[4] Ibid.

beneficial for growing companies that stand to lose EGC status for no other reason than time, despite still qualifying by all other metrics.

Sarbanes-Oxley 404(b)

One of the critical achievements of the JOBS Act was the exemption from Sarbanes-Oxley (SOX) Section 404(b) for EGCs for the first five years after their IPO. 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. Instead, biotech investors tend to demand information about the variables that will determine whether the company will ultimately succeed or fail to develop the next innovative breakthrough—such as the science and technology underpinning company's potential, the diseases it could treat, the patient population that could be impacted, and the FDA approval pathway, among others. SOX 404(b) is ultimately a key pain point for emerging growth biotech companies because of its extraordinary expense, their pre-revenue status, and the fact that it is of little use to their investors.

Accordingly, the JOBS Act's exemption from Section 404(b) is extremely valuable for pre-revenue biotechs and other emerging growth companies. This time-limited relief allows us to invest more dollars in research and development rather than raising funds solely to comply with the costly auditor attestation requirements under current law. However, as helpful as the five-year exemption is, 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 beginning of year six on the market, at which point they will face a SOX 404(b) compliance burden identical to that faced by commercial leaders and multinational corporations, even as they remain pre-revenue.

Public biotech companies are subject to extensive audit and disclosure requirements beyond SOX 404(b). After my company's IPO, our audit fees increased by roughly $500,000 due to the existing regulatory environment for public companies. These costs cover our external audits, and we also provide an annual assessment of our company's internal controls over financial reporting. Yet our audit fees will skyrocket even further once our Section 404(b) exemption expires. When GlycoMimetics rolls off its EGC status in a few short months, we expect our Section 404(b) compliance obligations alone to more than double our compliance costs to as much as $1.1 million annually, even though we are still years away from having a product on the market and generating product revenue. This is a substantial amount that will be diverted from R&D and the clinic, and instead spent on compliance requirements that offer little to no benefit to our investors. My company is far from being an outlier in this situation—most of the over 276 biotechs that have gone public since the JOBS Act was enacted are still years away from getting their drug approved and becoming a profitable company. It is counterproductive for these growth-stage companies to face a full-blown compliance burden identical to those faced by large, multi-national revenue-generating companies.

To alleviate these burdens for EGCs, we urge the Senate to pass the "Fostering Innovation Act," which was part of the JOBS & Investor Confidence Act that passed the House of Representatives last week with broad bipartisan support (S.488).

The Fostering Innovation Act would extend the Section 404(b) exemption for certain EGCs for an additional five years. BIO commends Senators Thom Tillis and Gary Peters for sponsoring this bipartisan bill in the Senate, and Representatives Kyrsten Sinema and Trey Hollingsworth for sponsoring it in the House. We also thank members of this Committee,

including Representative Delaney, for cosponsoring this piece of legislation. This bill recognizes that a company that maintains the characteristics of an EGC is still very much an emerging company even if it has been public for longer than five years. It provides a targeted exemption from Section 404(b) compliance requirements to companies in years 6-10 of being public that have a public float less than $700M and average annual revenues less than $50M. These restrictions ensure that only companies who are truly still EGCs are eligible—if a company eclipses the revenues or public float thresholds, their full compliance obligations kick in. The Senate Banking Committee recently considered it as part of a hearing on capital formation bills on June 26th. I urge the Senate to take up this important legislation in a timely manner, before any more companies are rolled off the JOBS Act provisions and subject to the onerous auditor attestation burdens.

It is also within the SEC's authority to provide regulatory relief from SOX 404(b) for small business innovators by expanding the definition of a "non-accelerated filer" under the Commission's disclosure rules. The SEC Chair recently directed the Commission staff to develop a proposal to expand the pool of smaller companies that would be designated "non-accelerated filers" to provide much-needed relief from SOX 404(b). Expanding this exemption would build on the progress made in the JOBS Act by right-sizing compliance requirements for smaller public companies to more accurately reflect the nature of emerging businesses and allow them to tailor certain disclosure obligations accordingly.

As you might expect, there is overwhelming support for an expanded exemption of Section 404(b). Proposals that would expand the Section 404(b) exemption have received the strong support of industry leaders.[5] Further, the SEC Advisory Committee on Small & Emerging Companies and SEC Government-Business Forum on Small Business Capital Formation have called for expanding the exemption for several years.[6]

Section 382 Net Operating Loss Reforms

Tax rules relating to the treatment of losses can unintentionally punish start-ups for investing in the growth of their companies. In particular, the rules in Section 382 of the tax code were written in the mid-1980s with the intent of preventing loss trafficking, or the strategy of companies acquiring failing firms with enormous losses on their books for the sole purpose of using the tax losses to offset other income. While we recognize the importance of preventing abusive loss trafficking, the excessive application of these rules has created an impediment for start-ups, which depend on investment capital and often accumulate net operating losses (NOLs) because of substantial R&D expenditures and rapid hiring.

For example, the typical biotech company does not have a product on the market yet, nor a steady source of revenue, and spends tens of millions of dollars on R&D annually. The biotech industry, as a whole, is responsible for more than 20 billion dollars of annual

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[5] See Comments on SEC's Proposed Rule: Amendments to Smaller Reporting Company Definition, in particular comments submitted by Nasdaq, NYSE, the National Venture Capital Association, CONNECT, Corporate Governance Coalition for Investor Value, https://www.sec.gov/comments/s7-12-16/s71216.htm. See also, IPO coalition report entitled "Expanding the On-Ramp: Recommendations to Help More Companies Go and Stay Public," Spring 2018, https://www.centerforcapitalmarkets.com/wp-content/uploads/2018/04/IPO-Report_EXPANDING-THE-ON-RAMP.pdf.

[6] See most recent reports of the: SEC Government-Business Forum on Small Business Capital Formation, November 30, 2017, https://www.sec.gov/files/gbfor36.pdf; and SEC Advisory Committee on Small and Emerging Companies, September 21, 2017, https://www.sec.gov/info/smallbus/acsec/acsec-final-report-2017-09.pdf.

research investment and employs millions of individuals nationwide. Absent a current tax liability, virtually all of this investment results in NOLs.

Unfortunately, under Section 382, raising new capital investments can trigger limitations on a start-up's ability to utilize its NOLs in the future. Thus, Section 382 discourages investment in innovation and works at cross purposes with tax policy that generally seeks to encourage R&D, such as the R&D credit.

BIO supports certain changes to Section 382 that would help free biotech investment from the specter of severe and unwarranted loss limitations. These include exempting capital contributions to the company from ownership change calculations and exempting R&D expenses (defined as Section 174 expenses) from limitation, preserving the company's ability to use its NOLs generated from R&D expenditures.

By enacting a 12-year limit as well as retaining anti-abuse protections and retaining the continuity of business enterprise test, Congress can ensure that the original intent of preventing loss-trafficking remains intact while also fostering economic growth and job creation.

Mr. Chairman, BIO appreciates your concern about this issue and looks forward to working with you to develop a solution that supports innovation.

Section 1202 Qualified Small Business Stock Reforms

Another critical tool for encouraging investment in small business innovators is the tax benefit under Section 1202 of the Internal Revenue Code.

Section 1202 provides an incentive for investment in smaller business by making capital gains from the investment in Qualified Small Business Stock (QSBS) tax free. This exemption was made permanent in 2015 in the Protecting Americans from Tax Hikes (PATH) Act and was retained in the Tax Cuts and Jobs Act in 2017. We believe that maintaining the permanent exemption on gains from investments in QSBS is vital to encourage the early-stage investment necessary to spur groundbreaking innovation. We applaud lawmakers for retaining this incentive in the new tax law.

Section 1202 has the potential to be one of the most powerful federal policies for encouraging an expansion of entrepreneurship across the country. However, the incentive is currently too narrowly drawn for many biotechs to qualify. Though they are still small pre-revenue companies, many biotechs hold valuable intellectual property that easily eclipses the $50 million gross assets limit, thus rendering them ineligible for qualified small business status.

BIO supports simplifying and expanding Section 1202 to encourage more investment in start-ups across the country. For example, raising the gross assets limit to $100 million would unleash a wave of investment in small but highly valued biotech companies. In addition, simplifications to the provision could also reduce uncertainty for investors and help fuel investment.

Section 41 Payroll R&D Credit Expansion

BIO applauds Congress for creating the payroll R&D credit in the Protecting Americans from Tax Hikes (PATH) Act in 2015. The provision allows companies in their first five years of operation with less than $5 million in annual gross receipts to utilize up to $250,000 in R&D credits annually. This was an important recognition by Congress that R&D tax credits do not yet benefit pre-revenue companies. Unfortunately, these size and age restrictions leave many biotech start-ups unable to access the benefits of the payroll R&D credit.

BIO supports expanding this provision to encompass a wider, more representative universe of start-ups and emerging innovators. Given the long development timelines of the biotechnology industry's groundbreaking innovation and the high costs of breakthrough research, targeted expansions to the payroll credit would ensure that more innovative pre-revenue companies can take full advantage of this new incentive.

Patent Reforms

Very few sectors of the nation's economy are as dependent on predictable, enforceable patent rights as the biotechnology industry. Robust patents that cannot be easily circumvented or invalidated, and that can be predictably enforced against infringers, enable biotechnology companies to secure the enormous financial resources needed to advance biotechnology products to the marketplace. Further, they allow biotechs to engage in the partnering and technology transfer that is necessary to translate basic scientific discoveries into real-world solutions for disease, pollution, and hunger. These financing pathways include venture financing, IPOs, follow-on offerings, and licensing partnerships, and are all predicated on the existence of stable and enforceable intellectual property rights. Without a dependable patent system, capital for the cures of the future will not be available.

These financing pathways have been critical to the success so far of GlycoMimetics. Without strong and reliable patents, we would not have been able to secure the investment or partnerships that have kept our doors open for so many years as we seek to prove the safety and efficacy of our leading therapeutic candidates.

If patents can be invalidated under overly broad criteria, if the ability to enforce them becomes limited, or if limits on patent eligibility call into question the ability to obtain patent protection for innovative cures, third parties would be less likely to invest in or license the technology, and major sources of R&D funding would move elsewhere. The result – patients waiting for the next new cure or treatment will have to wait longer or may not ever get it at all. Because investment-intensive businesses can tolerate only so much risk, even moderate additional uncertainty can cause business decisions to tip against developing a high-risk, but potentially highly-beneficial, product.

Unfortunately, changes to our patent laws through legislation, agency actions, and court decisions, have severely weakened our patent system. Although the U.S. patent system was once considered the gold standard for the rest of the world, in the latest global survey conducted by the U.S. Chamber of Commerce, our patent system was rated only 12th in the world, behind Singapore, France, and South Korea, among other countries.[7]

To remedy this concerning trend, BIO encourages Congress to advance patent litigation reform legislation that is currently pending review by the House and Senate Judiciary Committees and is highly relevant to the biotech business model. BIO supports the bipartisan STRONGER Patents Act, H.R. 5340, introduced by Representatives Steve Stivers

[7] Global Innovation Policy Center, Create: U.S. Chamber International IP Index, 6th ed. 35 (2018).

and Bill Foster, and S. 1390, introduced by Senators Chris Coons and Tom Cotton, which would address many of the deficiencies in the IPR process. It also incorporates the TROL Act, which would protect patent holders from predatory demand letters, and it would ensure that fees paid to the Patent and Trademark Office would not be diverted to other government functions.

BIO also commends the efforts of the U.S. Patent and Trademark Office to reform the IPR process. The recent proposal to harmonize claim construction standards with those used in Federal Court will go a long way to removing a significant incentive to game the system.[8]

Food and Drug Administration Safety and Innovation Act (FDASIA)

The Food and Drug Administration Safety and Innovation Act (FDASIA) provides a good example of how legislative and regulatory changes can create meaningful opportunities for innovative small businesses to attract investments that improve their potential to put a life-saving treatment on the market. FDASIA enabled the Food and Drug Administration (FDA) to review certain promising "breakthrough therapies" on an expedited basis, which has improved investor confidence in certain products' potential and helped increase the flow of capital to innovative biotech companies. The "breakthrough therapy" designation signals to investors that the FDA views a particular product as having promising potential to treat a serious condition and that may demonstrate substantial improvement over other available therapies. The "breakthrough therapy" designation is designed to expedite the review of designated therapies without changing FDA's safety and effectiveness standards for new drug approval. Receiving "breakthrough therapy" designation allows the FDA to provide intensive guidance during the regulatory review of a drug development program and reflects an organizational commitment involving senior FDA managers for products that receive such designation. Accordingly, the "breakthrough therapy" designation and associated benefits provide a powerful signal to investors that the product with designation has a promising path through regulatory review.

GlycoMimetics received "breakthrough therapy" designation for our drug candidate, GMI-1271, for treatment of adult relapsed/refractory acute myeloid leukemia or ALM in May 2017. In the year following that designation, we have been able to raise nearly $250 million, and this funding will enable us to conduct the definitive clinical testing of the drug. This underscores just how powerful of a signal the "breakthrough therapy" designation provides investors in terms of the pathway to receiving regulatory approval for a designated product.

I urge Congress to continue to support policies like these that provide investor certainty and encourage investment in innovative industries like biotech.

Conclusion

Thank you for the opportunity to testify today in support of policies to help ensure small business innovators like biotechs have access to sufficient capital. Policies enacted by

[8] U.S. Patent and Trademark Office, Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 F. Reg. 21221 (May 9, 2018).

Congress and regulators play a significant role in how emerging growth companies like biotechs attract, retain, and efficiently deploy their much-needed capital.

Despite past successes, there is still work to be done to encourage long-term investment in innovation. Building on legislation like the JOBS Act and FDASIA's "breakthrough therapies" designation, refining our tax code, and strengthening the patent system, would make the public capital markets a more attractive financing pathway for emerging biotech companies, improve investor confidence, and ease regulatory burdens for smaller companies. I look forward to working with you on these issues and I am happy to answer any questions you may have.