Kenneth I. Moch

President and Chief Executive Officer,
Chimerix, Inc.

On behalf of the Biotechnology Industry Organization

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Subcommittee on Capital Markets and Government Sponsored Enterprises

"Reducing Barriers to Capital Formation, Part II"

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Executive Summary

- Chimerix is a clinical-stage biotechnology company based in Durham, North Carolina. The Biotechnology Industry Organization (BIO) represents Chimerix and more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states.

- Chimerix undertook a successful IPO in April 2013 using key provisions in the Jumpstart Our Business Startups (JOBS) Act. Twenty-seven biotech companies have taken advantage of the JOBS Act to go public, and many more are on file with the SEC.

- A healthy public market is key to the success of the biotech industry, as growing innovators often turn to an IPO to fund late-stage clinical trials. BIO supports targeted market structure reforms that will decrease the cost of capital and increase liquidity for emerging biotechnology companies trading on the public market.

- BIO supports the Fostering Innovation Act, 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 the Tick Size Flexibility Act, which would institute a pilot program to allow companies that fall below a certain revenue or public float threshold to choose a new tick size for their stock.

- BIO supports the Spread Pricing Liquidity Act, which would allow companies with a public float below $500 million and an average trading volume below 500,000 shares daily to choose a new tick size for their stock.

- BIO supports the Audit Integrity and Job Protection Act, which would prevent PCAOB from mandating that public companies periodically rotate their external audit firms.

- BIO supports a small issuer exemption from XBRL compliance, which stalls the development process by unnecessarily diverting funds to reporting and away from R&D.

- BIO supports effective and expeditious implementation of the JOBS Act, the capital formation impact of which has been blunted by delays at the SEC.

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

Testimony of Kenneth I. Moch

Good morning Chairman Garrett, Ranking Member Maloney, Vice Chairman Hurt, and Members of the Subcommittee. My name is Kenneth Moch, and I am President and CEO of Chimerix, a small publicly-traded biotechnology company in Durham, North Carolina. I am also a member of the Emerging Companies Section Governing Board of the Biotechnology Industry Organization (BIO). I want to thank you for the opportunity to speak with you today about the pivotal role that the public market plays in financing the search for groundbreaking cures and treatments.

I have spent almost the entirety of my career in the biotechnology industry. I started working for a small life sciences consulting firm in 1976 and co-founded my first biotechnology company in 1982. During my career, I have worked with companies at all stages of the biotech life cycle, from venture-backed start-ups to later-stage public companies conducting costly and lengthy Phase III clinical trials with the hope of earning their first FDA approval. In large part, growing innovators are the heart of our industry. Chimerix has just 50 employees, which is typical for an industry where 90 percent of companies employ fewer than 100 people. These small businesses face a dual struggle – the daily challenge of running a growing company combined with the roadblocks intrinsic to groundbreaking scientific advancement. BIO represents hundreds of innovative companies like Chimerix, all of which must overcome capital formation barriers in order to fund their next generation R&D. The financing challenges that emerging biotechs face are unique, but when our industry is successful it has the potential to save lives and treat patients in desperate need of hope.

Bringing a breakthrough medicine from bench to bedside is a long and arduous process that often takes more than a decade and costs over $1 billion. In the biotech industry, we undertake this research process without the benefit of product revenue, so virtually all funding must come from external investors. During the early stages of R&D, private venture capitalists invest in promising companies, funding their initial studies, which include toxicity tests and the first safety trials involving human patients. As the research progresses and drug candidates show promise, further testing is required to show safety and efficacy in broad human populations. A single expansive Phase III trial can cost upwards of $100 million, to say nothing of the high risk (and, thus, the high likelihood of costs ballooning with additional tests and trials) at every stage of biotech research. With late-stage trials beyond the capital reach of private investors, companies entering their final stages of R&D often turn to the public market for financing, as we did at Chimerix.

The Jumpstart Our Business Startups (JOBS) Act

In the last year, the Jumpstart Our Business Startups (JOBS) Act has made the path to an IPO much smoother for emerging biotech companies. Chimerix went public in April of this year, and our offering was greatly enhanced by the provisions in the IPO On-Ramp. Leading up to the offering, we were able to use the “testing the waters” allowance in the On-Ramp to explore and evaluate the interest of potential investors, even before we filed our S-1 registration statement. Before the JOBS Act passed, we would have been forced into a quiet period as soon as we started preparing the registration statement, which would have meant a complete ban on contact with investors until the prospectus was made public.

Testing the waters made it possible to get the relevant facts in front of potential investors in order to generate interest in our offering. We were able to conduct literally dozens of meetings with potential investors in the months leading up to our IPO, which provided invaluable contact with the parties who later helped make Chimerix’s offering a success.

The practical impact of these meetings was that the investors were able to do their homework on both Chimerix and their own portfolio in the time between our testing the waters meeting and the actual IPO. This flexibility allowed them to gather the information necessary to make an investment in our company. In addition, these face-to-face meetings provided our managers and directors with important strategic information regarding how investors viewed our business and prospects that informed decision-making with respect to not only the offering but our business in general.

In our roadshow during the 10 days prior to the IPO launch, we met with 16 parties who had participated in testing the waters meetings, of which 12 ended up making investments. This high conversion rate was due in large part to the success of the JOBS Act. All told, nearly half of the investors with whom we met during one-on-ones placed an order – fully two-thirds of whom had previously met with our team during the testing the waters period. By any measure, our IPO was a success, raising $118 million by selling 8 million shares priced in the middle of our proposed range.

Thanks to our successful IPO, we have been able to set aside the significant funding necessary to conduct a Phase III trial for our lead drug candidate, CMX001, which if approved by the FDA will help bone marrow stem cell transplant recipients fight off potentially life-threatening viral infections. In particular, this therapy is intended to combat virulent viruses such as cytomegalovirus, which is found in 65 percent of the U.S. population and can cause significant complications when the immune system is compromised or suppressed.

As we move forward with our work on this groundbreaking medicine, the IPO On-Ramp will continue to support our research. The five-year exemption from the burden of Sarbanes-Oxley (SOX) Section 404(b) will forestall the diversion of valuable investment funds from science to compliance. Because Chimerix will not have product revenue during our late-stage trials, we, like most biotech companies, must fund our R&D by raising investment dollars. If we were forced to spend that capital complying with the regulatory burden of SOX Section 404(b), it would slow our development process and increase the time it would take to reach important scientific milestones.

SOX requires an expensive external attestation of a public company's internal controls, which must be disclosed to investors on an annual basis. The true value of a biotech company is found in scientific milestones and clinical development progress 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 interesting part of our business, and it is the most important thing for investors to understand. At Chimerix, 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. During the IPO process, the JOBS Act allowed us to focus on our offering rather than spend valuable time preparing financial statements for SOX compliance. Going forward, it will give us five years to spend time and capital on R&D rather than the onerous reporting burden of Sarbanes-Oxley.

In the year since the JOBS Act was enacted, other biotech companies like Chimerix have seen the promise of the IPO On-Ramp. Twenty-seven emerging biotechs have gone public using provisions in the law, and many more are on file with the SEC. This May was the best month for life sciences IPOs since 2000, with eight companies going public. (For comparison, there were only ten life sciences IPOs for the entire year in 2011.) Overall, IPO

valuations of life sciences companies so far this year are up by 21 percent, on average, compared to 2012. This improved market for biotech offerings is due in large part to the flexibility allowed by the JOBS Act.

The JOBS Act could not have come at a better time for the biotech industry. Venture fundraising is at a historic low, as venture capitalists diversify their portfolios and turn away from the risky nature of investment in biotech companies. Venture investment fell by 10 percent from 2011 to 2012, and it was even worse for early-stage companies. A recent survey of VCs found that 40 percent plan to further decrease their biopharmaceutical investments over the next three years. The public market has always been key to the biotech life cycle, but depressed VC financing combined with the opportunity presented by the JOBS Act has made the current IPO window even more important for our industry.

As these newly public companies find their feet on the market, the five-year IPO On-Ramp will smooth their transition and increase capital availability for innovative research. However, Congress has the opportunity to do more to ensure a positive trading environment for emerging innovators. Once public, many small companies face liquidity and pricing issues that can be detrimental to their public float and cash flow. Without legislation to supplement the JOBS Act, emerging growth companies could be left to die on the vine, in reach of the vital capital available on the public market but unable to fully access it. I support targeted market structure reforms that will decrease the cost of capital and increase liquidity for innovative emerging biotechnology companies.

The Tick Size Flexibility Act

The SEC adopted decimalization in 2000, changing the standard spread between bid and ask price (known as tick size) from 1/16 of a dollar (6.25 cents) to one cent, in an effort to increase trading activity for large issuers with millions of shares traded each day. However, as large companies enjoyed an influx of new investors, small issuers experienced a corresponding decrease in liquidity. Without strong liquidity available for small public companies, emerging biotechs can have difficulties raising the capital necessary to fund the decade-long, billion-dollar development timeline intrinsic to groundbreaking R&D.

Thinly-traded stocks, like those of most small biotechs, often need market-makers to stimulate trading activity, and the decreased tick size removed their incentive to do so. Market-makers profit on large spreads, so the reduced tick size diminished their potential profit margin, changing their market-making habits and leaving small cap stocks stagnant. The public market plays a vital role in financing next generation R&D, but a sluggish market bereft of liquidity does nothing to spur capital formation or fund research. The current one-size-fits-all approach to tick size does not reflect the realities of the market and subjects smaller issuers to the same trading framework as large, multinational companies with exponentially higher trading volumes and market caps.

I support flexibility in tick size for smaller issuers. Rep. Sean Duffy's discussion draft, the Tick Size Flexibility Act, would address the needs of small companies hamstrung by decimalization. Rep. Duffy's legislation would institute a five-year pilot program to allow small issuers to choose larger trading increments (either $0.05 or $0.10) in order to spur trading activity in their stock. Companies that meet a certain revenue or public float test would be eligible for the pilot program. A revenue test is an especially important marker for growing biotechs that do not have product revenue to fund their vital research. Allowing an increased tick size would grant flexibility to growing companies and increase the liquidity and capital availability necessary for emerging biotechs to be successful on the public market.

BIO and I support the Tick Size Flexibility Act because it takes into account the unique nature of the trading environment that small companies face as well as the high capital burden of biotech R&D. In order for this legislation to be a success, it is important that the increased tick sizes apply to both trading and quoting increments. Allowing for tick size flexibility will increase the effectiveness of the public market as a capital formation tool and speed the development of cures and breakthrough medicines.

The Spread Pricing Liquidity Act (H.R. 1952)

Rep. David Schweikert has also sponsored legislation that addresses the trading challenges that small companies face. His bipartisan bill, the Spread Pricing Liquidity Act, would allow issuers with a public float below $500 million and an average trading volume of less than 500,000 shares daily to choose a larger trading increment for their stock, recognizing the importance of tick size for small issuer liquidity.

The Spread Pricing Liquidity Act is an important acknowledgment that, as the JOBS Act continues to spur IPOs in the biotech industry, changes to the current one-size-fits-all trading regime must be made in order to alleviate the ongoing struggle to maintain healthy trading activity in small company stock.

The Fostering Innovation Act

As I have discussed, costly regulatory burdens have the potential to impede biotech research and delay the delivery of groundbreaking medicines to patients. Rep. Michael Fitzpatrick's Fostering Innovation Act would relieve smaller companies of the cost burden caused by Sarbanes-Oxley and other onerous regulations. The Fostering Innovation Act, which was approved by the Subcommittee on Capital Markets in the 112th Congress, would amend the filing status classifications in SEC Rule 12b-2 to provide a more accurate picture of the growing businesses that are weighed down by the various reporting requirements obligatory for public companies.

Because the filing statuses for accelerated and large accelerated filers under Rule 12b-2 carry with them onerous regulatory duties and compliance costs, finding a method of designation that fairly captures a company's profile is essential. The SEC understands that there should not be a one-size-fits-all approach to public company regulation, but the current filing classifications are outdated and do not reflect the true nature of many small public companies.

Currently, only those companies with a public float below $75 million are classified as non-accelerated filers. Despite their simple corporate structure and lack of product revenue, many biotech companies have a relatively high public float. Thus, biotechs often find themselves grouped with the accelerated filers and obliged to comply with the numerous regulatory burdens attendant to that definition, including SOX Section 404(b).

Rep. Fitzpatrick's legislation would raise the minimum public float requirement for accelerated filers to $250 million, classifying companies with a public float below that level as non-accelerated filers. This increase from $75 million to $250 million would allow start-ups to expand and change without fear of costly regulations impeding their growth. Many biotechs have public floats in or near that range, and the flexibility provided by the Fostering Innovation Act would allow them to focus on their innovative research rather than shifting funds to compliance costs.

The Fostering Innovation Act would also add a revenue component to the accelerated filer definition. Under the bill, accelerated filers would be described as those with revenues in excess of $100 million. Thus, any company with revenues below $100 million would be considered a non-accelerated filer as long as it did not cross the $700 million public float threshold and become a large accelerated filer. As I have mentioned, the most damaging facet of Section 404(b) for the biotech industry has been the diversion of investment funds from science to compliance in the absence of product revenue. Rep. Fitzpatrick's draft reflects this reality by classifying low-revenue companies as non-accelerated filers. If enacted, the Fostering Innovation Act would ensure that critical innovation capital is spent on groundbreaking research and development rather than regulatory burdens.

XBRL Reporting

Growing biotechs also face a regulatory burden in the form of XBRL compliance. Public companies are required to provide their financial statements in an interactive data format using eXtensible Business Reporting Language (XBRL). XBRL "tags" certain data points in an issuer's filing statement and exports them in a standardized format. The ostensible goal of XBRL is to provide more financial information to investors in a format that is easily comparable to other issuers' data. However, complying with XBRL places unnecessary burdens on emerging biotech companies.

In addition to instituting a new compliance burden for a small company's accounting department, 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. At Chimerix, we have estimated that compliance with XBRL will cost us approximately $50,000 annually. Those funds are investment dollars that will be spent on unnecessary accounting rather than vital scientific advancement.

Further, the information included in an XBRL report is often not indicative of the health of a smaller issuer. A biotech investor would be better served by comparing clinical trial results between companies rather than focusing on XBRL filings, which do not tell the whole story of a company's progress. Because XBRL reporting does not provide much insight for potential investors in small companies, the high cost of compliance far outweighs its benefits. BIO and I support an exemption from XBRL compliance for smaller issuers (or modified compliance, with exemptions from onerous detailed tagging), freeing them from a costly regulatory burden that does more harm than good.

The Audit Integrity and Job Protection Act (H.R. 1564)

In 2011, the Public Company Accounting Oversight Board (PCAOB) issued a concept release that, if adopted, would require that small public companies periodically rotate the external audit firm charged with verifying their internal financial controls. Such a change would place an undue burden on emerging biotech companies, who have few audit firms available to them and no product revenue to pay for expensive audit fees and other regulatory costs. Forcing small businesses to rotate their audit firm would increase costs as each new firm acclimated itself to the unique biotech business model, leading to a substantial diversion of capital from science to compliance.

The JOBS Act provides a five-year exemption from any such PCAOB requirement for emerging growth companies. However, the extended biotech development timeline often means that companies are on the public market for longer than five years before generating product revenue to pay for expensive compliance burdens. Reps. Robert Hurt and Gregory Meeks have introduced legislation, the Audit Integrity and Job Protection Act, that would prevent PCAOB from adopting an audit firm rotation requirement for any public company. I want to thank the House of Representatives for approving this legislation, as it will provide stability for growing biotechs funding their R&D on the public market.

JOBS Act Implementation

The IPO On-Ramp created by the JOBS Act has been a clear success for the biotech industry. As Congress moves forward with market structure reform, ensuring that the On-Ramp continues to benefit growing public companies is an important priority. Options to bolster the On-Ramp could include simplifying disclosure requirements for emerging growth companies or permitting confidential filings for follow-on offerings.

However, the majority of biotech small businesses are private companies. The JOBS Act included provisions to spur capital formation for these innovators as well, but delays at the SEC have blunted their impact. Over 70 percent of the biotech industry is private, so full implementation of the JOBS Act is vital for our industry. Although Chimerix is now public, we faced numerous fundraising challenges as a private company, and I believe that the reforms to Regulation D and Regulation A in the JOBS Act will support small company capital formation once they are implemented.

Biotech companies have expressed a particular interest in the changes to Regulation D that will allow general solicitation in Rule 506 private placements. The SEC issued a proposed Reg D rule in August 2012, and I am encouraged by recent reports that the Commission is planning to approve a final rule soon.

Even more delays have been seen with Regulation A reforms, which would permit direct public offerings of up to $50 million under a new Reg A+. There was no deadline for SEC action in Title IV of the JOBS Act, which authorized the Reg A changes, so the SEC has not made sufficient progress on the rulemaking process. BIO and I support Rep. Patrick McHenry's bill, H.R. 701, to institute a deadline for the SEC to implement Reg A+. The overwhelming bipartisan passage of H.R. 701 by the full House of Representatives sent a clear message to the SEC that action is needed to fulfill the full potential of the JOBS Act, and I applaud the House for taking that stand.

Biotech companies also benefit greatly from the JOBS Act's reforms to the Section 12(g) private shareholder rules. The exemption of employees from the shareholder limit gives private biotech companies the ability to hire the best available employees and compensate them with equity interests, allowing them to realize the financial upside of a company's success. This process could be further enhanced by amending SEC Rule 701 to increase the annual employee stock and options compensation limit (before triggering a set of disclosure requirements) beyond the current $5 million cap.

Closing Remarks

A functioning public market is vital to the success of the biotech industry and the American economy. At a time when venture capital financing of biotechnology is at a historic low, the ability to access public capital is increasingly important. We have seen the clear appetite for capital formation on the public market in the wake of the JOBS Act – and Chimerix was a

clear beneficiary of that law. The rise in biotech IPOs in the last year is a clear indication that public fundraising is fundamental in the search for groundbreaking medical advancements.

However, capital formation does not end with an IPO. A healthy public market bolstered by strong small company liquidity and reasonable regulatory obligations will ensure the success of public financing throughout the decade-plus biotech development cycle. Congress has the opportunity to build on the success of the JOBS Act by enacting market structure reform legislation that will support small company growth and fundraising. Allowing tick size flexibility, reducing regulatory burdens, and addressing the broad portfolio of other market structure issues, including off-exchange trading transparency and high-frequency trading, will stimulate both trading and IPO activity and improve the overall health of the public market. For growing biotech companies, reducing barriers to capital formation on the public market would lead to scientific advancement, novel medicines, and life-saving treatments for patients in need.