HEARING TESTIMONY

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On behalf of the Biotechnology Industry Organization

Before the United States Senate Committee on Banking, Housing, and Urban Affairs

"Spurring Job Growth Through Capital Formation While Protecting Investors, Part II"

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Executive Summary

- The Biotechnology Industry Organization (BIO) represents more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states.

- It can take over a decade and more than $1 billion to develop a single biotechnology therapy. Venture capital fundraising is stagnant and the IPO market is largely closed, forcing innovative companies to delay research on promising scientific breakthroughs.

- BIO supports S. 1933, the Reopening American Capital Markets to Emerging Growth Companies Act, which would create an "on-ramp" to the public market for "emerging growth companies." Most newly public biotech companies have no product revenue, so the five year transition period into compliance with Sarbanes-Oxley (SOX) Section 404(b) and certain accounting and disclosure requirements would allow growing biotechs to focus on the search for cures and treatments rather than costly regulations.

- BIO supports S. 1544, the Small Company Capital Formation Act, which would reform SEC Regulation A by expanding its eligibility requirements to include companies conducting direct public offerings of up to $50 million, an increase from the current threshold of $5 million. This increase would provide a valuable funding alternative for small biotech startups, giving them access to the market at an earlier stage in their growth cycle and allowing them to raise valuable innovation capital.

- BIO supports S. 1824, the Private Company Flexibility and Growth Act, which would increase the limit that requires private companies to register with the SEC from 500 to 2000 shareholders, giving growing biotech companies more investor options to finance their early-stage research. The bill would also exempt employees from the shareholder count, allowing biotech companies to attract and hire the most qualified researchers and scientists.

- BIO supports S. 1831, the Access to Capital for Job Creators Act, which would require the SEC to revise Rule 506 of Regulation D to permit general solicitation in direct public offerings, broadening the investor base.

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Testimony of William D. Waddill

Good morning Chairman Johnson, Ranking Member Shelby, Members of the Committee, ladies, and gentlemen. My name is William Waddill, and I am the Senior Vice President and Chief Financial Officer of OncoMed Pharmaceuticals in Redwood City, California. I am also the Co-chairman of the Finance and Tax Committee at the Biotechnology Industry Organization (BIO). I want to thank you for the opportunity to speak with you today about the unique hurdles that innovative biotechnology companies face as they work toward developing cures and breakthrough medicines to treat crippling illnesses that affect families across the nation.

Biotechnology has incredible potential to unlock the secrets to curing devastating disease and helping people to live longer, healthier, and more productive lives. My company, OncoMed Pharmaceuticals, is working at the cutting edge of oncology research, focusing on a specific set of cells within tumors that drives the growth of the tumor and can morph into various cell types within the tumor. We have developed the ability to isolate and monitor these tumor initiating cells, and our studies have shown that they are more resistant to standard chemotherapy agents. Some current treatments may succeed at initially decreasing the size of a cancer, but leave behind an increased proportion of these most malignant cells. We have developed a portfolio of antibodies that target biologic pathways critical for survival of tumor initiating cells, with the goal being to stop those cells from replicating. We believe these models are more representative of the effects of these treatments in cancer patients than traditional models using cancer cell lines, which may no longer accurately reflect the properties of the original tumor. Currently we have three antibodies that target tumor initiating cells in Phase I and are developing other promising therapeutic candidates.

BIO represents more than 1,100 innovative companies like mine, along with academic institutions, state biotechnology centers, and related organizations in all 50 states. Entrepreneurs across the biotech industry are conducting groundbreaking science like ours, and are deeply invested in treating the severe illnesses that families around the nation and world face. At the same time, biotech leaders must deal with the day-to-day challenges of running a small business. Of great import in the biotechnology industry is the constant struggle to find working capital. It takes 8 to 12 years for a breakthrough company to bring a new medicine from discovery through Phase I, Phase II, and Phase III clinical trials and on to FDA approval of a product. The entire endeavor costs between $800 million and $1.2 billion. For the majority of biotechnology companies that are without any product revenue, the significant capital requirements necessitate fundraising through any source available, particularly venture capital firms. Later, we must turn to the public markets in the final stages of research to fund large-scale and expensive clinical trials.

Startup companies depend on venture capital fundraising to finance the early stages of research and development. In fact, many companies, including mine, rely on venture financing to fund even middle- and late-stage clinical trials. However, the current venture landscape has made this type of funding difficult. In 2011, we saw only 98 first round venture deals with biotechnology companies, a significant drop from the industry's peak of 141 in 2007. Last year was only the third time since 2000 that the number of deals dropped below 100. Small, startup companies are

the innovative heart of our industry, but depressed financing means that potential cures and treatments are often left on the laboratory shelf.

Further, venture capitalists expect this downward trend to continue. A recent survey conducted by the National Venture Capital Association (NVCA) found that 41 percent of venture capital firms have decreased their investments in the biopharmaceutical sector in the past three years. Additionally, 40 percent of venture capitalists reported that they expect to further decrease biopharmaceutical investments over the next three years. Therapeutic areas that affect millions of Americans will be hit by this change in investment strategy, including cardiovascular disease, diabetes, and cancer.

A significant reason for reluctance in venture investing has been the inaccessibility of the public markets. Venture capital investors need to know that they will have an exit through which they can get a return on their investment; often, they look for this exit when a company enters the public market. Unfortunately, due to the current economic climate, it is becoming harder for biotech companies to go public. As a result, venture capital firms are turning elsewhere to make their investments, leading to a dearth of innovation capital for biotechnology.

Despite the desire on the part of companies and private investors for a clear path to a public offering, public markets remain essentially closed to growing biotech companies. There was only $1 billion in public financing for biotechnology last year, just a third of the total from 2007. Though funding totals are slowly climbing back toward pre-recession levels, this progress has been made almost entirely by larger, more mature companies. These more established companies are getting better deals and emerging companies making their first forays onto the public market are getting squeezed out. The weak demand for public offerings for smaller companies is restricting access to capital. This then hampers critical research, forces companies to stay private for longer, and depresses valuations of later-stage venture rounds. Although the industry is slowly recovering from its recession-induced nadir (in 2008 there was only one biotechnology IPO), this progress is not fast enough for struggling biotechs that need funding to innovate or patients waiting for breakthrough medicines.

These disturbing investment trends could be ameliorated by allowing emerging growth companies increased access to the public markets. In a recent survey conducted by NASDAQ and the NVCA, 86 percent of chief executive officers cited "accounting and compliance costs" and 80 percent cited "regulatory risks" as key concerns about going public. If burdens on public financing were removed, private investors would have greater certainty that they would have an avenue to exit, leading to augmented venture capital investment, the lifeblood of the biotechnology industry. Additionally, companies on the cusp of a public offering would have the confidence that a successful IPO could fund their late-stage trials and push therapies to patients who desperately need them.

Public Market On-Ramp

Senators Schumer and Toomey have introduced S. 1933, the Reopening American Capital Markets to Emerging Growth Companies Act. This bill would create a new category of issuers, called "emerging growth companies," and ease their transition onto the public market. The

legislation would give newly public companies much-needed relief by allowing them to transition into full regulatory compliance over time as they grow. This transitional "on-ramp" will encourage biotechnology companies and other small businesses on the cusp of going public to venture onto the public market.

One of the key components of the on-ramp is the five year transition period before emerging growth companies are subject to full Sarbanes-Oxley (SOX) Section 404(b) compliance. While we can all agree that investors benefit from greater transparency, the unintended consequence of the regulations found in Section 404(b) is the diversion of precious invested capital away from innovative product development and job growth to onerous, costly compliance with little to no benefit to investors or the general public. The opportunity cost of this compliance can prove damaging, resulting in delays to developing cures and treatments during a necessary and often prolonged search for investment capital.

SEC studies have shown that SOX compliance can cost companies more than $2 million per year. The biotechnology sector is especially disadvantaged by this burden due to the unique nature of our industry. Newly public biotech companies have little to no product revenue, so they are essentially asking investors to pay for SOX reporting rather than research and development. The compliance costs are fixed and ongoing, and have a severe impact on the long-term investing of microcap and small cap companies at the forefront of developing new treatments for severe diseases. Companies are the most vulnerable during their first few years on the public market, yet they are forced to shift funds from core research functions to compliance costs. This can lead to research programs being shelved or slowed as compliance takes precedence.

Further, the true value of biotech companies is found in scientific milestones and clinical trial advancement toward FDA approvals rather than financial disclosures of losses incurred during protracted development terms. Investors often make decisions based on these development milestones rather than the financial statements mandated by Section 404(b). Thus, the financial statements required do not provide much insight for potential investors, meaning that the high costs of compliance far outweigh its benefits.

In 2010, Congress made the important acknowledgement that SOX Section 404(b) is not an appropriate requirement for many small reporting companies. The Dodd-Frank Wall Street Reform and Consumer Protection Act sets a permanent exemption from Section 404(b) for companies with a public float below $75 million. Additionally, the SEC Small Business Advisory Board in 2006 recommended that the permanent exemption be extended to companies with public floats of less than $700 million.

Similarly, the Reopening American Capital Markets to Emerging Growth Companies Act would allow emerging growth companies time to find their footing on the public market without diverting precious funds to onerous SOX reporting. I support giving these companies five years to transition onto the public market, providing them with time to create jobs and continue research before entering full regulatory compliance.

Additionally, an on-ramp transition period would allow emerging growth companies to provide only two years of previous audited financial statements prior to going public rather than the three years currently required. Similar to the transition into SOX compliance, this change would save emerging biotech companies valuable innovation capital that could be used for important research and development. I fully appreciate and agree that strong auditing standards can enhance investor protection and confidence and I support this goal. However, overly burdensome auditing standards impose a significant cost burden on emerging growth companies without providing much pertinent information to their investors. By allowing for limits on the look-back requirements for audited financial statements, a public market on-ramp would balance the goals of cost-efficient auditing standards and investor protection. Two years of audited financials is sufficient for investors to gather information about companies going public. Further, most biotech investors look to scientific and development information when making investment decisions, so the extra year of audited financials imposes costs without providing benefit. Requiring just two years of audited financial statements would continue to protect investors but would allow emerging growth companies to expend more of their capital on the search for breakthrough medicines.

An on-ramp approach would also exempt emerging growth companies from certain rules issued by the Public Company Accounting Oversight Board (PCAOB), particularly a proposal being considered regarding mandatory audit firm rotation.

Audit fees would most certainly increase with the implementation of audit firm rotation. There would be a steep learning curve for any new audit firm, and the additional resources necessary to educate the audit firm about business and operations would raise audit fees. Companies might even need to hire more compliance personnel to avoid disruption of day-to-day operations, further increasing the cost burden. Audit firms have also suggested that audit firm rotation could increase the challenges and costs to maintain high quality personnel. The cost associated with these scenarios would be transferred to the company while making relationships between the audit firm and the company more difficult to establish. Each new cost burden would require funds to be diverted from research and development to the transition between audit firms, slowing the progress of cures and treatments for which patients are waiting.

I support the ongoing efforts to incentivize emerging growth companies to go public and make their transition smoother while continuing to protect investors. Easier access to the public market will improve the health and stability of the biotechnology industry, both for companies considering an IPO and for those which are still seeking private investment.

Financial Services Capital Formation Proposals

While easing entry onto the public market is a key component of capital formation for growing companies, there are several proposals being considered that would benefit companies that are not yet suited to enter the public markets but face their own unique burdens as they grow. These proposals would strengthen the fundraising potential for small, innovative biotech companies developing solutions to the health problems that our nation faces.

SEC Regulation A (Direct Public Offerings)

Regulation A, adopted by the SEC pursuant to Section 3(b) of the Securities Act of 1933, was created to provide smaller companies with a mechanism for capital formation with streamlined offering and disclosure requirements. Updating it to match today's market conditions could provide an important funding source for small private biotechnology companies.

Regulation A allows companies to conduct a direct public offering valued at less than $5 million while not burdening them with the disclosure requirements traditionally associated with public offerings. The intent of Regulation A was to give companies which would benefit from a $5 million influx (*i.e.*, small companies in need of capital formation) an opportunity to access the public markets without weighing them down through onerous reporting requirements.

However, the $5 million offering amount has not been adjusted to fit the realities of the costs of development and Regulation A is not used by small companies today. The current threshold was set in 1992 and is not indexed to inflation, pushing Regulation A into virtual obsolescence. As it stands, a direct public offering of just $5 million does not allow for a large enough capital influx for companies to justify the time and expense necessary to satisfy even the relaxed offering and disclosure requirements.

Senators Tester and Toomey have introduced a Regulation A reform bill, the Small Company Capital Formation Act (S. 1544), which I believe would have a positive impact for small biotechnology companies. The legislation increases the Regulation A eligibility threshold from $5 million to $50 million while maintaining the same disclosure requirements. This increase would allow companies to raise more capital from their direct public offering while still restricting the relaxed disclosure requirements to small, emerging companies. The Small Company Capital Formation Act could provide a valuable funding alternative for small biotech startups, giving them access to the public markets at an earlier stage in their growth cycle and allowing them to raise valuable innovation capital. I support this legislation.

SEC Reporting Standard (Shareholder Limit)

Although the SEC generally monitors public companies, the agency also keeps tabs on private companies when they reach a certain size. Modifying the SEC's public reporting standard would prevent small private biotechnology companies from being unnecessarily burdened by shareholder regulations.

Once a private company has 500 shareholders, it must begin to disclose its financial statements publicly. Biotechnology companies are particularly affected by this 500 shareholder rule due to our industry's growth cycle trends and compensation practices. As I have mentioned, the IPO market is essentially closed to biotechnology, leading many companies to choose to remain private for at least 10 years before going onto the public market. This long timeframe can easily result in a company having more than 500 current and former employees, most of whom have received stock options as part of their compensation package. Under the SEC's shareholder limit, a company with over 500 former employees holding stock, even if it had relatively few current employees, would trigger the public reporting requirements. Exempting employees from

any shareholder limit is a minimum necessary measure to ensure growing biotech companies are able to hire the best available employees and compensate them with equity interests, allowing them to realize the financial upside of a company's success.

Senators Carper and Toomey have introduced legislation, the Private Company Flexibility and Growth Act (S. 1824), which would address these barriers to private company growth. Their bill would increase the shareholder limit from 500 to 2000, relieving small biotech companies from unnecessary costs and burdens as they continue to grow. As it stands, the 500-person limit encumbers capital formation by forcing companies to focus their investor base on large institutional investors at the expense of smaller ones that have been the backbone of our industry. The legislation would also exempt employees from the shareholder count, allowing growing biotech companies to attract and hire the most qualified researchers and scientists. I support the Private Company Flexibility and Growth Act, as it would remove significant financing burdens from small, growing companies.

SEC Regulation D (Ban on General Solicitation)

Another potential avenue for capital formation in the biotech industry is SEC Regulation D. Under Rule 506 of Regulation D, companies can conduct offerings to accredited investors without complying with stringent SEC registration standards. This exemption allows companies to access sophisticated investors (who do not need as much SEC protection) without burdensome disclosure requirements. However, the upside of this fundraising avenue is hindered by the ban on general solicitation in Rule 506. Companies are limited in their investor base by this rule, meaning that a vast pool of investors remains untapped. If the ban on general solicitation were lifted, growing biotech companies would be able to access funds from the entire range of wealthy SEC accredited investors without undergoing the full SEC registration process.

I support Senator Thune's Access to Capital for Job Creators Act (S. 1831), which would require the SEC to revise Rule 506 and permit general solicitation in offerings under Regulation D. If enacted, this legislation would enhance fundraising options for growing biotech companies searching for innovative cures and treatments.

Closing Remarks

The U.S. biotechnology industry remains committed to developing a healthier American economy, creating high-quality jobs in every state, and improving the lives of all Americans. Additionally, the medical breakthroughs happening in labs across the country could unlock the secrets to curing the devastating diseases that affect all of our families. There are many pitfalls and obstacles endemic to this effort, including scientific uncertainty and the high costs of conducting research. However, the regulatory burdens I have discussed continue to stand in our way without providing any real benefit to the investors the laws purports to protect. By making targeted changes that support emerging growth companies in the biotechnology industry and elsewhere, Congress can unburden these innovators and job creators while maintaining important investor protections. Congress has the opportunity inspire biotechnology breakthroughs and allow innovators and entrepreneurs to continue working toward delivering the next generation of medical breakthroughs – and, one day, cures – to patients who need them.