HEARING TESTIMONY

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On behalf of the Biotechnology Industry Organization

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Subcommittee on Capital Markets and Government Sponsored Enterprises

"Legislative Proposals to Facilitate Small Business Capital Formation and Job Creation"

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Good morning Chairman Garrett, Ranking Member Waters, Members of the Committee, ladies, and gentlemen. My name is William Waddill, and I am 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 and the ways in which the federal government can encourage and speed the development of cures and treatments to the crippling illnesses that affect families across the nation by removing burdens to innovation.

Biotechnology has incredible potential to unlock the secrets to curing devastating disease and helping people to live longer, healthier, and more productive lives, but the barriers that small biotech companies encounter on a daily basis raise some important questions: Would we rather see the next generation of breakthrough cures discovered by researchers in New Jersey or New Delhi? Do we want the jobs associated with this groundbreaking science to go to workers in San Francisco or Shanghai? If we want more scientific breakthroughs that allow us to enjoy a high quality of life – indeed, breakthroughs that save the lives of our loved ones – then shouldn't we put in place policies that encourage innovation?

While the biotechnology industry faces significant challenges, we nonetheless have the ability to deliver the next generation of cures and treatments to the bedsides of patients who desperately need them while at the same time creating a healthier American economy. The 1.42 million Americans directly employed by biotech are driven to treat and heal the world, but in order for them to be able to do so, Congress must remove the barriers to innovation that we face.

Innovation in biotechnology leads to the medical breakthroughs that cure and treat devastating diseases like cancer and Alzheimer's and allow real people to see their grandkids graduate from college or walk their daughters down the aisle.

The leash that holds our industry back from helping more people is, in large part, the exorbitant costs of developing a treatment that must be undertaken by a growing company. Today, Congress has the opportunity to help speed lifesaving cures and treatments to patients by removing burdens to innovation in our industry.

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 using specific surface markers and technologies. Our studies have shown that tumor initiating cells are more resistant to standard chemotherapy agents and radiotherapy. So, some current treatments may succeed at initially decreasing the size of a cancer, but leave behind an increased proportion of the most malignant cells. We have developed a portfolio of antibodies and have tested them within xenograft models derived from freshly resected human cancers. These antibodies target biologic pathways critical for survival of tumor initiating cells. 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. Due to this capital-intensive process, we must turn to the public markets in the later stages of research to fund large-scale and expensive clinical trials.

Sarbanes-Oxley Section 404(b) Exemption

As you know, the Sarbanes-Oxley Act (SOX) was passed in 2002 with the intent of protecting public investors from corporate fraud. At the time, President Bush praised it as a collection of "the most far-reaching reforms of American business practices since the time of Franklin D. Roosevelt." While we can all agree that investors benefit from greater transparency, some of the regulations found in SOX, namely Section 404(b), are unnecessarily burdensome on smaller companies, and often involve onerous compliance with little to no benefit to investors or the general public. In fact, many biotech companies facing their first few years on the public market are forced to divert funds from scientific research and development to the stringent Section 404(b) auditing requirements. The opportunity cost of this compliance can prove damaging,

resulting in already limited resources being driven away from a company's search for cures and treatments.

The biotechnology sector is especially disadvantaged by the compliance burden of Section 404(b) due to the unique nature of our industry. The long, capital-intensive development period intrinsic to biotechnology often causes companies to have a relatively high market capitalization (caused by multiple rounds of venture financing prior to going public) but little to no revenue. All public companies with market caps greater than $75 million are forced to comply with Section 404(b), even though most biotech companies in a cash-strapped financial position can ill afford to pay for expensive external attestation of internal financial controls.

The main problem that these regulations cause for emerging public biotechnology companies is the need to divert resources away from innovation development to compliance for Section 404(b). 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. These small companies are the most affected by SOX at a time when they often have little or no product revenue to devote to compliance costs and must, as a result, shift funds from core research functions. 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.

As U.S. biotech companies face a mountain of regulatory hurdles, other countries are increasing their investments and enacting intellectual property protections to encourage their own biotech growth. The United States still holds its place as the leader in global biotechnology thanks to our large head start, but China and India rank first and second in biotech patent growth. These emerging powers are heavily investing in science, and particularly in biotechnology. Meanwhile, trouble in the U.S. IPO market has decreased the number of public biotech companies in the U.S. by 23% since 2008 as China's biotech IPO market continues to grow.

Strengthening the public market and removing regulatory burdens for public companies could incentivize U.S. companies that might otherwise remain private or list abroad to choose the U.S. public markets as their place of business. History has shown that job growth is accelerated when a company moves from private status to public. To encourage continued biotech innovation in the United States, as well as to grow and retain jobs, Congress should relieve small companies from the overly burdensome regulations found in Section 404(b).

Section 989G of the Dodd-Frank Wall Street Reform and Consumer Protection Act is an important acknowledgment by Congress that Section 404(b) of Sarbanes-Oxley is not an appropriate requirement for many small reporting companies. Dodd-Frank sets a permanent exemption from Section 404(b) for companies with a public float below $75 million. This

provision is particularly important because it provides consistency to companies who now have a clear understanding as to whether or not they are exempt. However, it is too narrow in practicality and must be raised. Because of the business model of innovative industries like biotechnology, companies generally have very low revenues compared to their market capitalizations. For example, it is not uncommon for a newly public biotech company to have a market capitalization in excess of $600 million but have product revenues of $1 million or less. Such a company would be required to fully comply with Section 404(b) despite its lack of revenue with which to pay for compliance.

In 2006, the SEC Small Business Advisory Board recommended that the permanent exemption be extended to companies with public floats less than $700 million to better fit the business model of industries like biotechnology. The Advisory Board's proposed ceiling would allow small innovative companies to focus on speeding cures and treatments to patients rather than SOX compliance.

The Advisory Board also realized that public float alone does not fully portray the complexity and risk associated with a reporting company, and suggested a revenue test to paint a fuller picture. Revenue should be a critical consideration when determining the appropriateness of Section 404(b) compliance, along with public float. The addition of a revenue test would better serve the congressional intent behind Sarbanes-Oxley by reflecting the truly small nature of companies with little or no product revenue. Public companies with a public float below $700 million and with product revenue below $100 million should be permanently exempt from Section 404(b), allowing them to focus their resources on critical research and development.

Financial Services Capital Formation Proposals

As you know, the regulations in Sarbanes-Oxley only apply to public companies. However, many small companies in the biotechnology industry have remained private, in large part due to the travails of the public market in general, and SOX in particular. Those companies that are not yet suited to enter the public markets face their own unique burdens as they seek growth.

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 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.

I believe that Regulation A could have a positive impact for small biotechnology companies if its eligibility threshold was increased 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. Regulation A reform 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.

SEC Reporting Standard (Shareholder Limit)

Although the SEC in general 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. Currently, 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.

Also, including accredited investors in the private company shareholder count does not serve the intended purpose of protecting retail investors. The SEC recognizes that accredited investors are a unique class that does not require the same level of protection as other investors. By including them in the 500 shareholder limit, growing private companies are forced to rely primarily on institutional investors because they need to maximize funding without triggering the limit. This excludes retail investors, whom the SEC was originally trying to protect, from taking part in this process.

Additionally, increasing the shareholder limit from 500 to 1000 would relieve small biotech companies from unnecessary costs and burdens as they continue to grow. As it stands, the 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. Further, it hinders a company's ability to compensate its employees with equity interests and

negatively affects the liquidity of its shares. Increasing the shareholder limit and exempting employees and accredited investors from the count are measures that, together, would remove significant financing burdens from small, growing companies.

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 challenges added via Sarbanes-Oxley continue to stand in our way without providing any real benefit to the investors the law purports to protect. Congress has the opportunity to support and inspire biotechnology breakthroughs by unburdening startup companies and allowing innovators and entrepreneurs to continue working toward delivering the next generation of medical breakthroughs – and, one day, cures – to patients who need them.

United States House of Representatives
Committee on Financial Services

"TRUTH IN TESTIMONY" DISCLOSURE FORM

Clause 2(g) of rule XI of the Rules of the House of Representatives and the Rules of the Committee on Financial Services require the disclosure of the following information. A copy of this form should be attached to your written testimony.

1. Name:	2. Organization or organizations you are representing:
William D. Waddill	OncoMed Pharmaceuticals, Inc. and BIO

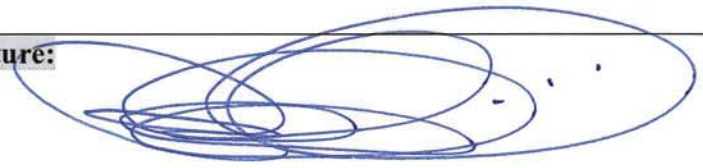
3. Business Address and telephone number:

[redacted]

4. Have you received any Federal grants or contracts (including any subgrants and subcontracts) since October 1, 2008 related to the subject on which you have been invited to testify?	5. Have any of the organizations you are representing received any Federal grants or contracts (including any subgrants and subcontracts) since October 1, 2008 related to the subject on which you have been invited to testify?
☐ Yes ☑ No	☐ Yes ☑ No

6. If you answered .yes. to either item 4 or 5, please list the source and amount of each grant or contract, and indicate whether the recipient of such grant was you or the organization(s) you are representing. You may list additional grants or contracts on additional sheets.

7. Signature:



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