Jeffrey S. Hatfield

President and Chief Executive Officer,
Vitae Pharmaceuticals

On behalf of the Biotechnology Industry Organization

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Subcommittee on Capital Markets and Government Sponsored Enterprises

"The 10th Anniversary of the Sarbanes-Oxley Act"

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Executive Summary

- Vitae Pharmaceuticals is a clinical-stage biotechnology company based in Fort Washington, Pennsylvania. The Biotechnology Industry Organization (BIO) represents Vitae and more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states.
- BIO supports H.R. 6161, the Fostering Innovation Act, which would amend the filing status classifications in SEC Rule 12b-2 to provide a more accurate picture of growing businesses.
  - The bill would raise the minimum public float requirement for accelerated filers to $250 million, allowing non-accelerated filer start-ups to expand and change without fear of impeding their growth with costly regulations.
  - The bill would add a revenue component to the accelerated filer definition, ensuring that companies with revenue below $100 million spend their critical innovation capital on groundbreaking research and development rather than regulatory burdens.
- It can take more than a decade and over $1 billion to bring a single biotechnology therapy from laboratory bench to hospital bedside.
- Biotech companies undertake the development process without the benefit of product revenue. Every dollar spent on regulatory compliance is an investment dollar diverted from innovation.
- Biotech companies have few employees, a simple corporate structure, and investors that are more concerned with clinical milestones than financial reporting. The cost of regulatory compliance often outweighs its benefit.
- Public company regulatory requirements deter early-stage private investors and prevent later-stage companies from accessing the capital available on the public market.
- The costs of Sarbanes-Oxley Section 404(b) compliance can be greater than $1 million per year for an average biotech company. These costs are borne at the expense of research and development.
- The SEC Rule 12b-2 filing status classifications that determine public company regulatory requirements are outdated and do not accurately represent the true nature of smaller companies.

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

Testimony of Jeffrey S. Hatfield

Good morning Chairman Garrett, Ranking Member Waters, and Members of the Subcommittee. My name is Jeff Hatfield, and I am the President and Chief Executive Officer of Vitae Pharmaceuticals in Fort Washington, Pennsylvania. I am also a member of the Emerging Companies Section Governing Board at the Biotechnology Industry Organization (BIO). I want to thank you for the opportunity to speak with you today about the unique hurdles that biotechnology companies face in their search for groundbreaking medicines and how finding the important balance between regulations that protect investors and regulatory burdens that stifle growth is key to speeding the delivery of cures and treatments to patients who desperately need them.

Vitae's experience is emblematic of a typical emerging biotech company. The long development period intrinsic to the groundbreaking research that we do means that it can take a decade to bring a therapy from laboratory bench to hospital bedside – and often, as in Vitae's case, it takes much longer. Our company was founded in late 2001, and we have spent the past ten years working toward treatments to some of the most widespread and devastating diseases that the world faces, including diabetes, Alzheimer's, atherosclerosis, and chronic kidney disease. Our lead product, a compound designed to preserve kidney function by inhibiting damage-causing renin, just completed Phase I clinical trials. Although we are optimistic about its progress, and that of the rest of our development pipeline, we expect to be in clinical trials for at least another four to six years before moving on to the approval process at the FDA. Quite simply, developing a novel therapy is a long, difficult process – but the results can save lives. 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.

The story of biotech drug development is one of advancement. As a given molecule moves through the development process, it requires an ever increasing amount of resources to progress the drug candidate closer to a stage where it could save a patient's life. From the initial discovery in the lab and basic toxicology research to early Phase I studies and, eventually, sweeping Phase III trials to determine efficacy – the science involved gets ever more complex, and the clinical stakes get higher as companies move closer to a cure. However, while the science is increasingly intricate, our corporate structure remains essentially the same. After all, over 90% of biotech companies have fewer than 100 employees.[1] Vitae has just 55. As scientists, we are innovators expanding the world's understanding of human life. As a corporation, we strive to stay as simple as possible so that the maximum amount of investment dollars can flow directly to our R&D.

This efficiency is extremely important given the massive amount of funding required to develop a biotechnology treatment. The extended development period and groundbreaking science require over $1 billion to bring a single therapy to market. Further, the entire process is undertaken without the benefit of product revenue. Early-stage biotech companies do not have the luxury of using the sale of one product to finance the development of another. Rather, the entire cost of drug development is borne by external investors. These funds can be raised in any number of ways – seed financing from an angel investor could lead to increased investment from venture capitalists, a larger pharmaceutical company could offer a partnership opportunity, or public financing via the IPO market might be the appropriate avenue for a given firm. Most companies use some combination of financing methods to continue their research. But the common message from all investors is the utmost importance of using their funds efficiently. Companies and

[1] BIO Emerging Companies Section Membership Survey, 2011.

investors alike understand this key aspect of the biotech business model – because investment dollars go directly from the investor to the lab, any diverted funds are, by definition, lost to innovation. And any delay in innovation has a corresponding delay in the delivery of new medicines to patients who need them.

The efficient use of investment funds has always been imperative for biotech companies, but it has taken on increased import given the current financing environment. In 2011, the total number of investment deals between biotech companies and venture capitalists dropped 8%,[2] and a recent National Venture Capital Association (NVCA) study found that 41% of VCs decreased their investments in the biopharma sector over the last three years.[3] This trend has hit small companies the hardest, as the number of start-ups receiving funding in 2011 dropped 19% from 2010. Further, there were only 98 first round venture deals with biotechnology companies in 2011, a significant drop from the industry's peak of 141 in 2007.[4] Small, start-up companies are the innovative heart of our industry, but depressed financing means that potential cures and treatments are often left on the laboratory shelf.

Biotech companies considering the public market are also facing a decline in capital availability. In 2011, there were only eight IPOs of venture-backed biotech companies. Those IPOs raised $517 million, down from the $1.2 billion raised in 2007 by 19 IPOs.[5] Although the industry is slowly recovering from its recession-induced nadir (in 2008 there was only one biotechnology IPO), 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. Small companies that do manage to make it onto the public market often face an underpriced IPO and a lack of liquidity.

These private and public financing problems are not independent of one another. 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 files for an IPO. With companies reluctant to go public, venture capital firms are turning elsewhere to make their investments, leading to a dearth of innovation capital for biotechnology.

Given the increased difficulty of obtaining essential funding, the efficient use of capital is of utmost importance. Regulatory burdens that impose significant costs, then, have become increasingly damaging. In a 2011 survey conducted by the IPO Task Force, 86% of CEOs cited "accounting and compliance costs" and 80% cited "SOX and regulatory risks" as key concerns about going public.[6] Biotech companies that would otherwise look to the public market to fund their late-stage trials are reconsidering, fearful of the costly regulations that often stifle their progress by siphoning off research dollars.

The Sarbanes-Oxley Act of 2002

This coming Sunday will mark ten years since the Sarbanes-Oxley Act (SOX) was signed into law by President Bush. Enacted as a response to scandals at Enron and WorldCom,

[2] NVCA/PWC MoneyTree Report: Q4 2011. Data provided by Thomson Reuters.
[3] NVCA and MedIC. "Vital Signs: The Crisis in Investment in U.S. Medical Innovation and the Imperative of FDA Reform." October 2011.
[4] Inside BIO Industry Analysis. "Venture Capital increases in 2011, but…" 24 January 2012.
[5] Rockoff, Jonathan D. and Pui-Wing Tam. "Biotech Funding Gets Harder to Find." *Wall Street Journal*. 16 March 2012.
[6] IPO Task Force. "Rebuilding the IPO On-Ramp." October 2011.

among others, SOX seeks to protect investors through greater transparency. I support this goal. Large, multi-national corporations have thousands of investors and a complicated corporate structure that can be obdurately opaque to an outside observer.

In the biotech industry, an informed investor is a good one. However, the information that these investors want and need does not always align with what is required by SOX. Section 404(b) requires an expensive external attestation of a public company's internal controls, to be disclosed to investors on an annual basis. The true value of a biotech company is found in scientific milestones and clinical trial advancement toward FDA approvals rather than financial disclosures of losses incurred during protracted development terms. The business model of biotechnology is simple – we take in millions 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. Investors make their decisions based on scientific results and development milestones, not the statements and reports mandated by Section 404(b). Thus, the financial reporting required does not provide much insight for potential investors, meaning that the high cost of compliance far outweighs its benefits.

In fact, spending capital on regulatory burdens can actually slow the development process, increasing the time it takes to reach the important milestones that trigger new investments. Without product revenue, biotech companies on the public market are forced to ask investors to pay for SOX reporting rather than scientific research. The cost burden of these regulations, and therefore the amount of capital diverted from R&D, is significant. In 2011, an SEC study found the costs of Section 404 compliance to be nearly $1 million for companies with a public float between $75 million and $250 million.[7] We have done internal analysis at Vitae and arrived at a similar figure – if we decided to go public, it would cost us roughly $1 million annually to comply with SOX Section 404(b), to say nothing of the steep learning curve, and corresponding costs, that the first few years of compliance would entail. For a company with just 55 employees, compliance would cost nearly $20,000 for each person on our staff. This cost would be borne entirely by our investors.

Congress has taken some steps to relieve the cost of this regulatory burden. In 2010, Dodd-Frank provided a permanent exemption from Section 404(b) compliance for non-accelerated filers, those with a public float below $75 million. This change was welcome, and has allowed the smallest of companies on the public market to escape the costs of SOX. More recently, Congress passed the JOBS Act, providing emerging growth companies five years to transition onto the public market, during which time they are exempt from 404(b) compliance provided their revenues remain below $1 billion and their public float stays under $700 million.

This five-year exemption, in combination with the other regulatory allowances provided by the JOBS Act IPO on-ramp, is already proving alluring to growing biotech companies. Since President Obama signed the JOBS Act into law on April 5, 46 companies have taken the step toward the public market as an emerging growth company, either by filing a new S-1 or by taking advantage of the provision's retroactivity to December 8, 2011 and submitting an S-1/A to amend their existing filing. Of those 46 filers, 12 were biotech companies.[8] Further, I understand that many other companies are taking advantage of the confidential filing process made available by the JOBS Act. The fact that over a quarter of the emerging

[7] SEC, Office of the Chief Accountant. "Study and Recommendations on Section 404(b) of the Sarbanes-Oxley Act of 2002 for Issuers With Public Float Between $75 and $250 Million." April 2011.
[8] Analysis of post-JOBS S-1 and S-1/A filings. This data only includes companies which have filed publicly. The JOBS Act contains a provision allowing emerging growth companies to file a confidential draft registration statement with the SEC; the confidential nature of those S-1s makes them impossible to track.

growth companies that have filed publicly are from the biotech industry shows both the desire of growing biotechs to access the capital available on the public market and their reluctance to do so in the face of costly regulatory burdens.

While the five years of non-compliance in the JOBS Act will provide an easier transition period post-IPO, it remains the reality that the biotech development period is much longer than five years, and that small biotech companies will still be without product revenue after the on-ramp expires and SOX compliance kicks in. They will then be forced to ask their investors to pay for bureaucratic red tape rather than innovative research. Further, the JOBS Act did not address the needs of companies that are currently on the public market. These companies are already complying with Section 404(b), with no relief in sight. The cost of this compliance is millions of dollars of diverted funds for the company, and delayed medical breakthroughs for patients.

H.R. 6161, the Fostering Innovation Act

Rep. Mike Fitzpatrick has introduced legislation to relieve smaller companies of the cost burden caused by Sarbanes-Oxley and other onerous regulations. H.R. 6161, the Fostering Innovation Act, 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.

Rule 12b-2 establishes three distinct classifications by which public companies determine their filing status. A company's filing status carries with it a designation of its regulatory burden, designed to increase as a company gets larger and more complex. The filing status classifications are defined in terms of a company's public float:

- large accelerated filers – companies with a public float of more than $700 million;
- accelerated filers – those with a public float of more than $75 million but less than $700 million; and
- non-accelerated filers – companies with a public float of less than $75 million.

Because the filing statuses for accelerated and large accelerated filers 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.

Despite their simple corporate structure and lack of product revenue, many biotechs have a relatively high public float. Although Vitae is still private, we believe that if we filed for an IPO our public float could be in the $75 million to $250 million range that the SEC studied in 2011, as mandated by Dodd-Frank. Biotechs often find themselves grouped with the accelerated filers and obliged to comply with the numerous regulatory burdens attendant to that definition, including SOX.

Rep. Fitzpatrick's bill would raise the minimum public float requirement for accelerated filers to $250 million, classifying companies with public floats 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 impeding their growth with costly regulations. Many biotechs have public floats in or near that range, and the flexibility provided by H.R. 6161 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, regardless of public float, would be considered a non-accelerated filer. As I have mentioned, the most damaging facet of SOX for the biotech industry has been the diversion of investment funds from science to compliance in the absence of product revenue. Rep. Fitzpatrick's bill reflects this reality by classifying low-revenue companies as non-accelerated filers. If enacted, H.R. 6161 will ensure that critical innovation capital is spent on groundbreaking research and development rather than regulatory burdens.

Complying with non-accelerated filer standards rather than those required of accelerated filers would provide tremendous relief for growing companies. The exemption from SOX Section 404(b) alone would save innovative start-ups millions of dollars. Additionally, non-accelerated filers have a relaxed timeline for their quarterly disclosures because their small size and lack of a large compliance department make the filings more onerous – attributes shared by biotech companies currently in the accelerated filer bucket. Non-accelerated filers also enjoy certain allowances within those filings, including exemptions from Compensation Discussion and Analysis (CD&A) reporting, the elimination of certain disclosures about market risk and other risk factors, and exclusions for some financial data. These changes would allow small biotech companies to focus on their mission of delivering cures and treatments to patients who need them rather than time-consuming and costly reporting.

The regulatory allowances in H.R. 6161 would not extend to accelerated or large accelerated filers. The bill maintains the important investor protections required of these large companies while recognizing the simpler corporate structure of non-accelerated filers. Updating the filing status definitions in Rule 12b-2 would reflect the true nature of small public companies while maintaining important requirements for larger corporations. New definitions would group companies with common characteristics together, giving the SEC more accurate classifications and providing important regulatory relief to innovative startups.

Public Company Accounting Oversight Board (PCAOB)

Section 404(b) compliance for small public companies has received the bulk of the attention paid to Sarbanes-Oxley in the ten years since its enactment, but the law contained much more than this one provision. Notably, Title I of SOX established the Public Company Accounting Oversight Board (PCAOB). Better alignment of the interests of shareholders with the interests of independent audit committees and oversight authorities was an important objective of SOX.

I do believe overall audit quality has been improved as a result of PCAOB inspections and standard-setting. However, there are other areas of concern in which potential PCAOB action could place additional undue burdens on small public companies.

Last August, the PCAOB issued a concept release on auditor independence and asked for public comment on mandatory audit firm rotation. The concept release suggested that requiring public companies to change audit firms periodically would increase independence and skepticism in the audit report. However, I believe such a requirement could result in a prohibitive added cost to the public company, with very little added benefit to the investor. Increased audit fees, combined with a steep learning curve for each new audit firm, would greatly increase the cost burden on growing companies. Biotech companies in particular would bear the brunt of the proposed changes, as there are relatively few audit firms that

are familiar with our industry. Increased costs combined with an extended transition period to bring a new firm up to speed would distract from and delay the search for cures and treatments.

Additionally, the PCAOB issued another concept release last year to revise the standard audit report to include more information. While I do not object to the principle proposed, it is important to prevent such a requirement from placing significant increased liability on the auditor, thus greatly increasing costs for small public companies.

It is important to note – especially when debating the value of 404(b) compliance – that SOX did enhance corporate accounting in many ways. Sarbanes-Oxley took necessary steps to combat corporate accounting fraud by boosting penalties for such white-collar crime. I believe these steps aided in restoring investor confidence and continue to help weed out corporate bad actors. That said, as we acknowledge the ten year anniversary of SOX, Congress has the opportunity to reexamine which parts of the Act continue to provide important investor protections and which are driving businesses away from the United States through costly overregulation.

Closing Remarks

The biotechnology industry is a significant economic growth engine, directly employing 1.6 million Americans and supporting an additional 3.4 million jobs.[9] The goal of our industry is to find and deliver cures for the devastating diseases that each of us – personally or among families and friends – will likely have to face. But there are tremendous challenges to overcome. One of the most significant for the broad array of small companies that make up the biotech industry is funding the extremely high cost of conducting research. It forces us to be very efficient and careful with each dollar we are able to attract from investors.

When regulatory requirements exceed or do not align with the primary needs of the public or investors, that regulation becomes an unnecessary expense burden, meaningfully and directly subtracting from the investment capital driving the discovery and advancement of potential scientific breakthroughs. Some of the regulatory requirements imposed by Sarbanes-Oxley fit that definition. Those regulations increase bureaucracy and operating costs for biotech companies, taking away money from research, blocking job creation, and slowing the overall development of science in our labs. If Congress can relax this regulatory burden on small companies like those found in the biotech industry, it will allow innovators and entrepreneurs to continue working toward delivering the next generation of medical breakthroughs – and, one day, cures – to patients who need them.

[9] Battelle/BIO State Bioscience Industry Development 2012. Battelle Technology Partnership Practice, June 2012.