March 28, 2013

Elizabeth M. Murphy
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-1090

Re: Release No. 34-69030, File No. SR-NASDAQ-2013-032: *Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change to Require that Listed Companies Have an Internal Audit Function*

To whom it may concern:

The Biotechnology Industry Organization ("BIO") is pleased to submit comments to the Securities and Exchange Commission ("SEC") on File Number SR-NASDAQ-2013-032, a proposed rule change filed by The NASDAQ Stock Market LLC ("Nasdaq") that would require listed companies to have an internal audit function.

BIO is a not-for-profit trade association that represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 states. BIO members are working toward groundbreaking cures and treatments for devastating diseases, developing technologies for advanced biofuels and renewable chemicals, and researching novel gene traits for identifying food sources that could help combat global hunger.

In the biotechnology industry, it can take more than a decade and over $1 billion to bring a single life-saving treatment from laboratory bench to hospital bedside. For most companies, this entire process is undertaken without the benefit of product revenue. Early-stage biotechs 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.

As companies near the later stages of research and begin conducting expansive clinical trials in human patients, they often turn to the public markets for capital formation. Most biotechs will spend years on the public market or as a public company before engaging with the Food and Drug Administration ("FDA") to begin the approval process for a new medicine. During this time, using investment funds efficiently is of utmost importance. Because early-stage innovators do not have product revenue to fund their research, each investment dollar spent on compliance with regulatory burdens is a dollar diverted from scientific advancement.

The proposed rule change filed by Nasdaq would impose a significant burden on growing biotech companies by requiring them to conduct an expensive internal audit of the internal financial controls already required by law. BIO applauds Nasdaq for its commitment to investor protection, but the internal audit function proposal is overly burdensome, unnecessary, and has the potential to delay life-saving research.

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1. **A mandatory internal audit function would impose significant and unnecessary cost burdens on growing biotech companies.**

As discussed above, biotech companies face a decade-long, billion-dollar development timeline, and their research is supported by private investment capital rather than product revenue. Any funds spent on instituting and maintaining an internal audit function would be, by definition, lost to innovation.

Spending capital on regulatory burdens can slow the development process, increasing the time it takes to reach the important milestones that trigger new investments. Without product revenue, most biotech companies on the public market would be forced to ask investors to pay for the internal audit rather than scientific research. The cost burden of the proposed regulation, and therefore the amount of capital diverted from R&D, could be significant.

The proposed rule change is presumably intended to inform, and therefore protect, investors, and BIO supports this goal. 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 would be disclosed in an internal audit. 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 – growing innovators take in millions of dollars to fund their research and often do not earn a single penny in product revenue for more than a decade. Their science is the complicated part of their business, and it is the most important aspect for investors to understand. Investors mainly make their decisions based on scientific results and development milestones, not financial disclosures: tracking cash and expenses is fairly straightforward. The proposed audit obligation would not provide much insight for potential investors, meaning that the high cost of compliance would far outweigh its benefits.

While the science behind biotech research grows ever more interesting and complex as a company moves closer to a cure, the corporate structure of the company itself remains essentially unchanged. Over 90% of biotech companies have fewer than 100 employees, almost all located in one research lab. The balance sheet shows investment capital coming in and the income statement clearly shows research spending going out. From a scientific perspective, biotech companies are innovators expanding the world's understanding of human life. As corporations, they strive to stay as simple as possible so that the maximum amount of investment dollars can flow directly to R&D. Disrupting that flow by diverting research funds to an unnecessary internal audit could slow research and hamper growth – all while failing to increase investor confidence or spur capital formation.

2. **The option to outsource the internal audit to a third party service provider would not preserve flexibility, as the proposal suggests, but would instead further increase costs.**

The proposed rule change offers companies the option to outsource the internal audit function to a third party service provider in order to "preserve flexibility." In practice, biotech companies would be forced to choose this onerous option and the auditor fees associated with it.

Growing biotech companies have limited financial and personnel resources in their compliance and accounting departments. Often, a small company's compliance team is made up of just a handful of employees and the CFO. They lack the internal resources to

comply with the proposed rule change, and would therefore have no choice but to hire an independent auditor. Bringing in an external firm carries a significant cost burden – one that would have to be met by diverting funds from R&D. Further, internal resources would be similarly strained in order to educate and acclimate the external auditor to the unique business model inherent to biotechnology. Biotech companies incur administrative expenses judiciously in order to preserve investment capital, but the proposed rule would force their hand and strain resources that would be better spent on research.

Additionally, the number of auditing firms from which a biotech company may choose, when forced to do so by the third party "option," is limited by firms' expertise in the biotech industry. When biotech companies turn to the public market for innovation capital, the "Big Four" auditing firms are the ones best-equipped to evaluate their internal controls. The proposed rule prohibits companies from choosing their independent auditor to perform the internal audit function, cutting down an already limited pool of four to just three choices. Rather than preserve flexibility, the proposal would instead curtail the audit committee's options while further increasing costs.

3. **The proposed rule change would create a new regulatory burden that goes beyond Congressional intent, is duplicative with existing regulations, and increases compliance costs at a time when Congress and the SEC are taking steps to spur capital formation.**

In her recent testimony before the Senate Banking Committee, Mary Jo White, President Obama's nominee to Chair the SEC, stated her belief that "the component parts [of the SEC's mission] should not be viewed as in conflict with each other." Ms. White detailed the SEC's obligations to "protect investors, maintain fair, orderly, and efficient markets, and facilitate capital formation;" however, the proposed rule change would bring purported investor protection in direct conflict with the facilitation of capital formation. Requiring an internal audit function would impose unnecessary costs, divert funds from building and sustaining company growth, and hinder important capital formation, all while duplicating rules and regulations that Congress and the SEC have determined are sufficient to protect investors and support a healthy public market.

It remains the case that all public companies are required by law – specifically, by Section 404(a) of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley" or "SOX") – to maintain a system of internal controls. A company's management must attest to these internal controls, and can be held liable in the case of fraud. The proposed internal audit function is duplicative with this requirement, imposing an additional cost burden while not providing any new insights.

Congress has determined that Section 404(a) provides sufficient protections for investors in companies with a public float below $75 million. The Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank") provides a permanent exemption from SOX Section 404(b) for non-accelerated filers, declaring that the internal controls required by Section 404(a) are adequate for smaller issuers. The proposed rule change would go much further than the requirements set by Congress, ignoring Dodd-Frank's direction to reduce compliance costs for growing companies.

The proposed internal audit function is also duplicative and unnecessary for companies with a public float in excess of $75 million. Due to the high costs of conducting research and the successive rounds of financing necessary to fund it, biotech companies often exceed the $75 million limit in the non-accelerated filer definition and are thus classified as accelerated filers despite their simple corporate structure and lack of product revenue. Accelerated filers are

required by SOX Section 404(b) to hire an independent auditor to provide external attestation of a company's internal controls. This expensive audit already imposes significant costs on growing biotech companies, and the proposed internal audit function would be entirely duplicative with current law. Section 404(a) requires that a company maintain internal controls and Section 404(b) requires an external audit to attest to them – whatever information the proposed rule change purports to collect through an internal audit would surely be captured by these two existing requirements. Congress has determined that Sarbanes-Oxley provides sufficient protections to public company investors, so there is no need for the duplicative and costly burden that would be imposed by the proposed rule change.

In 2012, Congress passed the Jumpstart Our Business Startups Act ("JOBS Act"), Title I of which provides a five-year exemption from compliance with SOX Section 404(b) for emerging growth companies. The universe of emerging growth companies includes all non-accelerated and accelerated filers with annual revenues below $1 billion. Congress deemed, in an overwhelmingly bipartisan fashion, that the internal controls required by SOX Section 404(a) are sufficient for these companies when they first enter the public markets, and yet the proposed rule change would require an internal audit on top of Section 404(a) compliance. The JOBS Act was designed to reduce regulatory burdens and spur capital formation, but the proposed rule change would instead create new bureaucratic red tape and impose additional compliance costs.

4. The proposed rule change takes a one-size-fits-all approach rather than recognizing the unique nature of small public companies.

As noted above, Congress and the SEC have repeatedly recognized that smaller issuers are uniquely burdened by new and costly regulations, and that a one-size-fits-all approach forcing growing companies to comply with the same regulatory burdens as large and established corporations hampers company growth and impedes capital formation. For biotech companies, such burdens can delay research on important and innovative new medicines.

The SEC's non-accelerated filer definition provides numerous exemptions and allowances for smaller issuers. Dodd-Frank exempts small companies from SOX Section 404(b) compliance. The JOBS Act allows growing businesses five full years of regulatory relief so that they can establish themselves on the public market and successfully raise important capital. And yet, the proposed rule change imposes a one-size-fits-all approach, setting the same standard for pre-revenue small businesses as it does for multinational corporations. This lack of awareness for the unique nature of small company innovators inflicts upon them a new and costly regulatory structure that is far more harmful to them than their more-established peers. This concern is not unique to the biotechnology industry, but is applicable to a wide swath of small businesses that need to dedicate their limited resources to creating products and services that will lead to sustainable growing businesses, adding jobs and spurring growth in the U.S. economy.

The proposed rule change mentions that the New York Stock Exchange ("NYSE") has a similar internal audit function requirement, but fails to note the different issuer constituencies served by Nasdaq and NYSE. Many small cap, emerging biotech companies choose to list on Nasdaq, in part due to its flexibility with regard to smaller issuers. These growing companies have already shown that they can successfully comply with existing rules and regulations absent the requirement to establish and maintain an internal audit function. Forcing all issuers listed on Nasdaq to implement an internal audit would unnecessarily burden these small businesses as they access capital on the public market.

The appropriateness of an internal audit should be determined by the needs of an individual business. Generally, the key driver for an internal audit function is the complexity and diversity of a company and the number of sites and people involved in the audit. If a business grows large and complex enough, the key decision-makers charged with maintaining its financial health (whether the CFO, controller, or audit committee) can choose to implement an internal audit if they feel it is appropriate for their business and their investors. However, for industries like biotechnology with a simple corporate structure and easy-to-track cash flow, this is rarely necessary – and even less so for the emerging innovators that the rule change makes no effort to protect. Taking decisions out of the hands of the individuals who know the company the best by forcing every listed company to institute the proposed rule change would be onerous, costly, and ultimately bad for business.

In summary, a mandatory internal audit function would be unnecessary, costly, and damaging to company growth and capital formation. In the biotech industry, investment capital flows directly to groundbreaking research, funding scientific advances that could save patients and improve their quality of life. The proposed rule change would force biotech innovators to divert valuable innovation dollars from science to compliance. BIO urges the SEC consider the unintended adverse consequences that mandating an internal audit function would have on small public companies in the biotech industry and disapprove the proposed rule change.

If you have any further questions or comments, please contact me or Charles Crain, Manager of Policy and Research, at (202) 962-9218.

Sincerely,

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