August 30, 2016

Brent J. Fields
Secretary
Securities and Exchange Commission
100 F Street NE
Washington, DC 20549-0609

Re: File No. S7-12-16: *Amendments to Smaller Reporting Company Definition*

To whom it may concern:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comment to the Securities and Exchange Commission (SEC) on File No. S7-12-16, its proposed rule to amend the smaller reporting company (SRC) definition. The SEC's issuer classifications directly impact BIO members – both those trading on the public market and those considering a future IPO to fund their research – and we are hopeful that the final rule will reform the small company definitions under Regulation S-K, Rule 12b-2, and Rule 405 in such a way that fulfills the SEC's tripartite mission to facilitate capital formation, maintain fair, orderly, and efficient markets, and protect investors.

BIO represents more than 1,100 biotech companies across the United States, the vast majority of which are pre-revenue innovators. These emerging biotechs do not generate product revenue, so they turn to the public markets for funding to support the decades-long, billion-dollar search for the next generation of medical breakthroughs. BIO supports a regulatory regime that enhances their access to capital while also allowing these groundbreaking companies to focus investor funds on life-saving research.

The SRC and non-accelerated filer definitions are vital components of the SEC's framework for small company regulation. By providing growing businesses with scaled disclosure opportunities, these issuer categorizations allow for important cost savings that decrease the amount of innovation capital diverted from the lab. As such, BIO applauds the SEC for considering expansions of these classifications in order to "promote capital formation and reduce compliance costs for smaller registrants while maintaining investor protections."

BIO commends the SEC for taking the encouraging first step of proposing an increased public float threshold for the SRC definition, and we urge the SEC to extend this commonsense reform to the non-accelerated filer definition as well. We also support an alternative revenue test for both definitions to ensure that pre-revenue companies who may be highly valued are not improperly classified.

1.) BIO supports the proposed reforms to the smaller reporting company definition.

The proposed rule would allow companies with a public float below $250 million to qualify as SRCs, a significant change from the current $75 million public float cap. In the absence of public float, the proposed rule would allow companies to qualify based on a $100 million revenue test, an increase from the $50 million test in the existing definition. BIO believes that these changes, which would increase the number of small companies eligible to provide

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scaled disclosures under Regulation S-K and Regulation S-X, would more accurately reflect the nature of emerging businesses and allow them to tailor their compliance obligations accordingly.

Resource efficiency is of paramount importance to emerging biotechs. Because every dollar spent on regulatory compliance is a dollar diverted from scientific advancement, biotech small businesses can be harmed by costly reporting requirements. Furthermore, many one-size-fits-all disclosure burdens do not provide meaningful insights for biotech investors, for whom clinical trial results and scientific data are more material concerns.

It is worth noting, as the proposing release does, that the reduced disclosures are optional for SRCs, and that all businesses are required, regardless of individual line-by-line mandates, to further provide any material information that would impact a reasonable investor's decision. This flexibility will allow investors in companies with a public float below $250 million to receive all relevant information about an issuer while permitting small businesses to avoid an overly prescriptive disclosure framework. Furthermore, companies are always incentivized to be responsive to their investors; if the market demands a certain disclosure, SRCs will likely provide it, regardless of whether it is technically required by the SEC.

BIO believes it is important that the flexibility allowed by SRC status apply to all SRCs. The proposing release solicits comment on whether "larger registrants [should] be limited in their ability to avail themselves of some of the scaled disclosure accommodations" available to SRCs. BIO's opinion is that SRCs should not be divided into additional subgroups, with the SEC cherry-picking which issuers count as real SRCs and which are only quasi-SRCs – and thus ineligible for some benefits of SRC status. The release notes that allowing scaled disclosures for *all* new SRCs is "unlikely to have a significantly negative effect on the overall information environment of smaller reporting companies." There is simply no reason to limit the benefits of SRC status to only a small subgroup of SRCs.

The proposing release also solicits general comment on whether the thresholds for SRC status should be raised, whether the proposed standards appropriately balance capital formation and investor protection, and whether the proposed reforms would promote capital formation and liquidity. To each of these questions, BIO emphatically answers *yes*.

2.) <u>BIO urges the SEC to adopt reforms to the non-accelerated filer definition in order to expand eligibility for the permanent exemption from Sarbanes-Oxley Section 404(b) established by Dodd-Frank.</u>

In 2013, and again in 2015, the Advisory Committee on Small and Emerging Companies (ACSEC) recommended that the SEC reform the definition of accelerated filer. Specifically, the Advisory Committee called for the accelerated filer definition to include companies with a public float between $250 million and $700 million, an adjustment to the existing $75 million to $700 million range. "As a result of such revision," the Committee wrote, "the requirement to provide an auditor attestation report under Section 404(b) of the Sarbanes-Oxley Act [SOX] would no longer apply to companies with public float between $75 million and $250 million." By reducing the number of companies considered an accelerated filer, this proposal would broaden the universe of non-accelerated filers and, as the ACSEC's proposal notes, expand Dodd-Frank's permanent exemption from SOX Section 404(b).[1]

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[1] Throughout this letter, we use the term "non-accelerated filer" to mean a company that is neither an accelerated filer nor a large accelerated filer. Under Rule 12b-2 in its current form, this encompasses all companies with a public float below $75 million. Though "non-accelerated filer" is not technically defined in Rule 12b-2, Section 989G of Dodd-Frank gives it the meaning described here, and we therefore use "non-accelerated filer" to provide a

The collection of companies identified by the ACSEC – those with a public float above the current SRC and non-accelerated filer cap of $75 million, but below $250 million – are the very ones granted new scaled disclosure allowances by the SEC's proposal on the SRC definition, but the SEC has declined to extend its SRC reforms to the non-accelerated filer definition.

SOX Section 404(b) is extremely costly for emerging businesses, far more so than the line item disclosures in Regulation S-K. Congress recognized this reality when it exempted non-accelerated filers from SOX 404(b) compliance in Dodd-Frank, and again when it exempted emerging growth companies (EGCs) in the JOBS Act.[2] BIO strongly believes that the SEC should apply any reforms it makes to the SRC definition to the non-accelerated filer definition in order to broaden the exemption from Section 404(b)'s costly external auditor attestation requirement.

For years, the SEC Government-Business Forum on Small Business Capital Formation has made a similar request. In 2015, the Forum's recommendation specifically called for identical reforms to the SRC and non-accelerated filer definitions.[3] In addition to definitional recommendations each year since 2009 (which would of course have the effect of modifying SOX and Regulation S-K compliance), the Forum also specifically recommended from 2009 to 2012 that the Dodd-Frank SOX 404(b) exemption be extended to a broader universe of companies. In 2009 and 2010 the proposed public float ceiling was $250 million; in 2011 and 2012 it was $500 million. The JOBS Act, passed in 2012 and based on recommendations from the Forum, includes a time-limited $700 million ceiling. It is clear that support for a broader exemption from Section 404(b) is widespread, and has been for years.

From a simple consistency standpoint, it makes little sense for the SEC's two small company definitions to diverge so dramatically. How can a smaller reporting company *not* be a non-accelerated filer? Rule 12b-2, as it currently stands, explicitly forbids such an incongruity (though the SEC is proposing to do away with that provision). The two definitions are often used interchangeably; many issuers with a public float under $75 million would (erroneously) report that their SRC status grants them a SOX exemption. Even the ACSEC gets the terms confused – a 2015 ACSEC recommendation on the SRC definition says that adopting its proposal would provide a broader range of companies with an "exemption from [the] auditor attestation requirement." In BIO's view, uniformity alone is a sufficiently compelling argument to align the two definitions. Avoiding investor confusion is an important responsibility of the SEC, and issuers and investors alike are used to having one standard for small company status.

More important than consistency, however, is the significant burden that Section 404(b) compliance imposes on an emerging biotech company. As noted already, high regulatory costs represent a damaging diversion of innovation capital from science to compliance. Because pre-revenue small businesses utilize only investment dollars to fund their work, they place a high value on policies that prioritize resource efficiency. Any policy that increases the flow of capital to emerging companies could lead to funding for a new life-

parallel with the SRC definition (which is also currently defined at $75 million in public float). The proposing release solicits comment on amendments to the accelerated filer definition; any comments we offer on non-accelerated filers should be understood to respond to this solicitation.

[2] It is worth noting that the EGC definition (and associated SOX 404(b) exemption) set by Congress – annual revenues below $1 billion and public float below $700 million – is much more far-reaching than any proposed definition for SRCs or non-accelerated filers.

[3] The proposing release cites the SRC half of the proposal, but neglects to mention the non-accelerated filer half.

saving medicine – while any policy that diverts capital to unnecessary and costly regulatory burdens, like Section 404(b), could lead to the same treatment being left on the laboratory shelf. As noted in the SEC's own SOX study, that capital diversion can total nearly $1 million every year.[4]

The SEC's proposing release is quite clear about the benefits of scaled disclosures for small companies. It notes that compliance costs "typically burden[] smaller registrants disproportionately" and that the SEC's small company definitions "facilitate small business capital formation and reduce the compliance burdens placed on small registrants." Furthermore, it predicts that capital and other resources currently devoted to compliance could be "productively deployed in alternative ways" (such as life-saving research?) if the proposal is adopted. BIO is simply asking for this line of reasoning to be applied to the non-accelerated filer definition as well as the SRC definition.

In explaining why it is declining to reform the non-accelerated filer definition, the proposing release declares that the SEC believes that companies with a public float between $75 million and $250 million do not have "sufficiently unique characteristics" that differentiate them from larger issuers. Yet is the entire proposing release not predicated on the proposition that sub-$250 million issuers are "sufficiently unique" and thus deserving of scaled disclosure requirements under Regulation S-K? What makes a small issuer "sufficiently unique" to qualify as an SRC, but not unique enough to be a non-accelerated filer?

In reality, all companies with a public float below $250 million should be considered both SRCs and non-accelerated filers. The additional 782 "sufficiently unique" registrants that would qualify under this new definition represent just 0.02% of the total public float on the market – a share so small that any possible risks to investors (which BIO contends are minimal in the first place) are dramatically, insurmountably outweighed by the cost savings for small businesses and growing innovators.

Furthermore, each of these newly exempt non-accelerated filers would retain the right to comply with Section 404(b) if the market demands it. As the proposing release notes, these companies "would weigh the costs and benefits of scaled disclosure for themselves and decide whether to take advantage" of the exemptions afforded by their new filing status. Allowing these issuers and their investors the flexibility to determine for themselves whether Section 404(b) is relevant to their business – as the SEC proposes to do with Regulation S-K through its reforms to the SRC definition – would represent a commonsense change that supports small businesses, enhances capital formation, and allows emerging biotechs to focus on life-saving R&D.

3.) <u>BIO supports an alternative revenue test for highly valued pre-revenue companies to qualify as SRCs and non-accelerated filers.</u>

Under the current definitions, many businesses that would be considered "small" by any reasonable observer are excluded from the SRC/non-accelerated filer universe because investors are optimistic about their future progress and thus value them highly. A high valuation means a high public float, and a corresponding loss of SRC and non-accelerated filer status. Because these definitions do not accurately capture what makes a company "small," emerging biotechs must often endure a compliance burden identical to that faced

[4] The 2011 study found that companies with a public float between $75 million and $250 million spent, on average, $840,276 on Section 404 compliance when taking into account the direct costs of a Section 404(b) audit and the outside vendor to conduct it plus the more indirect costs of internal labor and other non-labor costs.

by commercial leaders and multinational corporations. As such, BIO believes that the SEC should move away from its reliance on public float as the ultimate arbiter of company size. BIO urges the SEC to adopt a revenue-only test as an alternative to the existing public float standard in both the SRC and non-accelerated filer definitions.

Specifically, BIO supports the recommendation made by the 2015 Government-Business Forum, which proposed that "an issuer with annual revenues of less than $100 million…and a public float of less than $700 million" be considered both an SRC and a non-accelerated filer. The Forum also recommended an identical revenue test in 2014, 2013, and 2012, and an even broader test (without the $700 million public float cap) in 2010 and 2009.

The economic analysis section of the proposing release examines the impact of an alternative revenue test of $100 million, without the $700 million public float limitation proposed by the Forum and supported by BIO. The release finds that only 201 companies would be eligible for the new revenue test (assuming the SEC adopts the expanded public float test as proposed). Furthermore, the release reports that the average public float of these companies is $769 million, which means that a significant number would not qualify under a revenue test with a $700 million public float cap. Ultimately, an alternative revenue test would impact fewer than 200 companies, a significant percentage of which are the very pre-revenue innovators that BIO represents.[5]

This is an extraordinarily small universe of issuers – but these businesses are the very ones who would most benefit from scaled Regulation S-K disclosures and an exemption from SOX Section 404(b). Their investors want them to remain hyper-focused on innovation, and they certainly don't want their investment funds diverted away from scientific advancement in the absence of product revenue. This is why revenue would be such an effective determinant of a company's regulatory obligations. Pre-revenue small businesses simply do not have the capital to pay for expensive compliance requirements, so allowing them to qualify as SRCs and non-accelerated filers until they generate revenue would be a targeted, commonsense reform that stimulates innovation and drives business growth.

Conclusion

BIO applauds the SEC for being willing to reexamine its small company classifications. We also commend the Advisory Committee on Small and Emerging Companies and the Government-Business Forum on Small Business Capital Formation for taking the lead on this important issue.

As the SEC considers how to craft the SRC and non-accelerated filer definitions, BIO urges it to consider the impact that costly regulations can have on emerging companies. Our members strive to protect investors by keeping them informed – indeed, it is imperative that they appreciate both the perils of groundbreaking science and the promise of our life-saving work. But the costs of one-size-fits-all compliance requirements outweigh the benefits for growth-stage businesses. The very existence of the SRC and non-accelerated filer categories acknowledges that some regulatory burdens are not appropriate for smaller issuers.

We are encouraged that the SEC understands that the current SRC definition does not fully encompass the diverse universe of growing companies and that the proposing release reforms the SRC classification accordingly; we simply hope that the final rule acknowledges that the non-accelerated filer definition is similarly limiting. Reforming these two

[5] 41.5% of the 201 registrants studied are in the "Pharmaceutical Products" industry.

classifications, and including revenue as a component in that determination, would represent a dramatic change in our members' ability to access capital on the public market and to put that capital to work developing medicines for patients in need.

BIO looks forward to working with the SEC to make certain that the SRC and non-accelerated filer definitions accurately reflect America's small businesses. If you have further questions or comments, please contact Charles Crain, Director of Tax & Financial Services Policy, at [redacted].

Sincerely,

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