Biotechnology Innovation Organization

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March 21, 2019

Ms. Vanessa Countryman
Acting Secretary
Securities and Exchange Commission
100 F Street, NE
Washington, DC 20549-1090

Subject: Comment on Earnings Releases and Quarterly Reports

File Number: S7-26-18

Dear Ms. Countryman:

The Biotechnology Innovation Organization ("BIO")[1] appreciates the opportunity to comment on the nature and timing of disclosures that reporting companies are required to provide in their quarterly reports filed on Form 10-Q. BIO member companies vary in size—ranging from smaller reporting companies (SRCs) and emerging growth companies (EGCs) to large accelerated filers. Regardless of size, biotech innovators have unique business models and are heavily invested in research and development to pioneer breakthroughs to heat, feed and fuel the world.

BIO believes that the current quarterly reporting framework places an unhealthy emphasis on meeting or exceeding forecasts, which engenders an inefficient outlook on short-term results. Due to the lengthy timeline for drug development, which averages 10-15 years, biotech companies benefit from patient capital where investors seek long-term growth of companies delivering breakthroughs in scientific innovation that benefit patients and investors alike. By contrast, the current reporting system requires corporate managers to spend an inordinate amount of time and resources to prepare quarterly financial disclosures on which investors and industry analysts fixate. BIO supports the Commission's efforts to modernize the reporting regime to enable and encourage registrants to focus on demonstrating progress made against the company's long-term strategic plan.

BIO encourages the SEC to modify the financial reporting regime to a semiannual (rather than quarterly) basis for smaller registrants, to improve the efficiency and attractiveness of being a public company. SRCs and EGCs have less complex business structures and financial reporting issues than larger registrants, and a less frequent disclosure basis would enable them to focus their limited resources on long-term strategy to maximize strategic investments necessary to provide a return to their shareholders. This change is particularly important for companies in the life sciences sector that have not yet achieved commercial

[1] BIO is the world's largest trade organization in the biotechnology sector, representing over 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States.

stage, e.g. do not yet have recurring cash-generating revenue, either via their own product sales or royalty streams, as they advance their research and development to make breakthrough drug discoveries. Just as the Jumpstart Our Business Startups (JOBS) Act eased the initial public offering (IPO) onramp for innovative startup companies, we believe a less frequent reporting model would lessen the burden of being a public company and would likely further promote capital formation.

We also support the Commission providing additional flexibility by permitting companies to select an approach to periodic reporting that best suits their needs and the needs of their investors. For the life sciences sector, for instance, it would be beneficial for public companies to be able to adopt more frequent reporting as they advance in commercial stage. Granting SRCs and EGCs such flexibility with regard to the frequency of their reporting would still provide investors with the material information they need to make informed decisions, but it would reduce some of the burden of the current quarterly reporting system.

BIO's specific responses to the questions included in the SEC's request for comment are as follows:

1. Why do reporting companies choose to issue earnings releases, most typically quarterly? What are the costs to such companies in preparing earnings releases? Would companies choose to stop issuing these releases if disclosure of quarterly results was not required on Form 10-Q, or would this provide a greater incentive to issue them? Why do some companies choose to file only a Form 10-Q report and not to issue a separate earnings release?

Public biotechnology companies often choose to issue earnings releases to provide a summary of key financial results, including highlighting certain aspects of Form 10-Q or 10-K that may be contained in the footnotes but important to their investor base (e.g. stock-based compensation or other significant non-cash items, a recap of business and operating highlights and achievements, near-term milestones, and other prospective commentary/guidance). The costs of preparing such earnings releases are minimal relative to the cost of preparing either Form 10-Q or 10-K. If disclosure of quarterly results were not required on Form 10-Q, biotech companies would likely issue limited yet pertinent financial information to their investors, e.g., cash balance, cash burn rate, working capital and debt, and would continue to provide a summary of business and operating highlights, as well as some prospective commentary and guidance.

2. Do quarterly earnings releases provide benefits to investors, companies, or the marketplace separate and apart from the Form 10-Q report? If so, please describe the primary benefits. How do investors use earnings guidance to inform their investment decisions? To the extent there are benefits, do they stem largely from the content of the releases, their timing, or other reasons? Do they have any negative effects on investors, companies, or the marketplace? If so, please describe such effects.

Biotech companies often elect to issue quarterly earnings releases in addition to Form 10-Q. The benefit of issuing earnings releases for public biotech companies is that it allows their investors to focus on key indicators, including: progress on product development, clinical trials and regulatory approval, rather than the traditional financial metrics supplied by Form 10-Q. The summary nature of the earnings releases also provides biotech investors with quicker and more clear information, which should benefit investors that are analyzing multiple companies. Biotech investors tend to value information about the variables that will determine whether the company will ultimately succeed or fail to develop the next innovative breakthrough—such as the science and technology underpinning company's potential, the diseases it could treat, the patient population that could be impacted, the FDA approval pathway, and the progress the company is making toward product development, among others. In short, the information that is material to biotech investors is unique because companies are so dependent on the development and success of their drug candidates in clinical trials. Form 10-Q provides much more comprehensive and voluminous financial data, and thus companies often elect to issue a supplemental earnings release to highlight the information of interest to their investors, such as: (a) important financial indicators including cash position, R&D expenses, G&A expenses, and shares outstanding; (b) material updates on their portfolio of drug candidates (e.g. planned and ongoing clinical trials, clinical trial data, etc.); and/or (c) material developments in their path toward regulatory approval and commercialization of their drug candidates. The *content, timing and user-friendliness* of the information disclosed in earnings releases is valuable to biotech investors. Biotech companies tend to believe that their investor base utilizes earnings guidance to inform their investment decisions (e.g., to form or change their interest in the current or prospective value of the company). We are not aware of any negative effects that earnings releases have on investors, companies or the marketplace more generally.

3. How do companies determine the information to present in the earnings release? Is there a market standard, or are companies otherwise generally consistent in the type and amount of information they present in earnings releases? To what extent is the content of earnings releases provided in response to investor and analyst needs or demands? Are such releases satisfying those needs? How would the content of earning releases change if they were required to be filed with the Commission and become subject to applicable liability provisions?

Biotech companies typically present updates in their earnings releases on information needed by research analysts or investors covering their companies, and also reiterate key prior announcements that may have new or different contextual significance during that period of time. While there is no market standard, biotech companies generally present consistent information to investors in earnings releases. Biotech companies that have recently gained commercial status with a drug approved by the FDA, for instance, often focus on summarizing key achievements made during the quarter, such as patient enrollment (START) forms, which indicate key progress in commercializing new drug discoveries for biotech companies. Companies may also elect to highlight key non-GAAP financial results in the earnings releases, whereas Form 10-Q does not allow them to use those adjustments under US GAAP. Biotech companies, to a large extent, present information in earnings releases that are important to and demanded by their investors and analysts. The content of earnings releases would change very little if they were required to be filed with the Commission and became subject to applicable liability provisions. Biotech companies generally prepare earnings releases with the same accuracy and rigor as the information contained in Forms 10-Q or 10-K. However, the 10-Q or 10-K filings report other financial indicators, such as net product revenues for commercial companies.

4. Is the Form 10-Q or the earnings release the primary document upon which investors rely when a company provides both? What are the factors or circumstances that an investor considers when determining which document to rely on? Are there any benefits to investors and other market participants from having two sources of historical quarterly financial information, when only one is required? How do investors use quarterly financial information, and how does it inform, if at all, their investments decisions made throughout the year? Are there specific pieces of quarterly information that are important to long-term investors?

Biotech investors seem to rely more heavily on earnings releases rather than the Form 10-Q. Biotech investors likely find it valuable to have more timely access to the earnings release that is more user-friendly and provides clearer, readily assimilable information without sacrificing information accuracy and reliability. We are unaware of any meaningful benefits to investors from having two sources of historical quarterly financial information when only one is required. Investors likely use quarterly financial information differently depending on their investment horizons and philosophies; but biotech investors typically value information that updates them on near-term milestones, progress on advancing clinical trials and research and development, and potential financing events.

5. Are there meaningful differences between the financial information typically provided in an earnings release and the financial information required by Form 10-Q? What accounts for the differences?

It is unlikely that there are "meaningful differences" between financial information provided in earnings releases versus what is reported in Form 10-Q. Relevant financial data from Form 10-Q or 10-K is typically summarized in earnings releases.

6. When a company issues an earnings release that includes much of the information required by Form 10-Q before the form is filed, is the Form 10-Q still useful? Why or why not? How important to investors is the confirmation or interpretation by the Form 10-Q of the information in the earnings release? If investors rely on Form 10-Q as the primary document, is the historical financial information about the quarterly period included in the earnings release useful? Why or why not? Does the fact that Form 10-Qs are filed as opposed to furnished, and include certifications, impact the extent to which investors rely on them? Are there any instances when information disclosed in earnings releases may be useful to investors for purposes of interpreting the content of Form 10-Q? If so, when and how?

It does not seem that biotech investors gain value from Form 10-Q or 10-K when an earnings release is issued separately, as it is simply redundant information. In the experience of biotech companies, investors seldom depend on Form 10-Q to confirm or support information disclosed by the company in the earnings release. Additionally, we do not believe that investors rely more heavily on Form 10-Qs because they are filed and include certifications.

It is possible (albeit unlikely) that information disclosed in earnings releases is useful to investors to interpret Form 10-Q. For instance, if the earnings release coincides with another business announcement (such as collaboration or partnership arrangement), the CEO quote or a quote from the third party company would help investors interpret developments in Form 10-Q.

7. Does confusion arise from overlapping disclosures in the earnings release and Form 10-Q? If so, are there changes we could make to our rules that would discourage the practice of providing earnings releases that contain information that is different than what is contained in Form 10-Q? Are there unnecessary burdens to investors or other market participants associated with reviewing, comparing, and digesting two presentations of similar financial information?

We do not believe that confusion arises from overlapping disclosures in the earnings release and Form 10-Q, as companies spend resources (internal, legal and auditors) to detect and mitigate such overlap. Rather, we believe that investors rely principally on the earnings release, without feeling compelled to corroborate the information with the 10-Q or 10-K. Yet it may pose unnecessary burdens to investors or other market participants to review, compare and digest separate reports of financial information (which may include redundancies).

8. Some have suggested that the practice of providing quarterly forward-looking earnings guidance creates an undue focus on short-term financial results and thereby negatively affects the ability of companies to focus on long-term results. Is this the case and, if so, are there changes we could make to our rules that would discourage this practice or address this concern? For example, should we require that earnings guidance be filed with or furnished to the Commission? Are there other factors that promote a focus on short-term results? If so, what are they and what is their impact on investors and companies?

BIO members agree that the quarterly reporting framework creates an undue and unhealthy focus on short-term financial results and on meeting or exceeding short-term forecasts. To ameliorate this concern, the SEC could change the frequency of financial reporting from quarterly to semi-annually. We do not believe it is necessary or beneficial to investors to require that earnings guidance be filed or furnished to the Commission and would instead impose additional burdens on companies.

9. What are the specific benefits of the required Form 10-Q disclosures to investors and the marketplace separate and apart from the earnings releases? Do they stem largely from the incremental financial statement disclosures, incremental management discussion and analysis, auditor review, officer certificates or other items? Are there sections of the Form 10-Q that are particularly informative for investors? Are there any quarterly disclosure requirements that we should eliminate because they elicit disclosures that are not material to investors to make it easier for investors to focus on the disclosures that are material? If so, which requirements should be eliminated?

The specific benefits of Form 10-Q disclosures are the management discussion and analysis (MD&A), specifically "liquidity and capital resources" section, and the Statement of Cash Flows, which provides meaningful information to investors on cash flows essential to the short-term and long-term viability of the company.

We encourage the SEC to reconsider certain quarterly requirements that are not material to investors. For instance, the "Risk Factors" section on Form 10-Q is generally too voluminous and could be improved by focusing it only on significant changes from the most recently filed 10-K.

10. Do the XBRL requirements of Form 10-Q enhance accessibility and/or usability of quarterly information relative to what is available from earnings releases, which are not required to be structured for machine readability or processing? If so, how is that information used and by whom? Would similar benefits be achieved if companies structured earnings releases using XBRL? Why or why not? How would the costs of structuring earnings releases in XBRL compare to the costs of complying with the XBRL requirements for Form 10-Q?

XBRL data is little-used by biotech investors, yet the costs of preparing the data remain significant for smaller registrants. Thus, the cost of XBRL requirements are high for small and emerging biotech companies, while the benefits are low for investors. We do not believe structuring earnings releases in XBRL would improve the reporting framework or outcomes for investors.

11. What is the impact of the auditor review requirement of quarterly financial information on investors, companies, and other market participants? Do investors value the independent auditor review of quarterly financial information? Why or why not? Does the auditor review requirement have a relationship to the cost of capital for companies? If so, how?

Individual investors may value the auditor review of quarterly financial information differently, as it may provide an additional level of comfort to them. However, we believe investors generally assume the accuracy and reliability of disclosures provided by companies with or without independent auditor review. The auditor review requirement poses a meaningful cost to the company both in terms of fees paid to the auditor as well as use of significant internal resources and time as part of the review and audit process. Yet we do not believe that its presence or absence impacts the cost of capital significantly. In the case of underwritten offerings, companies do have to pay for the auditor comfort letter.

12. What are the cost burdens associated with the preparation of a Form 10-Q? Are these cost burdens borne solely from the preparation of the Form 10-Q? How do the costs of preparation vary among different sections of the report? Would there be costs to a company to the extent it does not file a Form 10-Q? Would additional cost burdens be associated with the preparation of a registration statement in which a company would otherwise incorporate by reference a previously filed Form 10-Q?

The cost burdens associated with the preparation of Form 10-Q are significant for companies. Those costs stem from external consulting assistance on technical accounting matters, internal individuals and systems specifically retained for SEC reporting preparation purposes, multiple levels of internal review of the document, as well as significant costs for external legal and independent auditor reviews. Yes, these cost burdens are borne solely from the preparation of Form 10-Q. The most expensive parts of the report are the financial statements and footnotes, followed by MD&A and Risk Factors. There would be costs to a company to the extent it does not file a Form 10-Q but it would be a relatively small fraction of the cost of preparing the report. Additional cost burdens would be associated with the preparation of a registration statement in which a company would otherwise incorporate by reference a previously filed Form 10-Q, assuming it would be required to have current 10-Q information in the registration statement.

13. Are there other sources of information investors use to supplement information from earnings releases or quarterly reports? If so, please describe these sources.

Other sources of information relevant to the biotech industry on which investors and analysts rely are press-releases of significant events reported on Form 8-K, and scientific publications the company presents at conventions and industry events. This underscores that financial information is not the primary focus of biotech investors, but rather the scientific progress the company is making.

14. Are there approaches the Commission should consider to help alleviate any burden associated with the preparation of a Form 10-Q without adversely affecting the total mix of information provided to investors? For example, should we permit

companies to omit certain disclosures currently furnished on Form 10-Q, such as unregistered sales of securities, so long as the information is provided elsewhere, such as on their websites? If so, should the information provided elsewhere be expressly incorporated by reference into the Form 10-Q, such that the same liability attaches to the disclosure of that information? What would be the benefits and drawbacks to investors and other market participants of such additional flexibility?

BIO encourages the Commission to eliminate the auditor review requirement, and limit quarterly financial disclosures to key financial metrics (focusing on what is relevant and material to companies' investors, such as cash-related data for small- and mid-cap biotech companies) and updates to significant annual financial information disclosures.

Timing of the Quarterly Review Process

15. One study indicates that the "average public company needed 31.7 days to announce its earnings . . . and another four days after that to file its formal quarterly report." The study finds that companies that release both documents on the same day tend to "take more time to deliver those pronouncements," while companies that publish an earnings release "soon after the end of the quarter take more time to file their quarterly report." Why do some companies publish an earnings release before filing Form 10-Q while other companies publish an earnings report and file Form 10-Q on the same day or near the same time? Should the Commission take any action to address time lapses between an earnings release and Form 10-Q, and if so, what action? If the Commission should take action to facilitate a decrease in this delay, what is the best mechanism to facilitate such a decrease? Is it more or less burdensome to issue the two documents concurrently?

Companies that release both the earnings release and Form 10-Q likely do so for several factors, including to: (i) be included, along with their competitors, in the "earnings season" window for analysts; (ii) open financial results-based "trading windows" earlier (rather than waiting for the 10-Q or 10-K filing date); and (iii) address timing needs to disclose information publicly in other forums, e.g., investor conferences. No, we do not believe that the Commission ought to take action to address time lapses between an earnings release and Form 10-Q. It is considered less risky and potentially less burdensome to companies to issue the two reports concurrently.

16. What is the impact on investors and other market participants participating in earnings calls when a company publishes its earnings release before filing its Form 10-Q? Are investors or other market participants disadvantaged at the time of the earnings call by not having access to the more detailed information contained in the Form 10-Q? If so, what are those disadvantages? Do the same disadvantages exist for the fourth quarter earnings release in comparison to the filing of Form 10-K?

BIO believes that investors appreciate earlier, summarized earnings releases over later, more voluminous information contained in Form 10-Q. Investors or other market participants are not disadvantaged at the time of the earnings call by not having access to more detailed information contained in Form 10-Q.

17. To what extent are auditors involved with earnings releases? Does such involvement or the auditor review of the quarterly financial statements contribute

to any delay between publication of an earnings release and the filing of a Form 10-Q? If so, how? What steps could or should be taken to help ameliorate this delay? Do auditors conduct their review of quarterly financial information in phases due to companies' preparation of two reporting documents? If so, does this result in efficiencies or inefficiencies based upon the nature of the two disclosure documents?

Auditors review the earnings release for accuracy and consistency with their review findings. In the case that the earnings release is issued concurrently with the Form 10-Q, then auditor review includes a comparison to relevant 10-Q content. The auditor review process does contribute to the delay between publication of an earnings release and the filing of Form 10-Q, as general reviews take several days/weeks to complete and document. In addition, the auditor prepares a quarterly review report and related presentation to the company's audit committee. To ameliorate this delay, the SEC could eliminate the auditor review requirement, and limit quarterly financial disclosures to key financial metrics and updates to significant annual financial information disclosures. No, auditors do not generally review quarterly financial information in phases due to companies' preparation of two reporting documents.

Earnings Release as Core Quarterly Disclosure

18. To what extent do companies take advantage of General Instructions D.1 and D.2 of Form 10-Q to satisfy the requirements of Form 10-Q? What changes to our rules, if any, would increase the use of these Instructions? Is the required quarterly reporting process complex and burdensome for investors or companies? If so, how is it complex and burdensome? If so, what approaches should we consider apart from the Supplemental Approach (hereafter "other suggested approach") to simplify the process by which investors collect and evaluate information and ease the burdens associated with the publication of earnings releases and the preparation and filing of Form 10-Q without adversely affecting the total mix of information provided to investors?

The ability to incorporate by reference (per General Instructions D.1 and D.2) of Form 10-Q is useful for BIO member companies. BIO believes that the quarterly reporting process is complex and burdensome for investors and companies, in many ways resulting in redundant information being reported on a schedule that unfortunately promotes short-termism. Under the quarterly reporting process, it is burdensome to report revenue recognition for biotech multi-element arrangements; and there are generally no material changes between a quarterly and semi-annual basis, yet the cost and effort to report and obtain auditor review is significant. Similarly, the "going concern analysis" required quarterly is not valuable on that frequency and could also be changed to a semi-annual basis to reduce burdens. Under the Supplemental Approach, a company would use its Form 10-Q to supplement a Form 8-K earnings release with additional material information required by the Form 10-Q not already presented in Form 8-K, or alternatively incorporate by reference disclosure from the Form 8-K earnings release into its Form 10-Q. We encourage the SEC to re-evaluate the required "total mix of information" provided to investors.

19. Should Commission rules, accounting standards, and auditing standards allow for the interim financial statements to be separated so that certain parts could be presented only in the earnings release to satisfy the Form 10-Q requirements under the Supplemental Approach or other suggested approach? For example, should a registrant be able to present condensed interim income statements only in the earnings release and the remaining Regulation S-X required

interim statements and footnotes in the Form 10-Q? What changes would be needed to the current accounting and/or auditing standards to accomplish such separation? Would separation of the financial statements help, harm, or have no effect on an investor's ability to evaluate a company's performance?

We do not believe that separation of the financial statements would help an investor's ability to evaluate a company's performance.

20. Should information in an earnings release that is submitted on Form 8-K be allowed to satisfy the Form 10-Q requirements? Why or why not, and if so to what extent? What are the potential benefits and drawbacks to investors, companies, and other market participants of the Supplemental Approach or other suggested approach?

Investors will most likely continue to rely principally on the information from earnings releases, for reasons described in previous answers. Form 8-K has little value other than to incorporate by reference.

21. If companies were permitted to omit from Form 10-Q information already contained in a Form 8-K earnings release, what specific information should they be allowed to omit? Is there any earnings release information that should not be allowed to satisfy the requirements of Form 10-Q? Would companies be likely to rely on the Supplemental Approach or other suggested approach, if available? If so, would certain types of companies benefit more from the Supplemental Approach other suggested approach than others?

Omitting information already contained in a Form 8-K earnings release from Form 10-Q would not be very meaningful or beneficial to companies.

22. If we adopt the Supplemental Approach or other suggested approach, should we require the relevant Form 8-K to be filed rather than furnished? Should we further require the relevant Form 8-K to be incorporated by reference into the Form 10-Q, in whole or in part? Should we require a hyperlink from the Form 10-Q to the relevant Form 8-K? Should we require the relevant Form 8-K to include certain disclosures that are otherwise required in Form 10-Q? If so, which disclosures should be required and why?

No, we believe that the Form 8-K should continue to be furnished. Relevant information from Form 8-K should be incorporated by reference into the Form 10-Q in part, but we do not believe that a corresponding hyperlink to the relevant Form 8-K is necessary. No, Form 8-K should not require certain disclosures that are otherwise required in Form 10-Q.

23. Are there issues or concerns with the above approaches in relation to a registration statement and the ability to incorporate by reference? If so, please describe. For example, should a company relying on the Supplemental Approach or other suggested approach have to incorporate by reference the historical financial information in its earnings release into a Securities Act registration statement so that Securities Act liability would apply to that information, just as such liability applies to Form 10-Q information that is incorporated by reference into a registration statement?

We do not have concerns or issues with the above approaches in relation to a registration statement and the ability to incorporate by reference.

24. Would the Supplemental Approach or other suggested approach affect the quantity, quality, or nature of the disclosure being made to the public? If so, how? Would the Supplemental Approach or other suggested approach simplify or complicate the process by which investors collect and evaluate information? How would the Supplemental Approach or other suggested approach affect investors' evaluation of company performance? Overall, what impact would the Supplemental Approach or other suggested approach have on investors?

The Supplemental Approach would not affect the quantity, quality or nature of the disclosure being made to the public; we also believe it would neither simplify nor complicate the process by which investors collect and evaluate information. We do not believe that the Supplemental Approach would affect investors' evaluation of company performance or have any impact on investors.

25. Would the Supplemental Approach affect the timing of earnings releases? If so, how? If we implement the Supplemental Approach or other suggested approach, should we modify the due date of Form 10-Q? Why or why not, and if so, how?

It is uncertain whether the Supplemental Approach would affect the timing of earnings releases. The due dates of Form 10-Q should remain unchanged.

26. How should the Supplemental Approach or other suggested approach take into consideration the XBRL requirements of Form 10-Q? If information currently required to be structured using the XBRL format on Form 10-Q were instead only disclosed in an unstructured format on Form 8-K, would this adversely affect investors or other market participants?

We do not believe that XBRL requirements enhance the overall reporting framework and, as such, if information were instead only disclosed in an unstructured format on Form 8-K, it would not adversely affect investors or other market participants.

27. If an earnings release were used to satisfy the requirements of Form 10-Q, should any financial statements included in an earnings release be subject to auditor review procedures at the time the Form 8-K is filed? Why or why not?

We understand that the overarching goal is to improve the reporting process and make it less burdensome to companies without any meaningful adverse impact on investors or market participants. Accordingly, we do not believe that financial statements included in the earnings release should be subject to auditor review procedures at the time the Form 8-K is filed. There is little value to management in the quarterly auditor reviews, other than a small benefit from frequent communication with auditors to discuss issues, but that could easily be accomplished without SEC requirements.

28. Would the Supplemental Approach or other suggested approach reduce or add to companies' disclosure or auditor review burdens? How should the Supplemental Approach other suggested approach take into consideration the requirements regarding disclosure controls and procedures set forth in Rules 13a-15 and 15d-15, as well as the related officer certification requirements, which apply to Forms 10-Q but not to earnings releases furnished on Form 8-K?

We support efforts to make the overall process less burdensome to companies without any meaningful negative impact on investors and market participants.

29. Does the Supplemental Approach or other suggested approach raise concerns regarding a company's liability under the federal securities laws? If so, please explain.

No.

Reporting Frequency

30. What are the benefits and costs to investors, companies, and other market participants associated with the current reporting frequency model, which requires from domestic issuers quarterly reports on Form 10-Q, annual reports on Form 10-K, and current reports on Form 8-K? Does the frequency of reporting lead managers to focus on short-term results to the detriment of long-term performance? Why or why not? If so, does this negatively affect investors? If so, how? Would less frequent reporting change management decision-making or otherwise positively affect investors? Or does the practice of issuing earnings guidance, including the frequency with which companies issue earnings guidance, lead managers to focus on short-term results to the detriment of long-term performance? Why or why not? Would more frequent reporting change management decision-making?

We support a move away from the current quarterly reporting framework toward a semi-annual system. The current reporting frequency demands too much of management teams' time, effort and attention to reporting, at the expense of a more acute focus on critical operational matters. In larger companies, the internal investment is more concentrated in financial and legal functions; however smaller companies tend to draw upon personnel across several operational functions to fulfill quarterly reporting requirements. There is evidence that smaller registrants are disproportionately impacted by the cost of audit review than larger companies due to the fixed costs of audit work, despite their relatively simple corporate structures and straightforward accounting issues.[2] Investors are negatively impacted by the current quarterly reporting process, in the sense that management teams are unable to pay proper attention to critical operational matters, which may have deleterious effects on the company and potentially result in diminution of shareholder value. We recognize that a move toward semi-annual reporting would change the scope of work of independent audit firms when they review reports on a less frequent basis. Ultimately, less frequent reporting would improve management decision-making, instill a long-term focus, and subsequently positively impact shareholders.

31. Should we move to a semi-annual reporting model for all or certain categories of reporting companies? Why or why not, and to which categories of reporting companies (e.g., smaller reporting companies, non-accelerated filers, emerging growth companies)? Are there other categories of reporting companies,

[2] For instance, it was reported recently that smaller reporting companies pay $3,345 per $1 million in revenue, while accelerated and large accelerated filers pay only $541 per $1 million in revenue. That is, SRCs pay over six times the amount of audit fees than larger companies despite their relatively simple corporate structures and straightforward financial accounting issues. Source: Analysis provided by the *Wall Street Journal* and data supplied by Audit Analytics. See more at *Wall Street Journal*, "Move to Semiannual Reporting Would Benefit Small Companies the Most," September 4, 2018, https://www.wsj.com/articles/move-to-semiannual-reporting-would-benefit-small-companies-the-most-1536053400.

such as by industry, that we should consider? For example, are there any unique considerations we should give to certain commodity trusts, business development companies, and other collective investment vehicles? Would any other frequency of reporting model be more appropriate for these or other types of companies?

BIO supports moving to a semi-annual reporting model for EGCs, SRCs, and any other categories of reporting companies the SEC deems appropriate. This change is particularly important for companies that have not yet achieved commercial stage, e.g. do not yet have recurring cash-generating revenue, either via their own product sales or royalty streams. The life sciences industry is a particularly relevant one for consideration for scaled disclosure, given the vast number of pre-commercial companies whose cash-bearing revenue, if any, is infrequent and inconsistent, comprised generally of upfront payments and/or period milestones and contingent payments from collaborators based on progress achieved in the research and development (clinical) pipeline.

32. What would the costs and benefits be to investors, companies, and other market participants of a semi-annual reporting model for all or certain categories of reporting companies? Are there market practices in place, for example contractually mandated reports to lenders and indenture trustees, that rely on the current regulatory reporting regime? If so, how would these market practices be affected by changes to that regime and what are the downstream effects?

Investors, companies, and other market participants would benefit from management teams and company personnel to focus their attention on strategic efforts to grow the business rather than administering frequent reporting obligations. In addition, companies would incur reduced costs in preparing and obtaining legal and auditor review of those quarterly filings, which would enable them to repurpose funds into other strategic investments to grow the company and improve outcomes for investors. Market participants that rely on the current reporting regime could adapt to a changed reporting frequency without any appreciable negative impact.

33. Would a change in reporting frequency affect the cost of capital to companies? Why or why not, and if so, how?

We are not aware of a change in reporting frequency affecting companies' cost of capital.

34. How would a semi-annual reporting model affect the general use of Form 8-K to report material information? Should we consider any particular additional Form 8-K requirements or triggers under a semi-annual reporting model? If so, what type(s)?

We do not believe there should be any changes to the general use of Form 8-K.

35. How would a semi-annual reporting model affect the use of earnings releases? If we were to allow semi-annual reporting, should we require voluntarily published earnings releases, either on a quarterly or semi-annual basis, to be filed rather than furnished? Or, if we were to allow semi-annual reporting, should we require companies to file earnings releases?

Under a semi-annual reporting system, while furnishing is preferable, either requirement could be acceptable.

36. Should we allow for additional flexibility by permitting companies to select an approach to periodic reporting that best suits their needs and the needs of their investors? For example, should we allow a company conducting an initial public offering to announce its approach to periodic reporting, such as semi-annual periodic reporting, during registration and implement the elected approach going forward? Should a company be permitted to change its approach to frequency of reporting once it selects a reporting frequency? Why or why not? If it is permitted to change the frequency of reporting after it has established an approach, how often should the company be permitted to change its reporting frequency?

Yes, we support the Commission providing additional flexibility by permitting companies to select an approach to periodic reporting that best suits their needs and the needs of their investors. We also think it would be ideal for the Commission to allow companies conducting IPOs to announce its approach to periodic reporting, such as semi-annual periodic reporting during registration. For the life sciences sector, for example, we think companies would benefit from (and should be permitted to adopt) more frequent reporting as they advance in commercial stage.

37. What are the downstream effects of changing the reporting frequency to investment companies, investment advisers, broker-dealers, data aggregators, and other users of the reports?

Users of the reports noted above could reasonably adapt their business models considering a regulatory change to reporting frequency. Just as the JOBS Act eased the IPO onramp for startup companies, a less frequent reporting model would lessen the burden of being a public company and would likely encourage further capital formation.

38. Should an emerging growth company or smaller reporting company be permitted to elect a semi-annual reporting frequency?

Yes. Small and emerging biotechnology companies view the current quarterly reporting framework as placing an unhealthy emphasis on meeting or exceeding short-term forecasts, which engenders an inefficient outlook on short-term results. Due to the lengthy timeline for drug development, which averages 10-15 years, biotech companies benefit from patient capital where investors seek long-term growth of companies delivering breakthroughs in scientific innovation that benefit patients and investors alike. By contrast, the current reporting system requires corporate managers to spend an inordinate amount of time and resources to prepare quarterly financial disclosures on which investors and industry analysts fixate. We support the Commission's efforts to modernize the reporting regime to enable and encourage registrants to focus on demonstrating progress made against the company's long-term strategic plan, through modifying the reporting regime to a semi-annual (rather than quarterly) basis and offering flexibility for smaller registrants to opt to provide more frequent reporting as they mature.

BIO believes that adopting a semiannual reporting regime would improve the attractiveness of being a small public company. SRCs and EGCs have less complex business structures and financial reporting issues than larger registrants, and a less frequent disclosure basis would enable them to focus their limited resources on long-term strategy to maximize profits to provide a return to their shareholders.

39. What would the costs and benefits be to investors, companies, and other market participants of moving to a flexible reporting frequency model (rather than a mandatory quarterly or mandatory semi-annual model)? How would a flexible

reporting frequency model (rather than a mandatory quarterly or mandatory semi-annual model) affect the ability of investors, analysts, and other market participants to compare results among companies, especially if companies in the same industry report on different schedules? Would companies that choose to report more frequently suffer adverse competitive consequences if peer companies choose to report less frequently (e.g., because relative performance and/or estimates of expected future cash flows would be measured on a less frequent basis)? Alternatively, would companies that choose to report more frequently benefit from their provision to investors of more and more timely information about historical results?

A less frequent, but fixed frequency reporting model would, in our view, be easier for users to understand and accommodate into their planning cycles.

40. What are the accounting and auditing changes that would be necessary for a flexible reporting frequency model (rather than a mandatory quarterly or mandatory semi-annual model)? For example, would there be concerns with how to apply ASC 270 Interim Reporting in U.S. GAAP or certain Regulation S-X disclosure requirements in a flexible reporting frequency model? Would there be concerns with how to apply auditing standards in relation to interim financial information, including procedures performed in relation to letters for underwriters and certain other requesting parties, in a flexible reporting frequency model?

41. What other topics may raise concerns or questions with application under a flexible reporting model, and what are those concerns or questions? Do these concerns and questions exist in the current quarterly reporting model and would they still exist with a mandatory semi-annual model?

42. Are existing U.S. GAAP taxonomies used for XBRL reporting appropriate for a flexible reporting frequency model?

We do not foresee any challenges with this approach.

43. Should we limit such flexibility in reporting frequency to a particular group of companies as an initial step before considering whether to provide such an option to all companies? If so, which group of companies and why? Should any potential election by a company be limited to a specific period of time?

44. How would a move to either a mandatory or optional semi-annual reporting model affect the current rules of self-regulatory organizations and national securities exchanges? For example, would exchanges still require quarterly reporting as a requirement of listing, as they did prior to 1970 when Form 10-Q was adopted?

We anticipate that SROs and national securities exchanges would adapt to a new reporting frequency.

45. How would a move to either a mandatory or optional semi-annual reporting model affect a company's ability to comply with current rules relating to Securities Act offerings? For example, given that Form 10-Q is often incorporated by reference into certain registration statements under the Securities Act, how would a company that reports semi-annually ensure that a registration statement currently in use does not contain a material omission of information? For example,

how would an issuer ensure that a shelf registration statement on Form S-3 remains current? Under a flexible approach, would companies nonetheless elect to maintain a quarterly reporting model to avoid concerns about keeping their Securities Act registration statements current? How would companies meet the requirements regarding the age of financial statements under Regulation S-X with respect to new registration statements under such an approach? How would a change in reporting frequency impact the Commission's integrated disclosure regime, including, for example, determining issuer eligibility and the speed by which a company may offer securities? How would a change in reporting frequency impact companies who use reports filed in the United States to satisfy state or international reporting requirements?

Form 8-K would help companies avoid a situation in which Form 10-Q, incorporated by reference on a semi-annual basis, would contain a material omission of information. It is possible that the S-3 rules would need to be modified to permit the flexible reporting regime.

46. Are there additional approaches that we should consider to better facilitate the dissemination of timely periodic information to investors and other market participants?

BIO looks forward to working with the SEC as it continues to improve the reporting framework for public companies and shareholders alike. Please contact Lisa Schaefer, Director of Financial Services Policy (Lschaefer@bio.org) if we can provide any additional support or information.

Sincerely,

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