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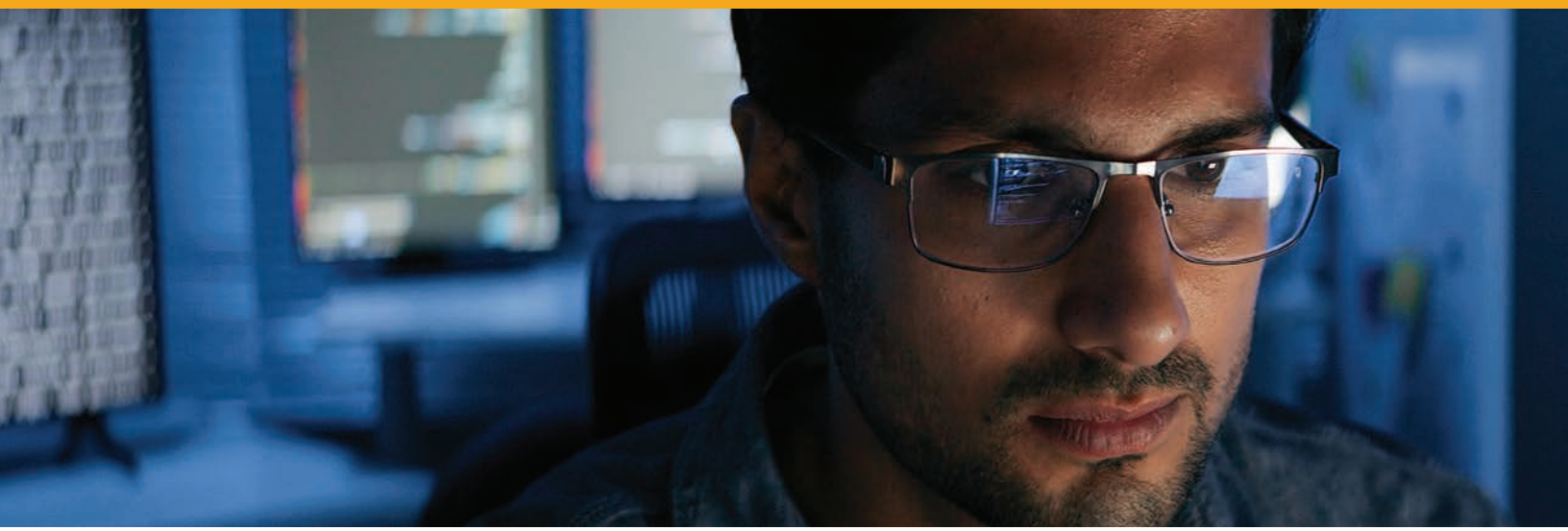
SEC Comment Letters in the Life Sciences Industry

2025 edition



Introduction

Life sciences companies stand at the intersection of innovation and uncertainty. While life sciences companies have long contended with the inherent uncertainty of whether intensive research and development (R&D) efforts ultimately will result in viable and marketable products, today that uncertainty is amplified by an increasingly complex global landscape. A confluence of macroeconomic, technological, and regulatory challenges now adds further unpredictability, shaping strategic and operational decisions in unprecedented ways. These developments have implications not only for business models and investment priorities but also for how companies manage risk, pursue innovation, and communicate with their stakeholders.

Emerging risks include the potential impact of global tariffs, particularly those affecting the import of specialized equipment, chemicals, and raw materials essential to R&D. Tariff volatility has introduced new risks to budgeting and long-term planning, potentially constraining R&D spending decisions and altering the pace of innovation. Cybersecurity vulnerabilities in digital health platforms present another layer of operational risk, as companies increase reliance on data-driven tools and cloud-based infrastructure to support clinical research and digital therapeutics.

The integration of artificial intelligence (AI) into the drug development pipeline is reshaping research workflows, from target identification to clinical trial optimization. While AI holds promise for increased efficiency and reduced time to market, it also raises new questions related to data governance, testing protocols, and the transparency of algorithmic decision-making. How a company communicates the risks and opportunities of AI adoption to investors and stakeholders is important in telling the company's story to its stakeholders, including articulating the intended use of AI tools, describing their role in the R&D process, and explaining how the company is managing associated uncertainties and compliance risks.

Private investment and capital formation trends also are evolving. Companies are navigating a dynamic funding environment, with continued interest in venture capital, strategic partnerships, and public offerings. At the same time, the U.S. Securities and Exchange Commission (SEC) has renewed its focus on capital formation as a core mission area, seeking to enhance access to capital markets while maintaining investor protections. Life sciences entities pursuing capital – whether in private placements or registered offerings – must clearly convey valuation methodologies, milestone-based payments, deal structures, and non-GAAP performance measures in their disclosures.

Adding further dimension to the financial reporting regulatory landscape, the Public Company Accounting Oversight Board (PCAOB) continues to focus inspections on higher-risk areas, including certain topics that are particularly relevant to the life sciences sector. PCAOB inspection reports recently have identified deficiencies in the audit procedures performed in areas including revenue, significant estimates, and IT general controls – all critical areas for life sciences entities with complex and rapidly evolving business models. These inspection findings influence not only the procedures auditors perform to comply with auditing standards but also how companies prepare and support their financial reporting processes.

Against this backdrop, SEC comment letters and PCAOB inspection reports collectively serve as critical lenses into how the regulators view disclosures, risk, and emerging issues that might materially affect the financial and operational decision-making of life sciences companies. Under the *Sarbanes-Oxley Act of 2002*, the SEC's Division of Corporation Finance (CorpFin) reviews the filings of every public company at least once every three years, while the PCAOB conducts annual or triennial inspections of registered audit firms. It is important to remember that SEC filings are not merely compliance documents – they are a vital means of communicating with investors, analysts, and other market stakeholders. The clarity, completeness, and accuracy of these filings and the audit inspection process play a central role in maintaining investor trust, supporting informed decision-making, and upholding the integrity of the capital markets.

Understanding the SEC's evolving expectations is essential for crafting robust and compliant disclosures while preparers communicate the company's story to its stakeholders. We discuss the topical themes from SEC comment letters issued to companies with North American Industry Classification System (NAICS) codes in the life sciences industry from March 1, 2023, through the date of this publication, and we provide example comments that illustrate each theme, which are lightly edited for clarity.

We hope you find this publication useful as you consider your financial reporting process and disclosure documents.

Business

Product pipeline

In life sciences, a company's product pipeline is central to its future value, with investors relying on disclosures about drug candidates, target indications, and development stages to evaluate progress and strategy. The SEC often comments and requests revisions when these disclosures are not clear, complete, and decision-useful – particularly regarding the status and financial impact of each product or program. The SEC also often comments if companies include product candidates in pipeline tables without adequately disclosing the product's target indications, the product's development status, or whether those programs are still active or under strategic review. The SEC also often requests further disaggregation of R&D expenses by product or indication to provide investors with transparency related to the company's resource allocation decisions and to assist investors' ability to assess program viability and prioritize risk.

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On Nov. 4, 2024, the FASB issued Accounting Standards Update (ASU) 2024-03, "Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," requiring public companies to disclose disaggregated information about specific natural expense categories (for example, purchase of inventory, employee compensation, depreciation) underlying certain income statement expense line items, which is likely to include R&D. While the ASU does not mandate disaggregation by product or program, those disclosures might complement the SEC's focus on product pipeline transparency and R&D resource allocation. Companies should assess whether voluntary disclosures by indication or product could enhance clarity and address investor expectation. For more information on this ASU, refer to the Crowe article "ASU Addresses Disaggregation of Income Statement Expenses."

ASU 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures," was effective for all public entities for fiscal years beginning after Dec. 15, 2023, and interim periods beginning after Dec. 15, 2024, and requires public entities to disclose information about significant expense categories that are regularly provided to the chief operating decision-maker. For life sciences companies, this might result in a different disaggregation of R&D expenses in the segment footnote compared to the SEC's requests for disaggregation by product or indication outside the financial statements. Refer to the Crowe article "FASB Issues Changes to Segment Reporting Requirements."

Example SEC comments:

We note that your product candidates appear in your pipeline table with undisclosed target indications and that there is either minimal or no discussion of the status of these programs in your disclosure. Please, to the extent these are currently material programs, disclose the targets and provide more fulsome descriptions of these programs. If you have not yet identified target indications that you are currently pursuing, please remove them from the table or explain the basis for your belief that they are material and should be included in your pipeline table. In an appropriate place in the business section, revise to explain what you mean when you say that your product candidates are "under strategic review," and disclose the current status of such reviews. To the extent you are not currently developing and/or do not plan to further develop these product candidates, please remove them from your pipeline table in future filings. Please note that we will not object to a narrative discussion of your aspirational plans for such product candidates or next steps with respect to these programs in your summary and business sections.

We note from the pipeline table that you have multiple products in clinical development for several indications. Please revise future filings to disclose the costs incurred during each period presented for each of your key R&D product candidates. If you do not track your R&D costs by project, disclose that fact and explain why you do not maintain and evaluate R&D costs by project. Also, revise to provide other quantitative and qualitative disclosures that give more transparency as to the type of R&D expenses incurred (that is, by nature or type of expense), which should reconcile to total R&D expenses on your statements of operations.

Clinical trials and research findings

While early clinical trial data and preliminary research findings might appear promising, the SEC frequently requests that registrants remove statements concluding on or implying the efficacy of registrants' products. Such statements could lead investors to overestimate the probability of successful R&D and subsequent commercialization and underestimate the risks and uncertainties involved in the subsequent stages of clinical trials and regulatory review.

Example SEC comments:

We note your disclosure that your product candidate has shown a favorable safety and tolerability profile. As safety and efficacy determinations are solely within the authority of the Food and Drug Administration and comparable regulatory bodies, please confirm that you will remove from future filings any statements that state or imply that your product candidates are safe or effective. We will not object to statements that your drug candidates were well tolerated or that no serious adverse events deemed to be study related were reported, if true.

Please revise your disclosure regarding the company's business to remove or revise all statements implying safety or efficacy, as the company's product candidates have not yet received regulatory approval.

Risk factors

Clinical and product development risks

The SEC staff expects life sciences companies to clearly disclose material clinical risks, such as adverse events, trial discontinuations, or safety concerns. When companies omit or downplay these issues in risk factor disclosures, the SEC often comments, which reflects the SEC's focus on transparency related to development challenges that could significantly affect a company's prospects.

Example SEC comments:

We note your disclosure in your press release that the company has paused its other development efforts in your product due to serious adverse events. Please provide proposed disclosure for future filings of risk factor disclosure relating to the serious adverse events, including the period(s) that the patient deaths occurred, all other serious adverse events related to your products, and potential risks to the company from those events.

Regulatory and jurisdictional risks

While companies might face regulatory risks in various jurisdictions, the SEC has focused especially on issuers with significant operations in China. The SEC has requested clear disclosure about how a China-based structure exposes investors to unique risks – including legal uncertainties, regulatory changes, and potential government intervention – so investors can fully appreciate the material risks associated with operating in China's regulatory environment.

Example SEC comments:

In future filings, in your summary of risk factors, please disclose with greater specificity the significant regulatory, liquidity, and enforcement risks that your corporate structure and being based in or having the majority of the company's operations in China pose to investors.

Prominently disclose the risks that your corporate structure and being based in or having the majority of the company's operations in China pose to investors. In particular, describe the significant regulatory, liquidity, and enforcement risks. For example, specifically discuss risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws, the fact that rules and regulations in China can change quickly with little advance notice, and the risk that the Chinese government may intervene or influence your operations at any time or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in your operations and/or the value of your securities. Acknowledge any risks that any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder your ability to offer or continue to offer securities to investors and cause the value of your securities to significantly decline or be worthless.

Patents

Patents are crucial assets for life sciences companies, and SEC staff pays close attention to patent portfolio disclosures. The SEC routinely requests enhanced disclosure of patent details, including the number of patents held, types of patent protections, applicable jurisdictions, and expiration dates.

Example SEC comments:

Please confirm that in future filings you will revise your disclosure with respect to the company's material patents to clearly describe on an individual or patent family basis the type of patent protection granted for each product candidate or technology (composition of matter, use, or process), whether such patent is owned or licensed, the expiration year of each patent, and the jurisdiction, including any foreign jurisdiction, of each material pending or issued patent.

Please also revise the disclosure regarding these licenses to clarify the specific product candidate or technology to which each of the underlying patents relate, the type of patent protection (for example, composition of matter, use, or process), and the patent expiration date. Ensure that you also disclose any up-front payments and termination provisions associated with each license. Refer to Item 601(b)(10) of Regulation S-K.

Please revise your intellectual property disclosure to clearly distinguish between owned patents and patents in-licensed from third parties. In this regard it might be useful to provide a tabular disclosure.

Revenue recognition

The SEC often comments on revenue recognition under Accounting Standards Codification (ASC) 606 because of the importance of revenue to investors and the complex nature of many revenue arrangements in the life sciences industry.

Significant judgments

The SEC staff frequently issues comments on areas that require significant management judgment such as variable consideration and payment terms, which might include consideration of whether payment terms include significant financing components. The SEC staff often requests more disclosure about how variable consideration or significant financing components are estimated and recognized. These elements might significantly affect the timing and amount of revenue reported and how an investor understands the company's revenue recognition. The SEC frequently emphasizes the need for registrants to provide clear, complete, and consistent explanations to ensure investors understand the assumptions, risks, and estimates that influence reported revenue.

Example SEC comments:

To the extent that you conclude the service revenues are material to your consolidated financial statements, we continue to request that you provide the disclosures for revenues related to the various services you provide including 1) identification of the performance obligations (that is, when typically satisfied, significant payment terms; nature of goods and services; obligations for returns, refunds, and other similar obligations; and types of warranties and related obligations) with reference to ASC 606-10-50-12 and 50-12A, 2) significant judgments for the method used to recognize revenue over time and why the method faithfully depicts the transfer of the services with reference to ASC 606-10-50-18, and 3) variable consideration and any other obligations with reference to ASC 606-10-50- 20.

We note you estimate variable consideration related to rebates, charge-backs, and product returns. Please provide in future filings qualitative and quantitative information about the significant judgments and changes in judgments that significantly affect the determination of your transaction price, as set forth in ASC 606-10-50-1(b), 50-17(b), and 50-20(a). Please provide us any intended revisions and the calculations used to determine variable consideration for the periods presented.

Please clarify for us and in future filings whether your consideration is variable as set forth in ASC 606-10-32-5 through 32-9 and whether your estimate of variable consideration is typically constrained in accordance with paragraphs ASC 606-10-32-11 through 32-13. Refer to ASC 606-10-50-12(b) for the required disclosure.

Given the significant returns adjustment in a prior period, please address the following regarding your revenue recognition policies and how they comply with the applicable guidance in ASC 606:

- At the time revenue was recorded, explain how you evaluated the probability that a significant reversal in the recognized product revenue would not occur before the uncertainty associated with the variable consideration was resolved (for example, when the right of return expired).
- As part of your response, specifically address how you determined that it was appropriate to use industry data when estimating returns and whether the referenced products were sufficiently comparable to your products.

Other disclosure requirements

In addition to significant judgments, ASC 606-10-50 also requires disclosures such as disaggregated revenue and performance obligations. The SEC often comments when the required disclosures are omitted, abbreviated, or not provided in sufficient detail.

Example SEC comments:

Please expand your revenue recognition policy to discuss the nature, amount, timing, and uncertainty of revenues and cash flows arising from contracts with customers. For instance, you should disclose the typical time frame and payment terms of contracts. Refer to ASC 606-10-50-1 and 606-10-50-12.

Provide us an analysis of your revenue recognition under ASC 606, including your determination of the performance obligations, the transaction price, the amount allocated to each performance obligation, and your revenue recognition method (that is, over time or point in time) for each performance obligation.

Please tell us how you considered providing additional disaggregated information such as by product line or geographic revenue information. Refer to ASC 606-10-55-89 through 55-91.

Please clarify for us whether your customer's option to renew represents a material right that represents a separate performance obligation as contemplated in ASC 606-10-55-42. Please revise your revenue recognition policy disclosure in future filings accordingly.

We note your contracts may include multiple performance obligations. Please revise your revenue recognition disclosure in future filings so that users can understand any impact from differences between recurring and nonrecurring revenues from your allocation of the transaction price.

Non-GAAP measures

Although non-GAAP measures are not required in SEC filings, many life sciences companies choose to include non-GAAP measures. The SEC often comments when the non-GAAP measures do not conform to non-GAAP rules (for example, Regulation G and Item 10(e) of Regulation S-K) or the SEC staff's Compliance and Disclosure Interpretations (C&DI).

CROWE PRACTICE NOTE

In November 2024, the FASB issued an Invitation to Comment, "Financial Key Performance Indicators for Business Entities," seeking feedback on whether and how financial key performance indicators, many of which overlap with commonly used non-GAAP measures like EBITDA and free cash flow, should be addressed in GAAP.

The SEC often comments when registrants do not sufficiently disaggregate non-GAAP adjustments or do not clearly explain why each excluded item is nonrecurring or what the adjustment represents.

Example SEC comments:

Please expand the footnote disclosures to quantify the components of the adjustment when the adjustment is broad and includes multiple types of adjustments. Refer to Item 10(e)(1)(i)(B) of Regulation S-K.

We note in calculating adjusted operating income, adjusted EBITDA, and adjusted net income, you excluded acquisition-related and exit and realignment charges. Please provide more information on the nature of the expenses included in the acquisition-related charges. Similarly, please further explain the nature of the expenses included in the exit and realignment charges.

We note you have included certain adjustments in your reconciliations for the adjusted, non-GAAP measures. Please provide us with an explanation of what specifically each of these adjustments represent, and quantify the components of each of these adjustments for each period presented.

Prominence of GAAP measures equal to or greater than non-GAAP measures

The SEC often comments when the most directly comparable GAAP measure is not presented as prominently as or with greater prominence than the non-GAAP metric.

Example SEC comments:

Within the header of your earnings release you discuss the non-GAAP measure adjusted EBITDA without also discussing the most comparable GAAP measure of net income. This presentation gives greater prominence to the non-GAAP measure and does not comply with Item 10(e)(1)(i)(A) of Regulation S-K.

You present adjusted EBITDA margin in the bullet points at the top of Exhibit 99.1 without the presentation of the corresponding GAAP measure. Revise here and in your Q2 23 summary results tables in future earnings releases to also present gross margin on a GAAP basis. Ensure that your presentation of the GAAP measure is presented with prominence equal to or greater than the non-GAAP measure. We refer you to Item 10(e) of Regulation S-K.

Liquidity versus performance measures and other compliance issues

Life sciences companies might use non-GAAP measures like adjusted free cash flow as either a liquidity measure or a performance measure. The SEC often comments when it is unclear whether the registrant is using a measure as a performance measure or as a liquidity measure. The SEC also often comments on compliance items including proper labeling, clear reconciliation to the most directly comparable GAAP measure, and clear explanation of the non-GAAP measure's purpose and relevance to investors.

Example SEC comments:

Revise your future filings to clearly label each of your non-GAAP measures as performance or liquidity measures.

Please explain how adjusted free cash flow is used by management and why you believe it is useful in highlighting trends in your operating results. Revise your future filings to expand your disclosure to explain how these non-GAAP measures provide useful information to investors. We refer you to Item 10(e)(1)(i)(C) and (D) of Regulation S-K.

Revise to reconcile adjusted free cash flow to its most directly comparable GAAP financial measure. Tell us how you considered the guidance of Question 102.07 of the C&DI related to non-GAAP measures.

Tell us the extent to which adjusted free cash flow is also a component of the financial covenant under your credit agreement.

Please help us understand how you determined that free cash flow excluding recall payments is a performance measure rather than a liquidity measure. In this regard, we note the measure is reconciled from cash provided by operating activities, the measure includes cash in the title, the adjustments are cash-based rather than accrual-based, and your non-GAAP conversion rate uses this measure as the numerator.

Management discussion and analysis (MD&A)

The MD&A section is typically the number one comment area across industries, and the life sciences industry is no exception. In particular, results of operations, liquidity, and financial condition in the life sciences industry are often driven by the results of complex R&D programs, evolving regulatory milestones, and the uncertainty of the ultimate commercial success of a product.

Results of operations

The SEC often comments on results of operations when registrants cite multiple reasons for changes in financial results (for example, pricing, volume, mix) but do not quantify the impact of each factor.

Example SEC comments:

Please expand your analyses to quantify the impact of the factors affecting the line items when multiple factors contribute positively and/or negatively to the change or amounts being discussed. Refer to Item 303(b)(2) of Regulation S-K and Section 501.12.b. of the Financial Reporting Codification for guidance. One example is your analysis of adjusted gross profit as a percentage of net sales in which you attribute the decline to 1) increased costs from purchases of electronic components at premium prices on the spot market; 2) inflationary pressures related to labor, steel, and transportation; 3) inefficiencies from supply chain disruptions; and 4) unfavorable product mix that does not quantify each of these factors. Furthermore, ensure that you are quantifying the impact of new products on net sales at the consolidated and segment levels in accordance with Item 303(b)(2)(iii) of Regulation S-K.

We note you have identified multiple factors that affect your operating results, but it does not appear that you have separately quantified each factor identified. In future filings, when you describe two or more business factors that contributed to a material change in a financial statement line item between periods, please quantify, where possible, the extent to which each factor contributed to the overall change in that line item, including any offsetting factors. For example, you state that revenue increase was due to recent acquisition, penetration in existing territories, and increase in volume of certain products; however, you do not separately quantify each component or discuss the amount attributable to acquisition versus other factors. We refer to guidance in Item 303(b) of Regulation S-K.

Critical accounting estimates

The SEC often comments when a registrant's disclosures of critical accounting estimates in MD&A repeat accounting policies included in the footnotes to the financial statements instead of focusing on judgment, uncertainty, and the potential impact of the estimate on financial results. Comments often request enhanced discussion of the uncertainties associated with each critical estimate, the methods and assumptions used, events or transactions that could significantly affect the assumptions made, and how changes in assumption might affect the financial statements.

Example SEC comments:

The disclosures you have provided for each of your identified critical estimates appear to provide investors with a discussion of how you are accounting for these items in accordance with U.S. GAAP and are similar to your significant accounting policies disclosures rather than providing investors with an understanding of what the critical estimates being made are and how the uncertainty associated with those estimates might affect your consolidated financial statements. Please revise the disclosures for each of your critical estimates made in preparing your consolidated financial statements to comply with the guidance in Section 501.14 of the Financial Reporting Codification. Ensure your disclosures sufficiently explain to investors what each critical estimate is; the uncertainties associated with the critical estimates; the methods and assumptions used to make the critical estimates, including an explanation of how you arrived at the assumptions used; the events or transactions that could materially affect the assumptions made; and how reasonably likely it is that changes to those assumptions could affect your consolidated financial statements. Provide investors with quantified information to the extent it is meaningful and available.

Given the significance of the recorded liability and your cautionary disclosures that you could incur material charges in excess of currently established accruals, please provide a fuller description of your critical accounting estimates that considers key judgments made in applying ASC 450 and more specifically explains the volatility of the assumptions and changes in the recorded liability.

Liquidity and capital resource disclosures

The SEC staff frequently comments on liquidity and capital resources disclosures across various sections of SEC filings – not just in MD&A. Companies sometimes provide liquidity disclosures that are essentially a recitation of changes from the statement of cash flows, but the SEC expects more decision-useful analyses, including clear explanations of what drove those changes and how they relate to operational performance or strategic decisions. In addition, the SEC often requests enhanced disclosure of how a registrant plans to deploy available capital, address funding risks, and navigate liquidity exposures in areas such as pipeline development or external market disruptions.

Example SEC comments:

Your liquidity and capital resource disclosures do not clearly describe the factors that caused the variance in operating cash flows between this fiscal year and the prior year and the extent of their effect. You cite an increase in revenue as a factor for the increase in operating cash flows. Typically, it is not the increase in the amount of revenue reported in a period that affects operating cash flows but the amount of revenue collected in the period that does. In this regard, we note the increased negative impact on operating cash flows of accounts receivable. In connection with this, you do not address the variance in expenses on operating cash flows. Furthermore, it appears the effect of revenues and expenses is covered by your cited factor of increased net income plus noncash expenses between the periods. Please revise your disclosure to identify the material underlying factors that actually changed operating cash between periods.

Your disclosure of net cash provided by or used in operating, investing, and financing activities appears to repeat information already provided in the statement of cash flows. Please represent to us that, in future filings, you will enhance your disclosure to provide a quantitative and qualitative analysis of the drivers of the change in cash flows between periods and the impact on future trends to provide a sufficient basis to understand changes in cash between periods. Refer to Item 303(b)(1) of Regulation S-K and Sections 1.B. and IV.B. of SEC Release 33-8350 and 33-10890 for guidance.

To the extent that the combined company plans to use a material portion of the funds received from the business combination to develop any specific pipeline candidates, please disclose the amounts it expects to allocate to each candidate and specify how far in the development of each of these product candidates it currently expects to reach with these funds.

Impairment of goodwill and intangibles

Life sciences companies often hold significant goodwill and intangible assets (for example, from acquisitions or in-process R&D). The SEC frequently requests more disclosure of how registrants assess impairment triggers, how specific events might affect asset recoverability, and what are key valuation assumptions.

CROWE PRACTICE NOTE

In its January 2025 Invitation to Comment, "Agenda Consultation," the FASB invited feedback on whether improvements to the subsequent accounting for goodwill could better balance cost and decision-usefulness. The consultation acknowledges stakeholders' concerns that the current impairment-only model is costly to apply and might not accurately reflect the underlying economics, particularly in acquisition-driven industries such as the life sciences sector. This consultation's exploration of alternatives such as amortization or immediate expensing after acquisition might offer a different framework for life sciences companies while maintaining investor insights into asset recoverability risks.

Example SEC comments:

You disclose that your annual fair value analysis performed on goodwill supported that goodwill is not impaired as of June 30, 2023. Please provide us with the following information and consider disclosing this information in future filings:

- The percentage by which fair value of your reporting unit exceeded its carrying value as of the date of the most recent quantitative test
- A description of the methods and key assumptions used to estimate the fair value of the reporting unit and how these key assumptions were determined
- A description of potential events and/or circumstances that reasonably could be expected to negatively affect the key assumptions

We reference the disclosure here and throughout the filing that you recognized an impairment for certain long-lived assets related to the technology, customer relationships, and customer backlog finite-lived intangible assets due to "a significant change in the business environment." In future filings, please provide more context regarding the nature and impact of any triggering events that require assessment for impairment of your intangible assets.

We note that your market capitalization during the third quarter of fiscal year 2023 has continued to decline below total equity as of Sept. 30, 2023. Please tell us how you considered performing an interim impairment test of goodwill during the third quarter of fiscal year 2023. Refer to ASC 350-20-35-30 for guidance.

Contingencies and legal claims

Life sciences companies sometimes face significant legal or regulatory exposure, making clear and accurate disclosure of litigation contingencies critical. The SEC often requests additional disclosures under ASC 450, particularly when companies reduce legal accruals, rely on court developments, or face matters with a potential material impact. Comment letters regularly request quantification of changes in litigation accruals, explanation of key assumptions, or clarity about the range of reasonably possible losses.

Example SEC comments:

Please quantify and tell us the methods and key assumptions underlying the change in estimate for legal contingencies that reduced the liability for accrued legal contingencies during the reporting period. In particular, explain how the court's decision vacating a prior judgment and remanding this case back to a lower court supported your release of this litigation loss provision. Refer us to the technical guidance upon which you relied, and revise your disclosure accordingly.

You have disclosed a number of legal proceedings to which you are a party. To the extent that you believe that it is reasonably possible that resolution of these proceedings could result in a material adverse effect on your financial condition, results of operations, or cash flows, please revise your future filings to provide the disclosures required by ASC 450-20-50, including an estimate of reasonably possible losses in excess of amounts accrued.

We note your disclosure that the various claims and litigation matters you are involved in could have a material adverse effect on your financial position, results of operations, and cash flows. Please provide specific disclosures for these matters. Otherwise, if true, then clearly state that other than as disclosed for the SEC inquiry your claims and litigation matters are not expected to materially affect your financial position, results of operations, or cash flows individually or in the aggregate. Disclosures for the amount or range of reasonably possible loss in the aggregate, or disclosure that you are unable to reasonably estimate the amount or range, also should be provided, noting that ASC 450-20-50-4 does not require the amount or range of reasonably possible loss to be estimated with precision or certainty.

Business combination versus asset acquisition

Life sciences industry acquisitions often involve a single drug candidate or technology, which can raise questions about whether the acquisition is a business combination or asset acquisition under ASC 805. The SEC frequently comments on this issue to determine whether companies properly apply the screen test and justify their conclusions, especially when most of the purchase price is allocated to in-process R&D or intangible assets.

CROWE PRACTICE NOTE

In its January 2025 Invitation to Comment, "Agenda Consultation," the FASB requested feedback on the definition of a business under ASC 805. Although ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business," introduced a screen test to simplify and narrow the application of business combination accounting, stakeholders have reported continued difficulty applying the test in practice. Whether an acquisition in the life sciences industry represents a business combination or an asset acquisition sometimes involves significant judgments, especially when in-process R&D constitutes most of the fair value in the transaction. The FASB's consultation signals a potential reexamination of the screen test criteria and interpretive guidance, which could enhance consistency and reduce interpretive burden for preparers.

Example SEC comments:

We note that you provided pro forma financial statements related to a recent acquisition in your proxy statement. Your pro forma presentation treats this acquisition as a business combination. Please tell us how you considered the guidance in ASC 805-10-55-5A in determining that the acquisition constitutes a business, given that substantially all of the fair value of the gross assets acquired appears to be concentrated in a single identifiable asset or group of similar identifiable assets. In this regard, your pro forma financial statements show that indefinite-lived intangible assets constitute the entirety of the purchase consideration transferred.

We note that you completed an acquisition involving a single drug candidate, for which a significant portion of the purchase price was allocated to in-process R&D. Please address each of the following:

- Provide us with your analysis of the guidance in ASC 805-10-55-5A through 55-5C, including the calculation of the screen test.
- To the extent that you are able to demonstrate the screen test is not met, provide us with your analysis of the acquired entity meeting the definition of a business based on the guidance in ASC 805-10-55.

Financial instruments

Life sciences companies often raise capital through complex financing arrangements such as convertible notes or preferred stock, which might include embedded features like conversion options, contingent adjustments, or make-whole provisions. The accounting analysis of these instruments might be challenging, and the SEC regularly comments on the accounting for these instruments to ensure registrants have properly assessed bifurcation, applied scope exceptions, and provided clear, consistent disclosures.

CROWE PRACTICE NOTE

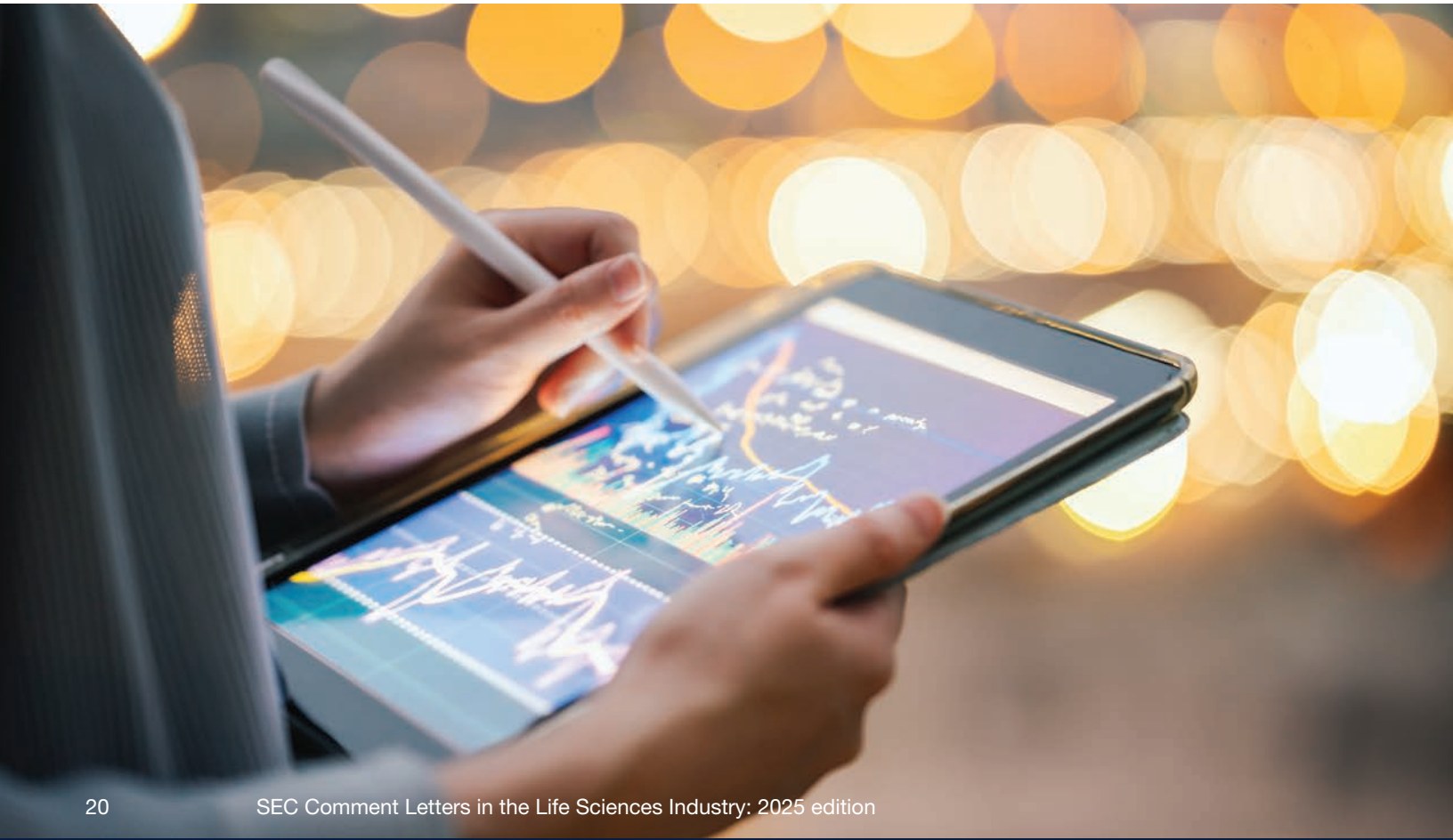
In its January 2025 Invitation to Comment, "Agenda Consultation," the FASB highlighted continued stakeholder concerns regarding the complexity of classifying financial instruments under Subtopic 815-40, particularly when assessing whether instruments indexed to an entity's own equity should be accounted for as liabilities or equity. The FASB is seeking input on whether to clarify indexation and settlement criteria, add illustrative examples, or redefine the liability/equity boundary to improve consistency and reduce restatement risk. These potential improvements directly intersect with the complex scenarios discussed in this section, where the structure and contractual language of complex financing transactions have significant implications for recognition, measurement, and disclosure.

Example SEC comments:

We note that your convertible notes are convertible at the option of the holder and that the make-whole fundamental change provision might trigger an increase in the conversion rate. Please explain to us how you evaluated the notes to determine whether each conversion feature was required to be bifurcated and accounted for as a derivative under ASC 815. In your response, please specifically address whether each conversion option contingency meets the definition of a derivative and, if so, whether it qualifies for the scope exception for contracts involving an entity's own equity as set forth in ASC 815-10-15-74(a). Specifically address the steps in ASC 815-40-15-7A through 15-7H, the conditions beginning in ASC 815-40-25-7, and if the make-whole provision violates the condition in ASC 815-40-25-39. Please also revise your accounting policy disclosure accordingly in your future filings.

Please clarify to us the accounting treatment and basis thereof for your convertible loans. In this regard, please address the following:

- You state in one section of your filing that the financial instrument liabilities are considered level three and the fair values of your financial instruments approximate their historical carrying amount. However, elsewhere you disclose there was a loss from convertible loan valuation for the periods presented. Please clarify.
- If the conversion terms resulted in derivative accounting treatment under ASC 815, please clarify.
- If you are recording the convertible loans at fair value pursuant to ASC 820, please tell us why there does not appear to be any change in fair value during the reporting period based on the disclosures elsewhere in the filing.



Internal control disclosures

Life sciences companies often operate with evolving systems and resource constraints, making internal control weaknesses possible. The SEC frequently comments when companies declare effective disclosure controls and procedures (DCP) despite ongoing material weaknesses in internal control over financial reporting (ICFR), fail to clearly disclose or update remediation plans, or provide vague conclusions on the effectiveness of DCP or ICFR.

Example SEC comments:

We note that your DCP were effective for the year ended Dec. 31, 2023. We also note your disclosure that management concluded that your ICFR is ineffective as of Dec. 31, 2023. Please clarify how you concluded effective DCP when you have a material weakness in ICFR that led to restatement of your financial statements. Refer to SEC Release 33-8238, "Final Rule: Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports," which states that DCP will include those components of ICFR that provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP.

We also note that you have had material weaknesses in your ICFR since 2019 that have not been remediated. Please revise to clarify what specific steps remain to be completed in your remediation plan. Also, revise to disclose how long you estimate it will take to complete your remediation plan and disclose any associated material costs that you have incurred or expect to incur.

We note that the company's management concluded, as of the end of the period covered by this report, that the company's DCP were "capable." Please amend your filing to disclose management's conclusion regarding whether your DCP were effective or not effective. If management concludes that the DCP are effective, please reference your prior material weaknesses in ICFR and provide us with sufficient information to understand how you reached your conclusion. If actions were undertaken to remediate the material weakness, such remediation requires disclosures to address the changes in ICFR. Refer to Rule 308(c) of Regulation S-K.

Mergers and acquisitions

Mergers and acquisitions are a common strategic path for growth, product pipeline expansion, or access to new technologies in the life sciences industry. These transactions often involve complex structures, such as equity consideration, convertible securities, and reverse mergers, which require robust and transparent disclosure. The SEC frequently comments on merger-related filings to ensure companies provide complete and accurate information, especially when shareholder approval is required. Common areas of comment include disclosure of merger terms and consideration, the negotiation process, fairness determinations, and the connection between related agreements. These disclosures are critical for investors to evaluate the transaction and understand the implications for corporate governance, ownership structure, and valuation.

Example SEC comments:

We note that the proposal seeks stockholder approval for the conversion of Series A convertible preferred stock into Class A common stock. We further note that you issued this convertible preferred stock as consideration in your merger with Company A and that this conversion vote for the merger consideration is required by New York Stock Exchange rules. Given that you did not solicit your pre-merger stockholders to approve either the merger or the merger consideration, please revise your preliminary proxy statement to include all of the information concerning the merger that is required by Items 11, 13, and 14 of Schedule 14A. For guidance refer to Note A to Schedule 14A.

Your Form 8-K indicates that you entered the exchange agreement in connection with the merger agreement, making it appear that the exchange agreement is not separate and apart from the merger agreement. Please revise your preliminary proxy statement to provide the disclosures required by Items 11, 13, and 14 of Schedule 14A with respect to those matters, as applicable, pursuant to Note A of Schedule 14A. Alternatively, please provide us with a more detailed analysis supporting why such disclosure is not required.

We note your disclosure that a preliminary draft of the merger agreement was shared and that an evaluation deemed the consideration for the transaction as fair to the shareholders. Please clarify how the amount of consideration ultimately was arrived at in the intervening time.

PCAOB inspection report themes

Those charged with governance, including the audit committee, likely will be interested in themes from PCAOB inspections as they execute their oversight responsibilities. We summarize findings in the healthcare industry[1] from the past two inspection cycles of the global network firms (GNFs) and certain considerations for those charged with governance.

The audit committee has a statutory responsibility to oversee the company's financial reporting and the external auditor. PCAOB inspection findings can inform the audit committee members as they seek to understand the company's risk assessment process (for example, identification of industry-specific risks for the internal audit plan or prioritization of risk areas to evaluate with management), understand how management approaches the entity's internal control structure (for example, to identify control areas that present enhanced risk or to facilitate continual improvement), and engage with the external auditor.

Revenue recognition

Revenue continues to be the most frequently cited area of deficiency in PCAOB inspections of the audits of healthcare issuers. Findings indicate that auditors often did not sufficiently evaluate whether performance obligations under ASC 606 were fully satisfied prior to revenue recognition. Particular concerns were noted around variable consideration, collectability assessments, and reliance on data from the service organization the issuers used. In many cases, substantive testing of contract terms and verification of the accuracy and completeness of transaction prices were either not performed or inadequately executed.

Questions for audit committees to consider asking the auditor:

- How did the audit team evaluate whether revenue recognition was in accordance with ASC 606?
- Were external data sources determined to be relevant and reliable?
- How did the auditors assess management's significant assumptions and judgments?

[1] The PCAOB uses Global Industry Classification Standard (GICS) codes to classify issuers, and we have summarized inspection findings for issuers classified in the "Health Care" GICS code, which includes life sciences companies.

Inventory and reserves

Deficiencies in the auditing of inventory primarily relate to insufficient testing of unit costs, inadequate support for reserve estimates for excess and obsolete stock, and insufficient testing of system-generated reports. In some cases, auditors failed to consider the impact of control deficiencies when determining the nature and extent of their audit procedures.

Questions for audit committees to consider asking the auditor:

- How did the audit team assess management's valuation of inventory and any related reserves, including assessing significant assumptions used in the valuation?
- If there were any system-related control deficiencies that affected inventory reporting, how did the auditor amend its audit approach?

Auditing estimates

The PCAOB frequently identifies deficiencies in areas that involve auditing accounting estimates. These estimates often are inherently subjective, complex, and high-risk areas of financial reporting. Deficiencies related to auditing estimates most often cited in life sciences audits include the following:

Business combinations

PCAOB findings consistently highlighted deficiencies in the auditing of valuation of acquired assets, especially intangible assets. Auditors often placed undue reliance on specialist valuations without independently assessing the reasonableness of significant assumptions such as sales growth, pricing, or product mix used in fair value models. Furthermore, adjustments made during the measurement period were not always evaluated for compliance with ASC 805.

Intangible assets and goodwill

Inspection reports revealed recurring deficiencies in auditing management's impairment analysis of intangible assets and goodwill. Auditors did not properly assess management's identification of impairment indicators or did not evaluate the appropriateness of significant assumptions used in management's forecasts. In several cases, year-end events that could have triggered impairment were not adequately considered.

Fair value and derivatives

Audit deficiencies identified included overreliance on issuer-prepared valuations and the auditor not evaluating whether assumptions were reasonable and market-consistent. Auditors also did not sufficiently assess the appropriateness of the valuation methodologies under ASC 820.

Questions for audit committees to consider asking the auditor:

- How did the auditors evaluate the consistency of management's assumptions used in multiple estimates?
- What testing was done on management's forecasts, significant assumptions, and the models used?
- How did the auditor assess the reliability and appropriateness of third-party specialists' work?

Accounts receivable and related reserves

In certain cases, the auditor did not perform substantive procedures on certain accounts receivable balances. In other cases, the auditor did not test, or test controls over, the accuracy and completeness of data used in reserve calculations.

Questions for audit committees to consider asking the auditor:

- What procedures did the audit team perform to validate receivable balances and reserves?
- How was the accuracy and completeness of underlying data evaluated?

Income taxes

The PCAOB flagged instances where auditors did not sufficiently evaluate whether the classification and recoverability of tax-related receivables were appropriate under ASC 740.

Question for audit committees to consider asking the auditor:

- How were significant tax assumptions and classifications evaluated?

CROWE PRACTICE NOTE

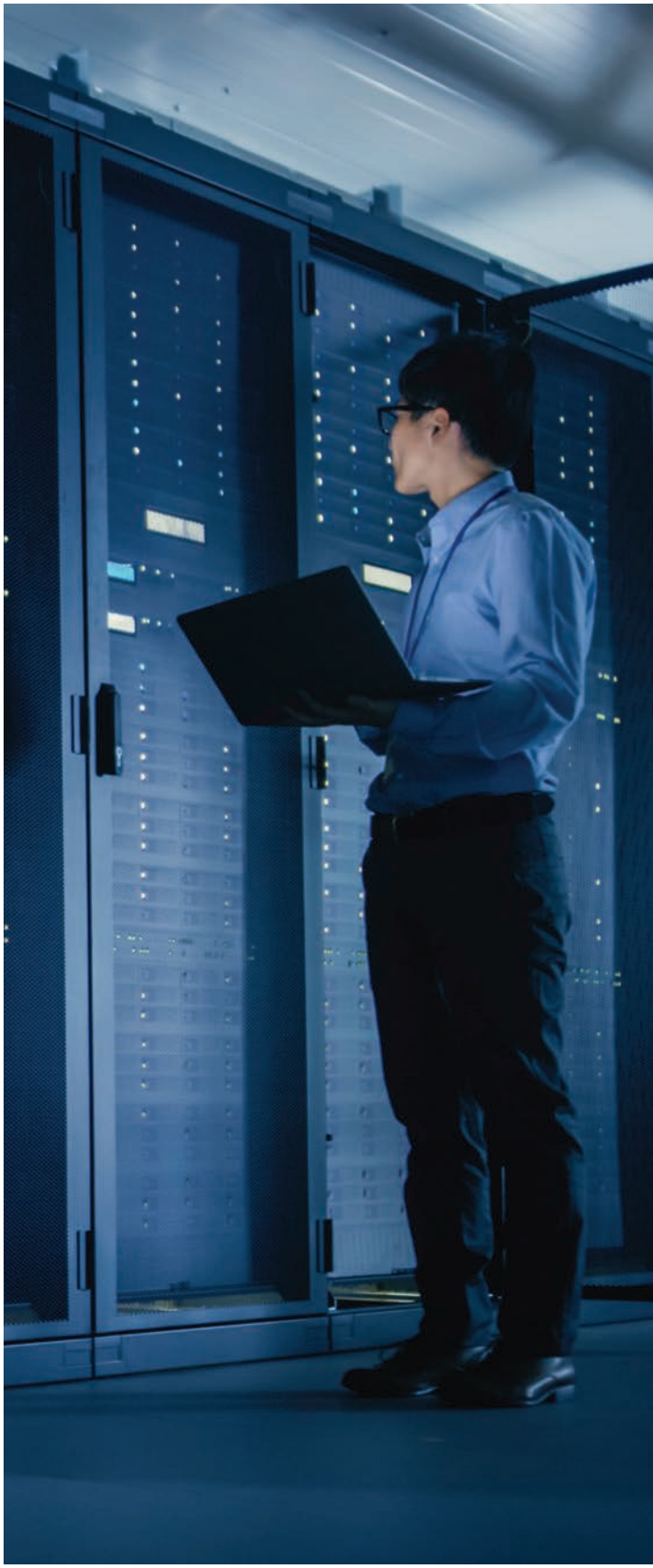
On Dec. 14, 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU 2023-09 is effective for calendar year public business entities in the Dec. 31, 2025, financial statements. The standard will require new judgments and disclosures, and audit committees might consider asking management to prepare a draft of the disclosures well in advance of the preparation of the Dec. 31, 2025, financial statements so the audit committee can evaluate the disclosures and review with management the appropriateness of any new judgments required.

IT general controls and data integrity

PCAOB inspection findings frequently included deficiencies related to auditors' identification and testing of IT general controls (ITGCs) and the integrity of system-generated data. In several audits, firms relied on automated or IT-dependent manual controls without testing the underlying IT environment, including user access rights, system change management, and report generation processes. These issues were particularly concerning where key financial reporting controls depended on IT systems or where substantive audit procedures relied on reports produced by those systems. In some cases, prior-year testing was improperly relied on, or access control deficiencies were not appropriately considered in evaluating the effectiveness of controls. As a result, related audit procedures lacked sufficient evidence to support reliance on internal controls or the accuracy of key financial statement items.

Questions for audit committees to consider asking the auditor:

- How did the audit team evaluate ITGCs and their impact on the audit approach?
- Were any deficiencies identified in access or change management controls?
- What was the auditor's approach to testing system-generated reports used in the financial audit?



Final thoughts

The SEC comments in this publication are not the complete population of all recent comments issued in the life sciences industry; however, they are representative of the types of issues CorpFin has addressed in its review program. Similarly, the PCAOB inspection observations are representative of the topical areas most commonly found in healthcare industry audits. The focus of the SEC staff and the PCAOB staff constantly evolve, and Crowe will endeavor to keep you informed of new trends.

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