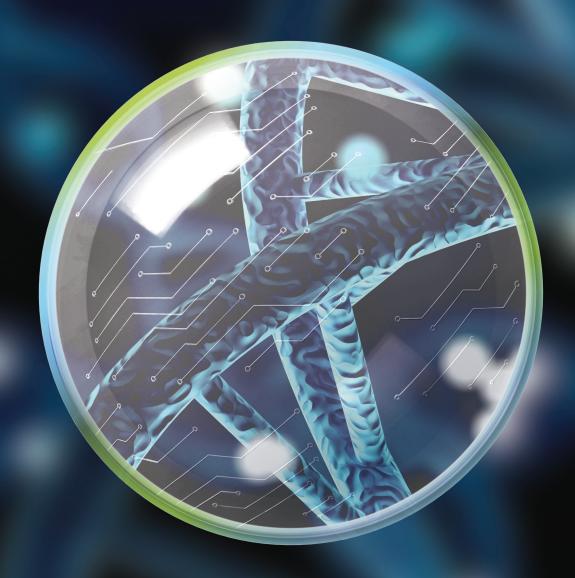
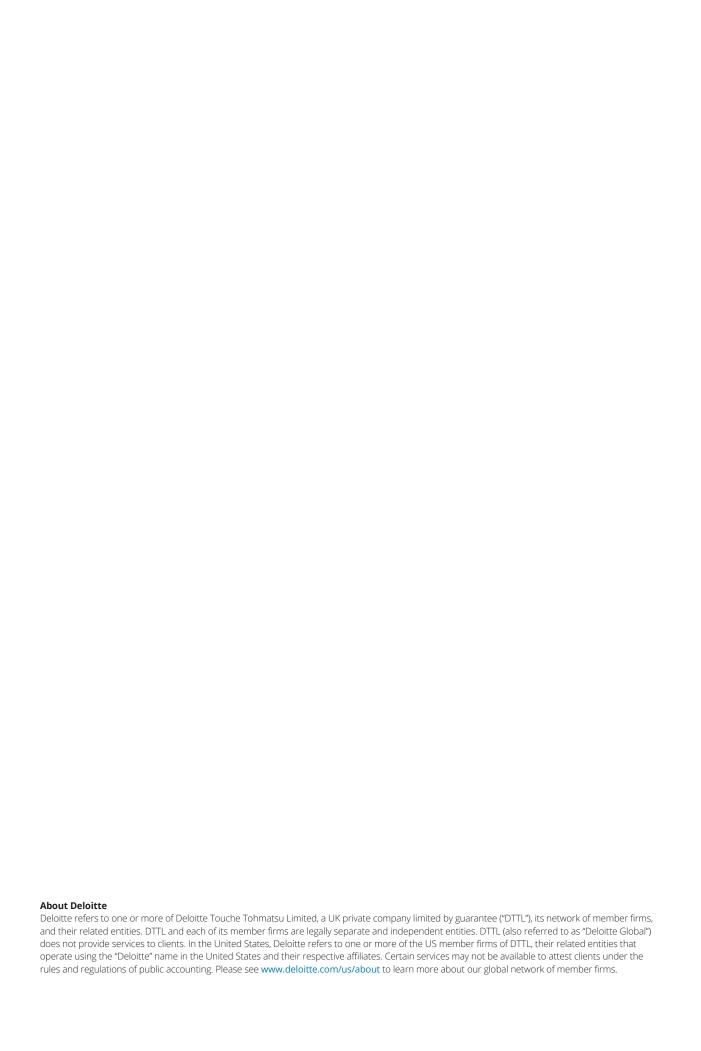
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## **Life Sciences Industry Accounting Guide**

Accounting and Financial Reporting Considerations for Life Sciences Entities Related to the Macroeconomic and Geopolitical Environment and COVID-19 Pandemic



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## **Preface**

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2023 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting developments (through February 28, 2023), and key differences between U.S. GAAP and IFRS® Accounting Standards. In addition, this Guide discusses (1) accounting and financial reporting considerations associated with the COVID-19 pandemic that apply specifically to the life sciences industry, (2) environmental, social, and governance (ESG) matters that have become topics of increased focus, and (3) the potential impact of the Inflation Reduction Act (IRA).

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2022 edition are summarized in Appendix D.

We hope this Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

## Contacts



Jeff Ellis
U.S. and Global Audit Leader —
Life Sciences
Life Sciences Industry
Professional Practice Director
Deloitte & Touche LLP
+1 412 338 7204
jeellis@deloitte.com



Dennis Howell
National Office Senior
Communications and
Consultation Partner,
Accounting and Reporting
Services
Life Sciences Deputy
Industry Professional
Practice Director
Deloitte & Touche LLP
+1 203 761 3478
dhowell@deloitte.com

# Chapter 1 — Accounting and Financial Reporting Considerations for Life Sciences Entities Related to the Macroeconomic and Geopolitical Environment and COVID-19 Pandemic

#### 1.1 Executive Summary

Today's consumers and companies face numerous challenges associated with the current macroeconomic and geopolitical environment. Reports of continuing global supply-chain disruptions and labor shortages dominate the news and are top of mind for many financial executives.

On the basis of Deloitte's recent Q3 2022 *CFO Signals* survey, some of the most common issues affecting CFOs include internal matters such as employee retention, employee working arrangements, and cost management, as well as external concerns such as inflation, stagflation, and geopolitical tensions.

Certain of these challenges started during the COVID-19 pandemic, which gave rise to new operational and financial difficulties, often with unique accounting and financial reporting implications (see Deloitte's March 25, 2020 [updated January 11, 2021], *Financial Reporting Alert*). For example, as a result of significant global supply-chain disruptions and labor shortages brought on by the pandemic, many product and employment costs increased. Global central banks have also been raising interest rates in an attempt to temper the impact of historically high inflation rates.

The discussion below highlights key accounting and financial reporting considerations for life sciences entities to consider.

#### 1.1.1 Forecasting

In an environment marked by the COVID-19 pandemic as well as by macroeconomic and geopolitical turbulence (referred to herein as the "current environment"), many companies have faced significant challenges related to forecasting as a result of the ongoing uncertainties. Even as the pandemic diminishes in intensity, it is causing what some consider to be **lingering ill effects**, such as inflation, supply-chain disruptions, and labor shortages. These effects continue to make forecasting particularly challenging in the current environment.

Patti Domm, "Labor Shortage, Supply Constraints and Inflation Hold Back Economy Trying to Emerge From Pandemic," CNBC.com, October 29, 2021

One of the many consequences of COVID-19 has been pent-up demand for a variety of goods and services. However, many companies are having difficulty satisfying the demand because of labor shortages and a disrupted supply chain. For life sciences entities, supply-chain disruptions may also involve the shortage of key components needed for production, such as microchips, assays, active pharmaceutical ingredients (APIs), or other inputs to the manufacturing cycle. Faced with the additional challenge of historically high inflation, life sciences companies are trying once again to develop forecasts amid a number of uncertainties.

As cost structures change with higher inventory and freight costs and pressure to increase employee compensation, life sciences companies should (1) consider how they expect the altered cost structures to continue into the future and (2) evaluate whether they will be able to offset any increased costs with pricing adjustments. Companies may see a significant decline in revenues if they are unable to procure resources needed to produce and deliver goods and services.

Inflation, supply-chain constraints, and labor shortages all affect a company's forecasts. Such forecasts are used in a variety of accounting estimates, including, but not limited to, those related to the assessment of (1) goodwill or other long-lived assets for impairment, (2) whether valuation allowances related to the recovery of deferred tax asset (DTA) balances are needed, and (3) liquidity and the appropriateness of the going-concern presumption. In developing forecasts and assessing the related accounting implications, companies should consider whether the effects of the uncertainties are short-term or long-term and how that determination will affect various accounting estimates. See Section 1.4 for further discussion of forecasting in the context of accounting and financial reporting considerations related to the current environment.

#### 1.1.2 Inflation

Although the effects of inflation vary by company, there are some common topics that life sciences companies should evaluate when considering how recent inflationary trends may affect their accounting and financial reporting.

Because inflation is most likely driving up costs of acquiring goods/inventory and related packaging materials, as well as employee wages, life sciences companies should consider whether they can pass along those increased costs to their customers.

Life sciences companies may also have increased costs associated with long-term revenue contracts that they may or may not be able to pass along to their customers. If a company is unable to raise its prices under a revenue contract, the company's estimated profitability on the contract may decline or result in a loss on the contract. Companies should consider the potential accounting implications of reduced or negative profitability on a revenue contract, including the period in which to record a loss if applicable.

Inflation may result in renegotiating long-term contracts, such as leases or long-term supply agreements, which in turn may have potential accounting implications. For example, depending on the terms, a modification to a lease contract may require a company to reassess the classification and measurement of the lease.

In addition, global central banks have been raising interest rates in an attempt to temper the impact of high inflation. Companies should consider whether the increase in interest rates has resulted in an impairment of financial assets. Companies should also consider potential impacts on estimated credit and loan loss reserves.

As life sciences companies review their investment strategies in light of recent inflation, they may consider making different types of investments or moving away from holding excess cash on hand. For example, a company may consider investing in digital assets (such as cryptocurrencies) or Treasury Inflation-Protected Securities as a hedge against inflation. Companies contemplating such investments should consider the complex accounting and financial reporting that may result from holding them. For example, inflation-indexed debt securities are subject to specific interest recognition guidance under U.S. GAAP and should be evaluated to determine whether they contain any derivative that is required to be accounted for separately for accounting purposes.

Further, life sciences companies should monitor the appropriateness of the discount rate used to measure any pension-related liabilities, particularly since even a seemingly small change in the discount rate can affect a company's pension liability significantly. For example, higher interest rates may lead to decreases in pension liabilities and required employer contributions. However, such decreases may be offset by higher employee wages, which are further discussed in **Section 1.1.4**.

#### 1.1.3 Supply-Chain Disruptions

Supply-chain disruptions have been well publicized. For example, it has been reported<sup>2</sup> that since the manufacturers, suppliers, and distributors in a supply chain are interconnected, "disruption in one part of the chain [has] a ripple-down effect on all parts of the chain" and "ultimately [affects] consumers and economic growth."

For some life sciences companies, such disruption could significantly increase the costs associated with moving goods through the supply chain. If higher costs are included in inventory, companies should consider whether these costs drive up the cost of the inventory in such a way that adjustments based on the expected net realizable value of the inventory are warranted. This determination is likely to vary by industry sector and by company given (1) the use of different types of materials, (2) diversity in suppliers, and (3) a company's ability to transfer cost increases to its customers through higher selling prices.

While the goods are making their way through the disrupted supply chain, companies should consider the point in time at which the buyer actually assumes ownership of the goods to ensure appropriate reporting of raw materials, finished goods, and supplies on their balance sheets. Companies that may have had only immaterial amounts of goods in transit because of historically short transit times may find it necessary to implement more robust accounting processes and internal controls to appropriately capture their inventories (some of which may be physically held by third parties). Likewise, companies should ensure that suitable cutoff procedures result in revenue recognition in the appropriate period.

In addition, companies struggling to obtain certain products that are inputs to finished goods, such as microchips, may consider adjusting their manufacturing processes to use different inputs or manufacture the products differently. Companies should consider whether the need to use alternate raw materials or processes affects the warranties offered and the accounting for those warranties. Changes to the terms and conditions of warranties, the expected life of the product, or expected warranty claims may differ by product type; such differences, combined with increased material and labor costs, could affect the related warranty accounting.

Holly Ellyatt, "Supply Chain Chaos Is Already Hitting Global Growth. And It's About to Get Worse," CNBC.com, October 18, 2021 (updated October 19, 2021).

#### 1.1.4 Labor Shortages

Labor shortages may manifest themselves in the form of employee turnover, departures, and demands for higher wages at all levels of the organization. As costs of retaining labor increase in a production environment, companies should consider how these increased labor costs affect the cost of inventory and whether these higher costs can be offset by price increases as companies sell these goods to their customers. Companies should also consider the potential accounting implications of including increased costs in inventory, as discussed in Section 1.1.3.

To address employee demands for increased compensation, many companies are revisiting their compensation structures. Adjustments may take the form of increased hourly wages, retention bonuses, improved incentive compensation or stock compensation, or other benefits. Companies should consider the accounting implications of these changes in compensation structure. For example, if a company provides retention bonuses to employees, the company should consider the contractual terms of those arrangements and assess during what period those bonuses should be recognized. In addition, certain companies may need to consider changes in their workforce and the related compensation structure when evaluating assumptions used to measure their pension liability.

In response to a shortage in labor, some companies may be forced to operate at a reduced capacity. In such a case, companies should consider whether there are costs that have been capitalized into inventory historically but should be expensed currently because of abnormal production levels (e.g., indirect costs such as rent and depreciation).

Further, to the extent that vaccine mandates are applicable, companies should consider what actions they will (or may) be required to take because of the mandates and whether the mandates will exacerbate the labor shortage and affect the considerations discussed above. Any departure of employees as a result of the mandates may put a strain on production and delivery forecasts and could pose additional challenges related to employee compensation, including termination benefits.

Increased turnover and the shortage of employees may also put stress on a company's internal control environment. As employee responsibilities shift, companies should assess whether appropriately skilled and trained individuals are in place to effectively design, implement, operate, and monitor controls, including controls related to information technology (IT).

#### 1.1.5 Communication With Stakeholders

In addition to considering potential accounting-related impacts of inflation, supply-chain disruptions, and labor shortages, life sciences companies will need to evaluate their communication strategies related to such risks and uncertainties. While private and public companies alike will need to comply with the disclosure requirements under U.S. GAAP, public companies will also need to consider the SEC's reporting requirements, including required disclosures about trends and uncertainties in the business, risk factors, and MD&A sections of filings. For many companies, these issues may require disclosure in MD&A of known trends or uncertainties that could affect sales, net income, or liquidity. For example, supply-chain disruptions may result in lower sales, increased costs, or increased working capital requirements, all of which may warrant disclosure in MD&A. Companies should consider disclosing the current effects of these matters on the business, expected future impacts, and how management is responding. Further, companies should tailor these disclosures to their specific circumstances and avoid generic boilerplate descriptions of inflation, supply-chain disruptions, and labor shortages.

For more information, see the SEC Reporting and Disclosure Considerations section in Deloitte's December 1, 2022, *Financial Reporting Alert*.

## 1.1.6 Ongoing Accounting and Financial Reporting Considerations Stemming From the Current Environment

We believe that in addition to the economic factors discussed above, the following accounting and reporting issues will continue to be the most pervasive and challenging for life sciences entities as a result of the current environment:

- Preparation of forward-looking cash flow estimates and forecasts The use of forward-looking information is pervasive in an entity's assessment of, among other things, the impairment of nonfinancial assets (including goodwill), the realizability of DTAs, and the entity's ability to continue as a going concern. Unique complexities associated with preparing forward-looking information in the current environment include the following:
  - There is an extremely wide range of possible outcomes. There is a particularly high degree of uncertainty about the ultimate trajectory of the pandemic and the path and time needed for a return to a "steady state."
  - The associated economic impact of the pandemic is highly dependent on variables that are difficult to predict and may not affect all subsectors the same. Examples include the degree to which governments restrict business and personal activities, the associated level of compliance by citizens, and the nature and effectiveness of government assistance.
  - Each entity must then translate the effect of those macro conditions into estimates of its own future cash flows

Nevertheless, entities will need to make good-faith estimates, prepare comprehensive documentation supporting the basis for such estimates, and provide robust disclosure of the key assumptions used and, potentially, their sensitivity to change.

- Recoverability and impairment of assets Perhaps the most acute examples of the increased challenge associated with forward-looking information are the impairment tests for long-lived assets, intangibles, and goodwill. These nonfinancial assets use recoverability and impairment models that rely on the development of cash flow projections that are subject to the significant uncertainties noted above. However, impairments establish a new cost basis for the assets and do not permit the subsequent reversal of the recorded impairment. Good-faith estimates in the current reporting period could result in material recorded impairments; if unforeseen favorable developments occur in subsequent quarters, the recognized impairment would no longer be indicated, but it cannot be reversed.
- Accounting for financial assets At the onset of the pandemic, many entities experienced severe
  declines in the fair value of financial assets, particularly equity securities. Likewise, the ability
  of debtors to comply with the terms of loans and similar instruments was adversely affected.
  Entities should continue to carefully consider and apply the appropriate impairment and loss
  recognition guidance.
- Contract modifications and penalties Changes in economic activity caused by the current environment may cause many entities to renegotiate the terms of existing contracts and arrangements. Examples include contracts with customers, compensation arrangements with employees, leases, and the terms of many financial assets and liabilities. As a result of these changes, entities will need to ensure that the appropriate guidance in U.S. GAAP is considered.
- Subsequent events It may be challenging for an entity to separate recognized and unrecognized subsequent events in a global marketplace that is extremely volatile and in which major developments occur daily (e.g., the stock market's daily reaction to new information). Although entities may not have all facts "on hand" on the balance sheet date, once such facts are gathered, an assessment must be based on conditions as they existed on the balance sheet

- date. As the global landscape evolves, entities are encouraged to remain vigilant, document the nature and timing of events, and consult with their accounting advisers.
- Going concern In the current environment, entities need to consider whether, in their specific circumstances, they have the ability to continue as a going concern within one year after the date on which the interim or annual financial statements are issued (or available to be issued, when applicable). The initial assessment (before consideration of management's plans) will require an entity to consider, among other things, (1) the extent of operational disruption, (2) potential diminished demand for products or services, (3) contractual obligations due or anticipated within one year, (4) potential liquidity and working capital shortfalls, and (5) access to existing sources of capital (e.g., available line of credit). An entity can only base this initial assessment on information that is available (i.e., known and reasonably knowable) as of the issuance date of the financial statements. An entity may be able to alleviate substantial doubt, if such doubt exists, if it is probable that the entity's plans will be effectively implemented and, when implemented, will mitigate the conditions that are raising substantial doubt in the first instance and will do so within one year after the issuance date of the financial statements. Further, an entity must provide comprehensive disclosures in its annual and interim financial statements when events and conditions are identified that raise substantial doubt about the entity's ability to continue as a going concern even when management's plans alleviate such doubt.
- Loss contingencies Many entities are facing disruption and delays or are incurring other contingencies in the current environment. Entities are required to disclose both recognized and unrecognized contingencies and the nature of the contingencies, particularly when loss is reasonably possible but not yet recorded in the financial statements.
- Share-based compensation Many life sciences entities provide share-based compensation to incentivize employees and retain talent. Share-based compensation awards may be subject to various vesting conditions and requirements that have been affected in the current environment or, as a result of declines in financial performance of the underlying stock, may be considered deeply out-of-the-money. Entities should carefully evaluate changes in these awards to ensure that the appropriate accounting treatments are being applied.

Entities must carefully consider their unique circumstances and risk exposures when analyzing how recent events may affect their financial reporting. Specifically, financial reporting and related financial statement disclosures need to convey all material current or potential effects of the current environment. It is also critical that management understand the risks entities face and how those risks affect them. Further, SEC registrants must consider whether (1) certain disclosures are required by Form 8-K (e.g., material impairment charges, liquidity events that result in a violation of debt covenants) and (2) to disclose information in areas such as MD&A or the risk factors section in addition to their disclosures in the footnotes to the financial statements.

Registrants must consider the impacts of the current environment on their required disclosures and public filings. Recent guidance issued by the SEC has included **CF Disclosure Guidance Topics 9** and **9A** (in response to the pandemic) and a **sample letter** discussing disclosure considerations (in response to the Russia-Ukraine War). While the guidance in those documents was prompted by specific events, it continues to apply in the current environment.

The remainder of this chapter further discusses key accounting and financial reporting considerations for life sciences entities related to conditions that may result from the current environment. In addition, disclosure matters related to the current environment are discussed in Section 1.13. For more information about the topics highlighted in the sections below, see the following Deloitte Financial Reporting Alert newsletters:

- "Accounting and Financial Reporting Considerations Related to the Current Macroeconomic and Geopolitical Environment."
- "Financial Reporting Considerations Related to COVID-19 and an Economic Downturn."
- "COVID-19 and Financial Reporting Trends Accounting for the Pandemic in the Current Quarter."
- "COVID-19 and Non-GAAP Measures."
- "COVID-19 Financial Reporting Trends Different News or More of the Same?"

#### 1.2 Potential Impact on Contract R&D Arrangements

Life sciences entities that have contractual arrangements to perform contract R&D for others (e.g., biotechs and CROs) may experience changes in the cost of performing contract R&D (e.g., as a result of a shift in the mix of in-person monitoring visits and remote monitoring, or because of changes in patterns of enrolling patients in clinical trials), which could have revenue recognition implications. For example, an entity that uses a cost-based input method to measure its progress toward complete satisfaction of a performance obligation would need to reevaluate whether its measure of progress is affected by changes in the overall cost of the R&D program or whether any increased costs should be excluded from the measure of progress because they do not depict the entity's performance in transferring control of the contract R&D (e.g., if the costs are due to unexpected amounts of wasted materials, labor, or other resources). Further, the potential disruption in an entity's performance of contract R&D could affect its estimate of variable consideration in circumstances in which the entity is entitled to receive R&D milestone payments if (1) clinical trial regulatory approvals are received by a certain date, (2) regulatory approval for commercialization is ultimately achieved, or (3) both. See Chapter 2 for more information about collaborative arrangements accounted for as revenue contracts.

#### 1.3 Impairment of Nonfinancial Assets (Including Goodwill)

As a result of the changes in the current environment, life sciences entities should consider whether they are experiencing any conditions (e.g., decreased revenues, order cancellations, supply-chain disruptions, or declines in share price) that indicate that their assets should be tested for impairment (i.e., a "triggering event" has occurred). Even assets that have an annual impairment testing requirement, such as goodwill or indefinite-lived intangible assets, should be tested for impairment when a triggering event occurs. For example, the decline in global equity markets in the current environment may have led an entity to conclude that it was required to test goodwill for impairment (because a decline in market capitalization could signal a change in facts and circumstances "that would more likely than not reduce the fair value of a reporting unit below its carrying amount," in accordance with ASC 350-20-35-30). The guidance on testing assets for impairment varies depending on the asset being tested. Some nonfinancial assets are tested for impairment individually, while others are tested as part of a larger unit of account. Further, some nonfinancial assets are tested by using a recoverability test, while others are tested by using a fair value or net realizable value test.

In addition, it is important to consider the order in which assets are tested so that the entity can ensure that any required adjustments are made before including those assets in the testing of larger units of account. Assets that are not held for sale should be tested for impairment in the following order: (1) assets outside the scope of ASC 360-10 (other than goodwill), such as inventory, capitalized costs of obtaining or fulfilling a revenue contract, and indefinite-lived intangible assets; (2) long-lived assets in accordance with ASC 360-10; and (3) goodwill in accordance with ASC 350-20.

#### 1.3.1 Indefinite-Lived Intangible Assets Other Than Goodwill

As stated in ASC 350-30-35-4, an indefinite-lived intangible asset is one for which "there is no foreseeable limit on the period of time over which it is expected to contribute to the cash flows of the reporting entity." Certain brands, trademarks, or licenses are common examples.

Indefinite-lived intangible assets are tested annually for impairment and more frequently if events or changes in circumstances indicate that it is more likely than not that the intangible asset is impaired in accordance with ASC 350-30. ASC 350-30-35-18B provides examples of these events or changes in circumstances, which include, but are not limited to, financial performance, legal or political factors, entity-specific events, and industry or market considerations. On the basis of the impairment assessment, if an entity determines that it is more likely than not that the carrying value of the intangible asset exceeds its fair value, the entity performs a valuation to determine the fair value of the asset and recognizes an impairment loss equal to the excess of the carrying amount of the intangible asset over its fair value.

A valuation technique that is often applied to the measurement of a brand or trademark is the relief from royalty method. This method, which focuses primarily on expected revenues and royalty rates, requires the entity to make fewer assumptions than other income methods. However, an entity may find it challenging to project revenues because of the current environment's unique impact not only on consumer buying decisions but also on the entity's ability to continue to (1) produce products in the event of supply-chain disruptions or (2) deliver services in the event of shelter in place or work at home requirements, for example. Entities are expected to use their best estimate of all required business and valuation assumptions for this or other income methods used to measure the fair value of an indefinite-lived intangible asset.

In addition to evaluating the need for an interim impairment test, an entity should also consider whether there are any indicators that an intangible asset classified as indefinite-lived has become finite-lived, which might occur if an entity changes its expected use of the asset in response to the effects of the current environment.



#### **Disclosure Considerations**

ASC 350-30-50-3 provides specific disclosure requirements for each recognized impairment loss related to an intangible asset.

#### 1.3.2 Long-Lived Assets

A life sciences entity should consider whether it is experiencing (1) a decline in revenues, (2) an increase in costs (i.e., a decline in net cash flows), or (3) both as a result of the current environment. Such changes may indicate that the entity should test its long-lived assets for recoverability. Although we expect each entity to be affected differently in terms of both the effects of the current environment on its cash flows and the susceptibility of its long-lived assets to impairment, an entity should document its considerations regarding the recoverability of its long-lived assets.

Entities are required by ASC 360-10-35-21 to test a long-lived asset (asset group) that is classified as held and used for recoverability "whenever events or changes in circumstances indicate that its carrying amount may not be recoverable" (e.g., a significant adverse change in the business climate that could affect the value of a long-lived asset [asset group]). Events or changes in circumstances that prompt a recoverability test are commonly referred to as "triggering events." In light of events such as the idling of manufacturing facilities, or trends related to decreases in consumer spending, many entities are likely to experience one or more of the triggering events listed in ASC 360-10-35-21. For example, triggering events that may be present as a result of the current environment include, but are not limited to, a "significant decrease in the market price of a long-lived asset (asset group)," a "significant adverse change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition," or a "current-period operating or cash flow loss combined with . . . a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset (asset group)."

ASC 360-10-35-23 states that "a long-lived asset or assets shall be grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities." Such a combination is called an asset group.

An asset group may include not only long-lived assets that are within the scope of ASC 360-10 but also other assets such as receivables, inventory, indefinite-lived intangible assets, or goodwill. ASC 360-10-15-5 provides a list of assets that are not within the scope of ASC 360-10. Note that ASC 360-10 applies to long-lived assets that are not within the scope of other GAAP, such as property, plant, and equipment (PP&E); finite-lived intangible assets (customer relationships, technology, brands, and tradenames); and right-of-use assets.

To test a long-lived asset (asset group) for recoverability, an entity compares the carrying value of the asset (asset group) to the undiscounted net cash flows generated from the asset's (asset group's) use and eventual disposal. While the use of undiscounted cash flows generally indicates that a long-lived asset (asset group) is less prone to impairment, reductions in the estimates of undiscounted cash flows based on the expected duration and magnitude of conditions in the current environment may indicate that the carrying amount of the long-lived asset (asset group) is not recoverable.

If an entity estimates future cash flows to test the recoverability of a long-lived asset (asset group), such an estimate should include only the future cash flows (cash inflows minus associated cash outflows) that are (1) directly associated with the asset (asset group) and (2) expected to arise as a direct result of the use and eventual disposition of the asset (asset group). To estimate future cash flows, the entity must consider both cash inflows and cash outflows. ASC 360 indicates that it may be useful for the entity to apply a probability-weighted approach when it is considering alternative courses of action to recover the carrying amount of a long-lived asset (asset group). Such an approach may also be beneficial when the entity is considering alternative courses of action to manage cash outflows in response to anticipated revenue declines as well as when evaluating the extent of government intervention and the potential effects of any such intervention on both cash inflows and cash outflows.

ASC 360-10-35-30 states, in part, that the "assumptions used in developing [cash flow estimates should] be reasonable in relation to the assumptions used in developing other information used by the entity for comparable periods, such as internal budgets and projections, accruals related to incentive compensation plans, or information communicated to others."

If the entity determines that the carrying amount of the long-lived asset (asset group) is not recoverable, the entity then performs the next step in the impairment test by recognizing an impairment loss for the amount by which the carrying amount of the long-lived asset (asset group) exceeds its fair value. It then allocates that amount to the long-lived assets that are within the scope of ASC 360-10 "on a pro rata basis using the relative carrying amounts of those assets, except that the loss allocated to an individual long-lived asset of the group shall not reduce the carrying amount of that asset below its fair value whenever that fair value is determinable without undue cost and effort."

If an entity determines that a long-lived asset (asset group) is recoverable, it does not recognize an impairment loss, even if the carrying value of that asset (asset group) exceeds its fair value. Regardless of whether an entity recognizes an impairment loss, it should still consider whether the existence of a trigger indicates that there has been a change in the useful life or salvage value of its long-lived assets. If so, it should revise its depreciation or amortization estimates accordingly.

Sometimes, an entity may conclude that the affected long-lived assets will be sold, abandoned, or otherwise disposed of. Under ASC 360, if the held-for-sale criteria in ASC 360-10-45-9 are met, the entity is required to measure the asset (asset group) "at the lower of its carrying amount or [its] fair value less cost to sell" in accordance with ASC 360-10-35-43. A long-lived asset that will be abandoned will continue to be classified as held and used until it is disposed of. Such an asset is disposed of when it ceases to be used. However, a "long-lived asset that [is] temporarily idled shall not be accounted for as if abandoned" in accordance with ASC 360-10-35-49. Further, when "a long-lived asset ceases to be used, the carrying amount of the asset should equal its salvage value, if any."



#### **Disclosure Considerations**

ASC 360-10-50 provides disclosure requirements for impairments of long-lived assets classified as held and used and for long-lived assets classified as held for sale or disposed of.

#### 1.4 Forecasting

Life sciences entities continue to face challenges related to forecasting as a result of the ongoing uncertainties associated with the current environment. Looking across the economic landscape, one might observe a tale of two markets: companies that are being challenged to get back to pre-outbreak operations and those that are benefiting from the outbreak.

For many of the companies negatively affected by current environment, we have observed the development of forecasts that use pre-COVID-19-affected results as an initial target on which such companies have based their assumptions for the resumption of "normal growth." However, we believe that companies should ask themselves whether achieving pre-COVID-19-affected results in the near term is reasonable or whether they are facing a "new normal" given the potential continuation of the existing economic environment or a permanent shift in their business models introduced by the pandemic in addition to inflationary pressures, supply-chain disruption, and increased labor, freight, and manufacturing costs.

In thinking about both a new normal and future trends, some life sciences companies are evaluating whether customer preferences have shifted in such a way that they most likely will not reach the same performance levels they achieved before the outbreak. Other companies that may be benefiting currently are assessing whether they will continue to outperform in future periods or revert back to historical performance.

With all the unknowns and uncertainties, including the timing and pattern of economic recovery, we have noted that more companies are preparing multiple forecasts with different recovery scenarios and are probability-weighting the likelihood of each outcome. In addition, with the increase of liquidity challenges and shortfalls of capital resources, many companies have enhanced their focus on forecasting cash position and cash flows rather than allowing cash flow estimates to be simply derived on the basis of forecasted operations.

While the approach to forecasting operations that some companies have taken leverages historical data from the 2008 financial crisis (the "financial crisis") as an appropriate benchmark, we believe that such companies should exercise caution in determining the extent to which the financial crisis is comparable to the current environment given the fundamental differences between the two economic periods. For example, the current environment may present a myriad of factors such as supply-chain disruption, change in customer behavior, workforce adjustments, and industry-specific impacts, which were not necessarily present during the financial crisis and may not affect all entities in the same fashion.

While we do not believe that there is a one-size-fits-all approach to addressing the forecasting challenges that exist currently, we have seen the following strategies prove to be effective for a number of companies:

- Evaluating recovery and financial forecasts from an outside-in perspective first. Specifically, focusing on the factors, issues, and conditions outside of a company's control that are known and knowable.
- Automating components of forecasting to help remove bias and facilitate more real-time and frequent reforecasting as key drivers and trends change, while also analyzing data at a more detailed level.
- Considering facts that both support and contradict assumptions regarding the company's timing and pattern of recovery, sustainability, and growth.

#### 1.5 Revenue Contracts

Some life sciences companies may seek to mitigate the effects of the current environment by offering features such as price concessions, discounts on the purchase of future goods or services, free goods or services, extended payment terms, opportunities to terminate agreements without penalty, or revisions to purchase commitments.

If revisions are made to a revenue contract, significantly different reporting outcomes may result depending on the nature of the changes. Companies must consider the specific facts and circumstances of changes in contractual terms (including their business practices and communications with customers) to determine whether to account for the impact of such changes at a single point in time or over a longer period. See Chapter 2 for more considerations related to revenue recognition.

#### 1.5.1 Failure-to-Supply Penalties

Some contracts with customers include a clause requiring the entity to pay a penalty to the customer if it is unable to fulfill an order on a timely basis or to meet certain performance conditions specified in the contract. As illustrated in Example 20 in ASC 606 (ASC 606-10-55-194 through 55-196), an entity should consider such a penalty to be variable consideration in estimating the transaction price with the customer. Further, the obligation to pay a penalty under such a scenario, once triggered, does not represent a contingent loss under ASC 450-20; rather, the obligation should be accounted for as a contractual liability. The probability of payment is irrelevant if settlement of the liability is required by law or by contract. That is, other than deferred revenues, liabilities established by law or contract should be recorded at their stated amounts unless the guidance in U.S. GAAP requires otherwise. An entity's

uncertainty about whether an obligee will require performance does not (1) allow the entity to choose to avoid the future sacrifice or (2) relieve the entity of the obligation. Once recognized, a contractual or legal liability that is not deferred revenue (i.e., a contract liability under ASC 606) should be derecognized only when the conditions for liability derecognition in ASC 405-20-40-1 have been met (i.e., relief through repayment, or through a legal release either judicially or by the creditor).

#### 1.5.2 Retroactive Payback Provisions

In certain countries, companies are required to pay rebates to the country's government health care system if domestic industry sales exceed specified thresholds in a given year. In such a case, the portion of the payback allocated to an individual company is based on that company's current market share (or sales) in relation to the industry as a whole. For revenue recognition purposes, a retroactive payback provision represents variable consideration that would need to be estimated, subject to the variable consideration constraint. In light of the significant health care costs being incurred in many jurisdictions with such provisions, there may be an increased likelihood that domestic industry sales will exceed specified thresholds. Conversely, a life sciences entity's market share could be negatively affected by supply-chain disruption as a result of the current environment. Therefore, an entity may need to consider revising its estimates of such provisions.

#### 1.6 Going-Concern Analysis and Disclosures

The current environment is significantly disrupting the operations of many businesses. Entities will need to consider whether such disruption will be prolonged and result in diminished demand for products or services or significant liquidity shortfalls (or both) that, among other things, raise substantial doubt about whether the entity may be able to continue as a going concern.

As part of performing this assessment, management may need to consider whether the entity's financial statements should continue to be prepared on a going-concern basis (i.e., whether ASC 205-30 is applicable). Even more importantly, management must consider whether (on the basis of ASC 205-40), (1) there are conditions and events that, when considered in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern within one year after the date on which the interim or annual financial statements are issued and (2) these conditions are able to be mitigated by management's plans.

ASC 205-40 requires an entity to provide disclosures in the **annual** and **interim** financial statements when events and conditions are identified that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued. Such disclosures are required even when management's plans alleviate such doubt about the entity's ability to continue as a going concern. If management's plans do not alleviate substantial doubt about the entity's ability to continue as a going concern, in addition to the required disclosures, management must state in the notes to the financial statements that there is substantial doubt about the entity's ability to continue as a going concern within one year after the date on which the annual or interim financial statements are issued.

As indicated in ASC 205-40-55-2, assessing whether there is substantial doubt about an entity's ability to continue as a going concern may involve the consideration of factors such as the following:

- a. Negative financial trends, for example, recurring operating losses, working capital deficiencies, negative cash flows from operating activities, and other adverse key financial ratios [Some of these items, such as working capital deficiencies and short-term negative cash flows from operating activities, may directly apply to an entity affected by COVID-19.]
- b. Other indications of possible financial difficulties, for example, default on loans or similar agreements, arrearages in dividends, denial of usual trade credit from suppliers, a need to restructure debt to

- avoid default, noncompliance with statutory capital requirements, and a need to seek new sources or methods of financing or to dispose of substantial assets [These items may or may not apply to an affected entity.]
- c. Internal matters, for example, work stoppages or other labor difficulties, substantial dependence on the success of a particular project, uneconomic long-term commitments, and a need to significantly revise operations [Among these items, project dependence and long-term commitments would perhaps be the most applicable to an affected entity.]
- d. External matters, for example, legal proceedings, legislation, or similar matters that might jeopardize the entity's ability to operate; loss of a key franchise, license, or patent; loss of a principal customer or supplier; and an uninsured or underinsured catastrophe such as a hurricane, tornado, earthquake, or flood. [These circumstances are probably the most relevant to affected entities but also the most unpredictable given the unprecedented nature of the pandemic.]

Entities should consider the impacts to their forecasts described earlier in this chapter when updating their going-concern analysis. Management should be mindful of the timing of certain forecasted transactions and the entity's ability to accurately predict and consummate those transactions in the current environment. See Section 13.6 for more information about a going concern.

#### 1.7 Subsequent Events

Given the current environment and the likelihood that events may occur rapidly or unexpectedly, entities should carefully evaluate information that becomes available after the balance sheet date but before the issuance of the financial statements. ASC 855-10-25-1 and ASC 855-10-25-3 provide the following guidance on evaluating subsequent events:

#### ASC 855-10

- **25-1** An entity shall recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements. See paragraph 855-10-55-1 for examples of recognized subsequent events.
- **25-3** An entity shall not recognize subsequent events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after the balance sheet date but before financial statements are issued or are available to be issued. See paragraph 855-10-55-2 for examples of nonrecognized subsequent events.

Often the "events" are (1) company-specific and (2) associated with a specific account that permits a more precise analysis. However, sometimes the "events" are macroeconomic (such as those resulting from the current environment) and have a pervasive impact on many estimates in a set of financial statements, which may make it difficult to ascertain whether such conditions "existed" on the balance sheet date. The medium-term and long-term effects of the current environment on economic activity are still unknown. However, the current environment will be a factor in an entity's analysis of estimates residing in the financial statements, including, but not limited to, estimates related to receivable reserves, obsolescence reserves, impairment analyses, variable and contingent compensation, and current expected credit loss reserves. While the events stemming from the current environment are extremely volatile, entities will nevertheless be required to consider conditions as they existed on the balance sheet date when evaluating subsequent events. There are currently many approaches to the consideration of subsequent events in complex estimate analyses such as impairment models (e.g., whether changes in circumstances that alter projection models before the issuance date can be considered given the fluidity of the situation).

Given the current environment, significant judgment will most likely be required in assessments related to subsequent event matters. Entities are encouraged to consult with their advisers as needed.



#### **Disclosure Considerations**

ASC 855-10-50-2 notes, in part, that "[s]ome nonrecognized subsequent events may be of such a nature that they must be disclosed to keep the financial statements from being misleading." In such circumstances, the disclosures must include (1) the "nature of the event" and (2) an "estimate of its financial effect, or a statement that such an estimate cannot be made."

#### 1.8 Loss Contingencies

ASC 450 defines a loss contingency as an "existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur." Instability in the economy resulting from the current environment may cause entities to incur losses that should be recognized, disclosed, or both.

All loss contingencies (including incurred but not reported [IBNR] claims such as those related to medical care) should be evaluated under ASC 450-20 unless the contingency is within the scope of other authoritative literature that specifically prescribes an alternate accounting model. ASC 450-20 requires accrual of a loss contingency when (1) it is probable that a loss has been incurred and (2) the amount can be reasonably estimated. To accrue a loss contingency, an entity must determine the probability of the uncertain event and demonstrate its ability to reasonably estimate the loss associated with the uncertain event. Loss contingencies that do not meet both recognition criteria may need to be disclosed in the financial statements. Given the general uncertainty associated with the current environment, entities may find it challenging to develop estimates for loss contingencies. For example, an entity that is self-insured for medical claims may have difficulty estimating its IBNR liability if it concludes that historical claim patterns may not be representative of future expected claims because of the current environment



#### **Disclosure Considerations**

Under ASC 450-20-50, entities must disclose both recognized and unrecognized contingencies if certain criteria are met. In some situations, disclosure of the nature of the accrual and amount accrued may be necessary to prevent the financial statements from being misleading. For unrecognized contingencies, disclosure of the nature of the contingency and an estimate of the possible loss or range of loss (or a statement that an estimate cannot be made) is required in certain situations. Specifically, disclosure is called for if there is a reasonable possibility that a loss may be incurred but has not been accrued in the financial statements because the amount is not probable or reasonably estimable. Disclosure is also required if there is a reasonable possibility of unrecorded losses in excess of the amount accrued in the financial statements.

For more information about loss contingencies, see Deloitte's Roadmap *Contingencies, Loss Recoveries, and Guarantees* and Chapter 6 of this Guide.

#### 1.9 Recognition of Losses on Firmly Committed Executory Contracts

At the inception of a firmly committed executory contract, both parties to the contract expect to receive benefits that are equal to or greater than the costs to be incurred under the contract. Because of the impacts of the current environment, the fair value of the remaining contractual rights of a firmly committed executory contract may unexpectedly decline below the remaining costs, resulting in a firmly committed executory loss contract. For example, an entity engaged to provide services to its customer in accordance with a firmly committed executory contract may experience a significant increase in the cost of providing the services (e.g., lack of availability of personnel to provide services resulting in the use of higher outsourced labor cost), which could result in an overall loss on the contract. We generally believe that in the absence of specific guidance to the contrary (e.g., a firm purchase commitment for goods or inventory under ASC 330 or certain executory contracts related to exit or disposal activities within the scope of ASC 420), it is inappropriate to accrue for a loss related to a firmly committed executory contract.

#### 1.10 Future Operating Losses

An entity may forecast operating losses for a certain period as a result of the current environment. Such losses may result from declines in customer demand or disruptions in the supply chain. Future operating losses do not meet the definition of a liability, nor do they qualify for accrual under ASC 450-20. Instead, they should be reflected in the period in which the related costs are incurred.

#### **1.11 Insurance Recoveries**

Entities that incur losses stemming from the current environment may be entitled to insurance recoveries. For example, losses associated with increased medical claims, asset impairments, or shareholder litigation may be considered insured losses by many entities. Further, entities may have business interruption insurance that provides coverage for lost profits due to a suspension of the entities' operations.

#### 1.11.1 Insured Losses

If an entity incurs a loss attributable to the impairment of an asset or to the incurrence of a liability and expects to recover all or a portion of that loss through an insurance claim, the entity should record an asset for the amount for which recovery from the insurance claim is considered probable (not to exceed the amount of the total losses recognized). The entity should subsequently recognize amounts greater than those for which recovery from an insurance claim was initially deemed probable only to the extent that those amounts do not exceed actual additional covered losses or direct, incremental costs incurred to obtain the insurance recovery. A conclusion that a potential insurance recovery is probable may involve significant judgment and should be based on all relevant facts and circumstances. In determining whether it is probable that an insurance recovery will be received, an entity will most likely need, among other factors, to understand the solvency of the insurance carrier and have had enough dialogue and historical experience with the insurer related to the type of claim in question to assess the likelihood of payment. Other potential challenges an entity may encounter when evaluating whether a loss is considered recoverable through insurance include, but are not limited to, (1) the need to consider whether losses stemming from a pandemic are specifically excluded as a covered event, (2) the extent of coverage and limits, including multiple layers of insurance from different carriers, and (3) the extent, if any, to which the insurance carrier disputes coverage. Consultation with legal counsel may also be necessary.



#### **Connecting the Dots**

We believe that while applicable to SEC registrants, the following guidance from footnote 49 of SAB Topic 5.Y applies to all entities evaluating an insured loss that is contested by the insurance carrier:

The staff believes there is a rebuttable presumption that no asset should be recognized for a claim for recovery from a party that is asserting that it is not liable to indemnify the registrant. Registrants that overcome that presumption should disclose the amount of recorded recoveries that are being contested and discuss the reasons for concluding that the amounts are probable of recovery.

Any expected recovery that is greater than covered losses or direct, incremental costs incurred represents a gain contingency and therefore has a higher recognition threshold. An entity should generally recognize insurance proceeds that will result in a gain when the proceeds are realized or realizable, whichever is earlier. Such insurance proceeds are realized when the insurance carrier settles the claim and no longer contests payment. Payment alone does not mean that realization has occurred if such payment is made under protest or is subject to refund.

#### 1.11.2 Business Interruption

Events associated with the current environment have led many entities to temporarily suspend operations for reasons ranging from supply-chain disruption to, earlier in the pandemic, state and local government orders requiring individuals to shelter in place and temporarily cease operations. Business interruption insurance differs from other types of insurance coverage in that it is designed to protect the prospective earnings or profits of the insured entity. That is, business interruption insurance provides coverage if business operations are suspended because of the loss of use of property and equipment resulting from a covered loss. Business interruption insurance also generally provides for reimbursement of certain costs and losses incurred during the interruption period. Such costs may be analogous to losses from property damage and, accordingly, it may be appropriate to record a receivable for amounts whose recovery is considered probable. We encourage entities to consult with their independent auditors in connection with their evaluation of whether a receivable may be recorded for expected insurance recoveries associated with fixed costs incurred during an interruption period.

The loss of profit margin is considered a gain contingency and should be recognized when the gain contingency is resolved (i.e., the proceeds are realized or realizable). Because of the complex and uncertain nature of the settlement negotiation process, such recognition generally occurs at the time of final settlement or when nonrefundable cash advances are made.

#### 1.11.3 Classification of Insurance Recoveries

ASC 220-30-45-1 addresses other income statement presentation matters related to business interruption insurance from the perspective of classification and allows an entity to "choose how to classify business interruption insurance recoveries in the statement of operations, as long as that classification is not contrary to existing [U.S. GAAP]."

For presentation within the statement of cash flows, ASC 230-10-45-21B indicates that "[c]ash receipts resulting from the settlement of insurance claims, excluding proceeds received from corporate-owned life insurance policies and bank-owned life insurance policies, shall be classified on the basis of the related insurance coverage (that is, the nature of the loss)." For example, insurance settlement proceeds received as a result of claims related to a business interruption should be classified as operating activities.

#### 1.12 Share-Based Compensation Plans and Awards

We have seen an increased level of activity related to share-based compensation plans and awards. The ongoing impact of the current environment has led to the obsolescence of many previously established company-specific performance targets and the possibility that employees' outstanding stock options could become "underwater" or out-of-the-money. While some companies have modified awards to revise performance targets, others have delayed the timing of granting awards, issued "off-cycle" grants, modified the strike price of existing underwater options, and extended the exercise period for awards, all presumably in an effort to ensure that share-based compensation arrangements continue to provide the intended motivation for company employees and executives to work toward accomplishing company goals and objectives.

Regardless of the specific action taken, modifications of stock awards can lead to a host of accounting challenges and consequences. For example, when revising performance targets, companies need to be mindful that the performance conditions are sufficiently objective and determinable; otherwise, an award may not be considered "granted," leading to variable and potentially increased expense if compensation cost must be recorded before the grant date is established. In addition, when modifying stock awards, companies need to consider whether such awards were expected to vest before the modification and, if so, whether the modified awards provide incremental value to the recipients. Further, companies that grant stock options or similar awards will need to consider recent market volatility when valuing their stock awards and the related compensation expense to be reported. See Chapter 9 for additional considerations related to share-based compensation.

## 1.13 Considerations Related to Reflecting Impacts of the Current Environment in Non-GAAP Measures

While some of the key SEC requirements and interpretations related to non-GAAP measures address the prominence, reconciliation, usefulness, and purpose of such measures, an overarching theme of the guidance is that they should not be misleading, regardless of whether the measures are used in a filing (e.g., Form 10-K) or elsewhere (e.g., press release). As described in Section 100 of the SEC Division of Corporation Finance (the "Division") Compliance and Disclosure Interpretations (C&DIs) on non-GAAP financial measures, non-GAAP measures that could mislead investors may include those that:

- Exclude normal, recurring cash operating expenses necessary for business operations.
- Are presented inconsistently between periods (e.g., adjusting for an item in the current reporting period but not doing so for a similar item in the prior period without appropriately disclosing the change and explaining the reasons for it).
- Exclude certain nonrecurring charges but do not exclude nonrecurring gains (e.g., "cherry picking" non-GAAP adjustments to achieve the most positive measure).
- Are based on individually tailored accounting principles, including certain adjusted revenue measures.
- Are mislabeled or not clearly labeled as non-GAAP measures or otherwise include adjustments that are not clearly or accurately labeled or described.

In interactions with the SEC staff regarding non-GAAP measures viewed as misleading, some registrants have proposed supporting continued presentation of such measures by adding transparent disclosures related to the calculation of the measures or about the measures' purpose and use. However, Question 100.06 of the C&DIs indicates that even detailed disclosures about a misleading measure would not prevent it from being misleading.

At the 2022 AICPA & CIMA Conference on Current SEC and PCAOB Developments, the SEC staff indicated that once a non-GAAP measure or adjustment is concluded to be misleading or otherwise inconsistent with non-GAAP rules, the staff expects the registrant to correct the presentation in the next filing or publicly available SEC document by removing the measure or adjustment. If comparable periods are presented, the non-GAAP measure or adjustment should be removed from all periods presented.



#### **Changing Lanes**

On December 13, 2022, the SEC staff released **new and updated C&DIs** on non-GAAP financial measures. The staff has observed that the volume of non-GAAP disclosure comments has remained high over the past several years and that it continues to receive questions on this topic. The new and updated C&DIs help increase the transparency of the SEC staff's process for evaluating certain non-GAAP measures as well as its criteria for considering such measures misleading.

At the 2022 AICPA & CIMA Conference on Current SEC and PCAOB Developments, Division Chief Accountant Lindsay McCord emphasized that the intent of the new and updated C&DIs is to communicate interpretive feedback that the SEC staff has provided to registrants in various speeches and the comment letter process. In addition, she noted that the updates to the C&DIs are not intended to change the SEC staff's position on non-GAAP adjustments that it has not objected to in the past (e.g., adjustments for restructuring costs and stock-based compensation). However, Ms. McCord further acknowledged that conclusions about the application of the C&DIs to non-GAAP measures and adjustments will depend on a registrant's individual facts and circumstances.

The following changes related to misleading non-GAAP measures were made to the C&DIs:

- C&DI Question 100.01 was updated to add interpretive guidance on what may be considered normal or recurring. The C&DI cautions issuers that a non-GAAP measure may be considered misleading if it excludes cash operating expenses that are normal and recurring in the operation of a registrant's business.
  - At the 2022 AICPA & CIMA Conference on Current SEC and PCAOB Developments, Ms. McCord explained that the SEC staff evaluates whether an expense is "normal" by considering the nature and effect of the non-GAAP adjustment and how the expense is related to the registrant's operations, revenue-generating activities, business strategy, industry, and regulatory environment. She also noted that the SEC staff evaluates whether an operating expense is considered "recurring" when it occurs repeatedly or occasionally, including at irregular intervals of reoccurrence.
- C&DI Question 100.04 was updated to clarify that adjustments that represent the
  application of individually tailored accounting principles extend beyond the original
  example of adjustments that accelerate revenue recognition. The C&DI specifies that
  non-GAAP adjustments that change the GAAP recognition and measurement principles
  would be considered individually tailored and may cause the non-GAAP measure
  presentation to be misleading. The C&DI includes new examples that illustrate the
  application of individually tailored accounting principles and thus may be misleading.
- C&DI Question 100.05 was added to highlight the SEC's guidance that non-GAAP
  measures should be labeled as such and that adjustments should be clearly labeled
  and described in the disclosures. The C&DI also gives examples of misleading labels and
  descriptions for non-GAAP measures.
- C&DI Question 100.06 was added to emphasize that no amount of disclosure can make a measure compliant with the non-GAAP rules if it has been determined to be misleading.

Further, when evaluating whether an adjustment stemming from the current environment is appropriate in a non-GAAP measure, a registrant should consider various factors, including, but not limited to, whether the adjustment is:

- Directly related to the current environment.
- Incremental to normal operations and nonrecurring (i.e., it is not expected to become the new normal).
- Objectively quantifiable, as opposed to an estimate or projection.

A registrant must use judgment when evaluating whether an adjustment is consistent with these factors. However, we believe that a non-GAAP measure of performance that eliminates normal recurring cash operating expenses would generally not be appropriate.

In addition, any new adjustments or changes to non-GAAP measures related to the current environment should be clearly labeled, and changes to such measures should be transparently disclosed. If new adjustments to non-GAAP measures are added because of the current environment, an entity should ensure that its disclosure controls and procedures address the assessment and approval of the revised non-GAAP measures, including the consistency of presentation between periods and transparent disclosures about any changes.

See Deloitte's Roadmap *Non-GAAP Financial Measures and Metrics* for more information about SEC requirements and interpretations related to such measures and metrics. In addition, see Deloitte's Roadmap *SEC Comment Letter Considerations, Including Industry Insights* for current trends in SEC comments.

#### 1.13.1 Alternatives to Non-GAAP Measures

Given the potential challenges associated with many of the adjustments discussed above, an SEC registrant may determine that transparent disclosure in MD&A may more effectively inform investors about certain impacts of the current environment than non-GAAP measures. For example, if a registrant elects to provide disclosures that simply quantify the estimated impact of the current environment on financial statement line items without adjusting the registrant's GAAP results (i.e., without establishing new totals or subtotals), those disclosures are not considered non-GAAP measures. If a registrant provides disclosure that does not adjust a GAAP measure but instead describes unusual or significant activities that occurred during the period, the disclosure would not be subject to the SEC's requirements and interpretations related to non-GAAP measures. When presenting disclosure alternatives, a registrant should disclose individually material financial statement impacts stemming from the current environment separately.

# Appendix B — Titles of Standards and Other Literature

#### **AICPA Literature**

#### **Accounting and Valuation Guides**

Assets Acquired to Be Used in Research and Development Activities

Valuation of Privately-Held-Company Equity Securities Issued as Compensation

#### **Clarified Statements on Auditing Standards**

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items" AU-C Section 620, "Using the Work of an Auditor's Specialist"

#### Other

Technical Q&As Section 4110.09, "Costs Incurred to Acquire Treasury Stock"

#### **FASB Literature**

#### **ASC Topics**

ASC 105, Generally Accepted Accounting Principles

ASC 205, Presentation of Financial Statements

ASC 210. Balance Sheet

ASC 220, Income Statement — Reporting Comprehensive Income

ASC 230, Statement of Cash Flows

ASC 235, Notes to Financial Statements

ASC 250, Accounting Changes and Error Corrections

ASC 260, Earnings per Share

ASC 270, Interim Reporting

ASC 275, Risks and Uncertainties

ASC 280, Segment Reporting

ASC 310, Receivables

ASC 320, Investments — Debt Securities

- ASC 321, Investments Equity Securities
- ASC 323, Investments Equity Method and Joint Ventures
- ASC 326, Financial Instruments Credit Losses
- ASC 330, Inventory
- ASC 340, Other Assets and Deferred Costs
- ASC 350, Intangibles Goodwill and Other
- ASC 360, Property, Plant, and Equipment
- ASC 405, Liabilities
- ASC 410, Asset Retirement and Environmental Obligations
- ASC 420, Exit or Disposal Cost Obligations
- ASC 440, Commitments
- ASC 450, Contingencies
- ASC 460, Guarantees
- ASC 470, Debt
- ASC 480, Distinguishing Liabilities From Equity
- ASC 505, Equity
- ASC 605, Revenue Recognition
- ASC 606, Revenue From Contracts With Customers
- ASC 610, Other Income
- ASC 705, Cost of Sales and Services
- ASC 710, Compensation General
- ASC 712, Compensation Nonretirement Postemployment Benefits
- ASC 715, Compensation Retirement Benefits
- ASC 718, Compensation Stock Compensation
- ASC 720, Other Expenses
- ASC 730, Research and Development
- ASC 740, Income Taxes
- ASC 805, Business Combinations
- ASC 808, Collaborative Arrangements
- ASC 810, Consolidation
- ASC 815, Derivatives and Hedging
- ASC 820, Fair Value Measurement
- ASC 825, Financial Instruments

ASC 830, Foreign Currency Matters

ASC 832, Government Assistance

ASC 835, Interest

ASC 840, Leases

ASC 842, Leases

ASC 845, Nonmonetary Transactions

ASC 848, Reference Rate Reform

ASC 855, Subsequent Events

ASC 860, Transfers and Servicing

ASC 905, Agriculture

ASC 915, Development Stage Entities

ASC 930, Extractive Activities — Mining

ASC 944, Financial Services — Insurance

ASC 946, Financial Services — Investment Companies

ASC 948, Financial Services — Mortgage Banking

ASC 954, Health Care Entities

ASC 958, Not-for-Profit Entities

ASC 960, Plan Accounting — Defined Benefit Pension Plans

ASC 970, Real Estate — General

ASC 985, Software

#### **ASUs**

ASU 2010-27, Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers — a consensus of the FASB Emerging Issues Task Force

ASU 2014-09, Revenue From Contracts With Customers (Topic 606)

ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation

ASU 2014-15, Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern

ASU 2014-16, Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity — a consensus of the FASB Emerging Issues Task Force

ASU 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments

ASU 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities

ASU 2016-02, Leases (Topic 842)

ASU 2016-10, Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing

ASU 2016-12, Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients

ASU 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments

ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments — a consensus of the FASB Emerging Issues Task Force

ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory

ASU 2016-17, Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-20, *Technical Corrections and Improvements to Topic 606,* Revenue From Contracts With Customers

ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business

ASU 2017-04, Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment

ASU 2017-11, Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception

ASU 2017-12, Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities

ASU 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

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## Appendix C — Abbreviations

Abbreviation	Description
AETR	annual effective tax rate
AFS	available for sale
AFSI	adjusted financial statement income
AICPA	American Institute of Certified Public Accountants
AMT	alternative minimum tax
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
ARO	asset retirement obligation
ASC	FASB Accounting Standards Codification
ASR	accelerated share repurchase
ASU	FASB Accounting Standards Update
BCF	beneficial conversion feature
BEAT	base erosion anti-abuse tax
ВЕМТА	base erosion minimum tax amount
BPD	branded prescription drug
C&DIs	Compliance and Disclosure Interpretations
CAM	critical audit matter
CAQ	Center for Audit Quality
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CCF	cash conversion feature
CECL	current expected credit loss
CFC	controlled foreign corporation
CIMA	Chartered Institute of Management Accountants
СМО	contract manufacturing organization

Abbreviation	Description
CRO	contract research organization
CSRD	Corporate Sustainability Reporting Directive
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
ED	exposure draft
EDGAR	SEC electronic data gathering, analysis, and retrieval system
EGC	emerging growth company
EITF	Emerging Issues Task Force
EPS	earnings per share
ESA	energy service agreement
ESG	environmental, social, and governance
ESPP	employee stock purchase plan
EUR	euros
Exchange Act	Securities Exchange Act of 1934
FASB	Financial Accounting Standards Board
FAST Act	Fixing America's Surface Transportation Act
FDA	U.S. Food and Drug Administration
FDII	foreign-derived intangible income
FOB	free on board
FRM	SEC Division of Corporation Finance Financial Reporting Manual
FVTOCI	fair value through other comprehensive income
GAAP	generally accepted accounting principles

Abbreviation	Description
GHG	greenhouse gas
GILTI	global intangible low-taxed income
GPO	group purchasing organization
HFI	held for investment
HFS	held for sale
HVAC	heating, ventilation, and air conditioning
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IBNR	incurred but not reported
ICFR	internal control over financial reporting
IFRIC	IFRS Interpretations Committee
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IP	intellectual property
IPO	initial public offering
IPR&D	in-process research and development
IRC	Internal Revenue Code
IRS	Internal Revenue Service
ISO	incentive stock option
ISSB	International Sustainability Standards Board
IT	information technology
JOBS Act	Jumpstart Our Business Startups Act
LCD	liquid-crystal display
LIBOR	London Interbank Offered Rate
LIFO	last in, first out
M&A	merger and acquisition
MD&A	Management's Discussion & Analysis
MCI	medical science liaison
MSL	

Abbreviation	Description
	Description
NFP	not-for-profit
NIH	National Institutes of Health
NOL	net operating loss
NQSO	nonqualified stock option
NSO	nonstatutory option
OCA	SEC's Office of the Chief Accountant
OCI	other comprehensive income
OECD	Organisation for Economic Co-operation and Development
ОЕМ	original equipment manufacturer
PBE	public business entity
РСАОВ	Public Company Accounting Oversight Board
PCC	Private Company Council
PIPE	private investment in public equity
PP&E	property, plant, and equipment
PRV	priority review voucher
PTRS	probability of technical and regulatory success
Q&A	question and answer
QIP	qualified improvement property
R&D	research and development
R&E	research and experimentation
REC	renewable energy credit
REMS	risk evaluation and mitigation strategy
RIM	retail inventory method
ROU	right of use
SaaS	software as a service
SAB	Staff Accounting Bulletin
SEC	U.S. Securities and Exchange Commission
Securities Act	Securities Act of 1933
SOX	Sarbanes-Oxley Act of 2002
SPAC	special-purpose acquisition company

Abbreviation	Description
SPPI	solely payments of principal and interest
SRC	smaller reporting entity
S&P 500	Standard & Poor's 500 Index
TD	Treasury Decision
TDR	troubled debt restructuring
TRG	transition resource group
TRWG	IFRS Foundation Technical Readiness Working Group
USD	U.S. dollars
UTB	unrecognized tax benefit
VIE	variable interest entity
VWAP	volume-weighted average daily market price

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