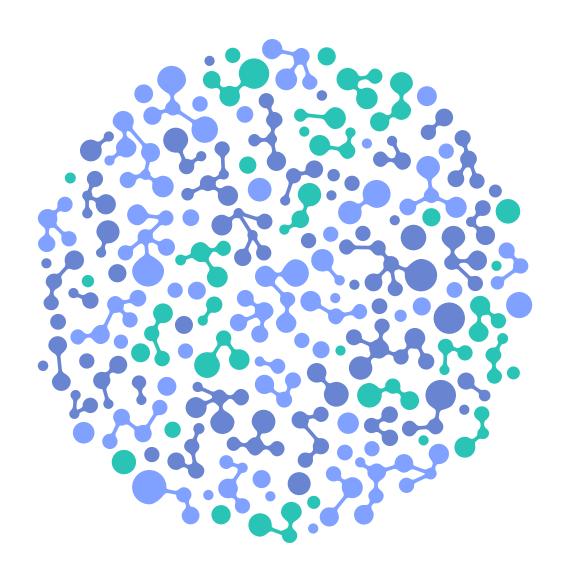
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Life Sciences Industry Accounting Guide

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Income Taxes

Initial Public Offerings

Leases

Noncontrolling Interests

Non-GAAP Financial Measures and Metrics

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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 2021 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, 2021), and key differences between U.S. GAAP and IFRS® Standards. In addition, this Guide discusses accounting and financial reporting considerations associated with the coronavirus disease 2019 ("COVID-19") pandemic that apply specifically to the life sciences industry.

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used.

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.

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Chapter 1 — COVID-19-Related Accounting and Financial Reporting Considerations for Life Sciences Entities

1.1 Executive Summary

The COVID-19 pandemic is affecting major economic and financial markets, and virtually all industries and governments are facing challenges associated with the economic conditions resulting from efforts to address it. For example, many life sciences entities have been affected by regulatory and organizational mandates (e.g., "shelter in place" mandates, school closures) and voluntary changes in consumer behavior (e.g., "social distancing," use of telemedicine, delay of elective surgical procedures). To address these economic challenges, some governments are pursuing laws or other related initiatives. For example, in March 2020, the U.S. government enacted several new laws, most notably the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), which provides \$2.2 trillion of economy-wide financial stimulus. For more information about the CARES Act and related financial reporting considerations, see Deloitte's *Heads Up*, "Highlights of the CARES Act." For more information about the Paycheck Protection Program under the CARES Act and related financial reporting considerations, see Deloitte's *Heads Up*, "Accounting and Reporting Considerations for Forgivable Loans Received by Business Entities Under the CARES Act's Paycheck Protection Program."

As the spread of the pandemic increases, entities are experiencing conditions often associated with a general economic downturn, including, but not limited to, financial market volatility and erosion of market value, deteriorating credit, liquidity concerns, further increases in government intervention, increasing unemployment, broad declines in consumer discretionary spending, increasing inventory levels, reductions in production because of decreased demand and supply constraints, layoffs and furloughs, and other restructuring activities. The continuation of these circumstances could have a prolonged negative impact on an entity's financial condition and results.

We believe that the following accounting and reporting issues will be the most pervasive and challenging for life sciences entities as a result of the pandemic's impact:

- Potential impacts on R&D costs The U.S. Food and Drug Administration (FDA) has announced
 that pandemic-related federal guidelines may have an impact on certain site visits, inspections,
 and related tasks, and this may in turn adversely affect an entity's R&D pipeline. In addition,
 certain CROs and CMOs may be adversely affected by supply chain disruption, lower enrollment,
 or other matters that require careful evaluation.
- 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 deferred tax assets, and the entity's

ability to continue as a going concern. Unique complexities associated with preparing forward-looking information as a result of the pandemic and economic downturn 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, the degree to which "flattening the curve" is successful, 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 were 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 pandemic will 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 As a result of COVID-19 and its associated effects, 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 as a result of the pandemic. 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 for share-based compensation to incentivize employees and retain talent. Share-based compensation awards may be subject to various vesting conditions and requirements affected by the pandemic 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.
- Disclosure matters COVID-19 has had varying impacts on SEC registrants' normal operations. Consequently, the SEC has issued guidance discussing its expectations and providing a framework for non-GAAP and nonrecurring transactions resulting from the pandemic. Since the use of non-GAAP measures remains a focus of the SEC, registrants are encouraged to (1) carefully evaluate changes in disclosures and the reasons for those changes and (2) reconcile non-GAAP measures to GAAP measures.
- Government assistance In response to the COVID-19 pandemic, domestic and foreign governments are considering, or may have implemented, legislation to help entities that have experienced financial difficulty associated with it. For more information about accounting considerations related to government assistance, see Section 13.1.1.

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 COVID-19 pandemic. It is also critical that management understand the risks entities face and how those risks affect them. Further, SEC registrants must consider whether 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.

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 COVID-19 pandemic. For more information about the topics highlighted in the sections below, see the following Deloitte *Financial Reporting Alert* newsletters:

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

1.2 Disruption in the Regulatory Approval Process

Many entities in the life sciences industry are directly affected by COVID-19. The FDA has acknowledged potential disruption to the industry as a result of the COVID-19 pandemic. In March 2020, the FDA published guidance on the significant disruption to the conduct of clinical trials, which, as **updated** in January 2021, states, in part:

FDA recognizes that the COVID-19 public health emergency may impact the conduct of clinical trials of medical products. Challenges may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product,⁴ or other considerations if site personnel or trial participants become infected with COVID-19. These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using the investigational product or adhering to protocol-mandated visits and laboratory/diagnostic testing. FDA recognizes that protocol modifications may be required, and that there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 public health control measures.

See Chapter 3 of this Guide for more information about R&D.

1.2.1 Delays in FDA Approvals Could Have Accounting Implications for Indefinite-Lived IPR&D Assets and Contingent Consideration Liabilities

In a March 10, 2020, statement, then FDA Commissioner Dr. Stephen Hahn noted:

After careful consideration, the FDA is postponing most foreign inspections through April, effective immediately. Inspections outside the U.S. deemed mission-critical will still be considered on a case-by-case basis. . . . We are aware of how this action may impact other FDA responsibilities, including product application reviews. We will be vigilant and monitor the situation very closely and will try to mitigate potential impacts from this outbreak in lockstep with the whole of the federal government. We stand ready to resume foreign inspections as soon as feasible.

Under ASC 350-30-35-18, an "intangible asset that is not subject to amortization shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired." The delay in product application reviews could represent a qualitative indicator that the value of capitalized in-process research and development (IPR&D) is impaired, thus necessitating an impairment test. Further, additional uncertainty in regulatory approval caused by a delay in product application reviews could affect the estimate of contingent consideration liabilities that have been recorded in connection with either a previous asset acquisition or business combination if such contingent payments are related to regulatory approval and commercialization milestones. See Chapter 4 of this Guide for more information about acquisitions.

⁴ For the purposes of this guidance, the term *investigational product* refers to human drugs and biological products, as well as medical devices.

1.3 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 a significant increase in the cost of performing contract R&D (e.g., the inability of an entity's personnel to perform monitoring visits or to enroll 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 a significant increase in the overall cost of the R&D program or whether such 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 or (2) regulatory approval for commercialization is ultimately achieved, or (3) both. See Chapter 2 of this Guide for more information about collaboration arrangements accounted for as revenue.

1.4 Impairment of Nonfinancial Assets (Including Goodwill)

As a result of the changes in the current economic environment related to the COVID-19 pandemic, 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. 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 at the onset of the pandemic 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.

1.4.1 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 pandemic'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 COVID-19 pandemic.



Disclosure Considerations

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

1.4.2 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 COVID-19 pandemic. 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 COVID-19 pandemic 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 COVID-19 pandemic 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 the COVID-19 pandemic 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.

1.5 Forecasting

Life sciences entities continue to face challenges related to forecasting as a result of the ongoing uncertainties associated with the COVID-19 pandemic. 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 COVID-19, we have observed the development of forecasts that use pre-COVID-19 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 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 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 economic 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.

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.

1.6 Revenue Contracts

Some life sciences companies may seek to mitigate the effects of the pandemic 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 of this Guide for more considerations related to revenue recognition.

1.6.1 Failure-to-Supply Penalties in Sales Contracts May Increase

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. Life sciences entities may be more likely to incur penalties as a result of supply chain disruption because of the concentration of active pharmaceutical ingredient (API) manufacturing in China. As illustrated in Example 20 of ASC 606 (ASC 606-10-55-194 through 55-196), an entity should consider such penalties 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).

1.6.2 Retroactive Payback Provisions May Require Reestimation

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. Given the significant health care costs being incurred in many jurisdictions with such provisions, the likelihood that domestic industry sales will exceed specified thresholds may be higher than initially estimated. Conversely, a life sciences entity's market share could be negatively affected by supply chain disruption as a result of the COVID-19 pandemic. Therefore, an entity may need to consider revising its estimates of such provisions.

1.7 Going-Concern Analysis and Disclosures

COVID-19 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 13.7 of this Guide for more information about a going concern.

1.8 Subsequent Events

Given the economic 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 in nature (such as those resulting from COVID-19) 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 COVID-19 pandemic on economic activity are still unknown. However, COVID-19 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 COVID-19 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 issuance date can be considered given the fluidity of the situation).

Given the COVID-19 pandemic and the significant judgment that will most likely need to be applied 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."

1.9 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 COVID-19 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 it. 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 COVID-19 pandemic, 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 COVID-19 pandemic.



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 *A Roadmap to Accounting for Contingencies, Loss Recoveries, and Guarantees* and Chapter 6 of this Guide.

1.10 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 COVID-19, 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.

1.11 Future Operating Losses

An entity may forecast operating losses for a certain period as a result of the COVID-19 pandemic. 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.

1.12 Insurance Recoveries

Entities that incur losses stemming from the COVID-19 pandemic 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.

1.12.1 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.

1.12.2 Business Interruption

Recent events associated with the COVID-19 pandemic have led many entities to temporarily suspend operations for reasons ranging from supply chain disruption to, on a broader scale, 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.

1.12.3 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.

1.13 Share-Based Compensation Plans and Awards

In recent months, we have seen an increased level of activity related to share-based compensation plans and awards. The ongoing impact of COVID-19 has led to the obsolescence of many previously established company-specific performance targets. 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 of this Guide for additional considerations related to share-based compensation.

1.14 Considerations Related to Reflecting COVID-19 Impacts in Non-GAAP Measures

While some of the key SEC requirements and interpretations related to non-GAAP measures address the prominence, reconciliation, clear labeling, 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 staff compliance and disclosure interpretations on non-GAAP measures, non-GAAP measures that could potentially 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.

Further, when evaluating whether a COVID-19-related adjustment is appropriate in a non-GAAP measure, a registrant should consider several factors, including, but not limited to, whether the adjustment is:

- Directly related to COVID-19 or the associated economic downturn.
- 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.

Regarding required disclosures, many companies have unusual or nonrecurring activities related to COVID-19 that result in various expenses (e.g., restructuring, severance, impairments, modifications of stock awards). They may have also received government assistance or insurance recoveries. Companies' disclosures about these types of activities should be robust and should describe the accounting treatment used as well as how such items are presented in the financial statements.

The SEC recently emphasized the importance of robust disclosures and issued disclosure guidance related to COVID-19¹ that, among other items, encouraged registrants to disclose how a company is dealing with short-term and long-term liquidity and funding risks in the current environment, particularly if funding sources and efforts present new risks or uncertainties to a company's business.

Throughout 2020, we observed that an increased number of companies provided non-GAAP metrics that included COVID-19-related adjustments. Notwithstanding that increase, we are aware of some companies that chose not to provide such non-GAAP metrics because they had concerns about either (1) determining which COVID-19-related costs were in fact "unusual or incremental" and objectively quantifying those costs or (2) creating potential negative comparisons in future periods to the extent that certain COVID-19-related costs (or a portion thereof) become recurring costs. In still other

¹ See CF Disclosure Guidance Topics 9 and 9A.

instances, companies determined that their potential COVID-19-related non-GAAP adjustments were immaterial.

We also noted that a significant number of COVID-19-related non-GAAP adjustments were associated with activities that are often included in non-GAAP adjustments but were described as being caused by or related to the impact of COVID-19, such as impairments, write-offs, and restructuring. To a lesser degree, we also observed COVID-19-related adjustments that were described as (1) incremental employee compensation or benefits and (2) incremental expenses associated with personal protective equipment, incremental cleaning, and sanitation efforts.

1.14.1 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 COVID-19-related impacts than non-GAAP measures. For example, if a registrant elects to provide disclosures that simply quantify the estimated impact of COVID-19 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 COVID-19-related impacts separately.

A company may consider presenting certain impacts of COVID-19 in a separate line item or line items in its statement of comprehensive income. We believe that if a company also intends to adjust for COVID-19-related amounts as part of a non-GAAP measure, each component of the COVID-19-related line item(s) would need to be assessed separately for compliance with non-GAAP reporting requirements (e.g., simply adding back the entire line item(s) may not be appropriate).

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

Audit and Accounting Guide

Revenue Recognition

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"

Issues Papers

Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories 86-2, Accounting for Options

Other

AICPA Technical Q&A Section 2260.03, "Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit"

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

Deloitte | Life Sciences Industry Accounting Guide

- 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 and Equity 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 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 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 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 942, Financial Services — Depository and Lending

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 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 2014-02, Intangibles — Goodwill and Other (Topic 350): Accounting for Goodwill — a consensus of the Private Company Council

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 2015-14, Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date

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 2016-08, Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)

ASU 2016-09, Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting

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

ASU 2016-11, Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting

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 2017-05, Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets

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 2017-13, Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments (SEC Update)

ASU 2017-14, Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606) (SEC Update)

ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842

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

ASU 2018-08, Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made

ASU 2018-10, Codification Improvements to Topic 842, Leases

ASU 2018-11, Leases (Topic 842): Targeted Improvements

ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement

ASU 2018-14, Compensation — Retirement Benefits — Defined Benefit Plans — General (Subtopic 715-20): Disclosure Framework — Changes to the Disclosure Requirements for Defined Benefit Plans

ASU 2018-15, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract — a consensus of the FASB Emerging Issues Task Force

ASU 2018-17, Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities

ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606

ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors

ASU 2019-01, Leases (Topic 842): Codification Improvements

ASU 2019-04, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses, *Topic 815,* Derivatives and Hedging, *and Topic 825,* Financial Instruments

ASU 2019-05, Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief

ASU 2019-08, Compensation — Stock Compensation (Topic 718) and Revenue From Contracts With Customers (Topic 606): Codification Improvements — Share-Based Consideration Payable to a Customer

ASU 2019-10, Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates

ASU 2019-11, Codification Improvements to Topic 326, Financial Instruments — Credit Losses

ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

ASU 2020-01, Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815 — a consensus of the FASB Emerging Issues Task Force

ASU 2020-02, Financial Instruments — Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842)

ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting

ASU 2020-05, Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities

ASU 2020-06, Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

ASU 2021-01, Reference Rate Reform

Concepts Statements

No. 5, Recognition and Measurement in Financial Statements of Business Enterprises

No. 6, Elements of Financial Statements

No. 8, Conceptual Framework for Financial Reporting — Chapter 8, Notes to Financial Statements

Proposed ASUs

No. 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance

No. 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory

No. 2017-280, Consolidation (Topic 812): Reorganization

No. 2019-500, Income Taxes (Topic 740): Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes (Revision of Exposure Draft Issued July 26, 2016)

No. 2019-790, Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting

Other

Proposed Concepts Statement 2014-200, Conceptual Framework for Financial Reporting: Chapter 8: Notes to Financial Statements

FASB Staff Revenue Recognition Implementation Q&As

IFRS Literature

IFRS 2, Share-Based Payment

IFRS 3, Business Combinations

IFRS 5, Non-Current Assets Held for Sale and Discontinued Operations

IFRS 9, Financial Instruments

IFRS 10, Consolidated Financial Statements

IFRS 11, Joint Arrangements

IFRS 12, Disclosure of Interests in Other Entities

IFRS 15, Revenue From Contracts With Customers

IFRS 16, Leases

IAS 1, Presentation of Financial Statements

IAS 7, Statement of Cash Flows

IAS 10, Events After the Reporting Period

IAS 12, Income Taxes

IAS 17, Leases

IAS 20, Accounting for Government Grants and Disclosure of Government Assistance

IAS 27, Separate Financial Statements

IAS 32, Financial Instruments: Presentation

IAS 37, Provisions, Contingent Liabilities and Contingent Assets

IAS 38, Intangible Assets

IAS 40, Investment Property

IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 163(j), "Interest; Limitation on Business Interest"

Section 382, "Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change"

Section 409A "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

PCAOB Literature

Release No. 2017-001, The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards

SEC Literature

CF Disclosure Guidance

Topic 9, "Coronavirus (COVID-19)"

Topic 9A, "Coronavirus (COVID-19) — Disclosure Considerations Regarding Operations, Liquidity, and Capital Resources"

Topic 11, "Special Purpose Acquisition Companies"

Final Rules

No. 34-88365, Accelerated Filer and Larger Accelerated Filer Definitions

No. 33-10786, Amendments to Financial Disclosures About Acquired and Disposed Business

No. 33-10890, Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information

FRM

Topic 1, "Registrant's Financial Statements"

Topic 2, "Other Financial Statements Required"

Topic 3, "Pro Forma Financial Information"

Topic 5, "Smaller Reporting Companies"

Topic 7, "Related Party Matters"

Topic 10, "Emerging Growth Companies"

Interpretive Release

33-10403, Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile

Regulation S-K

Item 103, "Business; Legal Proceedings"

Item 201, "Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters"

Item 301, "Selected Financial Data"

Item 302, "Supplementary Financial Information"

Item 303, "Management's Discussion and Analysis of Financial Condition and Results of Operations"

Item 305, "Quantitative and Qualitative Disclosures About Market Risk"

Item 402, "Executive Compensation"

Item 404, "Transactions With Related Persons, Promoters and Certain Control Persons"

Item 407, "Corporate Governance"

Item 503, "Prospectus Summary"

Item 601, "Exhibits"

Regulation S-X

Rule 1-02(w), "Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary"

Article 2, "Qualifications and Reports of Accountants"

Rule 3-01, "Consolidated Balance Sheet"

Rule 3-02, "Consolidated Statements of Comprehensive Income and Cash Flows"

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 3-09, "Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 3-10, "Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered"

Rule 3-14, "Special Instructions for Financial Statements of Real Estate Operations Acquired or to Be Acquired"

Rule 3-16, "Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered"

Rule 4-08(g), "General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 4-08(n), "General Notes to Financial Statements; Accounting Policies for Certain Derivative Instruments"

5-02, "Commercial and Industrial Companies; Balance Sheets"

5-03, "Commercial and Industrial Companies; Statements of Comprehensive Income"

Article 8, "Financial Statements of Smaller Reporting Companies"

Rule 10-01(b), "Interim Financial Statements; Other Instructions as to Content"

Article 11, "Pro Forma Financial Information"

Rule 11-01 "Presentation Requirements"

SAB Topics

No. 1.M, "Financial Statements; Materiality"

No. 5.A, "Miscellaneous Accounting; Expenses of Offering"

No. 5.Y, "Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies"

No 11.A, "Miscellaneous Disclosure; Operating-Differential Subsidies"

No. 13, "Revenue Recognition"

No. 14.B, "Share-Based Payment; Transition From Nonpublic to Public Entity Status"

No. 14.D, "Share-Based Payments; Certain Assumptions Used in Valuation Methods"

- No. 14.D.1, "Expected Volatility"
- No. 14.D.2, "Expected Term"

SEC Securities Act of 1933 General Rules and Regulations

Rule 144, "Persons Deemed Not to be Engaged in a Distribution and Therefore Not Underwriters — General Guidance"

TRG Agenda Papers

TRG Agenda Paper 6, Customer Options for Additional Goods and Services and Nonrefundable Upfront Fees

TRG Agenda Paper 11, October 2014 Meeting — Summary of Issues Discussed and Next Steps

TRG Agenda Paper 41, Measuring Progress When Multiple Goods or Services Are Included in a Single Performance Obligation

TRG Agenda Paper 44, July 2015 Meeting — Summary of Issues Discussed and Next Steps

TRG Agenda Paper 54, Considering Class of Customer When Evaluating Whether a Customer Option Gives Rise to a Material Right

TRG Agenda Paper 55, April 2016 Meeting — Summary of Issues Discussed and Next Steps

Superseded Literature

AICPA Statement of Position

96-1, Environmental Remediation Liabilities

EITF Issues

Issue 00-21, "Revenue Arrangements With Multiple Deliverables"

Issue 01-8, "Determining Whether an Arrangement Contains a Lease"

Issue 01-9, "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)"

Issue 01-10, "Accounting for the Impact of the Terrorist Attacks of September 11, 2001"

Issue 02-16, "Accounting by a Customer (Including a Reseller) for Certain Consideration Received From a Vendor"

Issue 08-6, "Equity Method Investment Accounting Considerations"

Issue 09-2, "Research and Development Assets Acquired in an Asset Acquisition"

Issue 09-4, "Seller Accounting for Contingent Consideration"

FASB Interpretations

No. 14, Reasonable Estimation of the Amount of a Loss — an interpretation of FASB Statement No. 5

No. 48, Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109

FASB Statements

No. 5, Accounting for Contingencies

No. 52, Foreign Currency Translation

No. 95, Statement of Cash Flows

No. 114, Accounting by Creditors for Impairment of a Loan — an amendment of FASB Statements No. 5 and 15

No. 123(R), Share-Based Payment

No. 133, Accounting for Derivative Instruments and Hedging Activities

No. 141, Business Combinations

No. 141(R), Business Combinations

No. 160, Noncontrolling Interests in Consolidated Financial Statements — an amendment of ARB No. 51

Appendix C — Abbreviations

| Abbreviation | Description |
|--------------|--|
| AETR | annual effective tax rate |
| | |
| AFS | available for sale |
| AICPA | American Institute of Certified Public Accountants |
| AMT | alternative minimum tax |
| API | active pharmaceutical ingredient |
| APIC | additional paid-in capital |
| ASC | FASB Accounting Standards Codification |
| ASR | accelerated share repurchase |
| ASU | FASB Accounting Standards Update |
| BCF | beneficial conversion feature |
| BEAT | base erosion anti-abuse tax |
| BEMTA | base erosion minimum tax amount |
| BPD | branded prescription drug |
| CAM | critical audit matter |
| CCF | cash conversion feature |
| CECL | current expected credit loss |
| CFC | controlled foreign corporation |
| CFR | Code of Federal Regulations |
| СМО | contract manufacturing organization |
| CODM | chief operating decision maker |
| CRO | contract research organization |
| DTA | deferred tax asset |
| DTL | deferred tax liability |
| EBITDA | earnings before interest, taxes, depreciation, and amortization |
| ED | exposure draft |
| | |

| Abbreviation | Description |
|--------------|---|
| EDGAR | SEC electronic data gathering, analysis, and retrieval system |
| EGC | emerging growth company |
| EITF | Emerging Issues Task Force |
| EPS | earnings per share |
| ESPP | employee stock purchase plan |
| EU | European Union |
| EUR | euros |
| FASB | Financial Accounting Standards Board |
| FDA | Food and Drug Administration |
| FDII | foreign derived intangible income |
| FIFO | first in, first out |
| FIN | FASB Interpretation |
| 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 |
| GILTI | global intangible low-taxed income |
| GPO | group purchasing organization |
| HFI | held for investment |
| HFS | held for sale |
| IAS | International Accounting Standard |
| IASB | International Accounting Standards Board |
| IBNR | incurred but not reported |
| | |

| Abbreviation | Description |
|--------------|---|
| 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 |
| IT | information technology |
| 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 |
| MSL | medical science liaison |
| NFP | not-for-profit entity |
| 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 |
| | |

| Abbreviation | Description |
|--------------|---|
| PCC | Private Company Council |
| 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 |
| REMS | risk evaluation and mitigation strategy |
| ROU | right of use |
| SaaS | software as a service |
| SAB | Staff Accounting Bulletin |
| SEC | Securities and Exchange Commission |
| SME | small to medium-sized entity |
| SPAC | special-purpose acquisition company |
| SPPI | solely payments of principal and interest |
| SRC | smaller reporting entity |
| S&P 500 | Standard & Poor's 500 Index |
| TD | Treasury Decision |
| TRG | transition resource group |
| USD | U.S. dollars |
| UTB | unrecognized tax benefit |
| VIE | variable interest entity |
| VWAP | volume-weighted average daily market price |
| | |

The following is a list of short references for the Acts mentioned in this Guide:

| Abbreviation | Act |
|----------------|--|
| CARES Act | Coronavirus Aid, Relief, and Economic Security Act |
| Exchange Act | Securities Exchange Act of 1934 |
| FAST Act | Fixing America's Surface Transportation Act |
| JOBS Act | Jumpstart Our Business Startups Act |
| Securities Act | Securities Act of 1933 |
| 2017 Act | Tax Cuts and Jobs Act of 2017 |