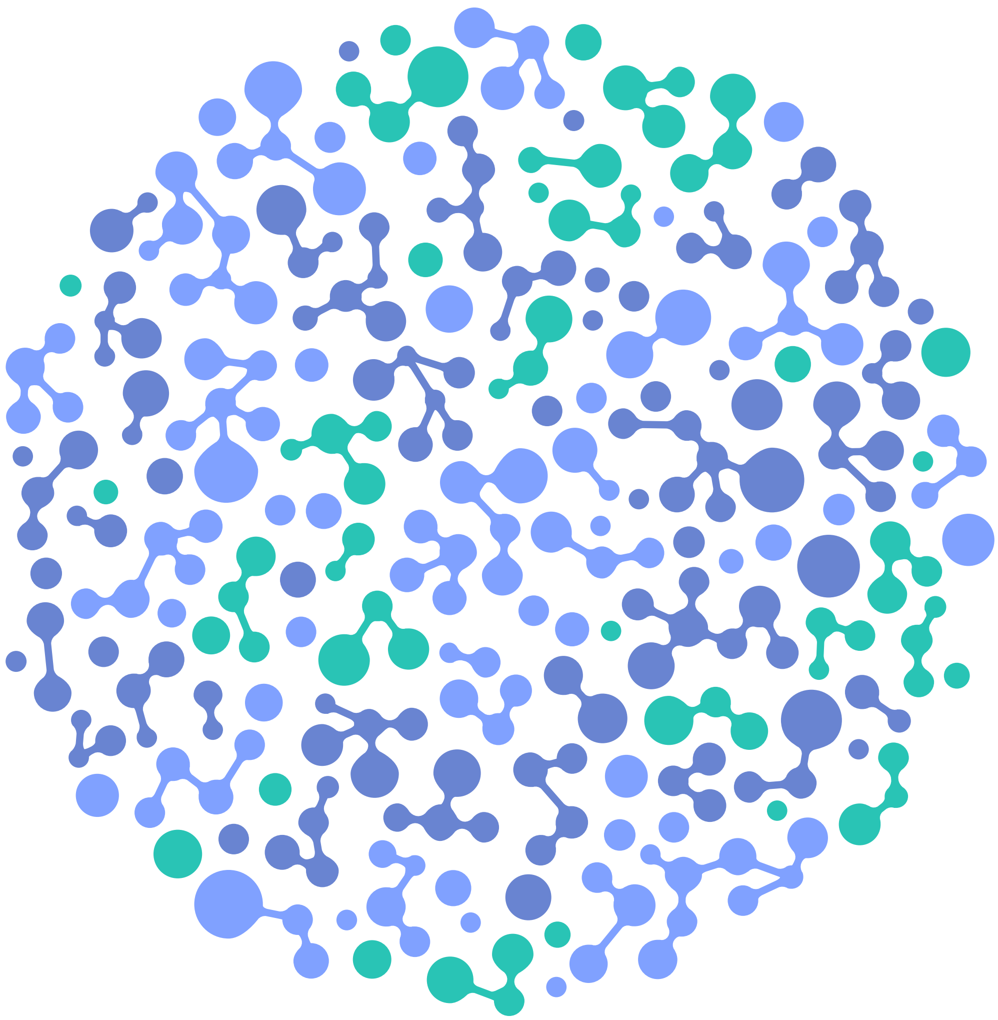

Life Sciences Industry Accounting Guide

Income Taxes

March 2021

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Segment Reporting

Share-Based Payment Awards

Statement of Cash Flows

Transfers and Servicing of Financial Assets

Contents

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 8 — Income Taxes

8.1 Introduction

The accounting for income taxes under ASC 740 is sometimes very specific and can be complex. The overall objective of accounting for income taxes is to reflect (1) the amount an entity currently owes to tax authorities and (2) a deferred tax asset (DTA) or deferred tax liability (DTL) for the tax effects of the transactions or events that have occurred but that have not yet been reflected in a tax return or vice versa (also referred to as “basis differences” or “temporary differences”). A DTA will be recorded for items that will result in future tax deductions (sometimes referred to as a benefit), and DTLs are recorded for items that will result in the inclusion of future taxable income in an entity’s tax return. This balance sheet approach is used to calculate temporary differences and, in effect, takes into account the total tax that would be payable (or receivable) if all of an entity’s assets and liabilities were realized at their carrying value at a specific time (the reporting date).

In accordance with ASC 740, the critical event for recognition of a DTA is the event that gives rise to the deductible temporary difference, tax credit, or net operating loss (NOL) carryforward. Once that event occurs, those tax benefits should be recognized, subject to a realizability assessment. In effect, earning taxable income in future years is treated as a confirmation of realizability and not as a prerequisite to asset recognition. At the same time, management should consider future events to record those DTAs at amounts that are more likely than not to be realized in future tax returns. In the case of DTLs, ASC 740 requires an entity to include in its balance sheet an obligation for the tax consequences of taxable temporary differences, even when losses are expected in future years.

The following is a brief, general summary of deferred tax accounting under ASC 740:

- DTLs are recognized for future taxable amounts.
- DTAs are recognized for future deductions, operating loss, and tax credit carryforwards.
- The marginal tax rate is used to measure DTAs and DTLs.
- A valuation allowance is recognized to reduce DTAs to the amounts that are more likely than not to be realized.
- The amount of the valuation allowance is based on all available positive and negative evidence about the future. The more objective the positive or negative evidence, the more weight the evidence carries in supporting the determination of whether DTAs will or will not be realized.
- Deferred tax expense or benefit is computed as the difference between the beginning and ending balance of the net DTA or DTL for the period.
- Entities present DTAs and DTLs as noncurrent in a classified balance sheet.
- The effects of changes in rates or laws are recognized on the date of enactment.

8.2 Industry Issues

The discussions and examples below contain guidance on income tax matters that frequently affect life sciences entities. The guidance cited is not intended to be all-inclusive or comprehensive; rather, it provides targeted considerations related to the application of ASC 740 that are most relevant to the industry.

For more information about the topics summarized below, see Deloitte's *A Roadmap to Accounting for Income Taxes*.

8.2.1 Scope Considerations

The scope of ASC 740 is limited to "taxes based on income" when income is determined after revenues and gains are reduced by some amount of expenses and losses allowed by the jurisdiction. Therefore, a tax based solely on revenues would not be within the scope of ASC 740 because the taxable base amount is not reduced by any expenses. A tax based on gross receipts, revenue, or capital should be accounted for under other applicable literature (e.g., ASC 450). In contrast, a tax whose base takes into account both income and expense is within the scope of ASC 740. A common question for life sciences entities to consider is whether certain R&D credits are within the scope of ASC 740.

Certain tax jurisdictions provide refundable credits (e.g., qualifying R&D credits in certain countries and state jurisdictions and alternative fuel tax credits for U.S. federal income tax) that do not depend on the entity's ongoing tax status or tax position (e.g., an entity may receive a refund despite being in a taxable loss position). Tax credits, such as refundable credits, whose realization does not depend on the entity's generation of taxable income or the entity's ongoing tax status or tax position, are not considered an element of income tax accounting under ASC 740. Thus, even if the credit claims are filed in connection with a tax return, the refunds are not considered to be part of income taxes and therefore are not within the scope of ASC 740. In such cases, an entity would not record the credit as a reduction of income tax expense; rather, the entity should determine the credit's classification on the basis of its nature.

When determining the classification of these credits, an entity may consider them to be a form of government grant or assistance. An entity may look to paragraphs 24 and 29 of IAS 20 for guidance on government grants. Under paragraph 24 of IAS 20, an entity presents government grants related to assets "either by setting up the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset." Further, paragraph 29 of IAS 20 states that "[g]rants related to income are presented as part of profit or loss, either separately or under a general heading such as 'Other Income'; alternatively, they are deducted in reporting the related expense."

In rare circumstances, a tax law may change the way a tax credit is realized. For example, a jurisdiction may have historically required that a credit be realized on the tax return as a reduction in taxes payable but subsequently changes the law so that the credit can be realized without an entity's first incurring a tax liability (i.e., the credit amount becomes refundable but was not when it arose). In this situation, an entity would generally continue to apply ASC 740 to the credits recognized at the time of the law change. Any new refundable credits earned after the tax law change would be accounted for in accordance with the guidance in this section.

Credits whose realization ultimately depends on taxable income (e.g., investment tax credits and R&D credits) are generally recognized as a reduction of income tax expense, regardless of whether they are accounted for under the flow-through method or the deferral method (as described in ASC 740-10-25-45 and 25-46).

8.2.2 Intra-Entity Transfers of IP

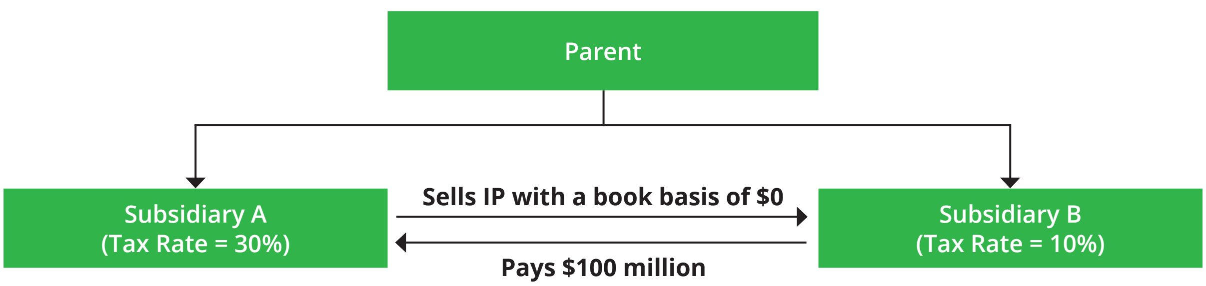
Life sciences entities often develop intellectual property (IP) such as drug formulas, trade secrets, know-how, and other proprietary information. This IP may be developed in one jurisdiction but subsequently transferred to a subsidiary in another jurisdiction. Such transfers are often tax-motivated, and both the initial and subsequent accounting for them has historically been complex. An entity should record the current and deferred tax effects of intra-entity transfers of assets other than inventory, including the tax consequences of intra-entity asset transfers involving IP.

ASC 740-10-25-3(e) prohibits recognition of the deferred tax consequences of intra-entity transfers of inventory. However, this prohibition does not apply to noninventory assets. Under ASC 740-10-25-20(i), the selling (transferring) entity in an intra-entity transfer of an asset other than inventory is required to recognize any current tax expense or benefit upon transfer of the asset. Similarly, the purchasing (receiving) entity is required to recognize a DTA or DTL, as well as the related deferred tax benefit or expense, upon receipt of the asset. An entity measures the resulting DTA or DTL by (1) computing the difference between the tax basis of the asset in the buyer's jurisdiction and the asset's financial reporting carrying value in the consolidated financial statements and (2) multiplying such difference by the enacted tax rate in the buyer's jurisdiction.

The example below compares the income tax accounting for intra-entity transfers of assets other than inventory.

Example 8-1

Consider the following:



In accordance with ASC 740-10-25-20(i), since the transferred asset is an asset other than inventory (IP in this case), A is required to recognize the current tax expense associated with the taxable gain on the sale of the IP by recording the following journal entry:

Current tax expense	30,000,000	
Current taxes payable		30,000,000

In addition, B is required to recognize the deferred tax effects associated with its purchase of the IP by recording the following journal entry:

DTA	10,000,000	
Deferred tax benefit		10,000,000

8.2.2.1 Interim Reporting Considerations

There is no explicit guidance in ASC 740-270 on whether the tax effects of intra-entity transfers of assets other than inventory should be recognized as discrete items or included in the estimated annual effective tax rate (AETR) for interim reporting purposes. Paragraph BC13 of ASU 2016-16 states, in part:

> Because of the variety of intra-entity asset transfers, the Board did not want to preclude an entity from making its own assessment about how to treat an intra-entity asset transfer for purposes of the estimate. The Board also agreed with stakeholders who indicated that if the Board had decided that all intra-entity asset transfers should be treated similarly for purposes of the estimate, it would have created an exception to the model in Topic 740. The Board's view is that it would not be unusual for entities following the guidance to conclude that many intra-entity transfers of assets other than inventory would be treated as discrete items for purposes of the computation. However, the Board understands from stakeholders' input that because the nature of, frequency of, and ability to estimate these transfers vary among entities, there are circumstances in which an entity could conclude that the transaction should be included in the computation of the estimated annual effective tax rate. The Board understands that an entity will need to apply judgment on the basis of the facts and circumstances to conclude whether the tax consequences of an intra-entity asset transfer other than inventory should be included in the computation of the estimated annual effective tax rate or treated as a discrete item in the interim period in which the transfer occurs.

Connecting the Dots

Entities should carefully consider all of the provisions and exceptions in ASC 740-270 to determine whether the tax effects of intra-entity asset transfers are appropriately treated for interim reporting.

8.2.3 Transfer Pricing

Many life sciences entities are global and operate legal entities in multiple countries. This may simply be owing to the size and scale of the business or may be the result of regulatory requirements. For example, life sciences entities are frequently required to have regulatory approval to manufacture or distribute products in each country in which its products are manufactured or sold. Similarly, CROs are often required to perform R&D services on different patient populations in multiple geographical locations. Because of the global nature of many life sciences entities, income tax accounting issues regarding the use of transfer pricing for intra-entity and related-party transactions arise. Generally, transfer pricing is the pricing used for transfers of tangible property, intangible property, services, or financing between affiliated entities in different tax jurisdictions. These transactions include transfers between domestic or international entities, such as (1) U.S. to foreign, (2) foreign to foreign, (3) U.S. to U.S., and (4) U.S. state to state.

The general transfer pricing principle is that the pricing of a related-party transaction should be consistent with the pricing of similar transactions between independent entities under similar circumstances (i.e., an arm's-length transaction). Transfer pricing tax regulations are intended to prevent entities from using intra-entity charges to evade taxes by inflating or deflating the profits of a particular jurisdiction in which the larger consolidated group does business. Even if a parent corporation or its subsidiaries are in tax jurisdictions with similar tax rates, an entity may have tax positions that are subject to the recognition and measurement principles in ASC 740-10-25-6 and ASC 740-10-30-7.

An entity's exposure to transfer pricing primarily occurs when the entity includes in its tax return the benefit received from a related-party transaction that was not conducted as though it was at arm's length. An unrecognized tax benefit (UTB) results when one of the related parties reports either lower revenue or higher costs than it can sustain (depending on the type of transaction). While a benefit is generally more likely than not to result from such a transaction (e.g., some amount will be allowed as an interest deduction, royalty expense, or cost of goods sold), the amount of benefit is often uncertain because of the subjectivity of valuing the related-party transaction.

An entity must perform two steps in applying ASC 740 to all uncertain tax positions within its scope: (1) recognition and (2) measurement. The requirements of ASC 740 in the context of transfer pricing arrangements, including related considerations, are outlined below.

8.2.3.1 Determining the Unit of Account

Before applying the recognition and measurement criteria, an entity must identify all material uncertain tax positions and determine the appropriate unit of account for assessment. As noted in ASC 740-10-20, a tax position encompasses an "allocation or a shift of income between jurisdictions" (i.e., a transfer pricing arrangement). Therefore, intra-entity and related-party transactions under transfer pricing arrangements are within the scope of ASC 740.

Further, tax positions related to transfer pricing generally should be evaluated individually, since two entities and two tax jurisdictions are involved in each transaction. Such an evaluation should be performed even when the transaction is supported by a transfer pricing study prepared by one of the entities. Typically, there would be at least two units of account. For example, the price at which one entity will sell goods to another entity will ultimately be the basis the second entity will use to determine its cost of goods sold. In addition, some transfer pricing arrangements could be made up of multiple components that could be challenged individually or in aggregate by a tax authority. Therefore, there could be multiple units of account associated with a particular transfer pricing arrangement.

8.2.3.2 Recognition

ASC 740-10-25-6 indicates that the threshold for recognition has been met "when it is more likely than not, based on the technical merits, that the position will be sustained upon examination." An entity should apply the recognition threshold and guidance in ASC 740 to each unit of account in a transfer pricing arrangement. In some cases, a tax position will be determined to have met the recognition threshold if a transaction has taken place to generate the tax positions and some level of benefit will therefore be sustained. For example, assume that a U.S. parent entity receives a royalty for the use of intangibles by a foreign subsidiary that results in taxable income for the parent and a tax deduction for the foreign subsidiary. The initial tax filing (income in the receiving jurisdiction and expense/deduction in the paying jurisdiction) may typically meet the more-likely-than-not recognition threshold on the basis of its technical merits, since a transaction between two parties has occurred. However, because there are two entities and two tax jurisdictions involved, the tax jurisdictions could question whether the income is sufficient, whether the deduction is excessive, or both. Such factors should generally be considered during the recognition phase as part of the determination of what the tax jurisdictions are more likely than not to accept on the basis of the technical merits.

8.2.3.3 Measurement

After an entity has assessed the recognition criteria in ASC 740 and has concluded that it is more likely than not that the tax position taken will be sustained upon examination, the entity should measure the associated tax benefit. This measurement should take into account all relevant information, including tax treaties and arrangements between tax authorities. As discussed above, each tax position should be assessed individually and a minimum of two tax positions should be assessed for recognition and measurement in each transfer pricing transaction.

For measurement purposes, ASC 740-10-30-7 requires that the tax benefit be based on the amount that is more than 50 percent likely to be realized upon settlement with a tax jurisdiction "that has full knowledge of all relevant information." Intra-entity or transfer pricing assessments present some unique measurement-related challenges that are based on the existence of tax treaties or other arrangements (or the lack of such arrangements) between two tax jurisdictions.

Measurement of uncertain tax positions is typically based on facts and circumstances. The following are some general considerations (not all-inclusive):

- *Transfer pricing studies* — An entity will often conduct a transfer pricing study with the objective of documenting the appropriate arm's-length pricing for the transactions. The entity should consider the following when using a transfer pricing study to support the tax positions taken:
  - The qualifications and independence of third-party specialists involved (if any).
  - The type of study performed (e.g., benchmarking analysis, limited or specified method analysis, U.S. documentation report, Organisation for Economic Co-operation and Development [OECD] report).
  - The specific transactions and tax jurisdictions covered in the study.
  - The period covered by the study.
  - The reasonableness of the model(s) and the underlying assumptions used in the study (i.e., comparability of companies or transactions used, risks borne, any adjustments made to input data).
  - Any changes in the current environment, including new tax laws in effect.
- *Historical experience* — An entity should consider previous settlement outcomes of similar tax positions in the same tax jurisdictions. Information about similar tax positions, in the same tax jurisdictions, that the entity has settled in previous years may serve as a good indicator of the expected settlement of current positions.
- *Applicability of tax treaties or other arrangements* — An entity should consider whether a tax treaty applies to a particular tax position and, if so, how the treaty would affect the negotiation and settlement with the tax authorities involved.
- *Symmetry of positions* — Even though each tax position should be evaluated individually for appropriate measurement, if there is a high likelihood of settlement through "competent-authority" procedures under the tax treaty or other agreement, an entity should generally use the same assumptions about such a settlement to measure both positions (i.e., the measurement assumptions are similar, but the positions are not offset). Under the terms of certain tax treaties entered into by the United States and foreign jurisdictions, countries mutually agree to competent-authority procedures to relieve companies of double taxation created by transfer pricing adjustments to previously filed returns.

An entity should carefully consider whether the tax jurisdictions involved strictly follow the arm's-length principle. For example, Brazil has a mandated statutory margin that may or may not equate to what is considered arm's length by another reciprocal taxing jurisdiction. Other jurisdictions may not strictly follow the arm's-length principle. In such situations, it may be inappropriate for an entity to assume symmetry of positions when measuring the positions.

8.2.3.4 Presentation

UTBs that result from transfer pricing arrangements may give rise to balance sheet presentation issues. For example, an entity with a transfer pricing arrangement may not be able to fully recognize a tax benefit in one jurisdiction but may recognize a tax benefit in the related party's jurisdiction on the basis of the assertion that the entity has competent-authority procedures available and will request that those procedures be applied if one of the tax authorities were to propose an adjustment. As noted above, countries mutually agree to competent-authority procedures to relieve companies of double taxation created by transfer pricing adjustments to previously filed tax returns. Typically, double taxation cases are resolved under the principles of the transfer pricing guidelines established by the OECD. If an entity elects to take a tax issue to a competent authority for resolution, the manner in which the double taxation issue is resolved is at the discretion of the respective jurisdictions' competent authorities. To avoid double taxation, one tax authority makes an adjustment (i.e., reduces a cost and increases taxable income) that would require a consistent transfer pricing adjustment (i.e., reducing revenue and decreasing taxable income) in the related party's tax jurisdiction. However, there is no guarantee that an agreement between the jurisdictions will be reached and that double taxation will be avoided.

In some cases, if two governments follow the OECD's transfer pricing guidelines to resolve substantive issues related to transfer pricing transactions between units of the same entity, an asset could be recognized in one jurisdiction because of the application of competent-authority procedures, and a liability could be recognized for UTBs from another tax jurisdiction that arose because of transactions between the entity's affiliates that are not considered at arm's length.

In this case, an entity should present the liability for UTBs and the tax benefit on a gross basis in its balance sheet. In addition, a public entity would include only the gross liability for UTBs in the tabular reconciliation disclosure. However, in the disclosure required by ASC 740-10-50-15A(b), the public entity would include the liability for UTBs and the tax benefit on a net basis in the amount of UTBs that, if recognized, would affect the effective tax rate.

8.2.4 Research and Development

For many life sciences entities, R&D activities represent a significant focus and expenditure. Beyond the above-mentioned scope considerations related to refundable R&D tax credits, these activities may result in various income tax accounting impacts that should be accounted for in accordance with ASC 740. For example, R&D cost-sharing agreements may affect an entity's accounting for the income tax effects of share-based payments. In addition, an entity may acquire R&D assets in a business combination that result in the creation of temporary differences. These issues are summarized below.

8.2.4.1 R&D Cost-Sharing Arrangements

A reporting entity may enter into an arrangement with a related entity (typically a foreign subsidiary) to share the cost of developing certain intangible assets. Under such an arrangement, which is often referred to as a cost-sharing arrangement, one company bears expenses on behalf of another company and is subsequently reimbursed for those costs. The shared costs may include the cost of share-based payments issued to employees of the reporting entity. Regarding the tax impact of the sharing of share-based payment costs, the discussion document for the FASB Statement 123(R) Resource Group's July 21, 2005, meeting states, in part:

> Related companies that plan to share the cost of developing intangible property may choose to enter into what is called a cost-sharing agreement whereby one company bears certain expenses on behalf of another company and is reimbursed for those expenses. U.S. tax regulations specify the expenses that must be included in a pool of shared costs; such expenses include costs related to stock-based compensation awards granted in tax years beginning after August 26, 2003.
>
> The tax regulations provide two methods for determining the amount and timing of share-based compensation that is to be included in the pool of shared costs: the "exercise method" and the "grant method." Under the exercise method, the timing and amount of the allocated expense is based on the intrinsic value that the award has on the exercise date. Companies that elect to follow the grant method use grant-date fair values that are determined based on the amount of U.S. GAAP compensation costs that are to be included in a pool of shared costs. Companies must include such costs in U.S. taxable income regardless of whether the options are ultimately exercised by the holder and result in an actual U.S. tax deduction.

Cost-sharing agreements affect the U.S. company's accounting for the income tax effects of share-based compensation. Companies should consider the impact of cost-sharing arrangements when measuring, on the basis of the tax election they have made or plan to make, the initial and subsequent deferred tax effects.

The example below, which is reproduced from the discussion document for the FASB Statement 123(R) Resource Group's July 21, 2005, meeting, illustrates the accounting for the tax effects of cost-sharing payments. Importantly, the example was developed before the adoption of ASU 2016-09, which is now effective for all entities. ASC 718-740-35-2, as amended by ASU 2016-09, indicates that all excess tax benefits and deficiencies should be recorded in the income statement. Nevertheless, the example remains a helpful illustration of accounting for the income tax effects of cost-sharing arrangements.

> Company A, which is located in the United States, enters into a cost-sharing arrangement with its subsidiary, Company B, which is located in Switzerland. Under the arrangement, the two companies share costs associated with the research and development of certain technology. Company B reimburses Company A for 30 percent of the research-and-development costs incurred by Company A. The U.S. tax rate is 40 percent. Cumulative book compensation for a fully vested option is $100 for the year ending on December 31, 2006. The award is exercised during 2007, when the intrinsic value of the option is $150.
>
> The tax accounting-impact is as follows:
>
> *Exercise method:* On December 31, 2006, Company A records $28 as the deferred tax asset related to the option ($100 [book compensation expense] × 70% [percentage not subject to reimbursement] × 40% [tax rate]). When, in 2007, the option is exercised, any net tax benefit that exceeds the deferred tax asset is an excess tax benefit and credited to [additional paid-in capital (APIC)]. The company is entitled to a U.S. deduction [while the discussion document describes this as the deduction, the calculation is actually the tax benefit] (net of the inclusion) of $42 ($150 [intrinsic value when the option is exercised] × 70% [percentage not reimbursed] × 40%). Accordingly, $14 ($42 – $28) would be recorded in APIC.
>
> *Grant method:* The cost-sharing impact is an increase of currently payable U.S. taxes each period; however, in contrast to the exercise method, the cost-sharing method should have no direct impact on the carrying amount of the U.S. deferred tax asset related to share-based compensation. If there was $100 of stock-based compensation during 2006, the impact on the December 31, 2006, current tax provision would be $12 ($100 [book compensation expense] × 30% [percentage reimbursed] × 40%). If the stock-based charge under [ASC 718] is considered a deductible temporary difference, a deferred tax asset also should be recorded in 2006 for the financial statement expense, in the amount of $40 ($100 [book compensation expense] × 40%). The net impact on the 2006 income statement is a tax benefit of $28 ($40 – $12). At settlement, the excess tax deduction of $20 ($50 × 40%) would be recorded in APIC.

Under each method described above, any excess tax benefits ($14 under the exercise method example and $20 under the grant method example) would be recorded as a credit to tax expense rather than to APIC.

8.2.4.2 R&D Assets Acquired in a Business Combination

Acquired R&D assets will be separately recognized and measured at their acquisition-date fair values. ASC 350-30-35-17A states that an R&D asset acquired in a business combination must be considered to be an indefinite-lived intangible asset until completion or abandonment of the associated R&D efforts. Once the R&D efforts are complete or abandoned, an entity should apply the guidance in ASC 350 to determine the useful life of the R&D assets and should amortize these assets accordingly in the financial statements. If the project is abandoned, the asset would be written off if it has no alternative use.

In accordance with ASC 740, deferred taxes should be recorded for temporary differences related to acquired R&D assets as of the business combination's acquisition date. As with all acquired assets and assumed liabilities, an entity must compare the amount recorded for an R&D intangible asset with its tax basis to determine whether a temporary difference exists. If the tax basis of the R&D intangible asset is zero, as it will be in a typical nontaxable business combination, a DTL will be recorded for that basis difference.

8.2.5 Valuation Allowances and Tax-Planning Strategies

A life sciences entity that has recurring losses or other negative evidence must consider all available evidence, both positive and negative, to determine whether a valuation allowance against its DTAs is needed. In assessing positive and negative evidence, an entity must consider the following four possible sources of taxable income discussed in ASC 740-10-30-18:

1. "Future reversals of existing taxable temporary differences."
2. "Future taxable income exclusive of reversing temporary differences and carryforwards."
3. "Taxable income in prior carryback year(s) if carryback is permitted under the tax law."
4. "Tax-planning strategies."

This analysis can be quite complex depending on the entity's facts and circumstances. Significant judgment is often required, particularly in the evaluation of items (2) and (4) above. It is difficult to assert that the entity will have future taxable income exclusive of reversing taxable temporary differences when it has cumulative losses in recent years. Further, tax-planning strategies must meet certain criteria to be treated as a source of taxable income, and evaluation of those criteria is often not straightforward.

8.2.6 Prescription Drug Fees

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, imposed an annual fee, payable to the U.S. Treasury, on the pharmaceutical manufacturing industry for each calendar year beginning on or after January 1, 2011. The amount of the fee to be paid by a given entity is based on the entity's branded prescription drug (BPD) sales for the preceding year as a percentage of the industry's BPD sales for the same period. Under current U.S. tax law, the fee is not tax deductible and will therefore result in a permanent difference between an entity's income for financial reporting purposes and its taxable income. This permanent difference will result in an increase in the entity's overall effective tax rate.

8.2.7 Section 382 Limitations on NOL Carryforwards

Because of the significant up-front costs required for companies to bring a new drug through regulatory approval and ultimately to market, it is common for companies in the life sciences industry to generate losses in the early stage of their life cycle. Companies can generally benefit from these losses in the form of NOL carryforwards that offset future taxable income.

However, Internal Revenue Code (IRC) Section 382 provides that loss corporations may be subject to a limitation on the amount of the NOL carryforward that can be realized in periods after a change in ownership (the "Section 382 limitation"). While ownership changes can result from a business combination or an IPO transaction, they can also be driven by a new round of equity financing that affects the company's ownership structure when certain thresholds are met. Companies should assess all changes to their ownership structure to determine whether any Section 382 limitation is required.

The determination of a Section 382 limitation involves a high degree of complexity and requires careful evaluation. An assessment of potential limitations on NOL carryforwards should be included as part of a company's ongoing tax-planning and tax-forecasting strategies, and the impacts of such limitations on potential funding, exit plans, or acquisition portfolio strategies should also be considered. Companies that may be subject to Section 382 limitations are encouraged to consult with their tax advisers.

In September 2019, the U.S. Treasury and the IRS issued proposed Treasury regulations on the items of income and deduction that are treated as built-in gains and losses under IRC Section 382. These proposed regulations, which include significant changes to the existing regulations, would be prospectively applied to ownership changes occurring after the proposals are finalized. Companies should continue monitoring the status of these proposed regulations and consult with their tax advisers to understand how the proposals could affect their income tax profile.

8.2.8 Tax Cuts and Jobs Act of 2017

The Tax Cuts and Jobs Act of 2017 (the "2017 Act") includes the following provisions that are relevant to life sciences entities:

- *Global intangible low-taxed income (GILTI)* — The 2017 Act requires certain income (i.e., GILTI) earned by controlled foreign corporations (CFCs) to be included currently in the gross income of the CFCs' U.S. shareholder. GILTI is the excess of the shareholder's "net CFC tested income" over the net deemed tangible income return (the "routine return"), which is defined as the excess of (1) 10 percent of the aggregate of the U.S. shareholder's pro rata share of the qualified business asset investment of each CFC with respect to which it is a U.S. shareholder over (2) the amount of certain interest expense taken into account in the determination of net CFC-tested income.

  A deduction is permitted to a domestic corporation in an amount equal to 50 percent of the sum of the GILTI inclusion and the amount treated as a dividend because the corporation has claimed a foreign tax credit as a result of the inclusion of the GILTI amount in income ("IRC Section 78 gross-up"). If the sum of the GILTI inclusion (and related IRC Section 78 gross-up) and the corporation's foreign-derived intangible income (FDII) exceeds the corporation's taxable income, the deductions for GILTI and for FDII are reduced by the excess. As a result, the GILTI deduction can be no more than 50 percent of the corporation's taxable income (and will be less if the corporation is also entitled to an FDII deduction). The maximum GILTI deduction is reduced to 37.5 percent for taxable years beginning after December 31, 2025.

- *Deduction for FDII* — The 2017 Act allows a domestic corporation a deduction for a portion of its FDII. The amount of the deduction depends, in part, on U.S. taxable income. The percentage of income that can be deducted is reduced in taxable years beginning after December 31, 2025.

- *Base erosion anti-abuse tax (BEAT)* — A corporation is potentially subject to tax under the BEAT provision if the controlled group of which it is a part has sufficient gross receipts and derives a sufficient level of "base erosion tax benefits." Under the BEAT, a corporation must pay a base erosion minimum tax amount (BEMTA) in addition to its regular tax liability after credits. The BEMTA is generally equal to the excess of (1) a fixed percentage of a corporation's modified taxable income (taxable income determined without regard to any base erosion tax benefit related to any base erosion payment, and without regard to a portion of its NOL deduction) over (2) its regular tax liability (reduced by certain credits). The fixed percentage is generally 5 percent for taxable years beginning in 2018, 10 percent for years beginning after 2018 and before 2026, and 12.5 percent for years after 2025. However, the fixed percentage is 1 percentage point higher for banks and securities dealers (i.e., 6, 11, and 13.5 percent, respectively).

- *Capital expensing* — The 2017 Act permits 100 percent immediate expensing for qualified property through 2022, which is phased down each subsequent year through 2026 (80 percent in 2023, 60 percent in 2024, 40 percent in 2025, 20 percent in 2026).

- *Orphan drug credit* — The 2017 Act halved the credit for research on rare diseases, known as the orphan drug credit.

- *Research and experimentation (R&E) expenses* — The 2017 Act requires R&E costs to be amortized over 5 years for R&E activities performed in the United States (or 15 years for R&E activities performed outside the United States).

For a discussion of other matters related to the income tax accounting consequences of the 2017 Act's provisions, see Deloitte's January 3, 2018, *Financial Reporting Alert* (updated August 30, 2018).

8.2.9 CARES Act

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), a massive tax-and-spending package intended to provide additional economic relief to address the impact of the coronavirus disease 2019 ("COVID-19") pandemic. Several significant business tax provisions in the CARES Act that are intended to improve cash flow and liquidity could affect a company's accounting for income taxes. Under ASC 740, the effects of new legislation are recognized upon enactment, which (for federal legislation) is the date the president signs the bill into law. Accordingly, recognition of the tax effects of the CARES Act was required in the interim and annual periods that included March 27, 2020.

The following provisions of the CARES Act are most likely to affect life sciences entities:

- *Modifications to limitations on deductibility of NOLs (Section 2303)* — The 2017 Act eliminated, with certain exceptions, the NOL carryback period and permits an indefinite carryforward period while limiting the NOL deduction to 80 percent of taxable income (computed without regard to the NOL deduction). The CARES Act repeals the 80 percent limitation for taxable years beginning before January 1, 2021. It further specifies that NOLs arising in a taxable year beginning after December 31, 2017, and before January 1, 2021, are allowed as a carryback to each of the five taxable years preceding the taxable year of such losses.
- *Modifications to limitations on deductibility of business interest (Section 2306)* — The CARES Act amends IRC Section 163(j) as applied to taxable years beginning in 2019 and 2020. IRC Section 163(j) limits the deduction for business interest expense to the sum of (1) the taxpayer's business interest income, (2) 30 percent of the taxpayer's adjusted taxable income, and (3) the taxpayer's floor plan financing interest expense for the taxable year. The CARES Act increases the 30 percent adjusted taxable income threshold to 50 percent for taxable years beginning in 2019 and 2020. In addition, the CARES Act allows taxpayers to elect to use their 2019 adjusted taxable income as their adjusted taxable income in 2020.[1]
- *Alternative minimum tax credit acceleration (Section 2305)* — The 2017 Act repealed the corporate alternative minimum tax (AMT), which operated in parallel with the regular tax system. The CARES Act amends Section 53(e) of the 2017 Act so that all prior-year minimum tax credits are potentially available for refund for the first taxable year of a corporation beginning in 2018. Companies will need to adjust the classification of any remaining AMT credits as a result of the AMT credit acceleration.
- *Expensing of qualified improvement property (Section 2307)* — The 2017 Act inadvertently failed to include qualified improvement property (QIP) in the 15-year property classification. Accordingly, QIP was classified by default as 39-year property and was consequently ineligible for the additional first-year bonus depreciation. To fix these inadvertent oversights, the CARES Act includes technical amendments that are retroactive to the effective date of the 2017 Act. Companies will need to consider (1) how the QIP technical correction affects their assessment of uncertain tax positions, including the impacts of interest and penalties; (2) the possibility of

[1] Special rules also apply for partnerships and short taxable years in 2019 and 2020. For additional information, see Deloitte's *COVID-19 Stimulus: A Taxpayer Guide*.

having to file amended tax returns; and (3) the related impact on current taxes payable and DTAs and DTLs.

- *Other tax considerations* — Depending on an entity's facts and circumstances, certain of the aforementioned sections of the CARES Act (e.g., those related to the NOL carryback and the QIP technical correction) could also affect various other aspects of an entity's tax provision (e.g., GILTI, BEAT, FDII). Accordingly, an entity will need to carefully consider its facts and circumstances to determine the appropriate accounting.
- *Interim reporting considerations* — An entity uses an estimated AETR to compute its taxes for interim periods related to ordinary income (or loss). Generally, the provisions of the CARES Act that affect ordinary income (e.g., credits that are not related to income taxes) should be considered and estimated as part of an entity's estimated AETR.

For more information about the CARES Act and its impacts, see Deloitte's ***Heads Up***, "Highlights of the CARES Act."

8.3 SEC Comment Letter Themes Related to Income Taxes

Overall, the themes of SEC staff comments issued to registrants on financial reporting and disclosures related to income taxes have remained consistent year over year. Such comments continue to focus on (1) valuation allowances, (2) disclosures related to the income tax rate, (3) tax effects of significant or unusual transactions that occurred during the period, and (4) noncompliance with disclosure requirements (e.g., omission of required disclosures).

The SEC staff continues to ask registrants to provide early-warning disclosures to help financial statement users understand key estimates and assumptions in recording these items and how changes to those estimates and assumptions could potentially affect the financial statements in the future. The SEC staff also continues to issue comments on non-GAAP measures with a particular focus on the income tax impact of the adjustments made to the GAAP measures. For additional information about non-GAAP measures, see Deloitte's *A Roadmap to Non-GAAP Financial Measures and Metrics*.

Historically, the SEC staff has stated that boilerplate language should be avoided with respect to income tax disclosures within MD&A and that approaches more conducive to effective disclosure would include:

- Using the income tax rate reconciliation as a starting point and describing the details of the material items.
- Discussing significant foreign jurisdictions, including statutory rates, effective rates, and the current and future impact of reconciling items.
- Providing meaningful disclosures about known trends and uncertainties, including expectations regarding the countries where registrants operate.

For more information about SEC comment letter themes that are relevant to the life sciences industry, see Deloitte's SEC Comment Letter Roadmap.

8.4 New Accounting Standard — Simplifying the Accounting for Income Taxes (ASU 2019-12)

In December 2019, the FASB issued ASU 2019-12, which modifies ASC 740 to simplify the accounting for income taxes. The ASU's amendments are based on changes that were suggested by stakeholders as part of the FASB's simplification initiative, which is intended to reduce complexity in accounting standards.

ASU 2019-12 affects various aspects of ASC 740, including the accounting for taxes under hybrid tax regimes, the accounting for increases in goodwill, the allocation of tax amounts to separate company financial statements within a group that files a consolidated tax return, intraperiod tax allocation, interim-period accounting, and the accounting for ownership changes in investments. In addition, the ASU makes minor Codification improvements.

For PBEs, the amendments in ASU 2019-12 are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption is permitted, including adoption in any interim period for which financial statements have not yet been issued.

For all other entities, the amendments in the ASU are effective for fiscal years beginning after December 15, 2021, and for interim periods beginning after December 15, 2022. Early adoption for these entities is also permitted, including adoption in any interim period for which financial statements have not yet been made available for issuance.

For additional information about the ASU, see Deloitte's December 19, 2019, *Heads Up*.

8.5 On the Horizon — Proposed ASU on Disclosure Requirements for Income Taxes

In March 2019, the FASB issued a proposed ASU that would modify or eliminate certain requirements related to income tax disclosures and establish new disclosure requirements. The proposed guidance, which is part of the FASB's disclosure framework project, is intended to increase the relevance of income tax disclosures for financial statement users.

The proposed ASU is a revised version of the FASB's July 2016 exposure draft (the "initial ED") on changes to income tax disclosure requirements. The FASB discussed stakeholder feedback on the initial ED in January 2017 and again in November 2018, when it also assessed whether updates would be needed as a result of the 2017 Act.

The proposed ASU would affect various disclosures under ASC 740, including those related to the disaggregation of certain metrics (i.e., income or loss from continuing operations), indefinitely reinvested foreign earnings, UTBs, valuation allowances, a company's rate reconciliation, and operating loss and tax credit carryforwards. It would also affect interim disclosure requirements and make other minor changes to existing guidance. Entities would be required to adopt the proposed ASU's guidance prospectively. In subsequent FASB meetings on the proposal, the Board will determine an effective date and whether to permit early adoption.

Comments on the proposed ASU were due by May 31, 2019. At the FASB's February 2020 meeting, the Board discussed comment letter feedback on the proposed ASU and directed its staff to perform additional research and outreach. The final standard will be drafted after redeliberations.

For additional information about the proposed ASU, see Deloitte's March 29, 2019, *Heads Up*.

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*

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
CMO	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
OEM	original equipment manufacturer
PBE	public business entity
PCAOB	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