Life Sciences
Accounting and Financial Reporting Update — Interpretive Guidance on Non-GAAP Measures
March 2018
Non-GAAP Measures

Introduction

A non-GAAP measure is a historical or future measure of financial performance, financial position, or cash flows that either (1) excludes amounts that are included in the most directly comparable GAAP measure or (2) includes amounts that are excluded from the most directly comparable GAAP measure. Common non-GAAP measures include adjusted earnings; earnings before interest, taxes, depreciation, and amortization (EBITDA); core earnings; and free cash flow, among others. Among life sciences companies, common non-GAAP adjustments in these measures include up-front and milestone payments for license and asset acquisitions, amortization and impairment of intangibles and adjustment of contingent consideration arising from prior business combinations, restructuring and litigation charges, and gains or losses from divestitures.

In May 2016, the SEC staff issued Compliance and Disclosure Interpretations (C&DIs) that clarify the SEC’s guidance on non-GAAP measures in response to concerns about (1) the increased use and prominence of such measures, (2) their potential to be misleading, and (3) the progressively larger difference between the amounts reported for non-GAAP and GAAP measures. The C&DIs do not prohibit companies from using non-GAAP measures that comply with the SEC’s existing rules; in fact, the SEC staff has acknowledged that in certain circumstances, non-GAAP measures may be useful. However, the updated guidance was intended to change certain practices about which the SEC has expressed concern, particularly regarding the prominence placed on such measures.

For the 12 months ended July 31, 2017, non-GAAP measures ranked first in the top-10 list of topics frequently commented on by the SEC’s Division of Corporation Finance as part of its filing review process.¹ The SEC staff has continued to issue comments on the prominence of non-GAAP measures. It also continues to issue comments in connection with the reconciliation requirements, the purpose and use of non-GAAP measures, and the use of potentially misleading measures, such as those that may adjust for normal, recurring cash operating expenses.

Although there was significant scrutiny of non-GAAP disclosures this past year, the volume of comments related to such disclosures is beginning to lessen. Many registrants have modified and improved their disclosures in response to the guidance in the C&DIs, to public remarks by various SEC staff members, and (in certain cases) to SEC comments. At the December 2017 AICPA Conference on Current SEC and PCAOB Developments, then Division of Corporation Finance Chief Accountant Mark Kronforst acknowledged the improvement, indicating that the volume of recent comments on non-GAAP measures has dropped to pre-2016 levels. While Mr. Kronforst hopes this trend continues, he noted that because of the market’s interest in these measures, the SEC staff will continue to closely monitor their use and issue comments.

The sections below (1) give an overview of SEC guidance on non-GAAP measures; (2) provide examples of SEC comments to registrants on non-GAAP measures and a summary of key C&DIs; and (3) discuss considerations for using non-GAAP measures and the related control framework for governing such disclosure.

¹ Comment letter trend information is based on data provided by Audit Analytics for the 12 months ended July 31, 2017.
Overview of SEC Guidance on Non-GAAP Measures

SEC Regulation G applies to all public releases or disclosure of non-GAAP measures, even if such information is not part of a registrant's SEC filing (e.g., conference calls, investor presentations, and webcasts) and regardless of whether the information is filed with or furnished to the SEC.

Regulation G states that:

- Non-GAAP financial measures must not be misleading.
- The most directly comparable GAAP measure must be presented.
- A quantitative reconciliation of the non-GAAP financial measure to the most comparable GAAP measure must be presented for (1) a historical non-GAAP measure and (2) forward-looking information (to the extent available without unreasonable effort).

SEC Regulation S-K, Item 10(e), applies to all SEC filings, such as registration statements, proxy statements, and Forms 10-K and 10-Q. Item 10(e) expands on Regulation G to require the following in addition to the three items above:

- That the prominence of the most directly comparable GAAP measure presented be equal to or greater than that of the non-GAAP measure.
- A statement indicating the reasons why the registrant believes that the non-GAAP measure provides useful information to investors about the registrant's financial condition and results of operations.
- To the extent material, a statement disclosing the additional purposes, if any, for which the registrant uses the non-GAAP measure.

In addition, press releases furnished to the SEC under Form 8-K, Item 2.02, such as those announcing quarterly earnings, are required to comply with the disclosure provisions of Item 10(e) listed above. Item 10(e) also sets forth certain prohibitions, such as using "titles or descriptions of non-GAAP financial measures that are the same as, or confusingly similar to, titles or descriptions used for GAAP financial measures." Although Regulation G and Form 8-K, Item 2.02, do not refer to the prohibitions in Item 10(e)(1)(ii), registrants should consider the concepts in these and other prohibitions when using non-GAAP measures. For additional information about the prohibitions described in Item 10(e), see Chapter 4 of Deloitte's A Roadmap to Non-GAAP Financial Measures.

Along with these regulations, the SEC staff published 33 frequently asked questions (FAQs) interpreting certain aspects of the rules in an attempt to help registrants comply with the guidance. In 2010, the SEC staff replaced the interpretive guidance in the FAQs with the C&DIs that exist today. The C&DIs were intended to give registrants more flexibility to disclose non-GAAP measures in filings with the SEC.

The May 2016 updates to the C&DIs provide additional guidance on what the SEC staff expects from registrants that use non-GAAP measures. As noted above, those updates were intended to promote changes in the use of non-GAAP measures, particularly related to potentially misleading measures and undue prominence placed on such measures, as well as compliance with other presentation and disclosure requirements.

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2 See C&DI Question 108.01, which discusses an exception for disclosures of target levels that are non-GAAP measures in Compensation Discussion and Analysis or other parts of the proxy statement.
3 Form 8-K, Item 2.02, requires registrants to furnish to the SEC all releases or announcements disclosing material nonpublic financial information about completed annual or quarterly fiscal periods, regardless of whether the release or announcement includes disclosure of a non-GAAP financial measure. If a registrant elects to file the release or announcement with the SEC, such disclosure is subject to the requirements of Item 10(e).
In October 2017, the SEC staff released an update to certain C&DIs on non-GAAP financial measures associated with business combinations. The update included a new C&DI that addresses whether financial measures in forecasts provided to financial advisers and used in connection with a business combination transaction constitute non-GAAP measures. See Section 2.6.3 of Deloitte’s A Roadmap to Non-GAAP Financial Measures for additional information about non-GAAP measures related to business combination transactions.

The C&DIs on non-GAAP measures are further discussed below.

**C&DIs and Related SEC Comments to Registrants**

The application of the C&DIs, together with related SEC comments to registrants, are discussed in the sections below. For more information about the C&DIs as well as other non-GAAP guidance, see Deloitte’s A Roadmap to Non-GAAP Financial Measures.

**Prominence**

Under Item 10(e), if a registrant presents a non-GAAP measure, it should present the most directly comparable GAAP measure with “equal or greater prominence.” Before the SEC staff’s May 2016 updates to the C&DIs, there was no formal guidance interpreting this requirement and, as a result, diversity developed in practice. C&DI Question 102.10 now provides the following examples that illustrate when the presentation of a non-GAAP measure may fail to meet the requirement:

- “Presenting a full income statement of non-GAAP measures or presenting a full non-GAAP income statement when reconciling non-GAAP measures to the most directly comparable GAAP measures.”
- “Omitting comparable GAAP measures from an earnings release headline or caption that includes non-GAAP measures.”
- “Presenting a non-GAAP measure using a style of presentation (e.g., bold, larger font) that emphasizes the non-GAAP measure over the comparable GAAP measure.”
- “A non-GAAP measure that precedes the most directly comparable GAAP measure (including in an earnings release headline or caption).”
- “Describing a non-GAAP measure as, for example, ‘record performance’ or ‘exceptional’ without at least an equally prominent descriptive characterization of the comparable GAAP measure.”
- “Providing tabular disclosure of non-GAAP financial measures without preceding it with an equally prominent tabular disclosure of the comparable GAAP measures or including the comparable GAAP measures in the same table.”
- “Excluding a quantitative reconciliation with respect to a forward-looking non-GAAP measure in reliance on the ‘unreasonable efforts’ exception in Item 10(e)(1)(i)(B) without disclosing that fact and identifying the information that is unavailable and its probable significance in a location of equal or greater prominence.”
- “Providing discussion and analysis of a non-GAAP measure without a similar discussion and analysis of the comparable GAAP measure in a location with equal or greater prominence.”
SEC Comments to Registrants on Prominence

The SEC comments below were issued to registrants with respect to undue prominence assigned to non-GAAP measures.

Examples of SEC Comments

- We note that in your executive summary you focus on key non-GAAP financial measures and not GAAP financial measures which may be inconsistent with the updated Compliance and Disclosure Interpretations issued on May 17, 2016 (specifically Question 102.10). We also note issues related to prominence within your earnings release . . . Please review this guidance when preparing your next earnings release.

- We note that you present Net margin, a non-GAAP measure, as a notable highlight but you do not discuss the most directly comparable GAAP measure. Your presentation appears to give greater prominence to the non-GAAP measure than to the comparable GAAP measure which is inconsistent with the updated Compliance and Disclosure Interpretations on Non-GAAP Financial Measures issued on May 17, 2016. Please revise your presentation in future filings to comply with that guidance.

- We note that you omit a quantitative reconciliation with respect to your forward looking non-GAAP guidance, but you do not provide the disclosures required when the reconciliation is omitted. In your next earnings release, please follow the guidance in Question 102.10 of the updated Non-GAAP Compliance and Disclosure Interpretations issued on May 17, 2016.

In assessing prominence, registrants should consider, among other items, the order of presentation, degree of emphasis, style of presentation, and volume of disclosures in a filing. Regarding order of presentation, the SEC staff has indicated that when reconciling a non-GAAP measure to the most directly comparable GAAP measure, a registrant should start with the GAAP measure. Since the SEC staff's release of the updated C&DIs on non-GAAP measures, C&DI Question 102.10 has been a leading source of SEC focus and comment.

Further, if a registrant presents forward-looking non-GAAP financial measures, it should provide a quantitative reconciliation unless it qualifies for the "unreasonable efforts" exception in Regulation G and Item 10(e). A registrant that qualifies for the exception should disclose that fact in a prominent location, identify the information that is not available, and indicate the probable significance of this information.

Misleading Measures

An overriding theme of the SEC’s updated guidance on the use of or references to non-GAAP measures in public statements or disclosures is that they should not be misleading, whether such measures are used in a filing (e.g., Form 10-K) or elsewhere (e.g., press release). Several of the updated C&DIs provide additional interpretive guidance on presentations that the SEC staff may consider misleading, such as:

- Excluding normal, recurring cash operating expenses necessary for business operations from a performance measure (C&DI Question 100.01).
- Presenting non-GAAP measures inconsistently between periods, such as by adjusting an item in the current reporting period, but not a similar item in the prior period, without appropriate disclosure about the change and an explanation of the reasons for it (C&DI Question 100.02).
- Excluding certain nonrecurring charges but including nonrecurring gains (e.g., “cherry picking” non-GAAP adjustments to achieve the most positive measure) (C&DI Question 100.03).
- Basing non-GAAP measures on individually tailored accounting principles (C&DI Question 100.04).
As companies conduct their internal reviews of non-GAAP presentations, any disclosure that could be potentially misleading should be carefully evaluated for compliance with the C&DI since misleading measures remain a source of SEC focus, as demonstrated by the SEC comment examples below.

**SEC Comments to Registrants That Are Consistent With C&DI Questions 100.01 Through 100.03**

**Examples of SEC Comments**

- Your statements that your non-GAAP measures reflect adjustment for items that are not indicative of your on-going core operating performance and are important components of how you measure your internal performance do not satisfy Item 10(e)(1)(i)(C) and (D) of Regulation S-K. . . . In this regard, we note that you disclose in your reconciliation table amounts for many of the line items in your statement of operations, including total revenues, selling, general and administrative expenses, research and development expenses, etc., and you do not explain why each of these non-GAAP amounts is relevant and useful to investors. Also, it is unclear why the removal of large expenses as non-GAAP adjustments for items that relate to prior acquisitions (such as amortization of intangibles, milestone payments and the change in fair value of contingent consideration) is not indicative of your core operating results given that part of your stated primary strategy relates to the acquisition of products.

- We note that you exclude restructuring and litigation-related charges from your non-GAAP measures. Please explain to us why these are not normal, recurring, cash operating expenses necessary to operate your business. See Question 100.01 of the updated Non-GAAP Compliance and Disclosure Interpretations issued on May 17, 2016.

- We note your disclosure of adjusted [earnings per share (EPS)] in the press release. Adjusted EPS for the fiscal year ended January 31, 2017 includes an adjustment for the gain on the sale of [Company Plant X] in [Foreign Jurisdiction A]. Please explain why you did not include an adjustment for the . . . gain from the sale of [other company assets] in [Foreign Jurisdiction B]. Additionally, the adjustments for discrete items do not appear consistent year to year. Please explain how you determine discrete items.

- We note that nearly all adjustments made to reconcile EBITDA to Adjusted EBITDA represent increases to EBITDA. It also appears that you adjust for all non-cash items presented on your statements of cash flows except for gains and losses on disposals of fixed assets and amortization of deferred gains on sale-leasebacks, which, if included, would have decreased Adjusted EBITDA for the periods presented. Please address how your presentation complies with Question 100.03 of the updated [C&DI] on Non-GAAP Financial Measures.

The SEC staff has indicated that during the comment letter process, the Division may gather additional information about the nature of and circumstances specific to certain adjustments, such as restructuring costs or litigation expenses, to determine whether such adjustments were appropriate. For example, in situations in which the Division identified companies that appeared to be “serial restructurers,” the staff has asked for further details about the facts and circumstances supporting an adjustment for what appeared to be a recurring cost. In most of those cases, the Division staff did not ultimately object to the use of the adjustment; however, in response to the SEC comment, the registrant may have revised its disclosures about the nature and purpose of the adjustment or the resulting non-GAAP measure.

**Per-Share Measures**

Item 10(e) does not specifically prohibit the presentation of non-GAAP per-share financial measures. However, the adopting release for Regulation G indicates that certain non-GAAP per-share measures are specifically prohibited under GAAP and SEC rules and therefore should not be presented in materials filed with or furnished to the SEC. Although cash flow per share and other per-share measures of liquidity are prohibited, registrants may disclose a non-GAAP per-share performance measure as long as it complies with other SEC requirements for such a measure.
A registrant must determine whether its non-GAAP measure is a performance measure or a liquidity measure. This determination influences certain requirements, including to which GAAP measure the non-GAAP measure should be reconciled and whether there are any prohibitions against certain presentations. Performance measures are generally reconciled to net income, whereas liquidity measures are generally reconciled to cash flows from operations. Historically, the SEC staff has shown deference to management’s determination of whether a non-GAAP measure is a performance measure or a liquidity measure. However, updated C&DI Question 102.05 indicates that when analyzing the characterization of a non-GAAP measure as a performance measure or a liquidity measure, “the staff will focus on the substance of the non-GAAP measure and not management’s characterization of the measure.”

**SEC Comments to Registrants on Per-Share Measures**

**Example of an SEC Comment**

It appears that your measure of Funds Available for Distribution can be used as a non-GAAP liquidity measure. Please explain to us how you have considered question 102.05 of the C&DI related to Non-GAAP Financial Measures in drafting your Non-GAAP disclosures related to FAD. In particular, explain to us how you determined presentation of FAD on a per share basis would be appropriate in light of this guidance.

Depending in part on the size and nature of the adjustments to the corresponding GAAP measure, there may be some level of judgment involved in the assessment of whether a non-GAAP performance measure can also be used as a liquidity measure. However, the SEC staff may question a non-GAAP measure that a registrant purports to be a performance measure if, for example:

- The non-GAAP measure includes several adjustments (many of which are noncash amounts) to reconcile it to the most comparable GAAP income measure, and only one or two adjustments would be needed to reconcile it to a GAAP measure from the statement of cash flows, such as operating cash flow.
- The total dollar amount of the non-GAAP adjustment is made up of a large percentage of noncash charges.

**Non-GAAP Tax Expense**

In certain circumstances, a registrant may reflect a non-GAAP measure after taxes and therefore show the tax adjustments when reconciling a non-GAAP measure to the appropriate GAAP measure. C&DI Question 102.11 indicates that the tax expense impact for a performance measure should be consistent with the amount of non-GAAP income since adjusting revenue or income before income tax could affect the tax expense or benefits assumed in the calculation of the tax provision. In addition, the C&DI indicates that all adjustments should be disclosed gross of tax, with a separate adjustment for the tax impact and an explanation of how the tax adjustment was calculated.
SEC Comments to Registrants on Tax Adjustments

The SEC comments below, which were issued to registrants in the life sciences industry, illustrate the SEC staff’s focus on tax adjustments to non-GAAP measures.

Examples of SEC Comments

- Tell us if you have included current and deferred income tax expense commensurate with the non-GAAP measure of profitability. Refer to question 102.11 in our C&DI on the use of non-GAAP financial measures updated May 17, 2016. In this regard, explain to us why it is appropriate to reflect the pre-tax non-GAAP adjustments . . . at zero effective tax rates. In your response tell us your consideration for whether the pre-tax non-GAAP adjustment in any individual jurisdiction, coupled with any similar adjustment in prior periods or expected adjustments in future periods, would create hypothetical income causing you to reverse the valuation allowance for non-GAAP purposes and record a tax provision related to the current adjustments.

- We note that you present the income tax effects of your non-GAAP adjustments as “Income tax expense, as adjusted” without providing the reconciliation required by Item 10(e)(1)(i)(B) of Regulation S-K or clearly explaining how it was calculated, which is inconsistent with Question 102.11 of the updated Compliance and Disclosure Interpretations issued on May 17, 2016. Please review this guidance when preparing your next earnings release.

As previously noted, C&DI Question 102.11 indicates that all adjustments should be disclosed gross of tax, with a separate adjustment for the tax impact and an explanation of how the tax adjustment was calculated. For example, suppose that a registrant has a $200 million GAAP loss for the most recent fiscal year, which resulted in a 3 percent effective tax rate. If the registrant makes various reconciling adjustments and then presents a non-GAAP adjusted income measure of $400 million, the SEC staff may comment if the registrant is using the same 3 percent effective tax rate to compute the tax provision.

In addition, as discussed in Deloitte’s January 3, 2018, Financial Reporting Alert (updated January 19, 2018), President Trump signed into law the tax legislation commonly known as the Tax Cuts and Jobs Act4 (the “Act”) on December 22, 2017. Because the Act could significantly affect registrants’ financial statements, registrants may seek to adjust post-tax non-GAAP measures related to the impact of tax reform. Registrants may also elect to make non-GAAP adjustments related to discrete amounts that affect income from, for example, (1) the adjustment of deferred taxes upon the change in corporate tax rates or (2) the recognition of incremental tax expense related to foreign earnings previously considered to be indefinitely reinvested abroad and not subject to U.S. taxation. If such adjustments are not misleading as described in Section 100 of the C&DIs, they may be permissible depending on the registrant’s specific facts and circumstances.

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4 H.R. 1/Public Law 115-97, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018.”
Some registrants may also consider adjustments that attempt to depict a “normalized” tax rate between comparable periods to enhance comparability of periods before and after tax reform. For example, a registrant might use a non-GAAP presentation to apply a lower tax rate to a period before enactment as if the new rates were in effect at that time (e.g., applying a post-reform effective tax rate to prior-year pretax earnings to create comparability to 2018 net income). In deciding whether to present such a measure, a registrant should evaluate whether the measure could be misleading on the basis of the SEC’s C&DIs, including whether it could be considered to be an “individually tailored” accounting principle as described in C&DI Question 100.04.

For more information, see Section 4.3 of Deloitte’s A Roadmap to Non-GAAP Financial Measures.

Considerations for Using Non-GAAP Measures

Registrants that use non-GAAP measures in earnings releases furnished on Form 8-K or on Forms 10-Q and 10-K (outside the financial statements) should consider the appropriateness of their disclosure controls and procedures (DCPs) in the context of their non-GAAP information.

Recently, oversight and controls over non-GAAP and other operational measures have been a focal point of discussion for the SEC staff, specifically with respect to the procedures and protocols in place to evaluate the accuracy of such measures and the consistency with prior periods’ presentation. Therefore, it is critical that companies proactively and thoughtfully understand and assess the risks that accompany non-GAAP and other supplemental information that are considered to be important sources of information to investors. The SEC staff has indicated that in some respects, these non-GAAP and other reporting processes may require more evaluative steps than some GAAP processes. That is, since the non-GAAP and other reporting processes lack the benefit of standard-setting due process, a company that uses such processes may have to look to its own policies, stakeholders, others outside the finance and accounting function, and the audit committee for input and insight into ways of maintaining the effective operation of these controls and procedures.

A critical aspect of such DCPs is the involvement of the appropriate levels of management and those charged with governance. Depending on the registrant, this may include reviewing the selection and determination of non-GAAP measures with a disclosure committee, the audit committee, or both. Establishing a written policy that (1) clearly describes the nature of allowable adjustments to GAAP measures, (2) defines the non-GAAP measure(s) to be used under the policy, and (3) explains how potential changes in the inputs, calculation, or adjustments will be evaluated and approved may help management identify its DCPs. For example, a policy might describe qualitatively the types of adjustments that are nonrecurring and abnormal and thus within the defined policy. It may also outline specific quantitative thresholds for which income or expense items might be evaluated in the determination of whether they should be included in non-GAAP adjustments. This could help ensure that appropriate non-GAAP measures are used as well as eliminate the need for numerous immaterial adjustments in the reconciliation that may confuse investors. See Appendix B of Deloitte’s A Roadmap to Non-GAAP Financial Measures for a sample non-GAAP measure policy and related sample procedures.

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As companies design their controls framework over non-GAAP and other reporting disclosures, management should ensure, at a minimum, that the DCPs contemplate review activities that reflect the following guiding principles:

- **Compliance** — Non-GAAP measures are presented in compliance with SEC rules, regulations, and guidance.
- **Consistency of preparation** — Non-GAAP measures are presented consistently each period, and potential non-GAAP adjustments are evaluated on an appropriate, consistent basis each period.
- **Data quality** — Non-GAAP measures are calculated on the basis of reliable inputs that are subject to appropriate controls.
- **Accuracy of calculation** — Non-GAAP measures are calculated with arithmetic accuracy, and the non-GAAP measures in the disclosure agree with the measures calculated.
- **Transparency of disclosure** — Descriptions of the non-GAAP measures, adjustments, and any other required disclosures are clear and not confusing.
- **Review** — Non-GAAP disclosures are reviewed by appropriate levels of management to confirm the appropriateness and completeness of the non-GAAP measures and related disclosures.
- **Monitoring** — The registrant’s monitoring function (e.g., internal audit, disclosure committee, or audit committee) appropriately reviews the DCPs related to non-GAAP disclosures. The audit committee is involved in the oversight of the preparation and use of non-GAAP measures.

A more complete discussion of DCPs related to non-GAAP measures can be found in Chapter 5 of Deloitte’s *A Roadmap to Non-GAAP Financial Measures*. 
Appendix A — Glossary of Standards and Other Literature

The standards and other literature below were cited or linked to in this publication.

**AICPA Literature**

Accounting and Valuation Guide *Assets Acquired to Be Used in Research and Development Activities*

AICPA Issues Paper, *Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories*

*AICPA Technical Questions and Answers*, Q&A paragraph 2260.03, “Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit”

**FASB Accounting Standards Updates (ASUs)**


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

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

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 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting*

ASU 2017-07, *Compensation — Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost*

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

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*
ASU 2016-20, *Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers*


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

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


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

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

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

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

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

ASU 2016-02, *Leases (Topic 842)*


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

ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*


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

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

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 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 2010-20, Receivables (Topic 310): Disclosures About the Credit Quality of Financing Receivables and the Allowance for Credit Losses

ASU 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements — a consensus of the FASB Emerging Issues Task Force

**FASB Accounting Standards Codification (ASC) Topics**

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 280, Segment Reporting

ASC 320, Investments — Debt and Equity Securities

ASC 321, Investments — Equity Securities

ASC 323, Investments — Equity Method and Joint Ventures

ASC 325, Investments — Other

ASC 326, Financial Instruments — Credit Losses

ASC 330, Inventory

ASC 350, Intangibles — Goodwill and Other

ASC 360, Property, Plant, and Equipment

ASC 410, Asset Retirement and Environmental Obligations
ASC 420, Exit or Disposal Cost Obligations
ASC 450, Contingencies
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 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 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 915, Development Stage Entities
ASC 958, Not-for-Profit Entities
ASC 985, Software
Proposed FASB Accounting Standards Updates (Proposed ASUs)
Proposed ASU 2018-200, Leases (Topic 842): Targeted Improvements


FASB Proposed Accounting Standards Update 2017-280, Consolidation (Topic 812): Reorganization


Proposed ASU 2017-220, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

Proposed ASU 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory

Proposed ASU 2017-200, Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)


Proposed ASU 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance

Proposed ASU 2015-310, Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material

Other FASB Proposal

FASB Statements (Pre-Codification Literature)
Statement No. 167, Amendments to FASB Interpretation No. 46(R)

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

Statement No. 141(R), Business Combinations

FASB Interpretations (Pre-Codification Literature)
FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109

FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities
FASB Concepts Statements
No. 5, Recognition and Measurement in Financial Statements of Business Enterprises
No. 6, Elements of Financial Statements

EITF Issues (Pre-Codification Literature)
Issue 09-4, “Seller Accounting for Contingent Consideration”
Issue 08-1, “Revenue Arrangements With Multiple Deliverables”
Issue 04-5, “Determining Whether a General Partner, or the General Partners as a Group, Controls a Limited Partnership or Similar Entity When the Limited Partners Have Certain Rights”
Issue 01-9, “Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor’s Products)”
Issue 01-8, “Determining Whether an Arrangement Contains a Lease”
Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

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SEC C&DI Topic
Non-GAAP Financial Measures

SEC 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

SEC Regulation G
“Conditions for Use of Non-GAAP Financial Measures”

SEC Regulation S-K
Item 10(e), “General; Use of Non-GAAP Financial Measures in Commission Filings”
Item 103, “Business; Legal Proceedings.”

SEC Regulation S-X
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 3-14, “Special Instructions for Real Estate Operations to Be Acquired”
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(h), “General Notes to Financial Statements; Income Tax Expense”

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SAB Topic 1.M, “Financial Statements; Materiality”

SAB Topic 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”

SAB Topic 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”

SAB Topic 13, “Revenue Recognition”

SAB Topic 13.A.4, “Revenue Recognition; Selected Revenue Recognition Issues; Fixed or Determinable Sales Price”

SAB Topic 13.B, “Revenue Recognition; Disclosures”

SAB 116, “Staff Accounting Bulletin No. 116”

SAB 118, codified as SEC Staff Accounting Bulletin Topic 5.EE, “Miscellaneous Accounting; Income Tax Accounting Implications of the Tax Cuts and Jobs Act”

**Internal Revenue Code (IRC)**

IRC Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”

IRC Section 163(j), “Interest; Limitation on Business Interest”

IRC Section 199, “Income Attributable to Domestic Production Activities”

IRC Section 383, “Special Limitations on Certain Excess Credits, Etc.”

IRC Section 787, “Termination of Private Foundation Status”

IRC Section 965, “Treatment of Deferred Foreign Income Upon Transition to Participation Exemption System of Taxation”

IRC Section 4191, “Medical Devices”

**International Standards**

IFRS 16, *Leases*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 11, *Joint Arrangements*

IFRS 3, *Business Combinations*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*
# Appendix B — Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFS</td>
<td>available for sale</td>
</tr>
<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
</tr>
<tr>
<td>AOCl</td>
<td>accumulated other comprehensive income</td>
</tr>
<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
</tr>
<tr>
<td>APIC</td>
<td>additional paid-in capital</td>
</tr>
<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
</tr>
<tr>
<td>ASU</td>
<td>FASB Accounting Standards Update</td>
</tr>
<tr>
<td>BCF</td>
<td>beneficial conversion feature</td>
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<tr>
<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
</tr>
<tr>
<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
</tr>
<tr>
<td>BPD</td>
<td>branded prescription drug</td>
</tr>
<tr>
<td>BOLI</td>
<td>bank-owned life insurance</td>
</tr>
<tr>
<td>CAM</td>
<td>critical audit matter</td>
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<tr>
<td>C&amp;DI</td>
<td>SEC Compliance and Disclosure Interpretation</td>
</tr>
<tr>
<td>CECL</td>
<td>current expected credit loss</td>
</tr>
<tr>
<td>CFC</td>
<td>controlled foreign corporation</td>
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<tr>
<td>CODM</td>
<td>chief operating decision maker</td>
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<tr>
<td>COlI</td>
<td>corporate-owned life insurance</td>
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<tr>
<td>CRO</td>
<td>contract research organization</td>
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<tr>
<td>CTA</td>
<td>cumulative translation adjustment</td>
</tr>
<tr>
<td>DCPs</td>
<td>disclosure controls and procedures</td>
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<tr>
<td>DTA</td>
<td>deferred tax asset</td>
</tr>
<tr>
<td>DTL</td>
<td>deferred tax liability</td>
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<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
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<tr>
<td>EITF</td>
<td>FASB Emerging Issues Task Force</td>
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<tr>
<td>E&amp;P</td>
<td>earnings and profits</td>
</tr>
<tr>
<td>EPS</td>
<td>earnings per share</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FAQ</td>
<td>frequently asked question</td>
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<tr>
<td>FASB</td>
<td>Financial Accounting Standards Board</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FDII</td>
<td>foreign derived intangible income</td>
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<tr>
<td>FIFO</td>
<td>first in, first out</td>
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<tr>
<td>FIN</td>
<td>FASB Interpretation Number (superseded)</td>
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<tr>
<td>FOB</td>
<td>free on board</td>
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<tr>
<td>GAAP</td>
<td>generally accepted accounting principles</td>
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<tr>
<td>GILTl</td>
<td>global intangible low-taxed income</td>
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<tr>
<td>GPO</td>
<td>group purchasing organization</td>
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<tr>
<td>IAS</td>
<td>International Accounting Standard</td>
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<td>IASB</td>
<td>International Accounting Standards Board</td>
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<td>IFRS</td>
<td>International Financial Reporting Standard</td>
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<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
</tr>
<tr>
<td>IP</td>
<td>intellectual property</td>
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<tr>
<td>IPO</td>
<td>initial public offering</td>
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<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
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<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
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<tr>
<td>IRS</td>
<td>Internal Revenue Service</td>
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<tr>
<td>IT</td>
<td>information technology</td>
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<tr>
<td>LIFO</td>
<td>last in, first out</td>
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<tr>
<td>LLC</td>
<td>limited liability company</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
<td>--------------------------------------------------</td>
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<tr>
<td>LP</td>
<td>limited partnership</td>
</tr>
<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
</tr>
<tr>
<td>MD&amp;A</td>
<td>Management's Discussion and Analysis</td>
</tr>
<tr>
<td>MDEET</td>
<td>medical device excise tax</td>
</tr>
<tr>
<td>MSL</td>
<td>medical science liaison</td>
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<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
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<tr>
<td>NOL</td>
<td>net operating loss</td>
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<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>PBE</td>
<td>public business entity</td>
</tr>
<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
</tr>
<tr>
<td>PCC</td>
<td>Private Company Council</td>
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<tr>
<td>PCD asset</td>
<td>purchased financial asset with credit deterioration</td>
</tr>
<tr>
<td>PRV</td>
<td>priority review voucher</td>
</tr>
<tr>
<td>PTRS</td>
<td>probability of technical and regulatory success</td>
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<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
</tr>
<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
</tr>
<tr>
<td>ROU</td>
<td>right-of-use</td>
</tr>
<tr>
<td>SAB</td>
<td>SEC Staff Accounting Bulletin</td>
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<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<tr>
<td>SFC</td>
<td>specified foreign corporation</td>
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<tr>
<td>SIFMA</td>
<td>Securities Industry and Financial Markets Association</td>
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<tr>
<td>T.D.</td>
<td>Treasury Decision</td>
</tr>
<tr>
<td>TRG</td>
<td>transition resource group</td>
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<tr>
<td>UTB</td>
<td>unrecognized tax benefit</td>
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<tr>
<td>VIE</td>
<td>variable interest entity</td>
</tr>
<tr>
<td>WAC</td>
<td>wholesaler acquisition cost</td>
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