Life Sciences

Accounting and Financial Reporting Update — Interpretive Guidance on Non-GAAP Measures

March 2017

Non-GAAP Measures

Introduction

A non-GAAP[1] 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.

Over the past year, we have seen an exponential increase in SEC scrutiny and press coverage regarding non-GAAP measures. The press coverage has been driven by numerous published studies that generally conclude two things: (1) the number of companies that use non-GAAP measures is significant and increasing and (2) the difference between GAAP and non-GAAP measures is increasing. For example, a study of seven large U.S. drug companies demonstrated that for the 13 quarters ended March 31, 2016, non-GAAP net income was 40 percent higher than net income reported in accordance with U.S. GAAP.[2] Prompted in part by the two conclusions above, beginning in late 2015, various SEC officials, including then Chair Mary Jo White and then Chief Accountant Jim Schnurr, began expressing concern over the prominence, prevalence, and appropriateness of non-GAAP measures. These concerns led the SEC staff to issue new and updated Compliance & Disclosure Interpretations (C&DIs) in May 2016 that clarify the SEC's guidance on non-GAAP measures.

Consistent with the concern expressed in public forums is a marked increase in the number of SEC comments issued to registrants regarding non-GAAP measures. The sections below (1) give an overview of SEC guidance on non-GAAP measures; (2) provide a summary of certain new and amended C&DIs, together with examples of related SEC comments to registrants; and (3) discuss considerations for using non-GAAP measures. For more information, see Deloitte's *A Roadmap to Non-GAAP Financial Measures*.

Overview of SEC Guidance on Non-GAAP Measures

SEC Regulation G[3] 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.

[1] For a list of abbreviations used in this publication, see Appendix B.
[2] Tatyana Shumsky, "Non-GAAP Accounting Lifts Adjusted Earnings by 38% in Pharmaceuticals — Credit Suisse," *Wall Street Journal* (July 15, 2016).
[3] For the full titles of standards and other literature referred to in this publication, see Appendix A.

- 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,[4] 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.[5] 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 on the prohibitions described in Item 10(e), see Chapter 4 in Deloitte's *A Roadmap to Non-GAAP Financial Measures*.

Along with these regulations, the SEC staff published 33 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 (as updated) today. The C&DIs were intended to give registrants more flexibility to disclose non-GAAP measures in filings with the SEC.

In May 2016, the SEC staff updated its C&DIs to provide additional guidance on what it expects from registrants when using non-GAAP measures. The SEC staff noted its expectation that the updated C&DIs would 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. Those C&DIs are discussed further below.

After the C&DIs were issued, the SEC's Division of Corporation Finance (the "Division") increased its focus on the use and presentation of non-GAAP measures during routine filing reviews of registrants' annual and quarterly reports and press releases. In fact, for reviews of Forms 10-K and 10-Q completed during the 12 months ended July 31, 2016, non-GAAP measures represented the second most frequent topic of comment (MD&A was the most frequent topic of comment).[6] Further, the Division has begun targeted reviews of earnings releases furnished to the SEC on Form 8-K. In some instances, the Division has issued comment letters solely related to the earnings releases, separate from its review of registrants' Forms 10-K; examples of SEC comments related to specific C&DIs are provided below. In addition, the SEC's Division of Enforcement has taken an interest in the use of non-GAAP measures.

[4] 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.

[5] 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).

[6] For more information, see Deloitte's *SEC Comment Letters — Statistics According to "Edgar": Supplement to the Ninth Edition*.

Further, registrants in the life sciences industry should be aware that the SEC staff continues to evaluate industry practices and may issue additional guidance, as noted in the SEC comment below.

> **Example of an SEC Comment**
> [W]e will evaluate the industry practices you described to us and consider whether additional comprehensive non-GAAP staff guidance is appropriate.

New and Updated C&DIs

New and amended C&DIs, together with related SEC comments to registrants, are discussed in the sections below. For more information about the new and amended 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 in the life sciences industry.

Examples of SEC Comments

- The following disclosure is or may be inconsistent with the updated Compliance and Disclosure Interpretations on Non-GAAP Measures issued on May 17, 2016:
  - Your presentation and discussion of non-GAAP measures prior to GAAP measures violates prominence under [C&DI Question] 102.10;
  - You present [future] guidance on non-GAAP measures without providing the most comparable GAAP measures or explaining why this information is not provided which violates the guidance in the penultimate bullet in [C&DI Question] 102.10.
- You disclose full [non-GAAP] income statements to reconcile to your [non-GAAP] core results, which is inconsistent with updated Compliance and Disclosure Interpretations 102.10 on Non-GAAP Measures issued on May 17, 2016.

In public forums, the SEC staff has been clear that when reconciling a non-GAAP measure to the most comparable GAAP measure, a registrant should start with the GAAP measure. Since the updated C&DIs on non-GAAP measures were published, C&DI Question 102.10 has been the leading source of SEC comments issued on such measures. Specifically, 37 percent of the SEC comment letters on non-GAAP measures issued from May 17, 2016, to October 4, 2016, have included a comment on the requirement to present the most directly comparable GAAP measure with equal or greater prominence.[7]

Misleading Measures

An overriding theme of the SEC's 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).

[7] Elizabeth Ising and Brian Lane, "Recent SEC Comment Letters Addressing Non-GAAP Financial Disclosures," *Securities Regulation and Corporate Governance Monitor* (October 4, 2016).

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

Examples of SEC Comments

- As you appear to incur upfront collaboration expenses in each period and have historically incurred these expenses in multiple periods, it appears that these expenses are normal, recurring, cash operating expenses whose exclusion from your non-GAAP income may be prohibited under [C&DI Question] 100.01.
- Given that your ongoing acquisition of businesses is a critical strategy you employ to achieve and maintain growth in your business, please tell us why you remove the impact of acquisition-related expenses and the amortization of intangible assets you acquire, as well as the impact of other fair value adjustments recorded under acquisition accounting in presenting your non-GAAP financial measures.
- We note that you disclose non-GAAP measures that adjust your . . . net income and net income per common share information to remove the impact of an inventory write-down during 2015. From your disclosures . . . we note that you had inventory write-downs in both 2015 and 2014 but you chose to remove the impact of the inventory write-down and related tax effect in the non-GAAP measures for [the current year] only and did not include similar non-GAAP disclosures that reflected the impact of inventory write-downs in [the prior year]. Accordingly, your 2015 non-GAAP measures may be inconsistent with Rule 100(b) of Regulation G as well as Question 100.02 of the updated Compliance and Disclosure Interpretations issued on May 17, 2016.
- 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&DIs] 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.

Individually Tailored Accounting Principles

In C&DI Question 100.04, the SEC staff provides an example of a prohibited non-GAAP performance measure that reflects revenue recognized over the service period under GAAP on an accelerated basis as if the registrant earned revenue when it billed its customers. The measure is prohibited because it is an individually tailored accounting principle and does not reflect the registrant’s required GAAP measurement method. While the example is about revenue recognition, the C&DI indicates that individually tailored accounting principles may also be prohibited when they are applied to other financial statement line items to create a non-GAAP measure.

SEC Comments to Registrants on Individually Tailored Accounting Principles

While SEC comments to registrants on individually tailored accounting principles initially focused on revenue, the staff has similarly questioned other adjustments, such as the adjustment discussed in the comment example below.

> **Example of an SEC Comment**
>
> Please note that the cash tax savings on indefinite-lived intangible assets adjustment to arrive at adjusted net income appears inconsistent with Question 100.04 of the updated Compliance and Disclosure Interpretations issued on May 17, 2016. Please consider this guidance when preparing your next earning release.

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**
>
> We continue to question whether your disclosure of non-GAAP diluted EPS is consistent with C&DI 102.05. In particular, you point out that the reconciling items from GAAP net income to non-GAAP net income will not require cash settlement. By adjusting your net income to exclude only non-cash items, it appears that you are attempting to present a cash-based earnings measure. Furthermore, we note that for the periods presented in both your [first-quarter] and [second-quarter] earnings releases, your non-GAAP net income was within 10% of your cash provided by operating activities in your Statements of Cash Flows for the same periods. In light of the above, please explain how you determined that your non-GAAP net income measure could not be used as a liquidity measure. Alternatively, please remove non-GAAP diluted EPS from your future earnings releases.

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.

Further, as illustrated in the SEC comment example above, when a performance measure can be used as a liquidity measure, per-share presentation of the measure is prohibited.

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 comment below, which was issued to a registrant in the life sciences industry, illustrates the SEC staff's focus on tax adjustments to non-GAAP measures.

> **Example of an SEC Comment**
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> 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.

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.

Considerations for Using Non-GAAP Measures

Registrants that use non-GAAP measures in earnings releases furnished on Form 8-K or in 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. Registrants should, at a minimum, consider designing DCPs to ensure that procedures are in place regarding:

- *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 registrant should also consider the involvement of the appropriate levels of management and those charged with governance when designing and implementing such DCPs. 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*

FASB Accounting Standards Updates

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

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

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 2016-07, *Investments — Equity Method and Joint Ventures (Topic 323): Simplifying the Transition to the Equity Method of Accounting*

ASU 2016-03, *Intangibles — Goodwill and Other (Topic 350), Business Combinations (Topic 805), Consolidation (Topic 810), Derivatives and Hedging (Topic 815): Effective Date and Transition Guidance* — a consensus of the Private Company Council

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

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

ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*

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

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

ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*

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

ASU 2014-18, *Business Combinations (Topic 805): Accounting for Identifiable Intangible Assets in a Business Combination* — a consensus of the Private Company Council

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

ASU 2014-10, *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 2014-08, *Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity*

ASU 2014-07, *Consolidation (Topic 810): Applying Variable Interest Entities Guidance to Common Control Leasing Arrangements* — a consensus of the Private Company Council

ASU 2014-03, *Derivatives and Hedging (Topic 815): Accounting for Certain Receive-Variable, Pay-Fixed Interest Rate Swaps — Simplified Hedge Accounting Approach* — a consensus of the Private Company Council

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

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

FASB ASC Topics and Subtopics

ASC 205, *Presentation of Financial Statements*

ASC 205-20, *Presentation of Financial Statements: Discontinued Operations*

ASC 230, *Statement of Cash Flows*

ASC 230-10, *Statement of Cash Flows: Overall*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 250-10, *Accounting Changes and Error Corrections: Overall*

ASC 280-10, *Segment Reporting: Overall*

ASC 320, *Investments — Debt and Equity Securities*

ASC 321-10, *Investments — Equity Securities: Overall*

ASC 323-10, *Investments — Equity Method and Joint Ventures: Overall*

ASC 325-10, *Investments — Other: Overall*

ASC 325-40, *Investments — Other: Beneficial Interests in Securitized Financial Assets*

ASC 326-20, *Financial Instruments — Credit Losses: Measured at Amortized Cost*

ASC 326-30, *Financial Instruments — Credit Losses: Available-for-Sale Debt Securities*

ASC 330, *Inventory*

ASC 330-10, *Inventory: Overall*

ASC 350, *Intangibles — Goodwill and Other*

ASC 350-30, *Intangibles — Goodwill and Other: General Intangibles Other Than Goodwill*

ASC 360-10, *Property, Plant, and Equipment: Overall*

ASC 450, *Contingencies*

ASC 450-10, *Contingencies: Overall*

ASC 450-20, *Contingencies: Loss Contingencies*

ASC 450-30, *Contingencies: Gain Contingencies*

ASC 470-10, *Debt: Overall*

ASC 470-20, *Debt: Debt With Conversion and Other Options*

ASC 480-10, *Distinguishing Liabilities From Equity: Overall*

ASC 605, *Revenue Recognition*

ASC 605-10, *Revenue Recognition: Overall*

ASC 605-15, *Revenue Recognition: Products*

ASC 605-25, *Revenue Recognition: Multiple-Element Arrangements*

ASC 605-28, *Revenue Recognition: Milestone Method*

ASC 605-45, *Revenue Recognition: Principal Agent Considerations*

ASC 605-50, *Revenue Recognition: Customer Payments and Incentives*

ASC 606, *Revenue From Contracts With Customers*

ASC 606-10, *Revenue From Contracts With Customers: Overall*

ASC 610-20, *Other Income: Gains and Losses From the Derecognition of Nonfinancial Assets*

ASC 730, *Research and Development*

ASC 730-10, *Research and Development: Overall*

ASC 730-20, *Research and Development: Research and Development Arrangements*

ASC 740, *Income Taxes*

ASC 740-10, *Income Taxes: Overall*

ASC 740-270, *Income Taxes: Interim Reporting*

ASC 805, *Business Combinations*

ASC 805-10, *Business Combinations: Overall*

ASC 805-20, *Business Combinations: Identifiable Assets and Liabilities, and Any Noncontrolling Interest*

ASC 805-30, *Business Combinations: Goodwill or Gain From Bargain Purchase, Including Consideration Transferred*

ASC 805-50, *Business Combinations: Related Issues*

ASC 808, *Collaborative Arrangements*

ASC 808-10, *Collaborative Arrangements: Overall*

ASC 810, *Consolidation*

ASC 810-10, *Consolidation: Overall*

ASC 810-20, *Consolidation: Control of Partnerships and Similar Entities*

ASC 810-30, *Consolidation: Research and Development Arrangements*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 915, *Development Stage Entities*

ASC 915-10, *Development Stage Entities: Overall*

ASC 985-605, *Software: Revenue Recognition*

FASB Proposed Accounting Standards Updates

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

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

Proposed ASU 2016-270, *Income Taxes (Topic 740) Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes*

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

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

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 Interpretation (Pre-Codification Literature)

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

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

Issue 00-21, “Revenue Arrangements With Multiple Deliverables”

SEC C&DI Topic

Non-GAAP Financial Measures

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 601(b)(10), “Exhibits; Description of Exhibits; Material Contracts”

SEC Regulation S-X

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

Rule 4-08(h), “General Notes to Financial Statements; Income Tax Expense”

Article 11, “Pro Forma Financial Information”

SEC Staff Accounting Bulletin

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

SAB Topic 13, “Revenue Recognition”

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

International Standards

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*

IAS 17, *Leases*

Appendix B — Abbreviations

Abbreviation	Description
AFS	available for sale
AICPA	American Institute of Certified Public Accountants
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
APIC	additional paid-in capital
ASC	FASB Accounting Standards Codification
ASU	FASB Accounting Standards Update
BOLI	bank-owned life insurance
C&DI	SEC Compliance and Disclosure Interpretation
CECL	current expected credit loss
CODM	chief operating decision maker
COLI	corporate-owned life insurance
CRO	contract research organization
DCP	disclosure control procedure
DTA	deferred tax asset
DTL	deferred tax liability
EBITDA	earnings before interest, taxes, depreciation, and amortization
EITF	Emerging Issues Task Force
EPS	earnings per share
EU	European Union
FAQ	frequently asked question
FASB	Financial Accounting Standards Board
FDA	Food and Drug Administration
FIFO	first in, first out

Abbreviation	Description
FIN	FASB Interpretation Number (superseded)
FOB	free on board
GAAP	generally accepted accounting principles
IAS	International Accounting Standard
IASB	International Accounting Standards Board
IFRS	International Financial Reporting Standard
IIR	investigator-initiated research
IPR&D	in-process research and development
LIFO	last in, first out
LLC	limited liability company
LP	limited partnership
M&A	merger and acquisition
MD&A	Management's Discussion and Analysis
MDET	medical device excise tax
MSL	medical science liaison
NDA	new drug application
OCI	other comprehensive income
OEM	original equipment manufacturer
PCAOB	Public Company Accounting Oversight Board
PCD asset	purchased financial asset with credit deterioration
PMA	premarket approval
PTRS	probability of technical and regulatory success
Q&A	question and answer

Abbreviation	Description
R&D	research and development
REMS	risk evaluation and mitigation strategy
ROU	right of use
SAB	SEC Staff Accounting Bulletin
SAC	subjective acceleration clause
SEC	Securities and Exchange Commission
TRG	transition resource group
VIE	variable interest entity
WAC	wholesaler acquisition cost

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