Life Sciences

Accounting and Financial Reporting Update — Interpretive Guidance on Contingencies

March 2017

Contingencies

Introduction

ASC 450[1] defines a contingency as an "existing condition, situation, or set of circumstances involving uncertainty . . . that will ultimately be resolved when . . . future events occur or fail to occur." In the life sciences industry, contingencies often arise as a result of product liability issues; patent litigation cases, such as suits filed against the entity for patent infringement (e.g., generic at-risk launches); the uncertainty of achieving regulatory approval for a new drug; and compliance issues related to pricing, promotions, or manufacturing standards. In addition, for biotech and pharmaceutical firms, environmental issues and remediation proceedings have been the subject of considerable public and legislative discussion and initiatives. As a result, accounting standard setters such as the FASB, AICPA, and SEC have emphasized the accounting for and disclosure of environmental liabilities in the financial statements.

In the life sciences industry, a single event could trigger multiple contingencies, requiring an entity to separately evaluate each contingent liability to determine its appropriate recognition, measurement, and classification. For example, a regulatory action may result in the incurrence of incremental costs related to product recalls, leading to a change in product strategy, adjustments to customer sales allowances, or other events. Further, a litigation settlement may contain multiple elements, including cash payments, required future services, and other agreements or concessions between the parties.

The accounting for and disclosures about contingencies under ASC 450 differ depending on whether the contingency could result in a gain or a loss. In addition to providing general disclosure guidance on both gain and loss contingencies, ASC 450 discusses specific application of the guidance to unasserted claims, litigation, guarantees, and events occurring after the date of the financial statements but before their issuance, all of which are common in the life sciences industry.

ASC 450 defines a loss contingency as an "existing condition, situation, or set of circumstances involving uncertainty as to possible loss to an entity that will ultimately be resolved when one or more future events occur or fail to occur." Accrual of an estimated loss contingency through a charge against earnings is required if it is probable that an asset has been impaired or a liability has been incurred as of the date of the financial statements and the amount of the loss can be reasonably estimated. If the estimated amount of loss is within a range of amounts, and some amount within the range of loss appears to be a better estimate than any other amount within the range, companies must accrue that amount. If no amount within the range of loss is a better estimate than any other amount, companies must accrue the minimum amount within that range of loss. Disclosure of the nature of the accrued loss

[1] For the full titles of standards and other literature referred to in this publication, see Appendix A. For a list of abbreviations used in this publication, see Appendix B.

and, in some circumstances, the amount accrued may be required so that the financial statements are not misleading. With respect to unrecognized loss contingencies, ASC 450-20-50-3 and 50-4 note the following:

ASC 450-20

50-3 Disclosure of the contingency shall be made if there is at least a reasonable possibility that a loss or an additional loss may have been incurred and either of the following conditions exists:

a. An accrual is not made for a loss contingency because any of the conditions in paragraph 450-20-25-2 are not met.
b. An exposure to loss exists in excess of the amount accrued pursuant to the provisions of paragraph 450-20-30-1.

Examples 1–3 (see paragraphs 450-20-55-18 through 55-37) illustrate the application of these disclosure standards.

50-4 The disclosure in the preceding paragraph shall include both of the following:

a. The nature of the contingency
b. An estimate of the possible loss or range of loss or a statement that such an estimate cannot be made.

A gain contingency arises if the outcome of future events may result in a possible gain or benefit to an entity (e.g., pending litigation whose outcome would result in a benefit). Unlike a loss contingency, a gain contingency is usually not reflected in the financial statements and should not be recorded in the financial statements before the contingency is realized. However, as stated in ASC 450-30-50-1, "[a]dequate disclosure shall be made of a contingency that might result in a gain, but care shall be exercised to avoid misleading implications as to the likelihood of realization."

Industry Issues

The Q&As in the sections below discuss guidance on contingency-related topics that frequently affect life sciences entities.

Product Recalls

Life sciences entities may be subject to recalls on their products (e.g., medical devices, pharmaceutical drugs). While some product recalls are voluntary (e.g., the drug manufacturer has chosen to take the drug off the shelves or notified consumers and doctors to stop using the product or return it), other recalls may be required by the FDA or other regulators.

Question

How should the liability recognition criteria of ASC 450-20-25 be applied to a product recall obligation?

Answer

Regarding the application of ASC 450-20 to product recalls, the obligating event triggering liability recognition is the announcement of a recall. Except as stipulated in the terms of a warranty arrangement, a company has no legal obligation or duty related to product design or manufacturing defects after the product is sold. Therefore, a probable loss would not arise until a recall is announced voluntarily or is mandated by regulators.

Offers to Settle Litigation

One of the major uncertainties in the life sciences industry is the risk of litigation. Class actions, individual suits, and actions brought by government agencies are not uncommon, and such contingencies may need to be accounted for or disclosed in the financial statements (e.g., a potential future obligation related to an uncertain amount resulting from past activities). With respect to pending or threatened litigation, ASC 450 requires the accrual of a loss contingency if certain criteria are met. Entities will often make offers to settle existing litigation; the accounting for the offer should be based on existing facts and circumstances associated with the litigation and related settlement.

Question

Does an offer by management to settle litigation need to be accrued in the financial statements?

Answer

An offer to settle litigation creates a strong presumption that it is probable that a liability has been incurred. The settlement offer presumably establishes a low end of the range under ASC 450-20-30-1, resulting in accrual of a liability. Withdrawal of a settlement offer before acceptance and before issuance of the financial statements generally would not change this conclusion since the existence of the offer indicates that a probable obligation existed as of the date of the financial statements.

In limited circumstances, it might be possible to overcome the presumption that an offer to settle litigation triggers accrual of a liability and establishes a low end of the range. However, rebutting the presumption should be a high hurdle to overcome and should be based on persuasive evidence to the contrary. At a minimum, the evidence would need to substantiate that it is remote that (1) the offer will be accepted and (2) further negotiations will lead to an out-of-court settlement. One form of such evidence could be an unequivocal representation from legal counsel. A company that believes that the presumption has been overcome should consider consulting with its accounting advisers.

Example

Company X is in the medical device business. Over the past year, X has been named as the defendant in a lawsuit alleging personal injury resulting from use of one of its surgical devices. After year-end, but before issuance of the annual financial statements, X offers to settle the litigation for $1 million. Management of X contends that this offer was made solely to accelerate the process of resolving the dispute. The plaintiff has not responded to the offer. Company X believes that if the matter ultimately goes to trial, the plaintiff will not prevail with its claim.

The offer to settle is evidence that it is probable that a liability has been incurred as of the date of the financial statements and that the amount of the loss can be reasonably estimated. Company X should consider the guidance in ASC 450-20-30-1 in determining the appropriate amount to accrue. The amount of the offer establishes the low end of the range. If this amount is accrued, X must also disclose any additional exposure to loss in its financial statements if the disclosure requirements in ASC 450-20-50-3 are met.

Thinking It Through

An entity should carefully consider all facts and circumstances when assessing whether an "offer" has been extended to settle litigation. For example, when the offer hinges on a counterparty's performance of certain actions to which the entity believes the counterparty is not likely to agree, the entity may conclude that an offer has not been extended.

Accounting for Litigation Settlements When One or More Elements Exist

While some legal settlements in the life sciences industry involve only a single element (e.g., a claim or lawsuit over patent infringement), challenges often arise when a litigation settlement contains multiple elements.

Question

How should an entity account for a litigation settlement involving multiple elements?

Answer

An entity should identify each item given and received in the arrangement and determine whether such items should be recognized. In a speech delivered at the 2007 AICPA Conference on Current SEC and PCAOB Developments, Eric West, associate chief accountant in the SEC's Office of the Chief Accountant, addressed how an entity should account for litigation settlements containing more than one element:

> **Elements of the Arrangement**
>
> To properly account for this arrangement, a company must identify each item given and received and determine whether those items should be recognized. We have found that errors generally occur when registrants don't fully consider the nature of each item. . . .
>
> **Allocating Consideration to Each Item**
>
> An additional challenge that may arise when accounting for a litigation settlement is determining the proper allocation of consideration among the recognizable elements. While EITF [Issue] 00-21 [ASC 605-25] was written for multiple element revenue arrangements, we believe that its allocation guidance is also useful to determine how to allocate consideration paid in a multiple element legal settlement. In this regard, we believe that it would be acceptable to value each element of the arrangement and allocate the consideration paid to each element using relative fair values. To the extent that one of the elements of the arrangement just can't be valued, we believe that a residual approach may be a reasonable solution. In fact, we have found that many companies are not able to reliably estimate the fair value of the litigation component of any settlement and have not objected to judgments made when registrants have measured this component as a residual. In a few circumstances companies have directly measured the value of the litigation settlement component. [Footnote omitted]

Example

Mr. West gave the following example of a litigation settlement:

> Assume a company pays cash and conveys licenses to a plaintiff in order to settle a patent infringement and misappropriation of trade secrets claim. In exchange for the payment and licenses given, the company receives a promise to drop the patent infringement lawsuit, a covenant not to sue with respect to the misappropriation of trade secrets claim, and a license to use the patents subject to the litigation.

In this arrangement, the items given include cash and licenses, and the items received include the promise to drop the patent infringement lawsuit, the covenant not to sue, and the license to use the patents. After identifying these items and determining whether to recognize them, the company must use the relative fair value method or another approach (e.g., the residual value approach if one of the elements cannot be valued) to determine the proper allocation of consideration among the recognizable elements. Mr. West further clarified:

> In the fact pattern that I just described, the company may be able to calculate the value of the settlement by applying a royalty rate to the revenues derived from the products sold using the patented technology during the infringement period. Admittedly, this approach requires judgment and we are willing to consider reasonable judgments.

Accounting for Liabilities When Demand for Payment Is Not Probable, and Whether Legally or Contractually Required Liabilities Can Be Derecognized on the Basis of a Probability Assessment

In the life sciences industry, obligations to a third party, such as a customer or patent holder, may arise as a result of a law or contract that may be unknown to the third party. Such obligations (e.g., a royalty liability required by contract for the use of a patent) should not be accounted for as loss contingencies under ASC 450-20 even if the third party is unaware of the obligation and is unlikely to demand payment. Further, if an entity believes that a liability for which payment is required by law or contract will ultimately be settled for less than the stated legal obligation, the entity should not derecognize the liability (or a portion of the liability).

Question 1

Should a liability for which payment is required by law or contract be accounted for as a loss contingency under ASC 450-20 if it is uncertain whether the creditor is aware of the obligation and will demand payment?

Answer

No. Generally, the probability of payment is irrelevant if settlement of the liability is required by law or contract. That is, other than deferred revenues, liabilities established by law or contract should be recorded at their stated amounts unless there is guidance under U.S.GAAP that requires otherwise.

Paragraph 36 of FASB Concepts Statement 6 describes a liability as follows:

> A liability has three essential characteristics: (a) it embodies a present duty or responsibility to one or more other entities that entails settlement by probable future transfer or use of assets at a specified or determinable date, on occurrence of a specified event, or on demand, (b) the duty or responsibility obligates a particular entity, leaving it little or no discretion to avoid the future sacrifice, and (c) the transaction or other event obligating the entity has already happened.

If an entity is required by current laws, regulations, or contracts to make a future payment associated with an event that has already occurred, that event imposes a present duty upon the entity. An entity's uncertainty about whether performance of an obligation will be required in the future does not allow the entity to choose to avoid the future sacrifice or relieve it of the obligation.

Once the obligating event has occurred, the probability of payment is irrelevant to the determination of whether a contractual or legal obligation is a liability or a loss contingency. That is, when the obligating event has occurred, the entity has incurred a liability, and thus there is no contingency.

In addition, a liability is not an unasserted claim or assessment under ASC 450-20 if the satisfaction of the liability is required by law or contract. The existence of the law or the contract constitutes an assertion of the claim.

Question 2

If an entity believes that a liability that is not deferred revenue, and for which payment is required by law or contract, will ultimately be settled for less than the stated legal obligation, can the liability be derecognized on the basis of a probability assessment of when and whether the creditor will demand payment?

Answer

No. ASC 405-20-40-1 states the following:

ASC 405-20
40-1 A debtor shall derecognize a liability if and only if it has been extinguished. A liability has been extinguished if either of the following conditions is met: a. The debtor pays the creditor and is relieved of its obligation for the liability. Paying the creditor includes the following: 1. Delivery of cash 2. Delivery of other financial assets 3. Delivery of goods or services 4. Reacquisition by the debtor of its outstanding debt securities whether the securities are cancelled or held as so-called treasury bonds. b. The debtor is legally released from being the primary obligor under the liability, either judicially or by the creditor. For purposes of applying this Subtopic, a sale and related assumption effectively accomplish a legal release if nonrecourse debt (such as certain mortgage loans) is assumed by a third party in conjunction with the sale of an asset that serves as sole collateral for that debt.

Example

Company Y manufactures medical equipment and has a contractual obligation to pay, on the basis of sales volume, royalties to various patent holders. The amount of royalties paid in each period is calculated by Y. In accordance with this obligation, patent holders have the right to audit Y's sales volume, but they have rarely exercised this right.

Company Y should record a royalty liability for the full amount that it is contractually obligated to pay according to the royalty agreements. The liability should be adjusted upward as sales are made and should be adjusted downward only when the liability is paid or otherwise extinguished.

The contract requires Y to make royalty payments on the basis of sales volume. Therefore, Y is under an obligation to the patent holder as the equipment is sold (i.e., Y has a present duty to the patent holder). Company Y's uncertainty about whether a patent holder will audit the sales volume does not allow it to avoid future payment. If a patent holder cannot be located, the contractual liability should not be reduced until the escheat laws for that jurisdiction are complied with and the obligation no longer exists. Further, Y should not record a royalty liability for future sales until those sales actually occur.

Events Occurring After the Date of the Financial Statements

Information that becomes available after the balance sheet date but before issuance of the financial statements may indicate that an asset was impaired or a liability incurred before the date of the financial statements. In the life sciences industry, events that occur after the balance sheet date may serve as confirmation of a condition that existed before the balance sheet date (e.g., the settlement of litigation that arose during prior periods covered by the financial statements and for which no liability had previously been recorded).

However, events occurring after the balance sheet date, such as the passage of new legislation, may be indicative of conditions that did not exist as of the balance sheet date. Financial statement disclosures about such events are required only if omission of such disclosures would cause the financial statements to be misleading.

Question

If legislation giving rise to a liability is enacted after the balance sheet date but before issuance of the financial statements, should a liability be accrued as of the balance sheet date?

Answer

No. The enactment of a law after the balance sheet date but before issuance of the financial statements would be accounted for as a nonrecognized subsequent event (because the newly enacted law does not provide evidence about conditions that existed as of the balance sheet date). The entity should consider whether it is required to disclose the event to keep the financial statements from being misleading. The determination of when a law is considered enacted is a legal interpretation based on an entity's facts and circumstances.

Example

Entity A, a public entity with a December 31, 20X1, year-end, operates in the pharmaceutical industry and is subject to proposed legislation that will impose an excise tax on existing branded pharmaceuticals as of June 30, 20X1. The legislation is expected to be enacted after year-end but before the issuance of the financial statements. Entity A believes that because the legislation is probable and is related to balances as of a date before the balance sheet date, a liability should be accrued. However, the obligating event in this case is the enactment of the legislation, and A did not incur a liability before this event even though the tax was assessed on preexisting branded pharmaceuticals; thus, no liability should be accrued. Instead, the impact of the new legislation is a nonrecognized subsequent event, and A should consider whether it is required to disclose the event to keep the financial statements from being misleading.

Favorable Legal Settlements

Usually, financial statements do not reflect contingencies that might result in gains since to do so might be to recognize income before it is realized. Entities should provide adequate disclosures about contingencies that might result in gains and should be careful to avoid misleading implications regarding the likelihood of realization. The term "probable" is relevant to the accounting for a loss contingency, but it is irrelevant to the accounting for a gain contingency. Realization must be assured beyond a reasonable doubt before a gain contingency can be recognized in the financial statements. Therefore, substantially all uncertainties, if any, about the timing and amount of realization of gain contingencies should be resolved before the contingencies are recognized in the financial statements.

Question

Is recognition of a gain contingency appropriate when a favorable verdict is returned in a court case?

Answer

Because of the numerous uncertainties inherent in a litigation proceeding, gain contingencies resulting from legal settlements generally cannot be recognized in income until cash or other forms of payment are received. This recognition threshold often results in the deferral of a gain even after a court rules in favor of a plaintiff.

Example

Company R was a plaintiff in a class action lawsuit against several drug manufacturers. After a lengthy appeals process, a settlement was reached. The funds were placed in an escrow account since an agreement had not been reached regarding the allocation of the settlement between the attorneys and each respective plaintiff. Because R does not know the timing or amount of cash to be received, gain recognition is inappropriate at this point.

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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