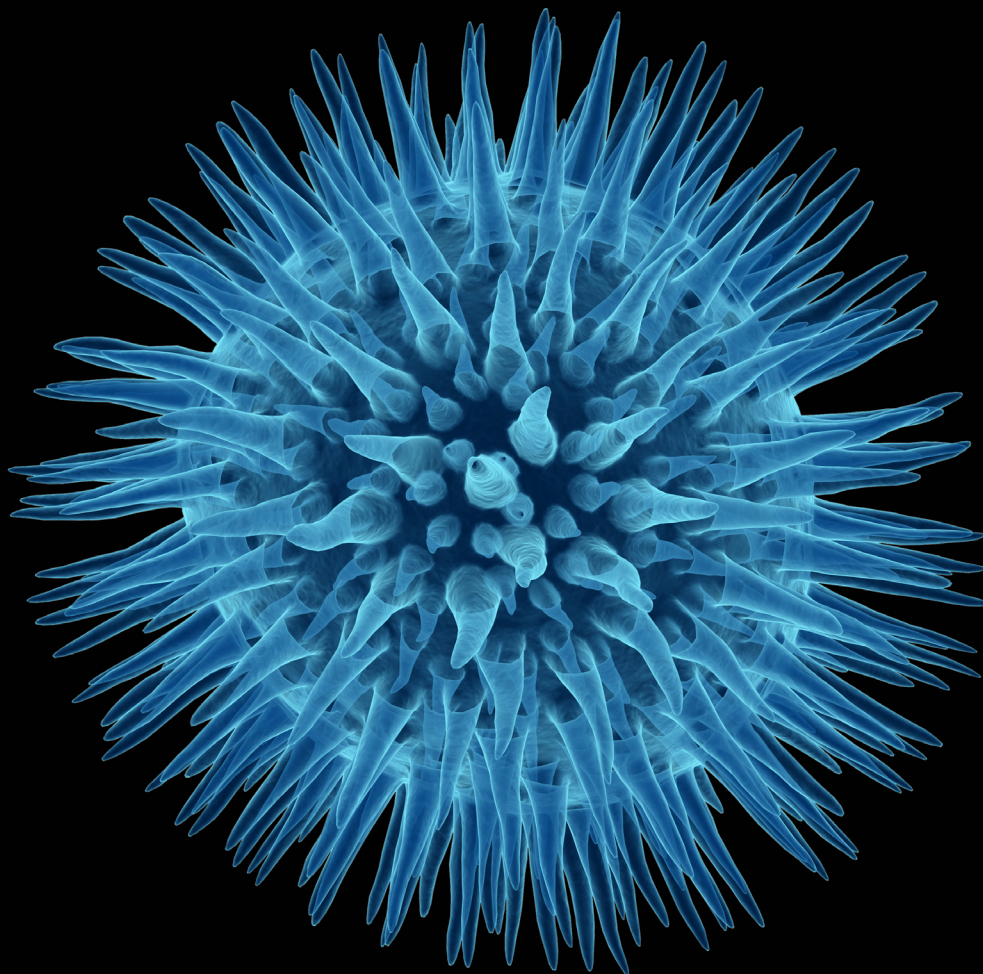


**Deloitte.**



**Life Sciences**

Accounting and Financial Reporting Update —  
Interpretive Guidance on Going Concern

March 2018

# Going Concern

## Introduction

Much of the life sciences industry consists of small, research-focused private biotechnology firms that represent an important source of innovation. These firms are generally focused on a specific technology platform, a mechanism of action, or a handful of early-stage compounds, and many of these firms are not profitable or do not have commercial revenue streams. Given the substantial costs and timelines associated with biopharmaceutical R&D, attracting and sustaining investment remains an ongoing challenge. This landscape requires many life sciences entities to evaluate the going-concern uncertainty in their financial statements.

**ASU 2014-15** (the “going-concern standard,” codified in ASC 205-40) provides guidance on how to determine when and how to disclose going-concern uncertainties in the financial statements. The going-concern standard requires management to perform interim and annual assessments of an entity’s ability to continue as a going concern within one year of the date the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable).<sup>1</sup> Under the standard, an entity must provide certain disclosures if conditions or events “raise substantial doubt about the entity’s ability to continue as a going concern.”

## Disclosure Threshold

An entity is required to disclose information about its potential inability to continue as a going concern when there is “substantial doubt” about its ability to continue as a going concern, which the going-concern standard defines as follows:

Substantial doubt about an entity’s ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The term *probable* is used consistently with its use in Topic 450 on contingencies.

When applying this disclosure threshold, entities are required to evaluate “relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued.” Reasonably knowable conditions or events are those that can be identified without undue cost and effort.

The going-concern standard provides the following examples of events that suggest that an entity may be unable to meet its obligations:

- a. Negative financial trends, for example, recurring operating losses, working capital deficiencies, negative cash flows from operating activities, and other adverse key financial ratios
- b. Other indications of possible financial difficulties, for example, default on loans or similar agreements, arrearages in dividends, denial of usual trade credit from suppliers, a need to restructure debt to avoid default, noncompliance with statutory capital requirements, and a need to seek new sources or methods of financing or to dispose of substantial assets

<sup>1</sup> An entity that is neither an SEC filer nor a conduit bond obligor for debt securities that are traded in a public market would use the date the financial statements are available to be issued (in a manner consistent with the going-concern standard’s definition of the term “financial statements are available to be issued”).

- c. Internal matters, for example, work stoppages or other labor difficulties, substantial dependence on the success of a particular project, uneconomic long-term commitments, and a need to significantly revise operations
- d. External matters, for example, legal proceedings, legislation, or similar matters that might jeopardize the entity's ability to operate; loss of a key franchise, license, or patent; loss of a principal customer or supplier; and an uninsured or underinsured catastrophe such as a hurricane, tornado, earthquake, or flood.

## Time Horizon

In each reporting period (including interim periods), an entity is required to assess its ability to meet its obligations as they become due for one year **after the date the financial statements are issued or available to be issued.**<sup>2</sup>

## Disclosure Content

If an entity triggers the substantial-doubt threshold, its footnote disclosures must contain the following information, as applicable:

<b>Substantial Doubt Is Raised but Is Alleviated by Management's Plans</b>	<b>Substantial Doubt Is Raised and Is Not Alleviated</b>
<ul style="list-style-type: none"> <li>• Principal conditions or events</li> <li>• Management's evaluation</li> <li>• Management's plans</li> </ul>	<ul style="list-style-type: none"> <li>• Principal conditions or events</li> <li>• Management's evaluation</li> <li>• Management's plans</li> <li>• Statement that there is "substantial doubt about the entity's ability to continue as a going concern"</li> </ul>

The going-concern standard explains that these disclosures may change over time as new information becomes available and that disclosure of how the substantial doubt was resolved is required in the period in which substantial doubt no longer exists (before or after consideration of management's plans). In addition, the going-concern standard states that the mitigating effects of management's plans to alleviate substantial doubt should be evaluated only if (1) the plans are approved before the financial statement issuance date and (2) both of the following conditions are met:

- a. It is probable that management's plans will be effectively implemented within one year after the date that the financial statements are issued.
- b. It is probable that management's plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

<sup>2</sup> See footnote 1.

# 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 2018-03, *Technical Corrections and Improvements to Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2018-02, *Income Statement — Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects From Accumulated Other Comprehensive Income*

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 2016-18, *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 2016-02, *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 2015-14, *Revenue From Contracts With Customers (Topic 606): Deferral of the Effective Date*

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

ASU 2015-01, *Income Statement — Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*

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 2014-02, *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*

Proposed ASU 2017-310, *Technical Corrections and Improvements to Recently Issued Standards: I. Accounting Standards Update No. 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities and II. Accounting Standards Update No. 2016-02, Leases (Topic 842)*

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

FASB Proposed Accounting Standards Update 2017-240, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

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 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 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"

## **PCAOB Auditing Standard**

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

## **SEC 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"

## **SEC Staff Accounting Bulletins (SABs)**

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 Subsidiaries"

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

Abbreviation	Description	Abbreviation	Description
<b>AFS</b>	available for sale	<b>E&amp;P</b>	earnings and profits
<b>AICPA</b>	American Institute of Certified Public Accountants	<b>EPS</b>	earnings per share
<b>AMT</b>	alternative minimum tax	<b>EU</b>	European Union
<b>AOCI</b>	accumulated other comprehensive income	<b>FAQ</b>	frequently asked question
<b>API</b>	active pharmaceutical ingredient	<b>FASB</b>	Financial Accounting Standards Board
<b>APIC</b>	additional paid-in capital	<b>FDA</b>	Food and Drug Administration
<b>ASC</b>	FASB Accounting Standards Codification	<b>FDII</b>	foreign derived intangible income
<b>ASU</b>	FASB Accounting Standards Update	<b>FIFO</b>	first in, first out
<b>BCF</b>	beneficial conversion feature	<b>FIN</b>	FASB Interpretation Number (superseded)
<b>BEAT</b>	base erosion anti-abuse tax	<b>FOB</b>	free on board
<b>BEMTA</b>	base erosion minimum tax amount	<b>GAAP</b>	generally accepted accounting principles
<b>BPD</b>	branded prescription drug	<b>GILTI</b>	global intangible low-taxed income
<b>BOLI</b>	bank-owned life insurance	<b>GPO</b>	group purchasing organization
<b>CAM</b>	critical audit matter	<b>IAS</b>	International Accounting Standard
<b>C&amp;DI</b>	SEC Compliance and Disclosure Interpretation	<b>IASB</b>	International Accounting Standards Board
<b>CECL</b>	current expected credit loss	<b>IFRS</b>	International Financial Reporting Standard
<b>CFC</b>	controlled foreign corporation	<b>IIR</b>	investigator-initiated research
<b>CODM</b>	chief operating decision maker	<b>IP</b>	intellectual property
<b>COLI</b>	corporate-owned life insurance	<b>IPO</b>	initial public offering
<b>CRO</b>	contract research organization	<b>IPR&amp;D</b>	in-process research and development
<b>CTA</b>	cumulative translation adjustment	<b>IRC</b>	Internal Revenue Code
<b>DCPs</b>	disclosure controls and procedures	<b>IRS</b>	Internal Revenue Service
<b>DTA</b>	deferred tax asset	<b>IT</b>	information technology
<b>DTL</b>	deferred tax liability	<b>LIFO</b>	last in, first out
<b>EBITDA</b>	earnings before interest, taxes, depreciation, and amortization	<b>LLC</b>	limited liability company
<b>EITF</b>	FASB Emerging Issues Task Force		

<b>Abbreviation</b>	<b>Description</b>
<b>LP</b>	limited partnership
<b>M&amp;A</b>	merger and acquisition
<b>MD&amp;A</b>	Management's Discussion and Analysis
<b>MDET</b>	medical device excise tax
<b>MSL</b>	medical science liaison
<b>NFP</b>	not-for-profit entity
<b>NOL</b>	net operating loss
<b>OCI</b>	other comprehensive income
<b>OEM</b>	original equipment manufacturer
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>PBE</b>	public business entity
<b>PCAOB</b>	Public Company Accounting Oversight Board
<b>PCC</b>	Private Company Council
<b>PCD asset</b>	purchased financial asset with credit deterioration
<b>PRV</b>	priority review voucher

<b>Abbreviation</b>	<b>Description</b>
<b>PTRS</b>	probability of technical and regulatory success
<b>Q&amp;A</b>	question and answer
<b>R&amp;D</b>	research and development
<b>R&amp;E</b>	research and experimentation
<b>REMS</b>	risk evaluation and mitigation strategy
<b>ROU</b>	right-of-use
<b>SAB</b>	SEC Staff Accounting Bulletin
<b>SEC</b>	Securities and Exchange Commission
<b>SFC</b>	specified foreign corporation
<b>SIFMA</b>	Securities Industry and Financial Markets Association
<b>T.D.</b>	Treasury Decision
<b>TRG</b>	transition resource group
<b>UTB</b>	unrecognized tax benefit
<b>VIE</b>	variable interest entity
<b>WAC</b>	wholesaler acquisition cost

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