Other Deloitte Publications

Other Deloitte publications, such as our Roadmap series, are available on the Deloitte Accounting Research Tool (DART), a comprehensive online library of accounting and financial disclosure literature. The Roadmap series includes titles on the following topics:

- Business Combinations
- Business Combinations — SEC Reporting Considerations
- Carve-Out Transactions
- Comparison of IFRS Standards and U.S. GAAP
- Consolidation — Identifying a Controlling Financial Interest
- Contingencies and Loss Recoveries
- Contracts on an Entity's Own Equity
- Convertible Debt
- Current Expected Credit Losses
- Disposals of Long-Lived Assets and Discontinued Operations
- Distinguishing Liabilities From Equity
- Earnings per Share
- Environmental Obligations and Asset Retirement Obligations
- Equity Method Investments and Joint Ventures
- Equity Method Investees — SEC Reporting Considerations
- Fair Value Measurements and Disclosures
- Foreign Currency Transactions and Translations
- Income Taxes
- Initial Public Offerings
- Leases
- Noncontrolling Interests
- Non-GAAP Financial Measures
- Revenue Recognition
- SEC Comment Letter Considerations, Including Industry Insights
- Segment Reporting
- Share-Based Payment Awards
- Statement of Cash Flows
Acknowledgments and Contact Information

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About Deloitte’s Life Sciences and Health Care Practice

Deloitte and its subsidiaries have approximately 312,000 professionals with a single focus: serving our clients and helping them solve their toughest problems. Deloitte’s Life Sciences and Health Care practice is among the largest in the world, leveraging the extensive knowledge, skills, and experience of over 24,000 professionals in 90 countries. Our practice offers a distinctive menu of professional services delivered in an integrated approach that address all segments of the life sciences and health care industry. We work in four key business areas — audit, advisory, tax, and consulting — but our real strength comes from combining the talents of those groups to address clients’ needs. Bloomberg Businessweek and Fortune consistently rank our organization among the best places in which to work, which is good news for our talent and our clients alike. When the best people tackle the most compelling challenges, everyone wins.

If you have any questions about this publication or ways in which we can help your organization, please contact the following Deloitte industry specialists.

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Preface

March 2020

To our clients, colleagues, and other friends:

The life sciences ecosystem encompasses a vast array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and medical equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2020 edition of Deloitte's Life Sciences Industry Accounting Guide (the “Guide”) addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting developments (through February 28, 2020), and key differences between U.S. GAAP and IFRS® Standards. In addition, this Guide discusses the outlook for the life sciences industry in 2020. Further, while many of the key accounting and financial reporting considerations stemming from the coronavirus disease 2019 (COVID-19) outbreak are related to topics addressed in this Guide, we encourage you to review Deloitte's March 25, 2020, Financial Reporting Alert, which discusses accounting and financial reporting considerations associated with COVID-19 that are broadly applicable as well as those that apply specifically to the life sciences industry.

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used.

This Guide is available on the Deloitte Accounting Research Tool (DART).

We hope this Guide helps you navigate the various accounting and reporting challenges you face. We encourage you to contact your Deloitte team for additional information and assistance.

Sincerely,

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Life Sciences        and Reporting Services
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Chapter 1 — 2020 Industry Outlook

Summary

The discussion in this chapter is substantially reproduced\(^1\) from the synopsis of Deloitte's 2020 *Global Life Sciences Outlook*.

1.1 Introduction

Biopharma and medtech organizations are in the fast lane, headed toward a future driven by evolving, data-driven technologies. As organizations strive to make sense of all the data signals, is it time to take a break to refuel and rethink what is being measured? In a rapidly changing world, what metrics really matter?

To find the next generation of key performance indicators, there are several questions organizations could be asking: What can be done to reduce complexity in the patient experience? What is the next level of performance, and how to get there in the next year? Is there adequate visibility of products, costs, and operations to help make timely, informed decisions? Is there a need to acquire, build, or partner for additional capabilities?

Deloitte's 2020 *Global Life Sciences Outlook* helps answer these questions and more. As leaders set their sights on 2020 and look to shift their strategic gears, here's what they can consider.

1.2 Creating New Value

Leaders should more deeply consider ways to increase value and meaning for all stakeholders. The experiences of workers, customers (patients), and ecosystem partners (vendors, alliances, advocacy groups) are interrelated.

1.2.1 Creating Value for Patients, Care Teams, and Partners

To create value for patients, organizations can focus on providing a holistic patient experience — mapping all the touchpoints that patients may experience throughout their journey and with their care teams. Building an empathetic solution — such as a "patient hub" — could help patients and caregivers connect digitally and address needs ranging from diagnosis to maintenance. Similarly, medtech companies can work to gain a deeper understanding of the end user, develop more user-friendly devices, and look at ways to offer patient-centered services in nonclinical settings.

In an era of precision medicine, clinical trials should be representative of the patients who will eventually use a drug or therapy. Efforts are under way to make trials more inclusive and increase participation from minorities and the elderly. Stakeholders can look at options such as telemedicine to reduce complexity and provide more virtual access to clinical trials.

\(^1\) Minor changes in spelling, punctuation, and formatting (e.g., the creation of numbered section headings) have been made to conform the text with the style of this Guide, and the source text's footnotes have been omitted. For ease of readability, the edits are not indicated by brackets or ellipses.
1.2.2 Creating Value for the Workforce
In the workplace, when conditions, tools, and requirements change rapidly, organizations, systems, and practices should assimilate these changes. To create value for the workforce, life sciences and medtech organizations can look at emerging technologies, meaningful work, and flexible work models. In 2020, leaders will likely look at how jobs can be redesigned and work reimagined around human-machine collaboration, working with machines to think exponentially.

1.2.3 Creating Value in the Market and Tracking Discernible Change
With a rocky market and talks of recession in many parts of the world, biopharma companies appear to be biding their time to ink merger and acquisition (M&A) deals. In biotech, ballooning valuations may be getting a reality check, but health-related technology companies are now being valued at over a billion dollars, with many reaching unicorn status in the last year. Medtech has also entered a billion-dollar era, having seen its largest year for multiple billion-dollar deals.

In 2020, the shift is expected to continue toward rare diseases and treatments for unmet needs. Biopharma is making the move to invest in or acquire companies specializing in gene therapies. Manufacturing is expected to be a key differentiator for gene therapies. Large pharmaceutical companies, CMOs, and contract development and manufacturing organizations are adding capacity, either from new facilities, expansions, or acquisitions. The demand for additional manufacturing capacity will likely be exacerbated by accelerated regulatory approvals.

Technology investments, either through acquisition or software licensing, will likely continue to play a dominant role in life sciences. In addition to compliance, risk management, and product life cycle management software, organizations should look to continue investing in applications to enhance real-world evidence and drug discovery.

The growing demand for personalized medicine and orphan drugs is driving R&D investments in large-molecule products. R&D was found to be a source of diminishing return on capital (ROC), especially having fewer assets in the late-stage pipeline and lower potential sales per asset. ROC could be one of the key metrics that matter for 2020 — providing insights for organizations that are considering potential partners and a new understanding of the efficiency of allocating capital under control to drive profitability.

In the future, smaller companies may ultimately take an increasing share of the market from Big Pharma by developing and commercializing products independently.

1.3 Leveraging Opportunities and Increasing Efficiencies
1.3.1 Accelerating R&D by Using Technology
Artificial intelligence (AI) is ushering in a new era of intelligent drug discovery, and the trend is likely to continue in 2020. There has been an explosion of AI start-ups, and tech giants such as Google have also made advances in AI-driven biochemistry that are expected to lead to new developments. Pharmaceutical companies are expected to continue to leverage partnerships.

Drug approval rates have also witnessed a spike. Fast-tracking new drugs is becoming “a new normal,” but there are also concerns over quality, safety, and costs.
1.3.2 Increasing Operational Efficiency

The demand for small-volume, personalized medicines is driving operations away from large-scale bulk production to multiproduct facilities. The lens is gradually zooming in on smart factories of the future that may offer digital automation solutions, industrial “Internet of things” connectivity, and flexible manufacturing processes. With a digitized core, the number of days it takes to release a drug product could potentially be reduced from 100 days to 7.

Data-driven manufacturing is generating more excitement in 2020, providing a renewed focus on quality. Companies are being nudged to revisit their approach toward managing the cost of quality and compliance, and businesses are expected to be more agile. With new technologies such as AI and augmented reality, organizations could track productivity in real time as well as reduce the risk of human error.

Partnering with other players and leveraging outsourcing opportunities are likely to be a huge success factor. Partner expertise could help address manufacturing, supply chain, and distribution challenges. Key outsourcing areas could be cell therapy manufacturing and big data capabilities.

1.4 Building Blocks for the Future

1.4.1 Innovative Financing for Innovative Therapies

Innovative therapies address unmet needs but typically carry high costs. Gene therapies, for example, are not just being touted as treatments but as cures. However, public and private systems will not likely be able to absorb the prices of these drugs. In 2020, companies are likely to move beyond just selling therapies and enter the business of health care financing — innovating drug pricing and reimbursement.

The commercialization of gene and cell therapies comes at a time of wider drug price scrutiny from policymakers and the public. In 2020, drug pricing, health care expenditures, and market accessibility will likely continue to be the main concerns.

1.4.2 Digital Transformation in Biopharma and Medtech

Devices and the data they generate are likely to inspire the development of new analytics tools, generating insights that drive personalized, real-time decision making and improve patient outcomes. While medtech companies may consider technology companies as competitors, collaborations may help develop more consumer-friendly devices.

Both medtech and technology companies will continue to come under consumers' scrutiny around data, privacy, and security. In 2020, expect the debate on data ownership and ethics to continue.

1.4.3 Marrying Innovation With Social Good

Research shows that corporate social responsibility (CSR) adds value to pharma companies' corporate financial performance. Increasingly, stakeholders, including investors, appear to be scrutinizing pharmaceutical firms' environmental and social performance. In addition to companies voluntarily taking up initiatives that are beneficial for society at large, some governments are also making CSR spending mandatory. Companies are likely to look at ways, including public-private partnerships, to more closely align CSR with innovation and patient programs, as it will not just benefit them but society as well.
1.5 Looking Ahead: Sales Trajectories

1.5.1 What Will Sell?
Worldwide prescription drug sales are projected to have a positive compound annual growth rate (CAGR) of 6.9 percent from 2019 to 2024. Oncology is expected to have almost a 20 percent share of the worldwide market and a CAGR of 11.4 percent by 2024. Over the same period, worldwide orphan drug sales are expected to have double the CAGR of nonorphan drugs, at 12.3 percent. The in vitro diagnosis segment is the largest medtech segment globally, accounting for a market share of 12.9 percent in 2018, and is expected to remain the number one device area in the foreseeable future.

1.5.2 What Will Not Sell?
In 2020, clouds of uncertainty will loom large over drug pricing, and challenges may come from lower investments in R&D as a proportion of sales (which is expected to drop from 21.6 percent in 2018 to 18 percent in 2024). By 2024, sales worth $198 billion are at risk due to patent expiries, and a decline is projected for anti-rheumatics (−1.0 percent CAGR).

As for medtech companies, downstream pricing pressures, nontraditional challengers, stringent regulations, and operational inefficiencies due to industry consolidation are forcing them to implement effective cost-reduction strategies to remain competitive. Future success can depend on being proactive and leveraging recent advances in digital technologies.

To learn more, read the full report.
Appendix B — Titles of Standards and Other Literature

The following are the titles of standards and other literature mentioned in this Guide:

**AICPA Literature**

**Accounting and Valuation Guides**
- Assets Acquired to Be Used in Research and Development Activities
- Valuation of Privately-Held-Company Equity Securities Issued as Compensation

**Audit and Accounting Guide**
- Revenue Recognition

**Issues Papers**
- Identification and Discussion of Certain Financial Accounting and Reporting Issues Concerning LIFO Inventories
- 86-2, Accounting for Options

**Other**
- AICPA Technical Q&A Section 2260.03, “Other Assets; Legal Expenses Incurred to Defend Patent Infringement Suit”

**FASB Literature**

**ASC Topics**
- ASC 205, Presentation of Financial Statements
- ASC 210, Balance Sheet
- ASC 220, Income Statement — Reporting Comprehensive Income
- ASC 230, Statement of Cash Flows
- ASC 235, Notes to Financial Statements
- ASC 250, Accounting Changes and Error Corrections
- ASC 260, Earnings per Share
- ASC 270, Interim Reporting
- ASC 275, Risks and Uncertainties
- ASC 280, Segment Reporting
ASC 310, Receivables
ASC 320, Investments — Debt and Equity Securities
ASC 321, Investments — Equity Securities
ASC 323, Investments — Equity Method and Joint Ventures
ASC 326, Financial Instruments — Credit Losses
ASC 330, Inventory
ASC 340, Other Assets and Deferred Costs
ASC 350, Intangibles — Goodwill and Other
ASC 360, Property, Plant, and Equipment
ASC 405, Liabilities
ASC 410, Asset Retirement and Environmental Obligations
ASC 420, Exit or Disposal Cost Obligations
ASC 450, Contingencies
ASC 460, Guarantees
ASC 470, Debt
ASC 480, Distinguishing Liabilities From Equity
ASC 505, Equity
ASC 605, Revenue Recognition
ASC 606, Revenue From Contracts With Customers
ASC 610, Other Income
ASC 705, Cost of Sales and Services
ASC 710, Compensation — General
ASC 712, Compensation — Nonretirement Postemployment Benefits
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 835, Financial Instruments
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ASC 840, Leases
ASC 842, Leases
ASC 845, Nonmonetary Transactions
ASC 860, Transfers and Servicing
ASC 915, Development Stage Entities
ASC 930, Extractive Activities — Mining
ASC 942, Financial Services — Depository and Lending
ASC 944, Financial Services — Insurance
ASC 946, Financial Services — Investment Companies
ASC 948, Financial Services — Mortgage Banking
ASC 954, Health Care Entities
ASC 958, Not-for-Profit Entities
ASC 960, Plan Accounting — Defined Benefit Pension Plans
ASC 985, Software

ASUs

ASU 2010-27, Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers — a consensus of the FASB Emerging Issues Task Force

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

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

ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation

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

ASU 2014-16, Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity — a consensus of the FASB Emerging Issues Task Force

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

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


ASU 2016-02, Leases (Topic 842)
ASU 2016-08, Revenue From Contracts With Customers (Topic 606): Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)

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

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

ASU 2016-11, Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting

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

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


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

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


ASU 2016-20, Technical Corrections and Improvements to Topic 606, Revenue From Contracts With Customers

ASU 2017-01, Business Combinations (Topic 805): Clarifying the Definition of a Business

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

ASU 2017-05, Other Income — Gains and Losses From the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets

ASU 2017-11, Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception

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

ASU 2017-13, Revenue Recognition (Topic 605), Revenue From Contracts With Customers (Topic 606), Leases (Topic 840), and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments (SEC Update)

ASU 2017-14, Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue From Contracts With Customers (Topic 606) (SEC Update)

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

ASU 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

ASU 2018-08, Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made

ASU 2018-10, Codification Improvements to Topic 842, Leases

ASU 2018-11, Leases (Topic 842): Targeted Improvements


ASU 2018-17, Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities

ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606

ASU 2018-20, Leases (Topic 842): Narrow-Scope Improvements for Lessors

ASU 2019-01, Leases (Topic 842): Codification Improvements

ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments — Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments

ASU 2019-05, Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief

ASU 2019-08, Compensation — Stock Compensation (Topic 718) and Revenue From Contracts With Customers (Topic 606): Codification Improvements — Share-Based Consideration Payable to a Customer

ASU 2019-10, Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates

ASU 2019-11, Codification Improvements to Topic 326, Financial Instruments — Credit Losses

ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

ASU 2020-01, Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815 — a consensus of the FASB Emerging Issues Task Force

**Concepts Statements**

No. 5, Recognition and Measurement in Financial Statements of Business Enterprises

No. 6, Elements of Financial Statements

No. 8, Conceptual Framework for Financial Reporting — Chapter 8, Notes to Financial Statements
Proposed ASUs
No. 2015-310, Notes to Financial Statements (Topic 235): Assessing Whether Disclosures Are Material
No. 2015-340, Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance
No. 2017-200, Debt (Topic 470): Simplifying the Classification of Debt in a Classified Balance Sheet (Current Versus Noncurrent)
No. 2017-210, Inventory (Topic 330): Disclosure Framework — Changes to the Disclosure Requirements for Inventory
No. 2017-280, Consolidation (Topic 812): Reorganization
No. 2019-730, Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity
No. 2019-770, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting
No. 2019-790, Derivatives and Hedging (Topic 815): Codification Improvements to Hedge Accounting

Other FASB Proposal

International Standards
IFRS 2, Share-Based Payment
IFRS 3, Business Combinations
IFRS 5, Non-Current Assets Held for Sale and Discontinued Operations
IFRS 9, Financial Statements
IFRS 10, Consolidated Financial Statements
IFRS 11, Joint Arrangements
IFRS 12, Disclosure of Interests in Other Entities
IFRS 15, Revenue From Contracts With Customers
IFRS 16, Leases
IAS 1 (Revised 2007), Presentation of Financial Statements
IAS 7, Statement of Cash Flows
IAS 10, Events After the Reporting Period
IAS 12, Income Taxes
Appendix B — Titles of Standards and Other Literature

IAS 17, Leases
IAS 20, Accounting for Government Grants and Disclosure of Government Assistance
IAS 27 (Revised 2011), Separate Financial Statements
IAS 32, Financial Instruments: Presentation
IAS 37, Provisions, Contingent Liabilities and Contingent Assets
IAS 38, Intangible Assets
IAS 40, Investment Property

IRC
Section 78, “Gross Up for Deemed Paid Foreign Tax Credit”
Section 163(j), “Interest; Limitation on Business Interest”
Section 199, “Income Attributable to Domestic Production Activities”
Section 382, “Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change”
Section 383, “Special Limitations on Certain Excess Credits, etc.”
Section 409A “Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans”
Section 422, “Incentive Stock Options”
Section 423, “Employee Stock Purchase Plans”

PCAOB Literature

SEC Literature

FRM
Topic 1, “Registrant’s Financial Information”
Topic 2, “Other Financial Statements Required”
Topic 3, “Pro Forma Financial Information”
Topic 5, “Smaller Reporting Companies”
Topic 7, “Related Party Matters”
Topic 9, “Management’s Discussion and Analysis of Financial Position and Results of Operations (MD&A)”
Topic 10, “Emerging Growth Companies”

Interpretive Release
33-10403, Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile
Proposed Rule Release
No. 33-10635, Amendments to Financial Disclosures About Acquired and Disposed Businesses

Regulation S-K
Item 101, “Description of Business”
Item 103, “Business; Legal Proceedings”
Item 201, “Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters”
Item 301, “Selected Financial Data”
Item 302, “Supplementary Financial Information”
Item 303, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”
Item 305, “Quantitative and Qualitative Disclosures About Market Risk”
Item 402, “Executive Compensation”
Item 404, “Transactions With Related Persons, Promoters and Certain Control Persons”
Item 407, “Corporate Governance”
Item 503, “Prospectus Summary”
Item 601, “Exhibits”

Regulation S-X
Rule 1-02(w), “Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary”
Article 2, “Qualifications and Reports of Accountants”
Rule 3-02, “Consolidated Statements of Comprehensive Income and Cash Flows”
Rule 3-05, “Financial Statements of Businesses Acquired or to Be Acquired”
Rule 3-09, “Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”
Rule 3-10, “Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered”
Rule 3-14, “Special Instructions for Real Estate Operations to Be Acquired”
Rule 3-16, “Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered”
Rule 4-08(g), “General Notes to Financial Statements: Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons”
Rule 4-08(h), “General Notes to Financial Statements: Income Tax Expense”
Rule 4-08(n), “Accounting Policies for Certain Derivative Instruments”
Article 8, “Financial Statements of Smaller Reporting Companies”
Rule 10-01(b), “Interim Financial Statements: Other Instructions as to Content”
Article 11, “Pro Forma Financial Information”
Rule 11-01 “Presentation Requirements”

**SAB Topics**
No. 1.M, “Financial Statements; Materiality”
No. 5.A, “Expenses of Offering”
No. 5.Y, “Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies”
No 11.A, “Miscellaneous Disclosure; Operating-Differential Subsidies”
No. 13, “Revenue Recognition”
No. 14.B, “Share-Based Payment; Transition From Nonpublic to Public Entity Status”
No. 14.D.1, “Certain Assumptions Used in Valuation Methods; Expected Volatility”
SAB 116, “Staff Accounting Bulletin No. 116”

**SEC Securities Act of 1933 General Rules and Regulations**
Rule 144, “Persons Deemed Not to be Engaged in a Distribution and Therefore Not Underwriters — General Guidance”

**Superseded Literature**

**EITF Issues**
Issue 00-21, “Revenue Arrangements With Multiple Deliverables”
Issue 01-10, “Accounting for the Impact of the Terrorist Attacks of September 11, 2001”
Issue 02-16, “Accounting by a Customer (Including a Reseller) for Certain Consideration Received From a Vendor”
Issue 01-8, “Determining Whether an Arrangement Contains a Lease”
Issue 08-6, “Equity Method Investment Accounting Considerations”
Issue 09-2, “Research and Development Assets Acquired in an Asset Acquisition”
Issue 09-4, “Seller Accounting for Contingent Consideration”

**FASB Interpretations**
No. 47, *Accounting for Conditional Asset Retirement Obligations* — an interpretation of FASB Statement No. 143
No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109
FASB Statements

No. 5, *Accounting for Contingencies*

No. 95, *Statement of Cash Flows*

No. 114, *Accounting by Creditors for Impairment of a Loan* — an amendment of FASB Statements No. 5 and 15

No. 123(R), *Share-Based Payment*

No. 133, *Accounting for Derivative Instruments and Hedging Activities*

No. 141, *Business Combinations*

No. 141(R), *Business Combinations*

No. 160, *Noncontrolling Interests in Consolidated Financial Statements* — an amendment of ARB No. 51
### Appendix C — Abbreviations

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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ABO</td>
<td>accumulated benefit obligation</td>
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<tr>
<td>AFS</td>
<td>available for sale</td>
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<tr>
<td>AI</td>
<td>artificial intelligence</td>
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<tr>
<td>AICPA</td>
<td>American Institute of Certified Public Accountants</td>
</tr>
<tr>
<td>AMT</td>
<td>alternative minimum tax</td>
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<tr>
<td>API</td>
<td>active pharmaceutical ingredient</td>
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<tr>
<td>APIC</td>
<td>additional paid-in capital</td>
</tr>
<tr>
<td>ASC</td>
<td>FASB Accounting Standards Codification</td>
</tr>
<tr>
<td>ASR</td>
<td>accelerated share repurchase</td>
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<td>ASU</td>
<td>FASB Accounting Standards Update</td>
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<tr>
<td>BCF</td>
<td>beneficial conversion feature</td>
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<tr>
<td>BEAT</td>
<td>base erosion anti-abuse tax</td>
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<tr>
<td>BEMTA</td>
<td>base erosion minimum tax amount</td>
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<tr>
<td>BPD</td>
<td>branded prescription drug</td>
</tr>
<tr>
<td>CAGR</td>
<td>compound annual growth rate</td>
</tr>
<tr>
<td>CAM</td>
<td>critical audit matter</td>
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<tr>
<td>CCF</td>
<td>cash conversion feature</td>
</tr>
<tr>
<td>CECL</td>
<td>current expected credit loss</td>
</tr>
<tr>
<td>CFC</td>
<td>controlled foreign corporation</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>CMO</td>
<td>contract manufacturing organization</td>
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<tr>
<td>CODM</td>
<td>chief operating decision maker</td>
</tr>
<tr>
<td>CRO</td>
<td>contract research organization</td>
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<tr>
<td>CSR</td>
<td>corporate social responsibility</td>
</tr>
<tr>
<td>DTA</td>
<td>deferred tax asset</td>
</tr>
<tr>
<td>DTL</td>
<td>deferred tax liability</td>
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<tr>
<td>EBITDA</td>
<td>earnings before interest, taxes, depreciation, and amortization</td>
</tr>
<tr>
<td>ED</td>
<td>exposure draft</td>
</tr>
<tr>
<td>EDGAR</td>
<td>SEC electronic data gathering, analysis, and retrieval system</td>
</tr>
<tr>
<td>EGC</td>
<td>emerging growth company</td>
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<tr>
<td>EITF</td>
<td>Emerging Issues Task Force</td>
</tr>
<tr>
<td>ESPP</td>
<td>employee stock purchase plan</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<td>FASB</td>
<td>Financial Accounting Standards Board</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>FDII</td>
<td>foreign derived intangible income</td>
</tr>
<tr>
<td>FIFO</td>
<td>first in, first out</td>
</tr>
<tr>
<td>FIN</td>
<td>FASB Interpretation</td>
</tr>
<tr>
<td>FOB</td>
<td>free on board</td>
</tr>
<tr>
<td>FRM</td>
<td>SEC Division of Corporation Finance Financial Reporting Manual</td>
</tr>
<tr>
<td>FVTOCI</td>
<td>fair value through other comprehensive income</td>
</tr>
<tr>
<td>GAAP</td>
<td>generally accepted accounting principles</td>
</tr>
<tr>
<td>GILTI</td>
<td>global intangible low-taxed income</td>
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<tr>
<td>GPO</td>
<td>group purchasing organization</td>
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<tr>
<td>HFI</td>
<td>held for investment</td>
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<tr>
<td>HFS</td>
<td>held for sale</td>
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<tr>
<td>IAS</td>
<td>International Accounting Standard</td>
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<tr>
<td>IASB</td>
<td>International Accounting Standards Board</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>--------------</td>
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<tr>
<td>IFRIC</td>
<td>IFRS Interpretaions Committee</td>
</tr>
<tr>
<td>IFRS</td>
<td>International Financial Reporting Standard</td>
</tr>
<tr>
<td>IIR</td>
<td>investigator-initiated research</td>
</tr>
<tr>
<td>IP</td>
<td>intellectual property</td>
</tr>
<tr>
<td>IPO</td>
<td>initial public offering</td>
</tr>
<tr>
<td>IPR&amp;D</td>
<td>in-process research and development</td>
</tr>
<tr>
<td>IRC</td>
<td>Internal Revenue Code</td>
</tr>
<tr>
<td>IRS</td>
<td>Internal Revenue Service</td>
</tr>
<tr>
<td>ISO</td>
<td>incentive stock option</td>
</tr>
<tr>
<td>IT</td>
<td>information technology</td>
</tr>
<tr>
<td>LCD</td>
<td>liquid-crystal display</td>
</tr>
<tr>
<td>LIBOR</td>
<td>London Interbank Offered Rate</td>
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<tr>
<td>LIFO</td>
<td>last in, first out</td>
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<tr>
<td>LLC</td>
<td>limited liability company</td>
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<tr>
<td>M&amp;A</td>
<td>merger and acquisition</td>
</tr>
<tr>
<td>MD&amp;A</td>
<td>Management's Discussion &amp; Analysis</td>
</tr>
<tr>
<td>MSL</td>
<td>medical science liaison</td>
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<tr>
<td>NFP</td>
<td>not-for-profit entity</td>
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<tr>
<td>NOL</td>
<td>net operating loss</td>
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<tr>
<td>NQSO</td>
<td>non-qualified stock option</td>
</tr>
<tr>
<td>NSO</td>
<td>nonstatutory option</td>
</tr>
<tr>
<td>OCI</td>
<td>other comprehensive income</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OEM</td>
<td>original equipment manufacturer</td>
</tr>
<tr>
<td>PBE</td>
<td>public business entity</td>
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PBO</td>
<td>projected benefit obligation</td>
</tr>
<tr>
<td>PCAOB</td>
<td>Public Company Accounting Oversight Board</td>
</tr>
<tr>
<td>PCC</td>
<td>Private Company Council</td>
</tr>
<tr>
<td>PP&amp;E</td>
<td>property, plant, and equipment</td>
</tr>
<tr>
<td>PRV</td>
<td>priority review voucher</td>
</tr>
<tr>
<td>PTRS</td>
<td>probability of technical and regulatory success</td>
</tr>
<tr>
<td>Q&amp;A</td>
<td>question and answer</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>research and development</td>
</tr>
<tr>
<td>R&amp;E</td>
<td>research and experimentation</td>
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<tr>
<td>REMS</td>
<td>risk evaluation and mitigation strategy</td>
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<tr>
<td>ROC</td>
<td>return on capital</td>
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<tr>
<td>ROU</td>
<td>right of use</td>
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<tr>
<td>SaaS</td>
<td>software as a service</td>
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<tr>
<td>SAB</td>
<td>Staff Accounting Bulletin</td>
</tr>
<tr>
<td>SEC</td>
<td>Securities and Exchange Commission</td>
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<tr>
<td>SME</td>
<td>small to medium-sized entity</td>
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<tr>
<td>SPPI</td>
<td>solely payments of principal and interest</td>
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<td>SRC</td>
<td>smaller reporting entity</td>
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<tr>
<td>S&amp;P 500</td>
<td>Standard &amp; Poor's 500 Index</td>
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<tr>
<td>TD</td>
<td>Treasury Decision</td>
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<tr>
<td>TRG</td>
<td>transition resource group</td>
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<tr>
<td>UTB</td>
<td>unrecognized tax benefit</td>
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<tr>
<td>VIE</td>
<td>variable interest entity</td>
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<tr>
<td>VWAP</td>
<td>volume-weighted average daily market price</td>
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</table>
The following is a list of short references for the Acts mentioned in this Guide:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAST Act</td>
<td>Fixing America's Surface Transportation Act</td>
</tr>
<tr>
<td>JOBS Act</td>
<td>Jumpstart Our Business Startups Act</td>
</tr>
<tr>
<td>Securities Act</td>
<td>Securities Act of 1933</td>
</tr>
<tr>
<td>TCJA</td>
<td>Tax Cuts and Jobs Act of 2017</td>
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