Rx Marketplace Quarterly

Finance and reporting trends in the pharmaceutical and life sciences industry

September 2014
Issue 3

In this issue

In this edition of Rx Marketplace Quarterly we discuss the most recent quarter's industry IPOs, venture capital funding, and M&A activity. The public equity market, led by pharmaceutical and life sciences (PLS) companies, recorded the highest volume of deal activity since late 2007. This momentum is expected to continue during the third quarter of 2014.

We also highlight the medical cost projections for the upcoming year — a key number that has become a major factor in setting insurance premiums for the past decade. We expect four factors to inflate the spending growth rate in 2015: economic upswing, specialty drugs, physician employment, and information technology investments.

On the regulatory front, the SEC recently commented on the implications of adopting the new revenue standard on registrants' five-year selected financial data table included in their SEC filings. Also, we explore how the PCAOB's staff consultation paper on standard-setting activities related to auditing accounting estimates and fair value measurements could directly impact the PLS industry.

In the area of accounting and reporting hot topics, we cover the FASB's new guidance that explicitly requires management to assess a company's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. We also provide an update on the FASB's consolidation project, which is expected to impact several areas within the variable interest entity assessment. Last, we discuss several areas where our CMAAS team can support companies during cross-border business combination transactions.

I hope you will find this publication of interest and welcome your thoughts on how these issues affect your organization. If you'd like to have a deeper conversation on this or any of our other PwC publications, please contact me or your local PwC partner. You'll find a direct link to this report on our website at www.pwc.com.

Regards,

Karen C. Young

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US Pharmaceutical & Life Sciences Assurance Leader

In the market

Initial public offerings

The market for initial public offerings (IPOs) finished strong in the second quarter of 2014, recording the highest quarterly deal volume since the fourth quarter of 2007, according to PwC's US IPO Watch, a quarterly survey of IPOs listed on US stock exchanges. The overall IPO volume for the second quarter of 2014 reached 89 public company debuts, representing a 41% increase over the 63 public listings in the second quarter of 2013. In addition, IPO proceeds raised during the second quarter of 2014 reached $21.5 billion, a 63% increase over the $13.2 billion raised in the second quarter of 2013. For the first half of the year, there were a total of 160 IPOs, generating $32.4 billion in proceeds compared with 97 IPOs totaling $21 billion in the same period the previous year.

Pharmaceutical and life sciences (PLS) companies continued to lead the IPO market in the quarter, with 24 IPOs. Proceeds from these offerings, however, totaled only $1.8 billion, or 8% of total IPO proceeds. These IPOs typically raise smaller investments because many biotechnology and biopharmaceutical IPOs are in the early development stages.

Robust IPO activity continued in the third quarter of 2014, with 20 IPOs completed through August 31, 2014 and another 22 companies publicly filing registration statements. The PLS companies that have priced through August 31 raised nearly $1.9 billion, already exceeding the amount raised during the second quarter of 2014. While this momentum should continue in the third quarter, cash-hungry life science companies should also consider alternative financing strategies to provide the funds needed for growth when the IPO window begins to close.

For additional information, guidance, and insight on the IPO process, please refer to PwC's *Weekly Capital Markets Watch*, PwC's Quarterly *US IPO Watch*, PwC's *Annual Capital Markets Watch*, and *Roadmap for an IPO: a guide to going public*. In addition, companies interested in pursuing an IPO should refer to *Executing a Successful IPO*, which provides helpful insights on the IPO process.

Venture capital funding

US venture capital (VC) funding for the life sciences industry, which includes biotechnology and medical devices, increased 25% by value, but declined 1% by volume, on a year-over-year basis during the second quarter of 2014. Venture capitalists invested $2.5 billion in 195 life sciences deals during the second quarter of 2014, compared with $2.0 billion in 197 deals during the same period in 2013. The medical device industry received $649 million in 73 deals in the second quarter of 2014 — an increase of 23% in dollars, but a decrease of 5% in deal volume compared with the same quarter last year. The biotechnology industry raised $1.84 billion in 122 deals during the second quarter, which was second (behind software) in terms of dollars raised. According to PwC's quarterly report on VC funding, 2014 is expected to be one of the strongest years for biotechnology investments. Please refer to PwC's *Biotech soars to record high* for further information related to VC funding and its impact on the PLS industry. This report, which includes data from *PwC's MoneyTree™ Report* and the National Venture Capital Association (NVCA), is based on data provided by Thomson Reuters.

Mergers and acquisitions

While the volume of mergers and acquisitions (M&A) decreased during the second quarter in terms of closed transactions, a dramatic rise in deal activity accounted for 62 announced transactions. That total represents $167.4 billion of value, according to *Pharmaceutical and Life Sciences Deals Insights Quarterly*, an analysis of M&A trends and outlook for the PLS industry issued by PwC's deals practice. The volume of closed PLS deals declined 35% to 33 deals in the second quarter of 2014, compared with 51 deals in the first quarter of 2014, but increased 43% from 23 deals in the second quarter of 2013. Deal activity increased at a frenzied pace in the second quarter of 2014, consistent with the predictions in the deals practice's first quarter report. Although the volume and value of announced deals in the second quarter may not be repeated, the industry is expected to continue to support a heightened level of activity throughout 2014. Please refer to PwC's *Pharmaceutical and Life Sciences Deals Insights Quarterly* for further information related to M&A deals and trends in the PLS industry.

Medical Cost Trend: Behind the Numbers 2015

In its annual report, *Behind the Numbers*, PwC's Health Research Institute (HRI) projects a medical cost trend of 6.8%, up from 6.5% projected for 2014.

The story of 2015 is a nuanced one. At first glance, the health industry appears to be reverting to historical patterns — bouncing back as the nation recovers from the economic doldrums. Whether spending more freely because of the improved economy or shopping with insurance provided through the Affordable Care Act, consumers drove the first bump in growth in the first quarter of 2014. We expect that to continue through next year.

But other factors are helping to moderate that growth. The $2.8 trillion industry is becoming more efficient. Doctors and hospitals are adopting standardized processes offering the prospect of better value for our health dollar. "At-risk" payment models that hold healthcare providers financially accountable for patient outcomes are beginning to take effect. One tangible sign of shrinkage: growth in healthcare system administrative and clinical employment has declined since 2011.

And major purchasers — namely the federal government and large employers — are tamping down the spending growth rate analyzed in this report, in part by demanding greater value and in part by shifting financial responsibility to consumers.

Eighty-five percent of employers in *PwC's 2014 Touchstone Survey* have already implemented or are considering an increase in employee cost sharing through plan design changes over the next three years. Eighteen percent of employers now offer a high-deductible health plan as the only insurance option for their employees.

A little more than 8 million Americans enrolled in the public exchanges this year. Millions of newly insured Americans accessing care are expected to cause a spike in medical costs in 2015. For more information or to download the full report please visit: www.pwc.com/hri.

Tax

FASB adds income tax accounting topics to its agenda

Income taxes continue to be a complex area of financial accounting. Stakeholders have pointed to operational challenges associated with applying the income tax guidance in a number of areas. For example, the current income tax accounting standard includes many mechanical rules and "exceptions," that can make it difficult to apply and often yields information that is challenging to understand. As such, during its Agenda Prioritization meeting on August 13, 2014, the Financial Accounting Standards Board (FASB) added the following two income tax accounting topics to its broader simplification initiative:

- Possible elimination of the exception for recognizing deferred taxes on certain intercompany transactions under ASC 740
- Possible classification of all deferred tax assets and liabilities as non-current

The Board also asked the staff to perform additional research on potentially eliminating the intra-period tax allocation rules by having income tax expense reported as a single line item.

We will continue to monitor further developments and report on forthcoming guidance.

Please refer to PwC's *Tax Insights* for further information.

OECD's Agreed Recommendations on BEPS 2014 Deliverables

On September 16, the Organization for Economic Cooperation and Development (OECD) published reports on the base erosion and profit shifting (BEPS) action plan items related to the following:

- Digitization of the economy
- Hybrid mismatches
- Treaty abuse
- Country-by-country reporting and transfer pricing documentation
- Transfer pricing and intangibles
- Harmful tax practices
- Use of a multi-lateral instrument

PLS companies will need to take action to comply with new requirements and to consider how they do business in different countries. Meanwhile, the OECD must carry out the process of redrafting and agreeing materials. Governments must decide which policy changes they will make, and tax authorities will have to work out how to implement them effectively.

Please refer to PwC's Tax Policy Bulletin, *OECD's agreed recommendations on BEPS 2014 deliverables: Few surprises — but no let up*, for further information on OECD's agreed recommendations.

Regulatory update

Securities and Exchange Commission

The Securities and Exchange Commission (SEC) staff generally expects all periods presented in the selected financial data table required by S-K Item 301 to be recast to give effect to the retrospective adoption of a new accounting standard or change in accounting principle. The revenue standard issued in May 2014 by the FASB and the International Accounting Standards Board (IASB) requires full or modified retrospective application. Entities have been anticipating an SEC announcement regarding the implications of adopting the new revenue standard on their five-year selected financial data table included in their SEC filings. Recently, the staff commented that the Division of Corporation Finance will not object if registrants apply the new standard only to selected financial data for the same years as presented in the registrant's primary financial statements. Earlier years of selected financial data may be presented without reflecting the retrospective application of the new standard. However, registrants should provide transparent disclosures regarding the difference in the basis of presentation and the lack of comparability of the data.

For more information on the revenue standard, please refer to the first edition of PwC's global accounting and financial reporting guide for *Revenue from contracts with customers*.

One other matter to note is that James Schnurr, a recently retired partner from Deloitte LLP, was appointed as the Chief Accountant of the SEC. Mr. Schnurr fills a vacancy created by the departure of Paul Beswick and will officially take office in October.

Public Company Accounting Oversight Board

On August 19, 2014, the Public Company Accounting Oversight Board (PCAOB) issued for public comment a staff consultation paper on standard-setting activities related to auditing accounting estimates and fair value measurements. The staff consultation paper discusses and solicits comment on certain issues related to auditing accounting estimates and fair value measurements. The comments will help the PCAOB staff evaluate whether the existing PCAOB auditing standards can and should be improved.

Although the PCAOB staff identified a number of alternative approaches that the PCAOB may wish to consider, the PCAOB staff is considering developing a single standard related to auditing accounting estimates and fair value measurements instead of separate standards that exist today. The staff consultation paper discusses that the potential new standard could be designed to:

- Align with the PCAOB's risk assessment standards
- Generally retain the approaches to internal control and substantive testing from the existing standards, but include requirements that apply to accounting estimates and fair value measurements
- Establish more specific audit requirements related to the use of third parties in developing accounting estimates and fair value measurements
- Create a more comprehensive standard related to auditing accounting estimates and fair value measurements to promote greater consistency and effectiveness in application

The PLS industry could be directly impacted; for example, if a company uses a specialist to develop an accounting estimate, a new standard could direct the auditor to test that information as if it were produced by the company. In this case, the auditor would be required, as applicable, to evaluate the appropriateness of the methods used, evaluate the reasonableness of significant assumption, and test the data used by the specialist — not just the information provided to the specialist.

Additionally, the PCAOB staff is considering how a potential new standard could address audit evidence obtained from third-party sources, such as pricing services and broker-dealers, and is exploring whether specific requirements should be set forth for evaluating information from third-party pricing sources as part of evaluating the reliability and relevance of the evidence.

The Board also announced that a Standing Advisory Group meeting will be held on October 2, 2014 to discuss matters related to auditing accounting estimates and fair value measurements.

PwC is currently evaluating the staff consultation paper and is expected to issue a response letter in due course.

The comment period closes on November 3, 2014.

For additional information related to the recent activities of the SEC and PCAOB, please refer to PwC's *Regulatory and Standard-Setting Developments*.

Accounting and financial reporting hot topics

Going Concern

In August, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which explicitly requires management to assess an entity's ability to continue as a going concern at each annual and interim reporting period, and to provide related footnote disclosures in certain circumstances. While similar footnote disclosures have been common before this new standard, there was no specific guidance in US GAAP defining management's responsibility to assess or disclose going-concern uncertainties.

The standard indicates that substantial doubt exists when it is probable that an entity will not meet its obligations one year from the date the financial statements are issued. The likelihood threshold of "probable" is similar to its current use in US GAAP for loss contingencies. Management's assessment should be based on relevant conditions known and reasonably knowable at the issuance date to determine if it is probable that the entity will be unable to meet its obligations within the assessment period. Management's assessment would consider the mitigating effect of its plans to the extent that it is probable that those plans will be effectively implemented and, when implemented, will mitigate the conditions that gave rise to substantial doubt within the assessment period.

Disclosures will be required if conditions give rise to substantial doubt. The disclosures will vary depending on whether management has plans that mitigate the conditions that created substantial doubt. However, an express statement indicating that there is substantial doubt about the company's ability to continue as a going concern is required if substantial doubt is not alleviated by management's plans.

The new standard will be effective for all entities in the first annual period ending after December 15, 2016. Earlier application is permitted.

Please refer to PwC's *In Depth*, *FASB defines management's going concern assessment and disclosure responsibilities*, for additional information and PwC's observations on the going-concern standard.

Consolidation Project

In July, the FASB completed deliberations on its consolidation project. The standard is primarily intended to limit the circumstances where asset managers will consolidate funds they manage, but consolidation conclusions, as well as applicable disclosure requirements, could change for entities in all industries. The final standard is expected to impact several areas within the variable interest entity (VIE) assessment. It could impact (i) whether a reporting entity has a variable interest, (ii) the determination of whether an entity is a VIE or a voting interest entity, and/or (iii) which party consolidates the entity. Because the changes are not limited to any particular industry, all reporting entities will need to re-evaluate entities in which they hold a variable interest. This process may be time consuming for certain reporting entities, particularly for those with numerous VIEs. Changes may be required to systems, processes, and controls to analyze and continuously monitor these relationships for presentation and disclosure purposes.

We expect the FASB to issue a final standard late in the fourth quarter of 2014. The new standard will be effective for public business entities for annual periods (and interim periods within those annual periods) beginning after December 15, 2015. Non-public business entities will apply the standard for annual periods beginning after December 2016, and for interim periods beginning after December 15, 2017. Early adoption will be allowed.

Please refer to PwC's *In Depth*, *Consolidation – a new standard is imminent*, for additional information and PwC's observations on the expected impact to the VIE assessment.

Cross border business combination support

PwC's Capital Markets & Accounting Advisory Services (CMAAS) group provides accounting advice and assistance on a variety of topics. In this issue of *Rx Marketplace Quarterly*, we highlight CMAAS' depth and breadth of accounting and financial reporting experience in cross-border business combination transactions.

Pharmaceutical, medical device, and other life sciences companies continue the industry trend toward global consolidation, as evidenced by the recent announcements of several large cross-border acquisitions. These transactions create a variety of accounting considerations and trigger certain additional financial reporting requirements that a buyer must anticipate and plan for early in the deal process, even before the announcement of a transaction.

CMAAS can help a buyer identify, analyze, and navigate the complexities of these cross-border transactions by assisting companies with the following:

- Pro forma financial reporting information
- Conversion from local GAAP to US GAAP
- Conformance of accounting policies
- Acquisition accounting for opening balance sheet

Pro forma financial reporting information

In many cases, a company will participate in public equity or debt offerings to finance a proposed transaction. As a result, pro forma financial information may need to be prepared to be included in the company's filings. CMAAS has extensive experience assisting clients with the preparation of these pro forma financial statements and can help companies realize efficiencies through its (i) approach and methodology, (ii) customizable tools and templates that can be tailored, and (iii) key pharmaceutical and medical device industry insights to identify the commonly applicable pro forma adjustments. Often, pro forma financial statements need to be prepared quickly to ensure that tight transaction timelines are met. CMAAS' involvement as the accounting advisor can mitigate some of the inherent pressures companies face throughout this time-sensitive process.

Conversion from local GAAP to US GAAP

As a result of a US buyer acquiring a foreign entity deemed significant for purposes of S-X 3-05, the buyer will need to evaluate whether a US GAAP conversion of the target's historical financial information is necessary. Even if not required for S-X 3-05 purposes, the GAAP conversion will likely be necessary for purposes of prospective financial reporting.

CMAAS can assist a company throughout the conversion process by (i) assisting in the development of a project plan to memorialize the planned approach and scope of the conversion, (ii) identifying accounts giving rise to differences between local GAAP and US GAAP, (iii) quantifying these identified differences, and (iv) assisting in the implementation and embedding of changes to existing systems and processes.

Conformance of accounting policies

In addition to converting the acquired entity's financial information from local GAAP to US GAAP, the company will need to ensure that its specific accounting policies are integrated into the prospective financial reporting of the acquired entity. Given the inherent estimates and significant judgments involved in a number of accounting areas under US GAAP, this may involve additional complexity during the embedding process.

Acquisition accounting for opening balance sheet

In many cross-border business combinations, accounting complexities arise related to the (i) identification of assets and liabilities to be recognized under the acquisition method of accounting, (ii) the determination of items subject to valuation procedures, and (iii) the evaluation of consideration transferred (including the evaluation of the potential impact of target's legacy equity awards and acquired contingent consideration), among other potential accounting issues.

CMAAS has developed tools to assist companies with the process of taking inventory of purchase accounting adjustments, reconciling the target's closing balance sheet to the buyer's opening balance sheet, and preparing white papers about complex technical accounting issues. In addition, CMAAS can provide comments to companies as they prepare their related financial statement business combination disclosures pursuant to US GAAP, including the required pro forma financial information.

Our dedicated subject matter specialists can assist and advise companies on these complex accounting and financial reporting matters throughout the deal process. If you have questions regarding our cross-border business combination support services, please contact your local PwC partner or any of the individuals listed under contact information.

Thought leadership

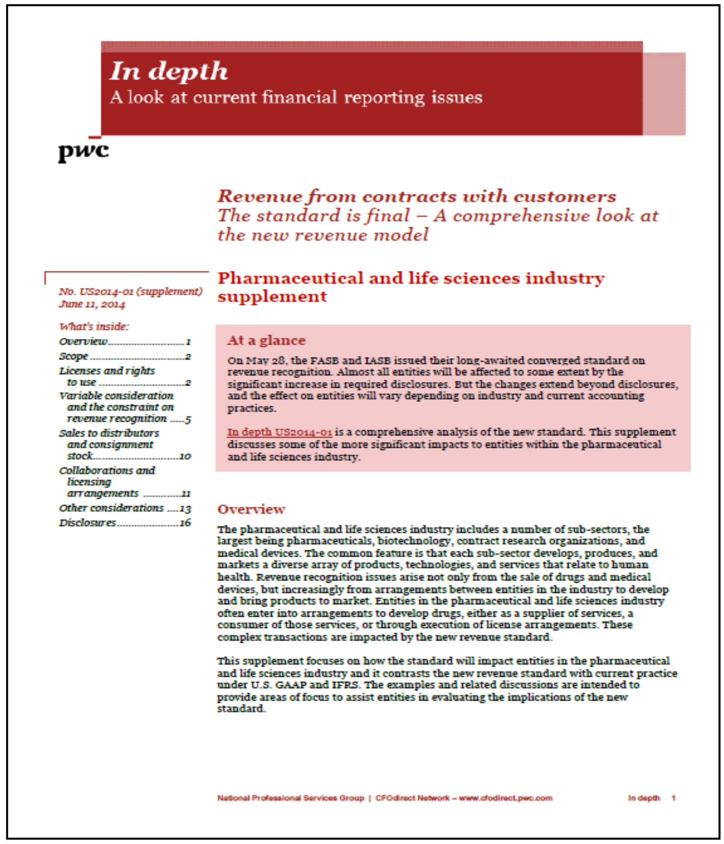
PwC invests in developing points of view on significant topics affecting PLS companies. Our thought leadership, including guides, reports, newsletters, and articles, provides insights on a wide range of technical and business topics covering accounting, tax, and finance-related issues, as well as industry reports that address strategy and operational concerns. Below is a representative list of recent and upcoming publications.

Published

- Revenue from contracts with customers – Pharmaceutical and life sciences industry supplement
- PLS Industry Alert 2014-2: IPR&D acquired in a business combination – How many pieces?
- PLS Industry Alert 2014-1: Potential impacts to pharma and life sciences companies of the new accounting definition of an "investment company"
- US GAAP: Issues and solutions for the pharmaceuticals and life sciences industries
- US GAAP: Issues and solutions for the medical technology industry
- Customer experience in the pharmaceutical sector: getting closer to the patient

Upcoming thought leadership

- October 2014 – PLS Industry Alert
- November 2014 – MoneyTree Report
- November 2014 – PLS Deals Insights Quarterly
- November 2014 – PLS SEC Comment Letter Trends
- November 2014 – PLS IPO Comment Letter Trends



In depth
A look at current financial reporting issues

pwc

Revenue from contracts with customers
The standard is final – A comprehensive look at the new revenue model

No. US2014-01 (supplement)
June 11, 2014

What's inside:

Pharmaceutical and life sciences industry supplement

At a glance

On May 28, the FASB and IASB issued their long-awaited converged standard on revenue recognition. Almost all entities will be affected to some extent by the significant increase in required disclosures. But the changes extend beyond disclosures, and the effect on entities will vary depending on industry and current accounting practices.

In depth US2014-01 is a comprehensive analysis of the new standard. This supplement discusses some of the more significant impacts to entities within the pharmaceutical and life sciences industry.

Overview

The pharmaceutical and life sciences industry includes a number of sub-sectors, the largest being pharmaceuticals, biotechnology, contract research organizations, and medical devices. The common feature is that each sub-sector develops, produces, and markets a diverse array of products, technologies, and services that relate to human health. Revenue recognition issues arise not only from the sale of drugs and medical devices, but increasingly from arrangements between entities in the industry to develop and bring products to market. Entities in the pharmaceutical and life sciences industry often enter into arrangements to develop drugs, either as a supplier of services, a consumer of those services, or through execution of license arrangements. These complex transactions are impacted by the new revenue standard.

This supplement focuses on how the standard will impact entities in the pharmaceutical and life sciences industry and it contrasts the new revenue standard with current practice under U.S. GAAP and IFRS. The examples and related discussions are intended to provide areas of focus to assist entities in evaluating the implications of the new standard.

National Professional Services Group | CFOdirect Network – www.cfodirect.pwc.com   In depth 1

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About PwC's Pharmaceutical and Life Sciences Industry Group

PwC's Pharmaceutical and Life Sciences practice, part of PwC's Health Industries Group, is a leading advisor to public and private organizations across the entire health industries landscape. This group also includes PwC's Health Research Institute, which provides new intelligence, perspectives, and analysis on trends affecting health-related industries. We provide industry-focused assurance, tax, and advisory services to build public trust and enhance value for our clients and their stakeholders. More than 185,000 people in 157 countries across the PwC global network share their thinking, experience, and solutions to develop fresh perspectives and practical advice.

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