WINTER 2015
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THE NEWSLETTER OF THE BDO TECHNOLOGY & LIFE SCIENCES PRACTICE

BDO LIFE SCIENCES LETTER

WILL BIOTECHS CONTINUE TO BLAZE IN 2015?

By Ryan Starkes

A recent *New York Times* article noted that the biotech industry is often overshadowed by their high-tech neighbors in Silicon Valley, like Google and Apple. But after stellar performance in 2014, life sciences companies are stepping out of the shadow into the limelight. The outlook for the industry in 2015 may be best summarized by one word: opportunity.

FLOWING CASH

Despite fears of a bubble, the biotech industry has continued to outperform. In fact, according to *Benzinga*, biotechnology has been the second-best performing industry over the last two years. In 2014, the NASDAQ Biotechnology Index increased 35 percent, according to *The New York Times*, which is especially notable when compared with the positive 11 percent increase that the S&P index saw last year. Cash is flowing into private biotechs as well, with venture capitalists taking a record 58 biotech companies public in 2014, according to *Dow Jones VentureSource*.

As cash continues to flow and interest in life sciences companies remains high, investors are optimistic about the year ahead.

FRUITFUL RESEARCH

Investors, strategic buyers and private buyers paying attention to biotechs are all buoyed by a strong pipeline of drugs and increased approvals. According to *Reuters*, the FDA approved 41 novel medicines in 2014, 14 more than a year earlier, and the most drugs

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DID YOU KNOW...

According to the 2015 ***BDO IPO Outlook***, 69 percent of capital markets executives surveyed predict an increase in IPO activity in biotech.

By 2020, specialty and biologic drugs requiring complex manufacturing protocols will make up more than half of industry sales, according to ***Pharmaceutical Executive***.

The ***U.S. Food and Drug Administration's Center for Drug Evaluation and Research*** approved 41 novel medicines in 2014, up from 79 in 2013 and 57 in 2012. This has been its highest level of approval in 18 years.

Pharma Letter reports that fiscal growth is to continue into 2015—driven by M&A and innovation—after statistics showed the Nasdaq Biotechnology Index rose by 35 percent in fiscal year 2014.

BloombergBusiness reports that there were more than $220 billion of drug-company acquisitions in 2014—a record for the industry.

In 2014, 69 of 100 healthcare IPOs were biotechs with returns averaging 31.7 percent, according to ***Renaissance Capital.***

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approved in nearly 20 years. This increase is significant, particularly when considering the high failure rate drug developers have historically experienced, as well as the lengthy road to approvals.

In addition to increased approvals, the types of new drugs and research results are particularly exciting. Advances in Hepatitis C treatment, eight new drugs that treat cancer and a resurgence in infectious disease drugs excited investors and consumers alike in 2014.

We also saw movement in biosimilars. In early March, the FDA approved the country's first biosimilar drug – Novartis' white blood cell-boosting Zarxio. While the future impact of biosimilars on the U.S. life sciences industry remains to be seen, some biotechs are investing heavily in development. *The Washington Post* reports that Amgen has nine biosimilars in development and expects to launch five of them over the next four years.

The outlook for the years ahead is also strong. According to *EP Vantage*, a dozen products due to be launched in 2015 are expected to reach blockbuster status by 2020.

FLURRY OF TRANSACTIONS

Perhaps the most prominent headlines in the biotech industry in 2014 were around the significant activity in deals and IPOs. *Silicon Valley Bank* notes that life science-related IPOs "rocketed" from 11 in 2012, to 37 in 2013, to 79 in 2014. Indeed, the healthcare industry overall was far and away the top contributor to IPOs in 2014—*Renaissance Capital* reports that healthcare accounted for 102 of 275 IPOs last year.

This year looks promising, as well. According to the 2015 BDO IPO Outlook, which recently polled 100 capital markets executives, 69 percent forecast an increase in biotech IPO activity in 2015, particularly notable when considering this comes on top of 2014's strong results.

The crop of newly public companies is also providing a bigger pool of acquisition candidates this year, according to *Bloomberg*. While M&A activity may have been outshined by IPOs last year, *Bloomberg* reports that 2014 saw $220 billion in drug acquisitions, an industry record.

Deal flow got off to a strong start this year. In January, Shire agreed to acquire NPS Pharmaceuticals for $5.2 billion, and *FierceBiotech* notes that Pfizer is sitting on $33 billion in cash that's ready for acquisitions. Companies sitting on cash are also likely to to fuel growth through takeovers of younger drugmakers with promising products in strategic categories like cancer and rare diseases this year. Moreover, according to Pharm Exec, deal pace will continue its strong track throughout 2015 as the cost of capital remains low and investor interest remains high.

With opportunity and optimism fueling the biotech flame, the industry is heading in a direction that key players would agree is a positive one. The increase of approvals, new drugs and research emerging in the market and additional acquisition candidacies taking place, all point to a bright and promising future for both early-stage and established companies.

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INTRODUCING THE BDO KNOWS **HEALTHCARE BLOG**

The BDO Center for Healthcare Excellence & Innovation is pleased to launch the BDO Knows Healthcare Blog, a new resource and discussion platform focused on critical issues impacting the industry and re-defining the future of care. Posts come from prominent industry thought leaders with a wealth of knowledge and experience in both business advisory and clinical practice. They explore how reimbursement and regulatory changes are re-shaping provider and payor business models, covering both the financial and clinical implications and drawing on our depth of experience in healthcare finance, operations and clinical practice. They also touch on the myriad compliance and risk management challenges healthcare organizations face, as well as M&A and capital strategies.

In today's increasingly complex healthcare environment, we understand that collaboration is crucial to creating robust organizational change.

We invite you to join us on this journey at http://healthcareblog.bdo.com.

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HOW COMPLIANCE OFFICERS ARE ADDING TO THE BOTTOM LINE: RESEARCH TAX CREDITS AND RECENT DEVELOPMENTS

By Chris Bard & Chai Hoang

Last year, pharmaceutical and life sciences (PLS) companies reported more than an estimated $2 billion in federal and state tax credits for conducting research. Dollar-for-dollar offsets against tax liability, the credits are helping these companies increase their cash flow and earnings per share, as well as reduce their effective tax rate. And while it's not their primary responsibility, many PLS compliance officers are helping identify and support qualified activities, aided by recent developments in the research-credit area.

RESEARCH TAX CREDITS: AN OVERVIEW

PLS companies that attempt to develop new or improved products, manufacturing processes, software, techniques, inventions and formulae are eligible for federal and state tax credits up to as much as 15 percent of "qualified research expenses" (QREs).

Generally, QREs include taxable wages paid to employees and a percentage of expenses paid to contractors who undertake these efforts, as well as the cost of supplies used in the research.

For PLS companies, QREs typically include preclinical and clinical expenses, as well as some post-clinical expenses, for product and process initiatives in biology, pharmacology, chemistry, drug metabolism, pharma development, analytical chemistry, pharma tech, drug safety, biostatistics, clinical R&D, medical services and medical affairs. In addition, some expenses incurred by drug surveillance and regulatory affairs departments can qualify (e.g., if they directly support qualified research). Activities don't have to succeed to qualify, and the nature of the activities—not the background of the people performing them—determines whether they qualify.

HOW COMPLIANCE IS HELPING WITH RESEARCH CREDITS

Due to its involvement in monitoring and reporting on the activities of business units throughout all areas and functions of a PLS company, the compliance department is often well positioned to help identify, document and support qualified activities and QREs, even if it's just helping other departments do so.

IRS Pharma Guide

One compliance officer at a mid-size pharma company reviewed and shared with her Tax Department the Internal Revenue Service's (IRS) *Pharmaceutical Industry Research Credit Audit Guidelines (IRS Pharma Guide)*. This document provides audit technique guidelines for IRS agents and managers examining PLS research credits, including identifying audit areas that have the lowest and highest probability for errors.

Leveraging the *Pharma Guide*, the compliance officer and Tax Department developed easy-to-make modifications to the company's accounting and documentation systems to enable the company to track its qualified activities and spending in a closer-to-real-time and more-research-tax-credit-friendly manner. This not only saved them time when reporting their research tax credits; it also created the kind of contemporaneous documentation tax that examiners favor.

Certification Statement

The compliance officer at a larger PLS company leveraged another recent IRS program to help reduce its compliance burden regarding research tax credits.

Initiated in December 2012, the program instructs IRS agents not to challenge expenses reported and certified as QREs if the taxpayer certifies that they were incurred in the discovery and preclinical and clinical stages of development, for "qualified research," and not for activities excluded by statute.

Although the company still needs to be prepared to provide records to support its QREs, the IRS will likely spend less time examining expenses incurred during the discovery, preclinical and clinical stages of development than it used to, and allow a higher percentage of those expenses.

A SIMPLIFIED WAY TO CLAIM THE CREDIT EXPANDED

There are two general ways to calculate the research credit: Regular and Alternative Simplified. Sometimes the Regular Credit is larger than the Alternative Simplified Credit (ASC); other times, it's smaller. Sometimes one is zero, and the other is significant.

Therefore, it is important to calculate the credit both ways to effectively factor the size of the credit into the decision about which one to report. Another factor that should be considered: The Regular Credit sometimes requires that its calculation include gross receipts and QREs from tax years 1984 through 1988, whereas the ASC, as its name implies, is a "simplified" method that requires only QREs for the current tax year and three prior tax years.

Some taxpayers, though, currently don't benefit from the research credit, and so they don't think it's worth the time or expense to calculate the credit one way, let alone both ways (e.g., taxpayers in a loss or Alternative Minimum Tax (AMT) position). Up until recently, taxpayers weren't allowed to elect the ASC on amended tax returns, so these taxpayers missed out on the opportunity to claim the ASC later—either when they became profitable or came out of AMT. As a result, some PLS companies lost literally millions of dollars of ASCs, because their Regular Credits were significantly smaller than their ASCs, and they weren't allowed to elect the ASC on an amended return.

Recent regulations have addressed this problem and, generally, taxpayers can now

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claim the ASC on amended returns. In addition, loss and AMT taxpayers who have never reported research credits can go back 15 years and identify research credits for each of those years; if the credits couldn't have been used in an earlier tax year, they can carry them forward into the current tax year.

EXECUTIVE COMPENSATION, PATENT EXPENSES & METHODOLOGY

Another development compliance officers and PLS companies generally can leverage is a recentlydecided U.S. Tax Court case, *Suder v. Commissioner*. *Suder* supports the following taxpayer-friendly points:

CEOs' and other officers' activities can qualify. In *Suder*, the CEO was held to have performed qualified activities 75 percent of the time, including attending strategy meetings, brainstorming ideas for new products and ways to improve existing products, and reviewing and signing off on specifications. A high percentage of other officers' time was allowed as qualified, as well.

Patent research and prosecution expenses. The Tax Court also permitted expenses paid to law firms for patent research and patent prosecution as QREs. This seemingly small detail in the case is significant because of the numerous patents filed by PLS companies. The legal basis for the court's ruling has been questioned by commentators, however, so these expenses should be reported with the expectation that the IRS may continue to challenge them.

Methodology to identify QREs. Tax examiners sometimes disallow research credits, claiming that taxpayers haven't adequately substantiated the "nexus" between particular QREs—like a particular employee's taxable wages—and the products or processes on which he or she performed qualified research. The case of *Bayer Corp. v. United States*, No. 2:09-cv-0035, 2012 WL 393469 (W.D. Pa. Feb. 6, 2012) required separate identification of all products and processes. *Suder* helps confront this claim, with the Tax Court giving considerable weight to the oral testimony and representations of the Senior Vice President of Product Operations.

TALES FROM THE JPMORGAN HEALTHCARE CONFERENCE: A BULLISH OUTLOOK FOR BIOTECH

By Dr. Scott Gottlieb

The mood was decidedly upbeat at January's JPMorgan Healthcare Conference in San Francisco, the largest annual meeting for the healthcare industry.

Presenters shared their optimism for the industry's future, pointing to the fact that the investment landscape has been strong this past year, and many healthcare segments experienced a robust market, including hospitals, managed care and healthcare information technology. Performance was particularly robust in the life sciences sector, evidenced by the 82 biotech IPOs completed in 2014, according to BioSpace. In total, $5.5 billion was raised by biotech initial public offerings in 2014 and even more was raised in a plethora of secondary offerings and debt issues.

But the question on many attendees' minds was whether the underlying fundamentals in the life science space had shifted, justifying the outperformance – or are we due for a correction?

While it's hard to predict whether the equity markets will remain as hot as they were in 2014, there are some reasons why the life science industry will continue to enjoy certain tailwinds and could show resilience if the broader markets stutter:

- Science that has been percolating for more than two decades is now manifesting in the form of new drugs, such as techniques to manipulate immune cells to fight cancer or tools that allow us to use gene therapy to essentially cure diseases.
- Investors and companies are also flush with resources, having benefited from a multi-year bull market. That collective capital will continue to support the sector.
- There's a palpable sense that the Food and Drug Administration has finally started to make the path to market more efficient, especially when it comes to "breakthrough" drugs that are targeted to unmet medical needs. In fact, the FDA approved 41 new drugs in 2014, one of its highest totals ever.
- Legislation is likely to advance in Congress this year (the MODDERN Cures Act) that will seek to make FDA's regulatory scheme more efficient, transparent, and predictable. Those political headlines will continue to support the perception that the FDA process is becoming more cordial to innovation.

While the boom years in biotech may eventually slow, there is reason to believe that the improved outlook represents more than just another bubble, and the industry is on a path for continued strong performance.

Read more at the BDO Knows Healthcare blog.

Dr. Scott Gottlieb is a practicing physician and Resident Fellow at the American Enterprise Institute. He is a Senior Fellow with BDO's Center and has been named as one of the Top 30 Social Influencers in Biotech by the Huffington Post. He can be reached at scott.gottlieb@aei.org.

Conclusion

The R&D tax credit is a great opportunity for PLS companies, one that many compliance officers are helping to realize. Before reporting the research credit, please consult with a tax professional with expertise in the area.

This article originally ran in *Pharmaceutical Compliance Monitor* on Dec. 1, 2014. You can view the online piece here.

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THE 340B "MEGA-REG" IS GONE, BUT NOT FORGOTTEN

By Venson Wallin, Managing Director and National Healthcare Compliance and Regulatory Leader, The BDO Center for Healthcare Excellence & Innovation

Parting is such sweet sorrow.

So says William Shakespeare in *Romeo and Juliet*. The Health Resources and Services Administration (HRSA) would no doubt agree with old Bill when it comes to the 340B Program's proposed "mega-reg." HRSA recently decided that the regulation that would have provided comprehensive 340B program guidance for hospitals and manufacturers would face insurmountable odds of implementation in light of the orphan drug ruling by the courts that found that HRSA has limited rulemaking authority. As a result, HRSA has withdrawn the "mega-reg" and will revisit guidance later in 2015.

The 340B Drug Pricing program requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices. HRSA's intention with the "mega-reg" was to provide clarifying guidance on the implementation of a 340B program. Manufacturers and federal officials were concerned that the program was being taken advantage of by health systems and that the original intent of the program (providing access to pharmaceuticals for those individuals who would otherwise not be able to afford them) was being lost to the chase for more program savings by those same health systems. The "mega-reg" would have addressed hospital eligibility, patient eligibility and contract pharmacy guidelines, among others. Not to be deterred, HRSA has indicated its intention to pick up the same issues in 2015. HRSA, on its website, states it plans "to issue a proposed guidance for notice and comment that will address key policy issues raised by various stakeholders committed to the integrity of the 340B program. HRSA is also planning to issue proposed rules pertaining to civil monetary penalties for manufacturers, calculation of the 340B ceiling price and administrative dispute resolution."

PhRMA (Pharmaceutical Research and Manufacturers of America) and its constituents are most likely torn over HRSA's decision to withdraw the "mega-reg." On one hand, they took on the government through their challenge of the applicability of the 340B regulations to orphan drugs and won, with the courts stating that HRSA does not have the authority to issue binding legislation except in very limited circumstances, orphan drugs not being one of them. While HRSA has appealed the ruling and issued interpretive rulings that still encompass orphan drugs, the ability to enforce those interpretive rulings is debatable. So PhRMA can certainly chalk this up as a victory of sorts. On the other hand, that victory comes with a price. That price is the perceived (based on the court's ruling) inability of HRSA to promulgate any substantial form of mandated guidance relative to the 340B program, thus, the withdrawal of the "mega-reg." As mentioned above, PhRMA and many of its members, as well as members of Congress, have been clamoring for more detailed guidance on the program to promote better stewardship of the program by its participants. The "mega-reg" had been a way of accomplishing that and minimizing the inefficiencies, duplications and other challenges that the 340B program currently presents to manufacturers. It is ironic that what is best for the manufacturers' business on one hand may in fact being detrimental on the other.

Health systems and pharmaceutical manufacturers should fully prepare for the eventuality of clarifying guidance from HRSA in 2015. Given the lobbying by manufacturers for more restrictive guidance and the increased focus on the part of federal officials, the push for more comprehensive regulations will only increase in intensity. The "mega-reg" itself may be gone, but its goals of more detailed program guidance are surely not forgotten. Manufacturers should prepare now with program assessments and minimize transition challenges when the guidance is issued.

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HEALTHTECH CONFERENCE: LOOKING BEYOND TRADITIONAL VENTURE CAPITAL FUNDING

Last quarter, BDO presented at the third annual HealthTech Conference in California. The conference brought together key healthcare industry players and focused on how emerging and established companies can develop their innovative products to adapt in a healthcare delivery system changing at viral speeds. The conference attracted a unique mix of professionals, such as providers, investors, payers, emerging companies and established organizations.

At the conference, **Aftab Jamil, a partner and leader of BDO's Technology & Life Sciences practice**, was a panelist for a discussion titled "Financing strategy and tactics beyond traditional VC," with Mark Cameron, senior vice president of Square 1 Bank's Specialty Finance Division, and Laureen DeBuono, a partner at FLG Partners.

Coming from diverse backgrounds, Aftab, Mark and Laureen provided participants unique insights and perspectives about the challenges, opportunities and strategies they have observed when working with public and private companies in various development stages that were pursuing traditional and nontraditional financing activities. Panelists also discussed the critical steps to evaluate and seek out different nontraditional financing options as well as the potential ramifications of certain terms typically contained under each financing opportunity. Lastly, the audience was informed about the steps and best practices that entrepreneurs can take to manage the overall process of employing various funding options.

Overall, conference attendees walked away with actionable takeaways to bring back to their respective teams, new ideas and strategies to fund the growth of their businesses and a more comprehensive outlook on different options available to entrepreneurs to launch and grow their businesses in the dynamic healthcare landscape.

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SEAL THE DEAL: CFOs PLAY CRUCIAL ROLE IN MINIMIZING POST-ACQUISITION DISPUTES IN THE LIFE SCIENCES INDUSTRY

By Jeffrey M. Katz, CPA/ABV, CFF, CFE

As discussed in the ***2014 BDO Life Sciences RiskFactor Report***, merger & acquisition (M&A) opportunities abound in the life sciences industry. With M&A transactions continuing to grow in the industry, it is important for CFOs involved in such transactions to understand the post-acquisition dispute issues that often arise after closing. CFOs who proactively consider common post-acquisition dispute issues before an agreement is reached can minimize the chances of being distracted with such post-closing disputes. Instead, they can focus on integrating the newly acquired business, driving operational efficiency and setting the company on a path for growth.

M&A agreements often contain a post-closing adjustment to the purchase price, which is generally intended to reflect differences in the balance sheet of an acquired company between the date a deal is negotiated and the date the transaction closes. While the metrics for adjustments vary from one agreement to the next, adjustments are often based on the change in a business' Net Working Capital, Net Assets and/or Company Debt. Disputes often arise because the parties to an M&A agreement have differing opinions regarding the amounts that should be recorded on the closing balance sheet. In the life sciences industry, these disputes often focus on the application of generally accepted accounting principles (GAAP) within the context of the terms of the M&A agreement.

For example, M&A agreements may contain language that requires the closing date balance sheet to be prepared in accordance with GAAP and consistent with a company's past policies, practices and procedures. Post-closing purchase price adjustment disputes often arise when a company's past practice is not in accordance with GAAP and the M&A agreement is silent on whether past practices or GAAP should prevail. Within M&A transactions in the life sciences industry, we often see this issue in regard to the accounting for chargebacks. Chargebacks often represent the largest difference between gross revenue and net revenues for life sciences companies. The amount of chargebacks recorded by a company is an estimate. The seller of a business commonly has a methodology it utilizes to record that estimate in the financial statements. If the buyer of a life sciences business prepares the closing balance sheet, it may argue that the seller's methodology for recording chargebacks did not result in a GAAP-compliant number, thereby resulting in the accounts receivable being overstated. CFOs can play an important role in minimizing transaction disputes by suggesting clarifying language in the agreement that specifies which methodology takes precedent. For example, the parties to a transaction could add a clarifying statement in the M&A agreement, which states whether GAAP or the past practice prevails, if in fact there is a difference.

As CFOs are aware, GAAP requires management to make judgments and estimates in preparing financial statements. However, in an M&A transaction, buyer management and seller management might have differing estimates for the same balance sheet item, yet both estimates may be in accordance with the technical requirements of GAAP. Life science companies may have products in inventory available for sale that have expiration dates in the near future (short-dated products). Such inventory items can lead to disagreement between buyer and seller management post-closing regarding the carrying value of these materials. For instance, buyer management may view these materials as having no value because they will not be able to sell all of them before the expiration dates, and therefore require a reserve on the closing date balance sheet. However, the seller management could argue that these materials are not worthless because they can be sold at a discount, though still above cost. Additionally, some products can be recertified and assigned a new expiration date. CFOs involved in an M&A transaction in the life sciences industry may want to suggest the inclusion of language in the agreement that removes the subjective nature of such estimates. For example, the parties might agree to a formula-based approach to recording such amounts in the closing balance sheet.

In addition to Net Working Capital adjustment provisions, many M&A agreements contain earn-out provisions intended to bridge the differing views of the buyer and seller on the value of a business. Because these provisions

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frequently have a financial-related metric that the seller needs to achieve in order for the buyer to pay the additional purchase price, it is important to be aware of changes in GAAP that could impact an earn-out calculation. For example, the Financial Accounting Standards Board (FASB) and the International Accounting Standards Board (IASB) recently issued new revenue recognition guidance intended to provide information in financial statements about the nature, timing and uncertainty of revenues from contracts with customers. While most of the changes do not go into effect until 2017, CFOs should be aware of how these changes might impact M&A transactions.

While earn-out provisions are not included in every life sciences M&A transaction, it serves as a good example to highlight how changes in GAAP can impact an M&A transaction. Because earn-out targets are often based on historical financial performance projected for future performance, the revenue recognition changes can result in establishing future financial targets according to current guidance, even though the actual future financial results will be calculated using the new revenue recognition standard. This inconsistency could result in post-closing issues because the seller may or may not earn contingent consideration solely due to a change in GAAP and not the underlying performance of the company. CFOs can add value to the deal team by making sure that changes in GAAP are taken into account when the parties are negotiating the terms of an M&A agreement.

The more CFOs take the time early on to consider common M&A post-acquisition dispute issues, the more proactive they can be in providing guidance to deal teams negotiating the terms of an agreement. Furthermore, understanding that M&A agreements are subject to interpretation and disagreement between the buyer and seller gives CFOs the advantage of minimizing post-acquisition disputes so they can avoid distraction and focus on a seamless integration with the newly acquired business.

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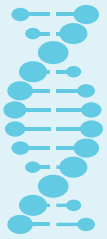
PErspective in Life Sciences



THE LIFE SCIENCES INDUSTRY IS FLUSH WITH CAPITAL AND AT THE PEAK OF AN UNPRECEDENTED IPO BOOM.

Industry watchers are wondering when the bubble will burst, but for the time being dealmakers are making hay while the sun shines. Last year saw over 110 biotech IPOs, raising a record $9 billion, according to BioCentury. Additionally, Investor Place reports that in 2014, 18 biotech IPOs posted gains of more than 100 percent—more than any other sector. The trend looks set to continue in the short term at least: shares in gene therapy firm Spark Therapeutics more than doubled in their January debut, valuing the company at nearly $1.5 billion, according to Reuters.

M&A activity is also strong. Despite high valuations, pharmaceutical companies are on the lookout for promising new treatments to add to their drug pipelines, and last year's hot IPO market adds new potential takeover targets to the mix, according to *Bloomberg*. January saw five deals with headline values of $1 billion or more, according to *PMLive,* a pharmaceutical market journal.

Venture capital exits were a huge part of last year's success story. Some 58 venture-backed biotech companies went public in 2014, reports *Dow Jones VentureSource*. Overall, 16 of the 27 VC-backed fourth quarter IPOs were for life sciences companies, according to *The Wall Street Journal's Venture Capital Dispatch* blog. Biotech venture funding reached a record $6 billion in 2014, with $2 billion worth of new deals in the fourth quarter alone, according to *FierceBiotech*.

Last year also saw record average total VC-backed M&A deal values of $420 million, and total upfront deal values of $68.4 billion in the U.S., in what was the best year for VC-backed biopharma exits over the last decade, according to HBM Partners, a healthcare-focused investment firm. The largest sales of VC-backed companies included Johnson & Johnson's $1.75 billion acquisition of antivirals developer Alios BioPharma, and the sale of Seragon to Genentech/Roche for $725 million upfront, plus $1 billion in potential future payments.

But it is not only venture capital that has been pouring into the space, with private equity firms also backing biotech offerings, including the biggest launch of last year—the IPO of Juno Therapeutics, a pioneer in the hot field of immuno-oncology. The company—backed by Arch Venture Partners, Bezos Expeditions and Venrock—raised $265 million at a $2.2 billion valuation in its December IPO. Buyout firms sold nine PE-backed pharma companies in 2014, including Omega Pharma's sale to Perrigo Company for $4.5 billion in Europe, and the $2.9 billion sale of Aptalis to Forest Laboratories in the U.S. PE-backed pharma company exits have generated over $10 billion of annual transaction volume every year since 2010, according to HBM Partners' 2014 Pharma/Biotech M&A report. However, despite these significant volumes, PE-backed deal activity in the biotech and pharmaceutical industries still lags behind that of strategic buyers.

It remains to be seen how this will evolve. The industry is currently very well capitalized and many recent deals—such as Shire's $5.2 billion takeover of NPS Pharmaceuticals—have been all-cash deals. One thing remains clear: the recent rush of capital into the biotech industry will fund research and development for years to come.

PErspective in life sciences is a feature examining the role of private equity in the life sciences industry.

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OFFICE OF PHARMACEUTICAL QUALITY: A NEW OFFICE WITHIN CENTER FOR DRUG EVALUATION AND RESEARCH

By Loren Friedman and Dr. David Friend

The Food and Drug Administration (FDA) officially established this past January—within its Center for Drug Evaluation and Research (CDER)—the Office of Pharmaceutical Quality (OPQ), an office dedicated to a coordinated organizational approach to regulating pharmaceutical quality. The OPQ will be able to provide improved oversight and an overall approach for the regulation of drug quality through the application of a centralized pharmaceutical quality product review, evaluation, inspection and surveillance over the life cycle of the drug product.

Originally introduced in 2012, the implementation of the OPQ has most recently come into focus with the increased prevalence of both domestic and international drug quality issues, as well as the ever-expanding global nature of pharmaceutical drug manufacturing. The OPQ was established to address these issues and provide consistent standards and expectations for quality through clear regulations and a transparent, efficient review process "across both domestic and foreign manufacturing sites, as well as across all drug product areas." [1]

The OPQ has adopted an organizational structure which will consist of eight offices/divisions, working in collaboration to oversee the drug manufacturing process through a product's entire life cycle—whether the product is brand-name, generic, or an over-the-counter pharmaceutical drug. [2]

There will be an increased emphasis and focus on collaborative internal organizational relationships within the OPQ offices/divisions, which will encourage review and inspection through the application of "team-based processes." Such collaboration, it is believed, will ultimately result in more highly effective life cycle drug quality evaluations through an enhanced alignment of review, inspection and research, while maximizing focus and efficiency of such regulation. For example, the OPQ proposes to have an integrated team consisting of members of multiple offices/divisions for generic drugs that will collectively review the quality of the product by dosage form, as well as review the facility and manufacturing process and assess the need for inspection and surveillance.

Ultimately, the establishment of the OPQ will provide a better barometer of production quality and an enhanced ability to ensure that quality drugs are available. This will include an improved ability to identify and help prevent potential shortages. It will also provide a significant benefit to drug manufacturers, as the OPQ will result in improved feedback on quality deficiencies earlier in the review cycle through a more targeted and efficient review process. This will result in a reduction in the time required for regulatory approval. In addition, the application of consistent quality standards and clear expectations will also, hopefully, require fewer repetitive reviews. In short, these policy changes and improved organization processes will enable greater innovation and improvement in drug manufacturing.

Overall, the OPQ is a significant change in the approach to regulating the drug quality and will require a substantial effort by the FDA. The implementation of a single unit dedicated to providing consistent quality standards through policy changes and coordinated organizational process improvements will be a multi-year process. Undoubtedly, it will undergo multiple iterations over the coming years to determine whether the OPQ is achieving the intended quality impact. Moreover, the OPQ plans to seek the input from external stakeholders, including experts in industry and professional societies throughout the process. With improved product and facility quality, the OPQ can better ensure that quality drugs are consistently available, while better aligning its function with the drug manufacturing industry.

1 http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm418347.htm; "New CDER "Super Office" to Promote Drug Quality, Jill Wechsler, PharmExec.com, October 17, 2014

2 In creating this new structure, there was the necessity to re-align the organizational process. As such, some of the drug quality functions within the Office of Pharmaceutical Science ("OPS"), the Office of Generic Drugs ("OGD"), the Office of Compliance ("OC"), and the Office of Manufacturing and Product Quality ("OMPQ") have been transitioned to the OPQ.

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OFFICE OF PHARMACEUTICAL QUALITY

Office of Pharmaceutical Quality Organizational Structure	
Office/Division	**Function**
Office of Program and Regulatory Operations (OPRO)	Develop, implement, and monitor the internal OPQ processes and procedures to support the drug quality reviews and inspections
Office of Policy for Pharmaceutical Quality (OPPQ)	Establish, develop, assess, and maintain scientifically sound and clear standards and providing relevant guidance and policies which support the same Consistent with the application of the aforementioned, it will provide clear and understandable enforcement policies through an overall quality management and evaluation system (employing both qualitative and quantitative assessments) Will support the FDA Council on Pharmaceutical Quality, the Center for Biologics Evaluation and Research, and the Office of Regulatory Affairs, amongst others
Office of Biotechnology Products (OBP)	Research and regulate the development, testing, and manufacturing of biological products and biosimilar biological products Will apply risk-based quality assessments of the product and manufacturing processes
Office of New Drug Products (ONDP) [3]	Will process Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC) applications for new drugs and conduct risk-based assessment of, amongst other things, product quality standards and conveys recommendations on approvability. Liaison to the CDER's Office of New Drugs
Office of Lifecycle Drug Products (OLDP) [3]	Will process Pharmaceutical Quality/CMC applications for generic drugs, as well as conduct risk-based assessment of, amongst other things, both the product quality standards of the brand and generic products so as to ensure that the generic version adequately mirrors the innovator drug product as lifecycle changes are made [SOURCE]
Office of Testing and Research (OTR)	Conduct research to establish quality, safety, and effectiveness standards on drug products Research includes the testing and analysis of new technologies and bioavailability/bioequivalence issues so as to conform regulations accordingly
Office of Process and Facilities (OPF)	Risk-based analysis to evaluate and assess manufacturing process and site to determine that the applicant can manufacture quality products Includes the pre-approval, pre-license, and post-approval inspection programs Will work closely with other OPQ offices to establish clear standards for review and inspection
Office of Surveillance (OS)	Develop, implements, and manages systems and platforms to monitor, assess, and report on the state of the inventory and production facilities for the regulated manufacturers, including the use of metrics

Source:
FDA Drug Quality Regulation (CDER Small Business - Regulatory Education for Industry (REdl) June 2014); Brian Hasselbach, Director (acting), Division of Policy, Collaboration & Data Operations; Associate Director (acting), Policy and Communications; Office of Manufacturing and Product Quality; Office of Compliance, CDER, FDA

3 The interplay of the ONDP and the OLDP serve as a prime example of the OPQ's aspiration to review, evaluate, and inspect the drug product across the drug regulation lifecycle, applying clinically relevant specifications.

Sources:
1. Office of Pharmaceutical Quality; Global Drug Development and its Impact on CDER's Drug Review Process Symposium, June 24, 2014; Robert Iser, Associate Director for Policy Development (acting), OPS; Member OPQ Transition Team & OPF Transition Sub-Team
2. FDA Drug Quality Regulation (CDER Small Business – Regulatory Education for Industry (REdl) June 2014); Brian Hasselbach, Director (acting), Division of Policy, Collaboration & Data Operations; Associate Director (acting)
3. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm418347.htm
4. CDER Creates "Super-Office" to Keep Closer Eye on Drug Quality, Genetic Engineering and Biotechnology News, http://www.genengnews.com/, October 16, 2104.
5. FDA Announces Major Agency Reorganization, With Focus on Drug Quality, Alexander Gaffney, RAC, www.raps.org, October 16, 2014
6. FDA/CDER's Office of Pharmaceutical Quality

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Huntington Beach, Calif.

APRIL 2015

April 10
Early-Stage Life Sciences Technology Conference X
Merck Research Laboratories
Boston, Mass.

April 21-23
Bio-IT World Conference & Expo
Seaport World Trade Center
Boston, Mass.

April 29-30
Advances in Processed Analytics and Control Technology (APACT) 2015
Hilton Manchester Deansgate
Manchester, United Kingdom

MAY 2015

May 26-27
The Boston Biotech CEO Conference
Four Seasons Hotel
Boston, Mass.

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