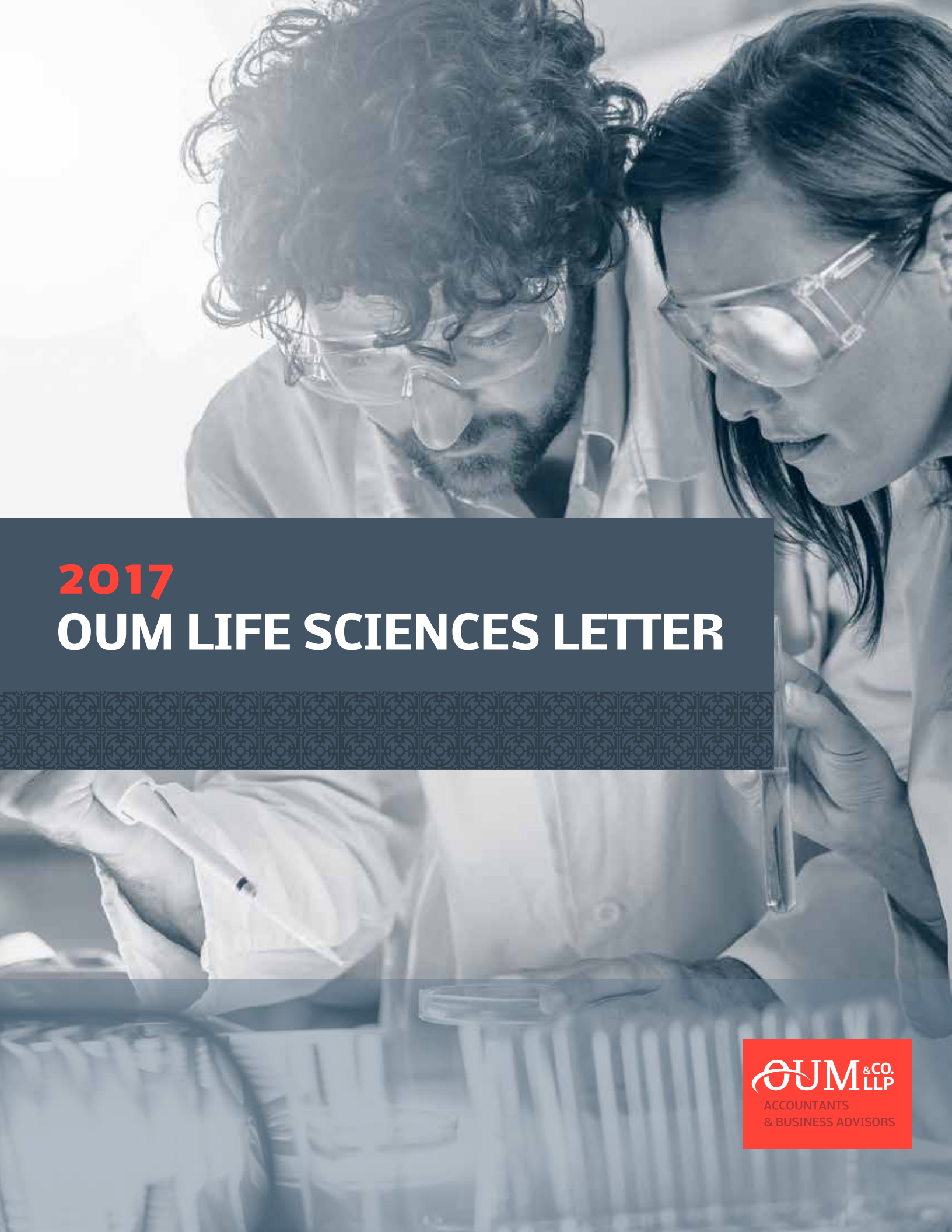

2017
OUM LIFE SCIENCES LETTER

OUM & CO. LLP
ACCOUNTANTS
& BUSINESS ADVISORS

LIFE SCIENCE COMPANIES NEED TO RETHINK GLOBAL IP HOLDING STRUCTURES

By Yosef Barbut and Ryan Starkes

Recent global international tax developments, coupled with potential U.S. tax law reform require a rethinking of current intellectual property (IP) holding structures used by U.S.-based life science companies, including big pharma.

CHANGING TAX LAWS AND ACCOUNTING RULES LANDSCAPE

In late 2015, the Organization for Economic Co-operation and Development (OECD), an umbrella organization of 20-plus countries that recommends tax law, commerce and trade guidelines to its member states, issued its Base Erosion and Profit Shifting (BEPS) guidelines. The BEPS guidelines are a set of 15 actions concerning global tax rules related to transfer pricing, permanent establishments, aggressive tax planning including use of IP holding structures, and more. These actions are designed to combat aggressive international tax planning that has caused significant erosion in the tax revenue base of major industrialized countries, and to promote greater transparency around transfer pricing and the use of certain tax-driven structures.

Many countries have already begun implementing BEPS-compliant tax laws. The United States has recently implemented BEPS guidance related to country-by-country reporting, which will require the disclosure of certain critical information that can be accessed by the taxing authorities of all member states. Additionally, the European Union (EU) has been pushing to eliminate certain tax benefits in its member countries that, under EU state aid law, are considered anti-competitive and unfair.

This article explores a confluence of global tax law developments, changing U.S. accounting rules, and a U.S. tax law environment ripe for major tax reform–the likes of which has not been seen since President Reagan. These developments, both individually and collectively, could force the modification of current IP holding structures and a new approach to global tax planning.

THE CURRENT U.S. ENVIRONMENT

The U.S. market continues to exhibit high demand for healthcare services and medical drugs. This trend is likely to continue as more medical drugs and therapeutically administered treatments are discovered to support a growing retirement population. Historically, the United States has been considered a desirable location to undertake research and development activities, and register and own patents and intellectual property (IP), due to advanced patent and IP laws. However, for income tax purposes, the economic ownership of IP is typically divided, putting the non-U.S. market rights to exploit the IP in tax-favorable jurisdictions. For example, Ireland, Singapore, the Cayman Islands and other low-tax jurisdictions might own the economic rights for sales of medical drugs and devices in non-U.S. markets. The benefit is a favorable industry global average effective tax rate ranging from 20 to 25 percent, which is much less than the U.S. federal rate of 35 percent.

A low effective tax rate is achieved because foreign income is generally taxed at an average rate significantly lower than 35 percent, and U.S. tax rules allow tax deferral of foreign business income until the income is repatriated as dividends or gains. The FASB's longstanding accounting rule related to foreign earnings also works in favor of U.S. companies with significant foreign operations. Management of U.S. corporations can represent that foreign income is indefinitely reinvested outside the United States, provided sufficient evidence of reinvestment plans exist. This intent-based accounting rule effectively allows management to indefinitely avoid recognition of the deferred U.S. tax liability that would be incurred if low-taxed foreign earnings were repatriated to the United States.

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OUM's life sciences practice professionals have the expertise, resources and relationships to assist both public and private life science companies bridge the gap between business and science in today's volatile business environment. Our life sciences group serves publicly traded and privately held companies in the biotechnology, specialty pharma, diagnostic, medical device and other sectors. We understand the need to manage for immediate and long-term value in the face of lengthy, high-cost research and development cycles, government approvals, and difficult clinical trials.

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OUM is one of the leading CPA firms in California, with offices in San Francisco, San Ramon and the San Diego area. We have over 80 professional staff and many of our partners and senior managers were previously partners and managers at Big 4 firms. Since 2000, the San Francisco Business Times has included OUM in their annual ranking of the "Top 25 Largest Bay Area Accounting Firms." We have also been included in Inside Public Accounting's annual list of the "Top 200 Accounting Firms in the Nation."

In 2004, our firm became an independent member of the BDO Alliance USA, a nationwide association of independently owned local and regional accounting, consulting and service firms with similar client service goals. Our membership in the BDO Alliance USA affords us access to national and international resources, technical experience, specialized knowledge, quality assurance, high caliber training, and the latest technical and reporting developments.

Our firm has been registered with the Public Company Accounting Oversight Board (PCAOB) since its inception. The PCAOB examines our assurance work papers at least every three years. We are currently the independent audit firm for thirteen public companies. The AICPA also examines our assurance work papers every three years, and has always issued unqualified opinions on our non-public assurance practice, most recently in November 2014.

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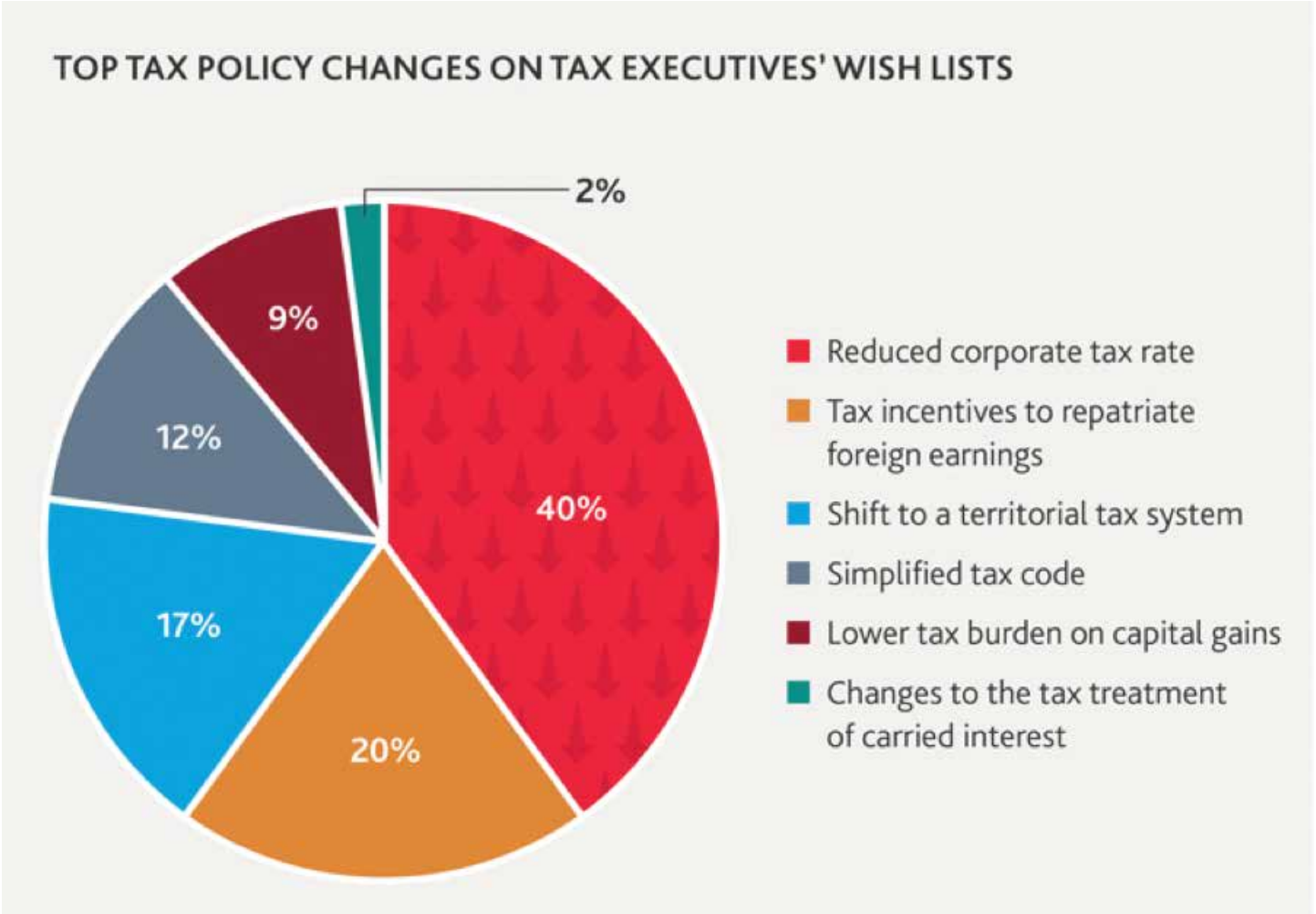
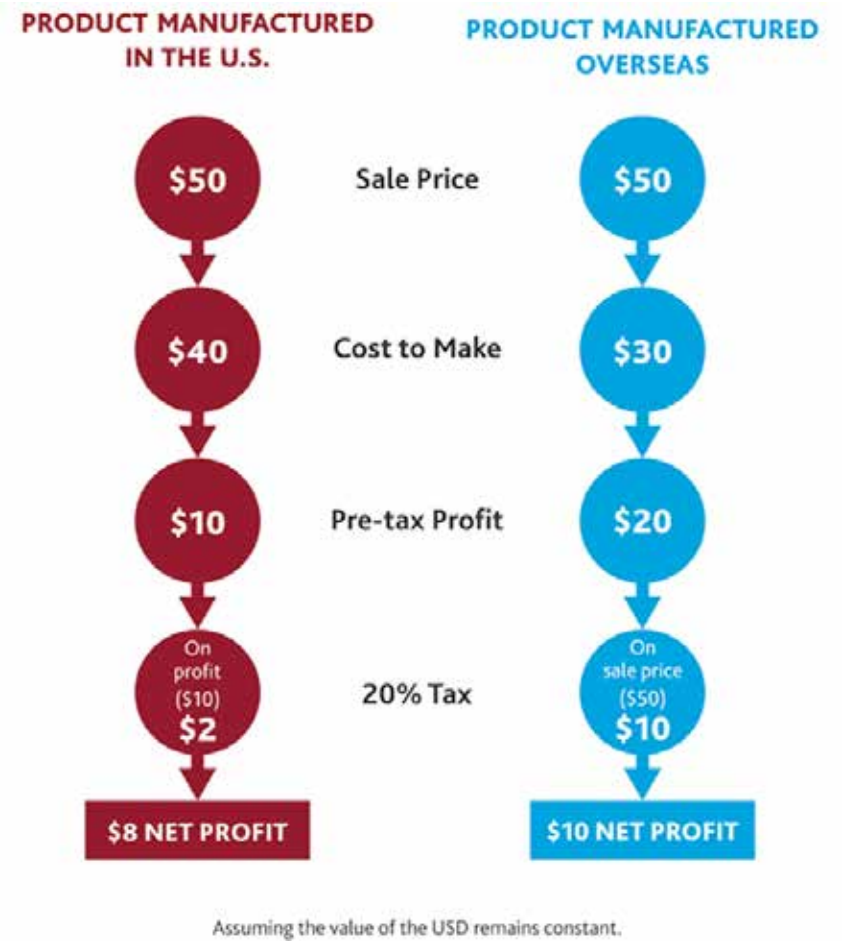
To implement a tax-efficient global IP holding structure, U.S. companies generally transfer the non-U.S. IP rights to controlled foreign subsidiaries. The transfers can take many forms and be taxable or tax-deferred transactions. Currently, a taxable outbound transfer of IP would trigger taxable income (measured on the fair market value at the time of transfer) but not tax expense for financial reporting under historic U.S. GAAP, and in some cases, no cash tax outlay assuming an appropriate utilization of net operating loss and tax credit carryforwards. The rule addressing intercompany transfers of property requires the current and deferred tax from an intercompany transfer of IP to be deferred until the income is recognized in the consolidated income statement, which can be many years into the future. The rule is considered an accounting exception to the comprehensive recognition of income taxes. It effectively spreads the tax consequence over the periods the income is earned and recognized for financial reporting purposes.

CHANGING U.S. ACCOUNTING RULES (ASU 2016-16)

In 2016, the FASB issued an accounting standard update (ASU 2016-16), removing the exception for intercompany transfers. The new rule, which goes into effect on Jan. 1, 2018, for calendar fiscal years will require full recognition of current and deferred income taxes from intercompany transfers of all property–except inventory–when the transfers occur, even though the intercompany pretax profit would still be eliminated and recognized in future periods. The impact will be significant. For example, an outbound transfer of IP from a U.S. parent to a foreign subsidiary in Ireland would trigger recognition of U.S. and Irish income tax effects (tax rates of 35 percent and 12.5 percent, respectively). Assuming the fair market value of the IP on the transfer date is $10 million, a taxable transfer would result in a $3.5 million U.S. tax expense (assuming zero tax basis for internally-developed IP) and a $1.25 million tax basis step-up in Ireland (net tax effect of $2.25 million). Prior to ASU 2016-16, this net tax effect would be deferred and recognized over several years (typically more than 10 years for drugs). Under ASU 2016-16, the net tax effect is recognized when the asset is transferred. This will mean no more spreading (over multiple periods) the tax consequence from intercompany transfers of IP and other assets.

The significance of this change should be considered in the new international tax landscape. For example, a multinational entity that currently owns the non-U.S. rights in a "zero" tax jurisdiction might have to restructure and transfer such rights to another foreign country where the tax rate is more than zero but is sustainable under BEPS-compliant rules requiring operational substance.





LOOMING U.S. TAX REFORM

With a new administration in Washington, there are high expectations of major tax reform. Details are still scant and current ideas are speculative at best. However, there are four proposals for potential tax reform that will be deliberated extensively. First, the U.S. corporate tax would be reduced from 35 percent to 20 percent, or a potentially lower rate of 15 percent. Second, the United States would adopt a territorial system whereby foreign source business income of U.S.-based multinationals would not be subject to a U.S. tax at all. Third, export income generated from the United States would be tax exempt, while import income would effectively be taxed at a higher rate by denying a U.S. deduction for the cost of goods imported into the United States. Fourth, U.S. corporations would receive a one-time "tax holiday," allowing them to pay reduced U.S. tax rates on profits generated and accumulated overseas.

Take a look at the chart above for a look into what's at the top of U.S. tax executives' wish lists.

If any of these ideas are eventually enacted, it could create a new global tax planning environment for U.S.-based businesses. The tax policy objectives of creating a competitive U.S. tax system and enticing investments and retention of capital in the United States could lead to reconsideration of current IP holding structures and to changes in supply chains (manufacturing, distributions, sales and support). A low corporate tax rate, complete exemption of foreign income (i.e., a territorial system), and export income tax benefit (i.e., the border-adjustment proposal) combined could transform the United States into a more desirable tax jurisdiction for IP holdings. These developments may have a significant impact on global IP structures and financial reporting.

Take a look at the graphic above for an illustration of the border-adjustment concept.

INSIGHTS

Numerous global tax law changes instigated by BEPS and the EU's state aid laws are forcing reconsideration of global tax structures that may require modifications to IP holding structures.

Financial reporting disclosures of material-enacted changes are important to keep users of financial statements informed about current and expected tax burdens. The accounting standard change required by ASU 2016-16 will cause tax rate volatility when IP (or other property, except inventory) is transferred via intercompany transfers, which will give greater prominence to material intercompany transfers and force greater transparency of IP holding structures and tax planning. However, uncertainties about potential U.S. tax reform might necessitate a "wait-and-see" approach before current IP holding structures are significantly modified.

PRIORITY REVIEW VOUCHERS PROVIDE PHARMA A STARTING POINT WORTH BUILDING UPON

David B. Ridley Talks About Hopes for the Program's Future

By John Kwon and Jennifer Cook

As Congress and the new administration hone in on prescription drug prices, a 10-year-old program initially created to encourage the development of treatments for neglected and rare pediatric diseases is coming under fire. Priority Review Vouchers (PRVs), created by the FDA in 2007, are tickets to the front of the line of an often-lengthy FDA approvals process, holding significant value for companies on the receiving end.

But have they been successful in serving their original purpose–bringing more drugs that treat some of the world's most neglected diseases to market? David B. Ridley, a Duke University professor whose 2006 paper formed the basis for the PRV program, explores its evolution–its strengths and weaknesses, along with hopes for the future.

A HUMBLE ACADEMIC BEGINNING

In their 2006 paper, Ridley and his colleagues proposed that priority review be given to treatments of infectious and parasitic diseases. Ridley noted that these diseases, often labeled as "tropical diseases," are commonly neglected by major drug developers due to their low return on investment as the recipient populations are generally impoverished. Ridley argued that creating a voucher program would provide the market incentive needed for drug developers to treat some of the world's most neglected diseases. Lawmakers listened, and in 2007, the Food and Drug Administration Amendments Act of 2007 was passed, creating the Tropical Disease PRV system.

The tropical disease PRV, when redeemed, grants an expedited FDA review of about six months, compared to the standard 10 months. Examples of tropical diseases eligible for the voucher include Dengue and sleeping sickness, as well as Ebola and Zika, which were recently added to the list of eligible diseases.

The program was expanded in 2012 to include rare pediatric diseases, considered "orphan diseases," which suffer similar neglect by major drug developers as the number of patients impacted by the diseases is small, making it difficult for a company to recover its development costs. The rare pediatric disease vouchers only required the FDA to be notified 90 days prior to use and could be resold an unlimited amount of times. The Tropical Disease PRV system was amended in 2014 to align with the rare pediatric disease voucher regulations.

The first PRV was awarded under the tropical disease portion of the program to Swiss company Novartis AG in 2009 after qualifying for its drug Coartem, developed to treat malaria. Since the original PRV was awarded in 2009, an additional 12 PRVs have been awarded, three for tropical disease treatments and nine for rare pediatric diseases.

So far, just four of the 13 vouchers have been redeemed, resulting in three successful drug approvals. So, have we made any progress in treating some of the world's most neglected diseases?

MORE QUALIFYING DRUGS, BUT NONE TO MARKET

The PRV program has received mixed reviews. Criticisms of the program include the fact that the vouchers can be awarded for drugs that may already exist in international markets. The first voucher awarded to Novartis AG, for example, was awarded for a combination malaria drug that had already been licensed and used outside the U.S. since 2001. Additionally, while the vouchers are awarded only for qualifying tropical or rare pediatric diseases, they can be redeemed for any drug the company pleases. This was also evident in the Novartis AG redemption, as the company was awarded the voucher for the qualifying malaria treatment drug but redeemed its voucher to expedite review of a more profitable gouty arthritis attack treatment drug.

These potential shortfalls in regulation only add to the market value of these vouchers. With no regulation on drug type redemption or resale for either voucher program, companies can submit certain qualifying

drugs for the PRVs with full intention to redeem the vouchers for more profitable drugs under development or capitalize on the market value of the vouchers.

Of the 13 vouchers awarded, five have been sold to third parties (**see Exhibit A**), exhibiting an outsized return on investment for companies cashing in on these vouchers. Three of the five vouchers sold have subsequently been redeemed, none for drugs qualifying as tropical or rare pediatric diseases. While generating attention to some of the world's most neglected diseases, the drug market has not yet seen any new treatments as the program originally intended.

CAN THE PROGRAM BE FIXED?

Not unnoticed by global health organizations, a group of seven, led by Doctors Without Borders, lobbied the Senate Committee on Health, Education, Labor and Pensions in November 2015, requesting an amendment to the PRV program.

The group proposed that companies awarded the vouchers should be held to some level of responsibility to ensure the neglected and rare disease drugs make it to market at a reasonable price and do not overlap with drugs already on the international market.

"Critically, the PRV program for neglected diseases does not ensure that the qualifying products will be accessible and affordable to patients in need," the group wrote. "PRV recipients are not even required to market a product that earns a PRV."

Taking notice, the House included proposed amendments to the PRV program in its September 2016 amendment to the H.R. 3299 bill addressing strengthening of public health emergency response. Facing the regulatory end of the PRV program in September 2016, Congress and President Obama elected to extend the program through 2020, but did not address all its problems. The FDA also acknowledged problems with the PRV program, noting a company can essentially purchase a priority review at the expense of other important public health work.

"Two major revisions that would be beneficial to the PRV program would be, one, to limit eligibility in a way that only new drugs would be awarded the PRV," Ridley told us during a recent interview. "Additionally, an access plan should be required so that people, regardless of socioeconomic status or location, can receive treatment."

FACING POLITICAL PRESSURE

With a new administration and leadership changes in Congress, the future of the PRV program and any amendments is uncertain.

The latest recipient of a PRV, Marathon Pharmaceuticals, has put commercialization of its steroid to treat Duchenne Muscular Dystrophy (DMD) on hold after receiving widespread criticism of its aggressive pricing, which included a letter from a group of senators demanding to see development costs that would result in the proposed price of $89,000 a year. The steroid Marathon Pharmaceuticals has developed at its core is already available for a fraction of the cost in other countries. With President Trump and Congress focused on aggressive drug pricing, Marathon has likely opened itself–and the PRV program–up to heavy criticism and political risk.

As recently as early February, a key House committee had taken up legislation targeting high prescription drug costs, with the goal of expediting FDA approval of generic products where branded products have limited competition. The proposed generic PRVs would be a distinct market from the tropical and pediatric PRVs.

COULD $350 MILLION BECOME THE NORM FOR PRV SALES?

Based on the current regulatory and political environment, it is likely the value of PRVs will decline. However, it is difficult to truly pinpoint the value of an individual voucher, as there is inherent information asymmetry between the parties negotiating the sale of a PRV, which will have more or less value depending on the specific drug the holder is trying to get to market. This is evident by the range of sale prices PRVs have historically sold for as seen in Exhibit A.

Theoretically, a sale should go to the party that can get the most value out of it. To appraisers, this type of information is unavailable and so they are relegated to looking at past transactions. Future sales are truly market driven, so sales could go even higher than $350 million if fewer PRV vouchers are awarded–or lower, if the value is diluted by additional FDA fast-tracking regulation.

A HOPEFUL FUTURE

Although the market has yet to see treatments for some of the world's most neglected diseases, the PRV program has been beneficial to the cause in other ways.

The program did, after all, provide inspiration for a component of the bipartisan 21st Century Cures Act, one of the last bills President Obama signed into law. Although the impact the new administration could have on the law remains to be seen, it provides the FDA with $500 million to streamline regulations to move drugs and medical devices through approvals more quickly; create incentives to develop drugs for pediatric diseases and medical countermeasures; and provides greater flexibility in reviewing and approving medical devices that provide first-of-a-kind technologies.

The program has also helped infuse capital into the pharma/biotech industry for the development of neglected and rare disease treatments–whether through the channels originally intended or not.

"We are seeing a number of venture capital firms and entrepreneurs providing the funding biotech companies need to develop the treatments for these neglected diseases through the sale of these vouchers," Ridley said. "So, to me, the program has been successful in serving its original purpose."

EXHIBIT A

EXHIBIT A

Award Date	Voucher Type	Company	Drug	Disease	Status	Drug Redeemed for	Disease Redeemed Drug Treats	Sale Value	Sale Date	Purchaser
Apr 2009	Tropical Disease	Novartis AG	Coartem (artemether/ lumefantrine)	Malaria	Used - redeemed Feb 2011 to unsuccessful results	ILARIS sBLA	Gout	N/A	N/A	N/A
Sept 2012	Tropical Disease	Janssen Pharmaceuticals, Inc.	Sirturo (bedaquiline)	Tuberculosis	Unused	N/A	N/A	N/A	N/A	N/A
Feb 2014	Rare Pediatric Disease	BioMarin Pharmaceutical Inc.	Vimizim (elosulfase alfa)	Morquio A syndrome	Sold, then redeemed by buyers July 2015 to successful results	Praluent (alirocumab)	heterozygous familial hypercholesterolemia (HeFH)	$67.5 mil	July 2014	Sanofi and Regeneron Pharmaceuticals, Inc.
Mar 2014	Tropical Disease	Knight Therapeutics	Impavido (miltefosine	Leishmaniasis	Sold, then redeemed by buyers July 2015 to successful results	R/F/TAF	HIV	$125 mil	Nov 2014	Gilead Sciences, Inc.
Mar 2015	Rare Pediatric Disease	United Therapeutics Corporation	Unituxin (dinutuximab)	High-risk neuroblastoma	Unused	N/A	N/A	$350 mil	Aug 2015	AbbVie Inc.
Mar 2015	Rare Pediatric Disease	Asklepion Pharmaceutics, LLC	Cholbam	Rare bile acid synthesis disorders	Transferred to Recrophin Inc. (a BDO client) under an existing agreement. Sold, then redeemed by buyers Feb 2016 to successful results	Lixilan	Type 2 Diabetes	$245 mil	May 2015	Sanofi
Sept 2015	Rare Pediatric Disease	Wellstat Therapeutics	Xuriden	Hereditary orotic aciduria	Transferred to AstraZeneca under an existing PRV, Unused	N/A	N/A	N/A	N/A	N/A
Nov 2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Strensiq (asfotase alfa)	Hypophosphatasia	Unused	N/A	N/A	N/A	N/A	N/A
Dec 2015	Rare Pediatric Disease	Alexion Pharmaceuticals	Kanuma (sebelipase alfa)	Lysosomal acid lipase (LAL) deficiency	Unused	N/A	N/A	N/A	N/A	N/A
Jun 2016	Tropical Disease	PaxVax Corporation	Vaxchora	Cholera	Unused*	N/A	N/A	N/A	N/A	N/A
Sept 2016	Rare Pediatric Disease	Sarepta Therapeutics, Inc.	Exondys 51 (eteplirsen)	Duchenne muscular dystrophy	Sold, Unused	N/A	N/A	$125 mil	Feb 2017	Gilead Sciences, Inc.
Dec 2016	Rare Pediatric Disease	Ionis Pharmaceuticals	Spinraza (nusinersen)	Spinal muscular atrophy (SMA)	Unused	N/A	N/A	N/A	N/A	N/A
Feb 2017	Rare Pediatric Disease	Marathon Pharmaceuticals	Emflaza (deflazacort)	Duchenne muscular dystrophy	Unused	N/A	N/A	N/A	N/A	N/A

**Likely sold to Gilead for approximately $200 mil, based on an undisclosed PRV purchase in Gilead's Q2 2016 statement, a disclosure of $624m increase in R&D spend, less $400m Nimbus purchase and undisclosed clinical trial progression*

BUSINESS COMBINATIONS COULD IMPACT ACCOUNTING IN LIFE SCIENCES

By Jeffrey Keene and Liza Prossnitz

The development of medical breakthroughs in the life sciences industry requires an incredible amount of talent and dedication, as well as the capital to fund the necessary studies to achieve regulatory approval. Over the years, the industry has evolved into a dichotomy dominated by large, well-capitalized companies with blockbuster therapies that enjoy lengthened market exclusivity, as well as start-ups comprised of scientists and researchers working on the next big development.

The well-capitalized companies are always on the search to broaden and deepen their development pipelines, while the start-ups are often searching for the funding necessary to advance their therapies. These complementary needs often result in a collaboration agreement between the two parties, under which the well-capitalized company (the licensor) agrees to pay funds upfront to receive a license to a compound in development (the licensee). Under this agreement, the licensor agrees to fund milestones based on regulatory successes and royalties upon commercialization to the licensor. Other factors that may be part of these agreements include an acquisition of shares in the licensor, contribution to future development costs and a supply agreement between the two parties.

Under existing accounting rules, the licensee needs to evaluate if the license represents a business. A business is the acquisition of a set of activities that represents inputs and processes which are capable of producing outputs (sales or profits) under existing accounting rules. When conducting an evaluation, the licensee should consider what has been acquired, including the Intellectual Property (IP) rights, the medical product or therapy's stage of development, regulatory applications and filings, and arranged and approved manufacturing facilities. These items are evaluated to determine whether they represent inputs and processes. In addition, the licensee must consider what other inputs and processes were not acquired but are necessary to achieve outputs–and whether they are readily available or whether a market participant (oftentimes the typical acquirer) would have these inputs or processes. A key element typically not included in the arrangement is a sales force, which accounts for why there are many outsourced commercial sales organizations in the industry.

Under these rules, many licenses–especially those for therapies in late-stage trials–are categorized as businesses. This has resulted in challenging accounting consequences. If the collaboration agreement is deemed a business, the licensee then needs to fair value the assets acquired and liabilities assumed. The value attributed to the agreement would be the upfront payment, as well as the fair value of all the additional payments due under the agreement. This can be a challenging task, as the fair value estimate needs to also consider the external factors involved, including the probability of success, potential market size and presence of competitors that could render the therapy obsolete, among others.

In January 2017, the Financial Accounting Standards Board (FASB) released updates to the current accounting standards, the Accounting Standards Update 2017-01: Business Combinations (Topic 805) - *Clarifying the Definition of a Business*. Much of this update was fueled by comments and feedback from life sciences companies that claimed that the current definition of a business in "Topic 805, Business Combinations," is defined too broadly. As a result, many transactions that were more akin to asset acquisitions were being recorded as business acquisitions instead.

In response to this feedback, the update has made the definition of a business more stringent. The accounting update narrows the scope of a business to be a set of acquired assets and activities that includes inputs, processes and outputs. If the set does not include outputs–for example, a license for a therapy that is not yet approved for commercialization–then it must include inputs and substantive processes to be a business. A substantive process is a process that is critical to developing outputs and requires an assembled workforce to develop. Contracted or outsourced development does not apply. In other words, if there are no outputs and no employees, then the transaction will not be considered a business, as the accounting update does not require the acquirer to consider what a market participant would have or could obtain.

The accounting update requires the consideration transferred in asset acquisitions, which is not a business acquisition, to be allocated to the principal assets acquired. Contingent consideration is not fair valued, but only recorded when probable. In addition, transaction costs are capitalized to the asset acquired–whereas in a business combination, they are expensed as incurred.

The update becomes effective for fiscal years beginning after Dec. 15, 2017 for public business entities and for fiscal years beginning after Dec. 15, 2018 for all other entities. It is applied prospectively to future transactions and can be adopted early for transactions that have not been previously reported in financial statements.

Life sciences companies should familiarize themselves with the updated definitions now. We have seen many life sciences companies adopt the standard early to account for the acquisition of a license as the purchase of an asset.

HOW INNOVATIONS, PAYMENT MODELS SEEK TO TIE DRUG PRICING TO PATIENT OUTCOMES

By Bill Bithoney

Rising pharmaceutical prices are weighing on the bottom lines of providers, payers and pharma companies–and patients' wallets. To understand drug efficacy across large patient populations and improve pricing models, some healthcare industry players are leveraging new and innovative tools and pricing techniques. The goal? To better our understanding of the value of certain high-cost drugs and set reasonable outcomes expectations for patients.

Along with determining the value of certain drugs based on how many lives they save, healthcare leaders will determine value based on a more fine-tuned approach called QALY, or quality-adjusted-life-years. This addresses the cost of medications per year of life saved, as well as the quality of the lives of those treated with the medication.

In a recent Q&A with HFMA's CFO Forum, this and other issues related to drug pricing are addressed, including steps providers, health plans and other industry stakeholders are exploring to address the challenges patients face paying for costly–but potentially life-saving–prescription drugs, including new research tools and frameworks to evaluate their costs, benefits and side effects.

WHEN IT COMES TO NEW REVENUE RECOGNITION MODEL, ASC 606, IT'S TIME TO PLAY BALL!

By Ryan Starkes

As winter changes to spring, two things happen: 1) Companies complete and publish their annual financial statements and 2) Major League Baseball teams begin their spring training. As players regroup and plan for their upcoming season, companies start to execute on critical projects and strategies for the current year.

If not already underway, public companies will need to plan for a significant change during 2017: the introduction of a new revenue recognition standard that becomes effective Jan. 1, 2018. While private companies can choose to adopt the new model early, they too must comply by 2019.

The new standard stems from the Accounting Standard Update (ASU) 2014-09, or ASC Topic 606 Revenue from Contracts with Customers, issued by the Financial Accounting Standards Board (FASB) in May 2014. ASC 606 establishes comprehensive accounting guidance for revenue recognition and will substantially replace all existing U.S. GAAP on this topic.

Prior to adopting the new model, the Securities Exchange Commission (SEC) also expects companies to provide SAB 74 disclosures in their annual and quarterly reports. The SAB 74 disclosure is meant to inform stakeholders of the impact the adoption of the new standard will have on companies' financial statements. For companies that are unsure of what this impact will look like, the SEC recommends that they make a statement to their users to that effect.

Since its release, the FASB has issued several amendments clarifying ASC 606. Perhaps as a result, early adoption of this new standard has been rare: A December 2016 Audit Analytics analysis stated that only six S&P 500 companies are planning to adopt the standard early based on the disclosures from quarterly reports. Unfortunately, many organizations have left this task to the upcoming year.

For companies that have not yet started evaluating how ASC 606 will affect their business, they may encounter moments of uncertainty in applying the new model due to differing assumptions and approaches. Yogi Berra once said, "A nickel ain't worth a dime anymore," which, fortunately, is not the expected result of applying the new revenue standard, as the economic value of a transaction will still prevail. However, ASC 606 can change the timing of when certain revenue transactions are recognized, in the way revenue is allocated amongst promises in a contract and the information disclosed in financial statements.

The adoption of ASC 606 will affect multiple departments and business lines, as forecasting, deal structures (e.g. license agreements, milestones, etc.) and the presentation of revenue in 2018 financial statements and footnotes (e.g. grant proceeds are no longer considered revenue from contracts with customers) will all be evaluated through this new model. For life sciences companies, the impact of ASC 606 adoption will ultimately vary based on the nature and stage of each business. Some transactions (e.g. license transactions) will face more significant changes than others, requiring careful planning.

THE NEW MODEL

The core principles of ASC 606 are built around the contract between a vendor and a customer for the provision of goods and services. ASC 606 utilizes the transfer of control between the parties to determine the pattern of revenue recognition based on the consideration to which the vendor is entitled. To accomplish this objective, the standard requires five basic steps:

1. Identify the contract with the customer;
2. Identify the performance obligations in the contract;
3. Determine the transaction price;
4. Allocate the transaction price to the performance obligations in the contract; and
5. Recognize revenue when (or as) the entity satisfies a performance obligation.

WHAT LIFE SCIENCES ENTITIES NEED TO KNOW

For life sciences companies, adopting ASC 606 could be more complicated than other industries due to the nature and structure of various arrangements. Thus, each company should conduct an in-depth analysis of the related agreements.

A sample of such arrangements and some related considerations include:

Research and Development Arrangements

Arrangements are often complex, involving multiple deliverables and various types of consideration and often spanning several years. The analysis of whether a party to an arrangement is a customer (as defined

in ASC 606) is important when evaluating whether "reimbursements" or "funded R&D" should be accounted for as revenue from contracts with customers. In answering this question, entities should determine whether the reimbursement relates to goods or services that are an output of the company's ordinary activities. If the company's ordinary activities are performing research and development, then it is likely that the relationship between the company and the counterparty is a vendor-customer relationship, and the consideration could be recognized as revenue.

Collaboration Agreements

These agreements (including historical agreements) need to be thoroughly re-evaluated as elements of the arrangements could be subject to ASC 606. Additionally, entities will need to consider the applicability of ASC 808, Collaborative Arrangements.

Milestones (a Form of Variable Consideration)

Many arrangements call for milestone payments that are contingent on the achievement of certain development thresholds and/or royalties on future sales of commercialized products.

The treatment of variable consideration is very different under ASC 606 versus existing GAAP. Current accounting rules typically preclude the recognition of revenue until the contingency or variable consideration becomes fixed or determinable. The "milestone method" currently permitted by ASC 605-28 will no longer be applicable under ASC 606.

In determining the transaction price, ASC 606 requires that companies include an estimate of variable consideration, either using the "expected value" (which is the sum of the probability-weighted potential outcomes), or the "most likely amount" of the consideration. Nevertheless, variable consideration should only be included in the transaction price to the extent that it is "probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty underlying the variable consideration is resolved"–a concept known as the variable consideration "constraint."

In contrast, estimates of variable consideration are included in the transaction price under ASC 606 (if not constrained) and the fact that an arrangement contains variable consideration does not, in itself, preclude the recognition of revenue.

Sales-based Royalties

Royalties are another form of variable consideration. However, ASC 606 contains an exception to the principle requiring an estimate of variable consideration for a sales-based royalty for a license of Intellectual Property (IP). This is because estimating future royalties is quite difficult and would likely result in significant adjustments to the amount of revenue recognized due to changes in circumstances not related to the entity's performance. Instead, royalties received in exchange for a license of IP are recognized as revenue at the later of when the sale occurs or when the performance obligation to which the royalty relates has been satisfied.

This guidance only applies to royalties received in exchange for a license of IP. Where the arrangement consists of a license and other deliverables, such as research and development services, life sciences companies will need to assess whether the license is the predominant deliverable to which the royalties relate. If so, then the royalty is subject to express guidance discussed in the prior paragraph. If not, then it should be treated like other variable consideration–i.e., estimated and included in the transaction price to the extent not constrained.

Licenses of Intellectual Property

ASC 606 contains special rules in making this determination for licenses. By way of background, the FASB believes that there are two types of licenses:

1. Those which provide the customer with a right to access the entity's Intellectual Property throughout the license period, which are recognized over time, and;

2. Those which provide the customer with a right to use the entity's IP as it exists at a point in time in which the license is granted, which is recognized at a point in time

The determination of whether the license is a right to access IP or a right to use IP depends on its nature. "Functional IP" typically grants a right to use an entity's IP as it exists at a point in time, and has significant standalone functionality (e.g. a compound, technology or product). "Symbolic IP" provides the customer with a right to access the IP throughout the license period, and its utility is derived from the vendor's past or ongoing activities (e.g. use of a brand).

In the life sciences industry, no two contracts are alike due to the numerous variables inherent in the development, production and ultimate marketing of compounds or products. This will require significant effort in evaluating contract terms in accordance with ASC 606. In many cases, when a life sciences company enters into a license and development arrangement, the IP (presuming it's a separate performance obligation) will be considered functional. Revenue for a license to functional IP is typically recognized at a point in time–i.e., at the moment control over the license is transferred to the customer. However, if a license grants a right to use IP as it exists at a point in time, but the functionality of the IP is expected to substantively change during the license period due to activities of the vendor that do not represent a separate performance obligation, and the customer is contractually or practically required to use the updated IP to continue to derive a benefit from it, then the license grants a right to access the entity's IP and is considered a symbolic license, which is accounted for over time. As such, an appropriate method would be selected to measure the vendor's progress toward complete satisfaction of its performance obligation to provide access to the IP.

As noted above, evaluating license transactions in accordance with ASC 606 will require significant effort and a thorough understanding of each participant's rights and obligations pursuant to the contract. Slight differences in structure or terms could result in different accounting results in when revenue is recognized.

The above considerations are based on straightforward contract terms between a vendor and a customer.

In practice, each contract is unique and will require its own assessment of the related terms to reach the appropriate conclusion.

The new model will affect all businesses–and even biotech companies with no current revenue should familiarize themselves with the new requirements as future licensing or other revenue-related transactions for themselves or with other entities will be subject to the requirements of ASC 606.

Nevertheless, most companies will need to begin their planning and preparation now and focus on how ASC 606 will impact their financial statements and business. With enough focused effort, consultation and coordination, having a clear, well-documented path towards ASC 606 adoption at the beginning of 2018 is achievable.

DID YOU KNOW...

In 2016, plaintiffs filed a total of 67 class action securities lawsuits against life sciences companies, more than a 70 percent increase from 2014, according to Dechert.

The International Trade Administration estimates that the worldwide market for pharmaceuticals is projected to grow from around $1 trillion in 2015 to $1.3 trillion by 2020, representing an annual growth rate of 4.9 percent.

Biopharmaceutical R&D accounts for about 85 percent of the life sciences industry's total R&D spending, according to the Industrial Research Institute.

The U.S. Food and Drug Administration approved just 22 novel drugs in 2016, down from 45 in 2015 and 41 in 2014. This year, the agency has so far approved 11 novel drugs.

More than 500 new medicines treating a range of diseases have been approved by the FDA since 2000, according to PhRMA.

ABOUT OUM & CO. LLP

OUM & Co. was formed in 1976, when Roger Odenberg and James Ullakko left an international accounting firm to establish their own tax practice. John Muranishi, Paul Ainslie, and Chris Millias joined OUM shortly thereafter, to expand the tax practice and add an assurance and advisory practice. The rest, as they say, is history.

OUM is one of the leading CPA firms in California, with offices in San Francisco, San Ramon and the San Diego area. We have over 80 professional staff and many of our partners and senior managers were previously partners and managers at Big 4 firms. Since 2000, the San Francisco Business Times has included OUM in their annual ranking of the "Top 25 Largest Bay Area Accounting Firms." We have also been included in Inside Public Accounting's annual list of the "Top 200 Accounting Firms in the Nation."

In 2004, our firm became an independent member of the BDO Alliance USA, a nationwide association of independently owned local and regional accounting, consulting and service firms with similar client service goals. Our membership in the BDO Alliance USA affords us access to national and international resources, technical experience, specialized knowledge, quality assurance, high caliber training, and the latest technical and reporting developments.

Our firm has been registered with the Public Company Accounting Oversight Board (PCAOB) since its inception. The PCAOB examines our assurance work papers at least every three years. We currently serve thirteen publicly-traded companies. The AICPA also examines our assurance work papers every three years, and has always issued unqualified opinions on our non-public assurance practice, most recently in November 2014.

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