2017
OUM BIOTECH BRIEFING

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INNOVATION OVER ALL: NAME OF THE GAME IN BIOTECH?

Advances in biological sciences and pharmaceuticals continue to grow, positioning the biotechnology (biotech) industry as one of the most innovative industries today.

By Yosef Barbut and Ryan Starkes

As companies continue to develop solutions that address significant unmet needs, future innovations in biotech research will bring exciting new medical advances that could help millions. However, due to a consistently changing landscape, biotech companies will need to understand and consider variables such as recent financial trends, healthcare regulatory changes, and the future of both the biotech and healthcare industries, in order to best position themselves in an increasingly competitive market.

With innovation as the foundation, there are key trends and variables that continue to drive research and development (R&D), and therefore drive product development in healthcare and biotech/pharma sectors. For example, rising life expectancy for the U.S. population has resulted in an increased incidence of age-related illnesses and chronic disease, and is projected to continue to increase. Therefore, an aging population increases demand for medical treatments.

Moreover, the public sector will seek to reduce the cost of treatment by using more effective drugs, as well as curative and preventive treatments developed by the biotech industry. This industry continues to expand its product offerings to enhance the quality of human life; and many deem it to be the future of health science. Additionally, it is delivering improved health outcomes and innovations that are transforming the way patients are treated. Due to the industry's evolving and diverse nature, the need for better products and related revenue growth are impacted by a similarly wide array of factors.

As the **2017 Biotech Briefing** shows, these factors are giving rise to an industry ripe for innovation, with new regulations likely to bring greater opportunities for growth. The primary fuel for innovation is investment in R&D. Average R&D spending across all mid-market biotech companies increased about 18 percent from 2015 to 2016, from an average $65.9 million to an average $80.6 million, the analysis revealed.

Broken down by size, small biotechs surged R&D spending by 24 percent, from $65.4 million in 2015 to $81.2 million in 2016.

ABOUT THE BIOTECH BRIEFING

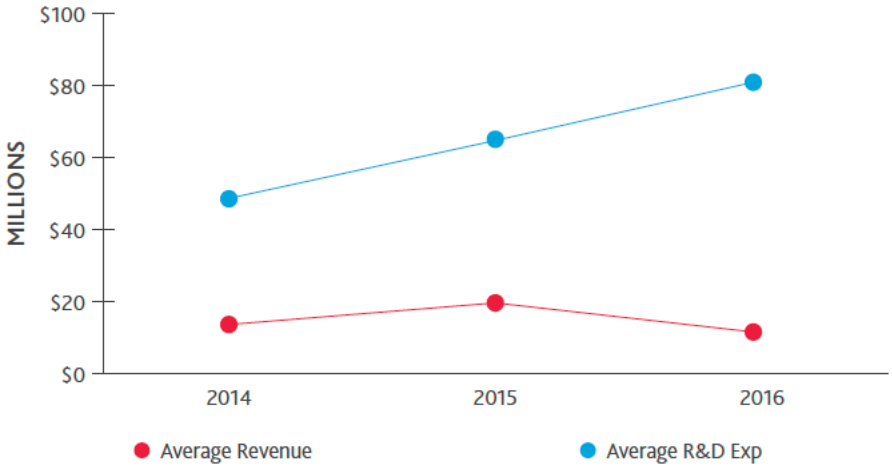
The Biotech Briefing examines the most recent 10-K SEC filings of companies listed on the NASDAQ Biotechnology Index (NBI). Companies reporting more than $300 million in revenue were excluded to ensure findings are representative of the vast majority of companies included in the NASDAQ Index. Remaining companies were divided into two groups–those with more than $50 million in revenue (large) and those with less than $50 million in revenue (small)–to identify trends and key metrics relevant to each group. The average market cap of companies in the study, as of the end of their most recent fiscal year, is $857.8 million.

Not surprisingly, large biotechs, those with more than $50 million in revenue, also followed suit, boosting R&D spending by 20 percent in 2016, from $66.4 million in 2015 to $80 million in 2016. Large biotechs generally have started to see the benefits of their R&D investments with average revenue increasing 24 percent, from $113.7 million in 2015 to $141.1 million in 2016.

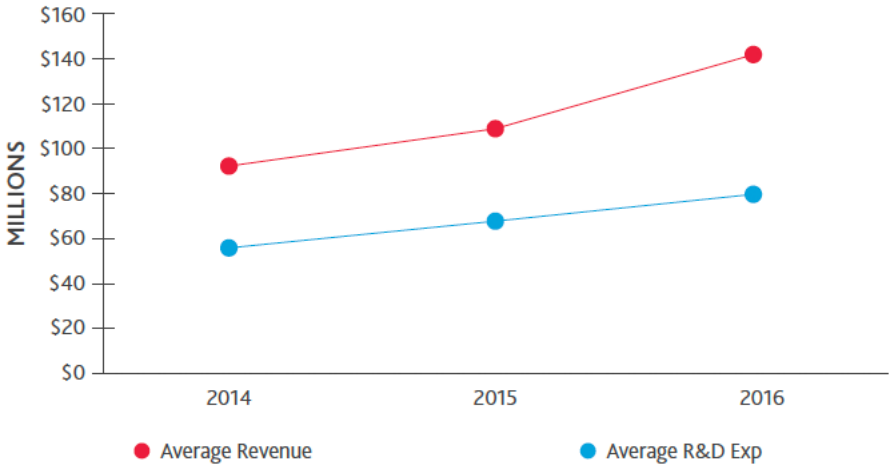
Biotech companies will continue to develop and address significant unmet needs–a trend that will perhaps quicken as the recently enacted 21st Century Cures Act, aimed at streamlining Food and Drug Administration (FDA) approval processes and boosting innovation, takes hold. Already in 2017, the FDA has approved 23 novel drugs as of June 26, compared to 22 in all of 2016.

The biotech industry's notably high level of patent activity adds to its innovation trajectory and the ability for companies to gain competitive advantages within the market, which will only serve to add momentum to innovation.

AVERAGE REVENUE & R&D EXPENSE (<$50M)



AVERAGE REVENUE & R&D EXPENSE (>$50M)



MAPPING INNOVATION AND VENTURE CAPITAL INVESTMENTS

The strategic and natural coalescence of scientific R&D, education, intellectual and investment capital, and commercialization is creating innovation economies, and leading academic and research institutions are at the center of it all.

Biotech companies are positioning their operations close to these institutions, allowing them to recruit more easily and attracting federal funding and private investments as they relate to the development and clustering of biotech industries. These private investments may foster public-private partnerships and create commercialization centers, positioning the private sectors to explore new partnerships that integrate entrepreneurship and industry involvement into the university research experience and facilitate the path from research to commercialization.

This is critical to understanding where biotech venture capital investments see promise. Most middle-market biotechnology companies are headquartered in major national biotechnology regional clusters that are among the leading recipients of venture capital funding and also in close proximity to leading research institutions. The tables below reflect states where bioscience venture capital investments have been made and the corporate headquarters of the mid-market biotech companies in the NBI.

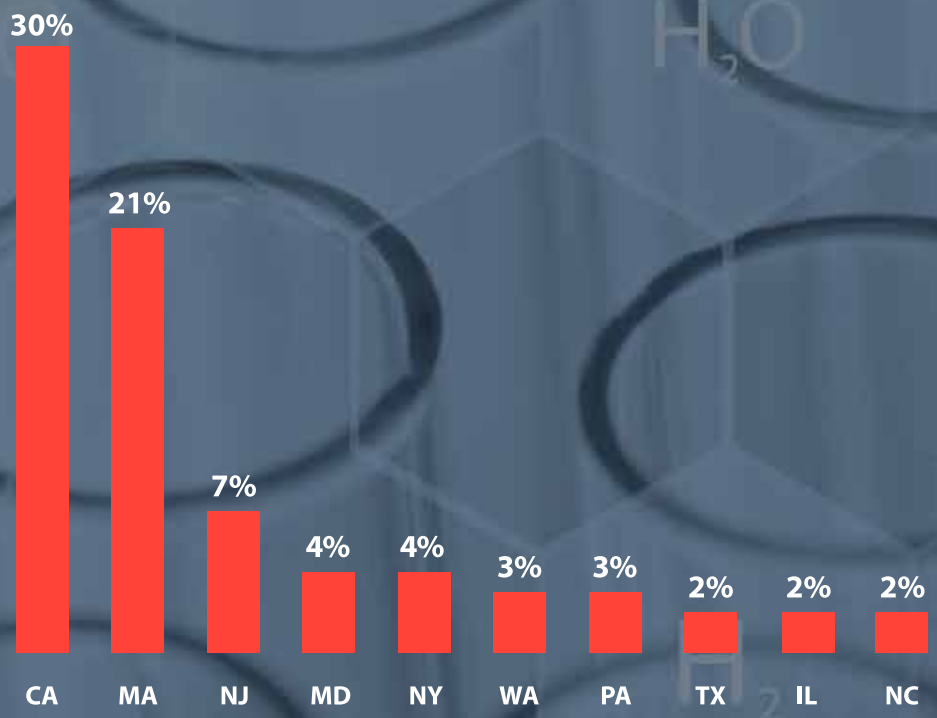
TOTAL BIOSCIENCE VENTURE CAPITAL INVESTMENTS

(2012-2015)

LEADING STATES	TOTAL ($ per 1Million Population)
California	$19,161
Massachusetts	$9,476
Texas	$1,664
Pennsylvania	$1,564
Washington	$1,523
New York	$1,308
Maryland	$1,292
North Carolina	$1,262
New Jersey	$1,214
Illinois	$1,139

Source: ***Biotechnology Innovation Organization***

NASDAQ MIDDLE MARKET COMPANIES NATIONAL HEADQUARTERS



BIOTECH RIPE FOR EMPLOYMENT OPPORTUNITIES

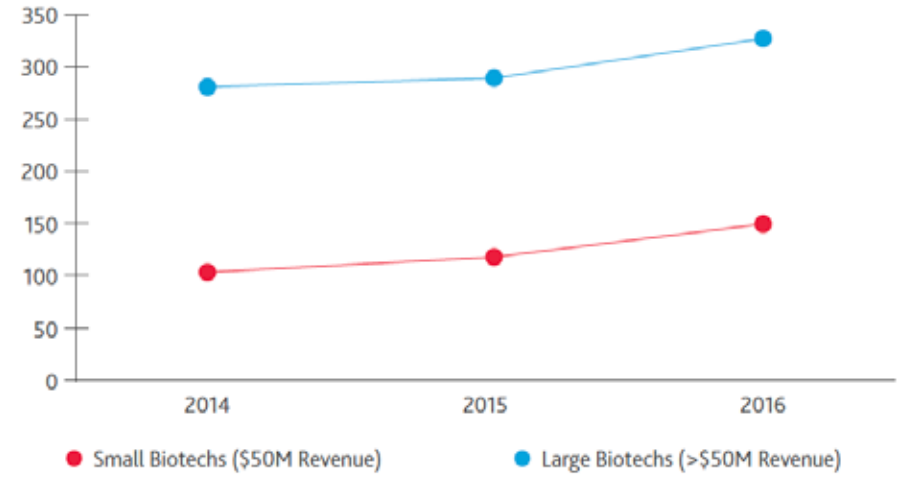
Continued growth innovation, combined with boosts from state governments and regional economic development organizations, have made companies in the biotech industry competitive employers. The biotech industry has been labeled an economic engine providing high-wage, high-skilled jobs across a broad range of occupations, and regional and state bodies alike have sought to make R&D profitable by offering incentives to private companies through tax exemptions and grants.

Hiring across mid-market biotech companies from 2015 to 2016 increased about 16 percent, from an average 205 employees to about 238.

Among large biotech companies, hiring grew from an average of 290 employees to about 327, or 13 percent; small biotech companies saw hiring increase about 24 percent, from an average 121 employees to about 150.

The industry is immensely competitive with high barriers of entry, need for specialization and dependence on large capital. Companies are continuously in need of recruiting and hiring top talent, so looking ahead, the hiring trend is likely to escalate.

AVERAGE NUMBER OF EMPLOYEES



EQUITY DIPS IN FAVOR OF DEBT FINANCING

Overall, equity raises showed a large decline from 2015 to 2016, falling almost 35 percent across all mid-market biotech companies, from $117.2 million to $75.7 million.

Among large biotechs, equity raises declined from $103.7 million to $52.1 million; among small ones, from $130.6 million to $99.4 million. Behind this trend, among large biotechs, just 18 companies secured equity financing, compared to 23 in 2015 and 29 the prior year; among small biotechs, the figure fell to 48 from 57 in 2015 and 61 the year prior.

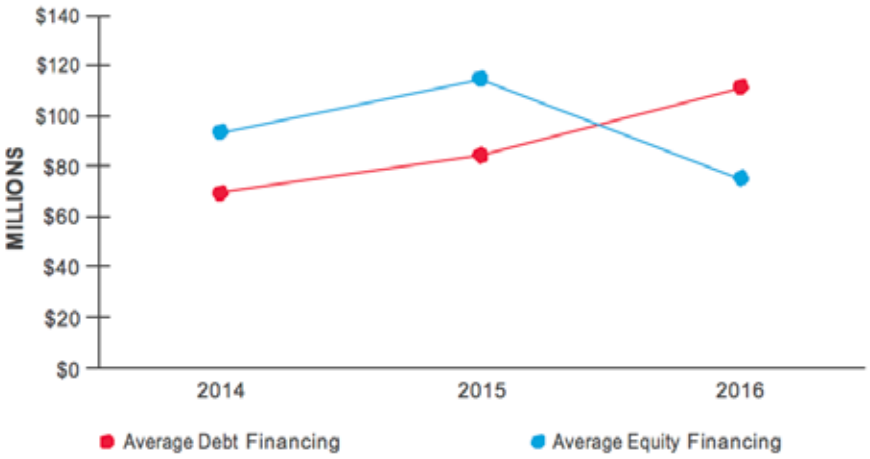
Forty life sciences companies filed IPOs in 2016, compared to 72 in 2015 and 98 in 2014, according to Harvard's 2017 IPO Report. Although life sciences companies made up a smaller portion of the IPO market compared to 2015, their market share compares favorably to the 40 percent figure in 2014 and is well above the 17 percent figure for the five-year period preceding 2014.

And while average mid-market equity raises decreased from 2015 to 2016, a large portion of equity raises were found among companies specializing in oncology, Central Nervous System (CNS) and gene therapy–which all make up a large portion of the biotech industry. This is indicative of a thriving market for biotech companies in these sectors, and an overall indicator that lenders and investors see potential growth, continued innovation and new discoveries in the biotech industry. Fifty-five percent of bankers forecast an increase in IPOs in the biotech industry.

Debt financing, meanwhile, increased slightly among large biotech companies, while showing a more noticeable increase among small ones.

> Debt financing among large biotechs increased, on average, from **$134.8 million in 2015 to $135.6 million in 2016.** Among small biotechs, it increased, on average, from **$34.8 million to $96.5 million.**

FINANCING ACROSS BIOTECHS



WHERE IS THE FOCUS?

Medical advances that continue to revolutionize diagnostics of genetic diseases, alongside consistent efforts to address safety challenges in gene therapy, will positively support an increase in companies entering the field of gene therapy.

As the cost to develop a new drug now exceeds $2.5 billion, according to the Tufts Center for the Study of Drug Development, continued equity and financing activities will be critical to this innovation as the capital raised will continue to allow drug research and development.

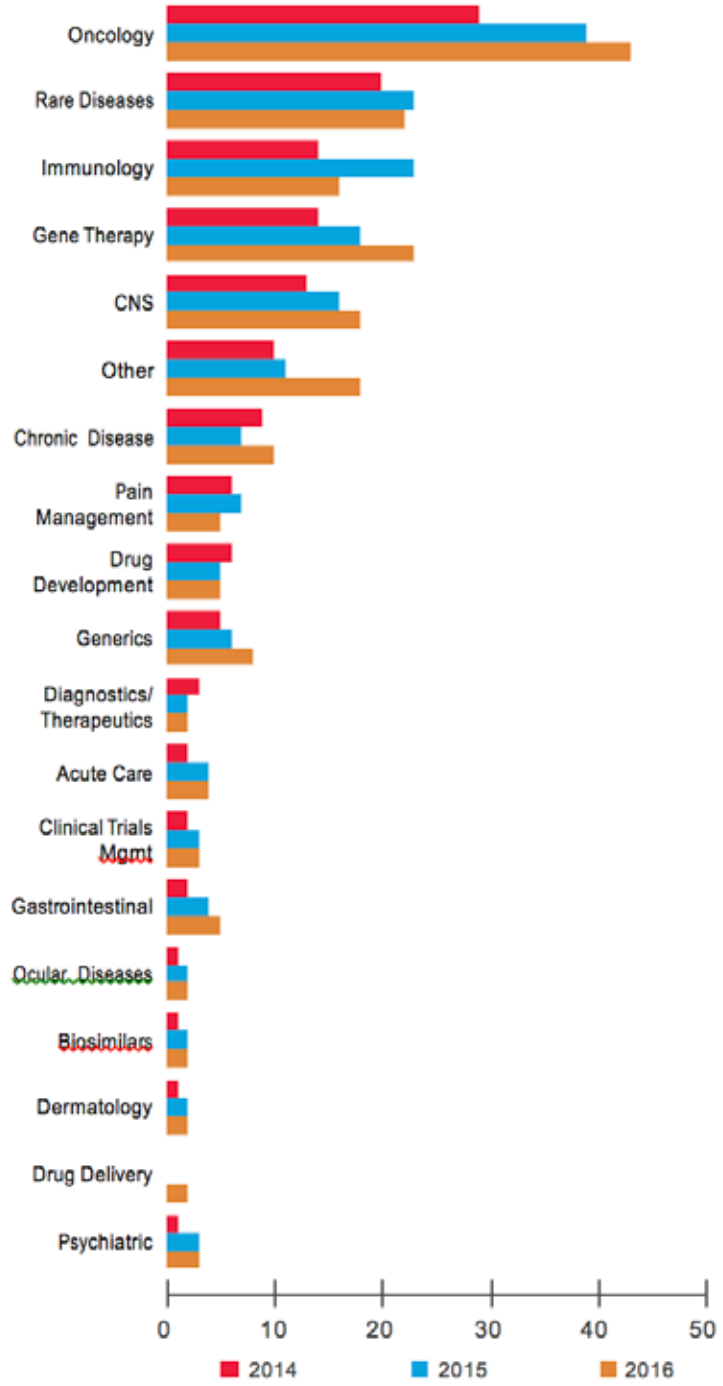
Continued investment in R&D actively promotes the development of new products within the biotech community. Past and current trends associated with the sector show that companies specializing in oncology, gene therapy, rare diseases and immunology will remain areas of investor interest as treatment personalization and efficacy continue to improve, according to data compiled from Nasdaq and referenced in the table to the right.

LESS CASH RESERVES, MORE INVESTMENT

Biotech companies typically prioritize cash reserves to demonstrate their ability to fund the clinical studies necessary to bring a new product to market. Not surprisingly, in 2016 and inline with the decline in equity and debt financings overall, they have shown a decrease in total years' worth of R&D spending in liquid assets: from 2.88 in 2015 to 2.49 in 2016.

The decline illustrates that as companies in the biotech industry worked through the capital market challenges of 2016, their need to secure future rounds of financing increased. Deals will continue to get completed, but biotech companies may have to raise capital with terms or at levels that are not as favorable as in the past.

BIOTECH INDUSTRY BREAKDOWN 2014-2016



Source: Produced using data from Nasdaq.

TOTAL YEARS' WORTH OF R&D SPENDING IN LIQUID ASSETS

SPOTLIGHT

HEALTHCARE-DRIVEN TRENDS FOR BIOTECH TO WATCH

It's no secret that the overall healthcare industry is transforming the way it delivers care: shifting from a fee-for-service model to a value-based one. The aftershocks of this shift, combined with rapid technological advances, have reverberated across numerous industries–perhaps none so much as biotech–and are expected to quicken the move to value-driven drug pricing.

As biotechs evaluate near-and-long-term strategies, they should pay attention to several proposed regulatory changes that could quicken this move to outcomes-based models, while being mindful of growing cybersecurity risk stemming from the increased integration of technology into care delivery.

VALUE-BASED CARE REGULATORY CHANGES

Medicare Access and CHIP Reauthorization Act (MACRA)

The implementation of MACRA, a new payment model which transforms how Medicare pays physicians to promote efficient and effective care while reducing unnecessary costs, will accelerate the trend towards value-based payment. As reimbursement models shift towards incentivizing quality and outcomes of care, it is likely that this trend will continue to impact the biotech and pharmaceutical industry.

The ongoing shift towards value-based reimbursement will increasingly tie health systems, biotech companies, payers and providers to not only their own outcomes, but also the outcomes of their partners across the care spectrum under risk-sharing arrangements.

A drug's efficacy may be based on variables other than just mortality and morbidity rates, though, including patient-centric metrics such as quality-adjusted-life-years (QALY), which addresses the quality of lives saved. For example, biologics and genomic-based drugs are already emerging as one category of drugs where providers can analyze cost versus efficacy by tracking populations on a series of value-based metrics such as mortality and morbidity rates, hospital readmissions and QALY. Drug manufacturers are already developing new cancer drugs for which the effectiveness can be predicted based on a patient's genome.

International regulations

The Identification of Medicinal Products (IDMP), a set of regulatory standards set forth by the European Medicines Agency (EMA), will require unique identification of a product throughout its life cycle and is expected to be finalized this year.

The resulting normalization of data will enable better transparency and collaboration of information among all stages of a product's lifecycle, from regulation and development to commercialization and distribution, thus ensuring greater public safety. However, the vast amount of data disclosure required to comply with these new standards may pose a serious challenge for organizations that fail to prepare and could, in turn, present itself negatively in their financials, R&D and innovation progression, or even funding.

Cures Act and potential for deregulation

Biotech and pharmaceutical companies have recently faced heightened scrutiny over the rising costs of drugs for consumers. U.S. drugs typically hold higher price tags than foreign ones, in large part because governments in other countries can negotiate prices directly with manufacturers, while the U.S. strictly prohibits negotiating on drugs purchased through government- funded programs such as Medicare.

The FDA also has more stringent drug and medical device approval processes than its international

counterparts, which allow for high levels of safety and efficacy but create astronomical R&D costs which drive up pricing.

Forms of deregulation, including under the Cures Act, which provides the FDA with $500 million to move drugs and medical devices through approvals more quickly, have been proposed to help lower costs. Another proposal under consideration is eliminating certain efficacy trials to allow generics to enter the market faster and create more competition. Efforts to streamline approval processes could lower development expenses, and in turn, drug prices, but could also increase risk from a payer perspective if efficacy is compromised.

Less than a month after his confirmation and perhaps signaling future efforts to streamline approvals processes, FDA Commissioner Scott Gottlieb echoed calls to drive down drug prices through measures aimed at boosting both competition and transparency around pricing, reported *Bloomberg*.

First, he said the agency is considering streamlining new drug applications to the front of the approvals process when there are less than three competing generics. The eventual goal is to ensure three manufacturers for every generic version of a drug–a threshold he argues will drive prices down.

Second, he said the agency is weighing whether it could publish a list of the 180 brand-name drugs that have no patent protection yet still face no generic competition. Doing so "might create a more compelling business opportunity," he told Bloomberg.

EMERGING CYBERSECURITY RISKS

The May 12 WannaCry ransomware attack, which unleashed more than 75,000 ransomware attacks in 153 countries and hit 47 of the U.K.'s 248 National Health Service (NHS) trusts, underlined the growing cybersecurity risk healthcare organizations and their partners face.

Healthcare remains uniquely at risk to cyber incidents for a variety of reasons, including a lack of resources devoted to cybersecurity, a complexity of networks and a vast array of internet-connected devices. Add to that the fact that many hospitals still maintain and rely on end-of-life technologies and might prioritize immediate data access over security, and cybercriminals have found their systems relatively easy to penetrate.

Life sciences companies have grown increasingly concerned. About 89 percent cited cyber concerns as a risk to business in 2016, up by 19 percentage points from 2015 and 43 percentage points from 2013.

Many device manufacturers are already struggling to address the FDA's January 2016 guidance on mobile device security, which includes pre- and post-market surveillance of products. But as care becomes more patient-centric, moving outside of the hospital walls and into the homes of patients through technology, the connectedness of medical devices will only increase, and regulation around security is likely to increase with it. The Cures Act, while it opens new (and quicker) avenues to secure medical device approvals, also presents greater risk for product discrepancies–like security vulnerabilities–to slip through the cracks.

Manufacturers who can develop and incorporate an efficient security process that aligns with FDA regulatory guidance may gain faster approval on their products and bring them to market more quickly in an already competitive market.

POSITIONING FOR THE FUTURE

Potential for upcoming M&A activity

In addition to pricing and approvals for new drugs, another focus of deregulation is the potential repatriation of cash. Preliminary plans to offer a tax repatriation holiday could potentially generate more cash, spur M&A transactions and increase companies' share values.

Staying ahead of market trends

Overall, the market landscape is constantly changing. Not only is the biotech industry experiencing continuous growth, but its remarkable innovation is key to the evidenced trends in increased R&D, competition and financing. While this opens opportunity for revolutionary advances and partnerships, companies will need to prepare and adapt to the upcoming regulatory changes to thrive in this market.

Uncertainty surrounding the regulatory space alongside the volatile nature of both the biotech and healthcare industries only creates an additional level of apprehension. It is prudent for organizations to keep abreast with the latest industry trends while keeping a cautious eye on new regulatory proposals. Diligence in complying with existing laws and guidance, and preparation for forthcoming regulations will be key for new and existing companies alike to build and maintain a competitive advantage in the marketplace. While companies should exercise caution at amending business practices based on speculative claims, it is critical to stay informed of regulatory-driven industry trends already occurring and those that are anticipated in the upcoming years.

ABOUT OUM & CO. LLP

OUM is one of the leading CPA firms in California, with offices in San Francisco 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 fifteen publicly-traded companies. The AICPA also examines our assurance work papers every three years, and has always issued unqualified opinions on our nonpublic assurance practice.

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