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Catalyst

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Outlook for the Biopharmaceutical Industry in 2021 Following Biden's Victory

By Elana Margulies-Snyderman

With Joe Biden's victory in the U.S. presidential election -- and despite the fact that people across the globe have already received COVID-19 vaccines from Pfizer and Moderna -- the true impact on the biopharmaceutical industry will focus on a few highlights. They include collaboration with the U.S. Food & Drug Administration (FDA), providing affordable drugs to patients, innovation and venture capital investment. Obviously, the first priority will be to eliminate the current pandemic.

Biden has a history of working with the biopharmaceutical industry, which is expected to continue during his term in office. Between his Cancer Moonshot initiative, a bipartisan effort to increase cancer research; his 21st Century Cures negotiations in his role as vice president during the Obama Administration; working to reduce drug costs; and expanding the Affordable Care Act (ACA) to give more Americans access to health insurance; biopharma has been a top priority for him. He also hails from Delaware with its own longstanding tradition in life sciences research and development.

EisnerAmper spoke with a series of executives to get their perspectives on how the biopharmaceutical industry will be impacted with Biden taking office.

FDA Collaboration with Biopharmaceutical Companies

During the COVID-19 pandemic, the FDA was in the spotlight and collaborated with various companies to come up with COVID-19 vaccines, despite pushback that the vaccines rolled out too quickly.

"The COVID-19 pandemic changed everything, most notability the accessibility to the FDA who has been good at collaborating with pharmaceutical companies and academics and the hope is that continues going forward," said J. Christopher Mizer, president and CEO of Vivaris Capital, a private equity group in San Diego that invests in middle-market health care and life sciences businesses. "The FDA's Right to Try allowed for expedited development of unapproved drug treatments."

The Biden Administration is expected to work to restore the public's trust in the FDA and that its Emergency Use Authorization (EUA)

to make medical devices and therapeutics available as quickly as possible to treat COVID-19 is used dependent on good science.

Affordable Drugs

Given Biden's background with the Affordable Care Act, he is expected to press the biopharmaceutical industry to lower out-of-pocket costs for patients in health care.

"We must mention Trump's plan to sabotage the ACA, something that was implemented when Biden served as vice president. And now with his takeover, we would expect higher coverage, more access to patients, and a thus easier-to-reach consumer base for pharma," said Hector Jirau, managing partner of Jirau Capital Management, a Puerto Rico-based investment management firm focused on the biotechnology and pharmaceutical industries.

Debbie Hart, the president and CEO of BioNJ, a life sciences trade association in New Jersey, added: "We share the president-elect's concerns that any patient is somehow unable to afford necessary and lifesaving medications. We look forward to working with our Congressional delegation and the new Biden Administration to enact common sense reforms that both protect patient access and biopharmaceutical innovation and address the pandemic and other health challenges head on."

Beth Halpern, a partner at law firm Hogan Lovells who spoke at California Life Sciences Association's (CLSA's) Pantheon 2020 Virtual Conference in December, added that Biden is expected to expand access to affordable health care.

"There are two prongs to this," she said. "The first one is building on and expanding the Affordable Care Act (Bidencare) including making Medicare available for younger people and making premiums more affordable. The second one is the affordable side including looking at drug pricing and addressing the Most Favored Nation (MFN) pricing model."

Trump's MFN was deemed detrimental for the biopharmaceutical industry since it lowered reimbursement to physicians, fostering challenges for people to pay for medicine.

Innovation

Amid pressing affordable health care concerns, Biden is expected to ensure the biopharmaceutical industry continues to innovate on many fronts. Throughout the COVID-19 pandemic, the FDA innovated in numerous ways: adopting remote policies such as telemedicine, fostering a new approach to clinical trials, leveraging technology to remotely inspect a factory rather than going on premise and more.

"Biden is known to support innovation and understands the complexity of the pharmaceutical industry and how biotechnology is a leading asset in our country, rather than an industry polluted with greed and not patient-centric," Jirau said. "Lead by a science-driven agenda, 2021 will be the year of gene and cell therapies. Certainty brings risk-led opportunity, and I expect these two niches to dominate the industry."

Biden is also expected to push for increased efforts to make coding and payments for new technologies accessible to patients, implement breakthrough devices being eligible for Medicare coverage, accelerating coverage of innovative technologies, and more.

Fritz Bittenbender, senior vice president of access and external affairs at Genentech, who also spoke at Pantheon 2020, said: "We have never seen a greater time for innovation between device, diagnostics and the pharmaceutical

industry focus on how we can have the best outcomes against COVID-19, bringing hope to get America back up and running, bringing hope to allow families to gather again."

Mizer added: "AI technology is starting to bear some fruit in terms of drug development and clinical trials and point of care, which will all accelerate in 2021."

However, the industry needs to keep in mind that legislation needs to be created around innovation.

Mike Guerra, president and CEO of the California Life Sciences Association (CLSA), added: "American innovation leads the world. Investment into this innovation is critical; if drug prices are set arbitrarily low, based on what is paid by governments in foreign countries who spent nothing developing these products, then the ability to attract new investment within the United States virtually disappears. This is especially true for rare diseases or diseases with smaller patient populations."

Venture Capital Interest

Due to continued innovation in the biopharmaceutical industry, venture capital interest has increased during the last year. According to data, in the first half of 2020, there has been $12.6 billion put to work by venture capital firms in the life sciences sector versus only $7.3 billion in the first half of 2019. In addition, including the larger life sciences plus the bio sector, the first half of 2020 saw $16.5 billion across 450 deals versus $13.4 billion across 600 deals in 2019 with a 50% increase in the plus $100 million rounds. With regards to sectors, oncology followed by cell and gene therapy received the most investor dollars.

"We see large scale Series A financings being done," said John Pennett, the partner-in-charge of EisnerAmper's Life Sciences Group, during BioNJ's recent Virtual Finance Briefing. "Venture capital firms are drawn to great teams and high-potential novel technology, whether in later stage clinical trials or recently extracted from academia.

In 2021, the market is poised to be robust and the rise of special purpose acquisition companies (SPACs) in biotech are slated to continue.

Conclusion

The year 2021 will be a year where the biopharma industry plays a major role in bringing back some "normalcy" to everyone's daily lives.

"It is a terrific opportunity to continue highlighting the innovation and cures we are delivering to patients around the world," Hart said. "I believe the collaboration and resulting successes in vaccine and treatment development will only shine a bright and positive light on our sector in 2021."

"For consensus, I would expect 2021 to be a very good year in pharma, but more specifically focusing on biotechnology, being it the leading innovation branch of the health care sector," Jirau said. "No question that the industry should see a decent revenue growth, a boost in M&A activity and shifting towards higher-than-usual interest in the sector from both institutional investors and retail."

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Technology Disruption

By Richard Cleaveland and Christine Gagnon

The year 2020 has been an extremely challenging one and through it all, technology innovation has allowed many to stay connected with one another, continue working and even enable on-line commerce while physical locations were shut down. In fact, while some industries continue to struggle due to the COVID-19 pandemic, technology-focused companies have carved a path forward for business and have even thrived in this environment. The shutdowns have caused widespread adoption of collaboration technology, e-commerce platforms and mobile platforms, and have enabled many to re-think how they work, learn, shop and even engage with their medical providers.

Companies in these areas have led the significant positive performance of the stock market and have fueled a flurry of M&A and IPOs as 2020 closed out. Companies such as Zoom Technologies, DocuSign, Amazon and Shopify, among many others, have encountered growth in market capitalization that range from 100% to 300%, and some of the hottest IPOs of the year were e-commerce platforms such as DoorDash and Airbnb. 2020 has truly been a blockbuster year for IPO activity, which demonstrates how the public markets have valued technology companies than earlier private funding rounds. Enterprise solutions providers also realized the need to add collaboration and mobile functionality to their platforms to be competitive as evidenced by the recent announced transaction between Salesforce.com, Inc., a widely used CRM solution, and the business communications platform developer Slack Technologies.

Equally significant was the growth encountered by infrastructure and cloud services companies that support collaboration and e-commerce platforms. The need to operate in a virtual environment and build increased resiliency into systems led to significant growth for

those industries. In addition, for entities that did not already have their systems and infrastructure in the cloud, it became an imperative to move there as quickly as possible, which further fueled growth in the sector.

Finally payment platforms have seen significant growth in customer accounts, customer engagement and transactions during the year. Payment applications such as Venmo, PayPal and ApplePay have made it increasingly easy to have a touchless, germ-free way of instantly making payments and also simplified bill splitting. Additionally, the payment-based analytics provide business owners with more precise payment data and allow for better monitoring of customer transactions and spending.

Even with the full recovery from the pandemic, the demand for collaboration tools, e-commerce and payments platforms will continue and will fuel further innovation and M&A activities in these areas.

Steve Socolof, managing partner of Tech Council Ventures, an early stage venture capital firm, said: "The COVID-19 pandemic accelerated a trend already occurring to a more remote, mobile working environment. Not only does this provide an opportunity for collaboration tools, but will also increase demands for automation and security. This will be seen in industry as Industry 4.0 with data collection and analytics providing optimization and visibility across supply chain, manufacturing, and delivery with more connection directly to the end-customer."

The focus on innovation in the upcoming year will include those technologies supporting increased collaboration and mobility. Virtual meetings are going to continue to play an important role in how business is being conducted in the post-pandemic workplace and even more so, mobile technology will be required for immediate access at any time, from any place.

In addition, the continued transition to Industry 4.0 and the demands for automation and transparency will lead to further innovations and adoption of solutions using artificial intelligence and machine learning, and further use of data analytics.

On the Fintech front, PitchBook, in their Q3 Emerging Tech Research, believes large incumbent players in the financial services sector and high levels of regulation may continue to limit the disruption to core services such as banking and lending. In addition, they believe while e-commerce and peer-to-peer payments activity is up, volume of purchases may be adversely impacted by the prolonged economic stress of the pandemic. Despite this mixed outlook, while the payments and wealth sectors of technology may not have seen the growth other areas of technology experienced, there continues to be wider adoption of mobile and virtual banking services and areas such as cryptocurrency which continues to garner credibility with the industry. In fact, Coinbase Global, the largest U.S.-based cryptocurrency exchange has filed with the SEC for an IPO. This is actually the first major bitcoin-focused company to test the public markets. In addition, Square in its third quarter letter to shareholders discussed a continued acceleration of secular shift such as omnichannel commerce, contactless payments, and digital wallets for consumers.

Finally, there continues to be significant changes to health care. With the new administration, there is likely to be an increased focus on access. With the successful use of telehealth platforms over this past year, expect continued use of this technology to reach those groups currently underserved. In addition, the continued focus on behavioral health solutions will also drive demand

for applications using AI and data analytics.

These advances in automation, mobility, collaboration and data analytics drive across multiple verticals and provide a significant demand for better security over data and personally identifiable information. This perfect storm of a world extremely dependent on technology has become a breeding ground for cyber attacks and threats. In a recent article on cybersecurity risk assessment planning, Jason Connotillo, a Director in EisnerAmper's Process, Risk, and Technology Solutions, states that although "cybersecurity threats themselves are no longer novel, clients are taking notice that attacks appear to be rising during the pandemic and moving to a virtual work environment." In addition, increasingly regulators have questioned policies used by aggregators of data to safeguard personal information. The wave of regulation in this area will also drive innovation.

The COVID-19 pandemic was the perfect storm to cause significant technological disruption to how people work and live. This coming year will bring even more innovation and continue to drive the acceleration of the trend to a more distributed, connected and data driven society.

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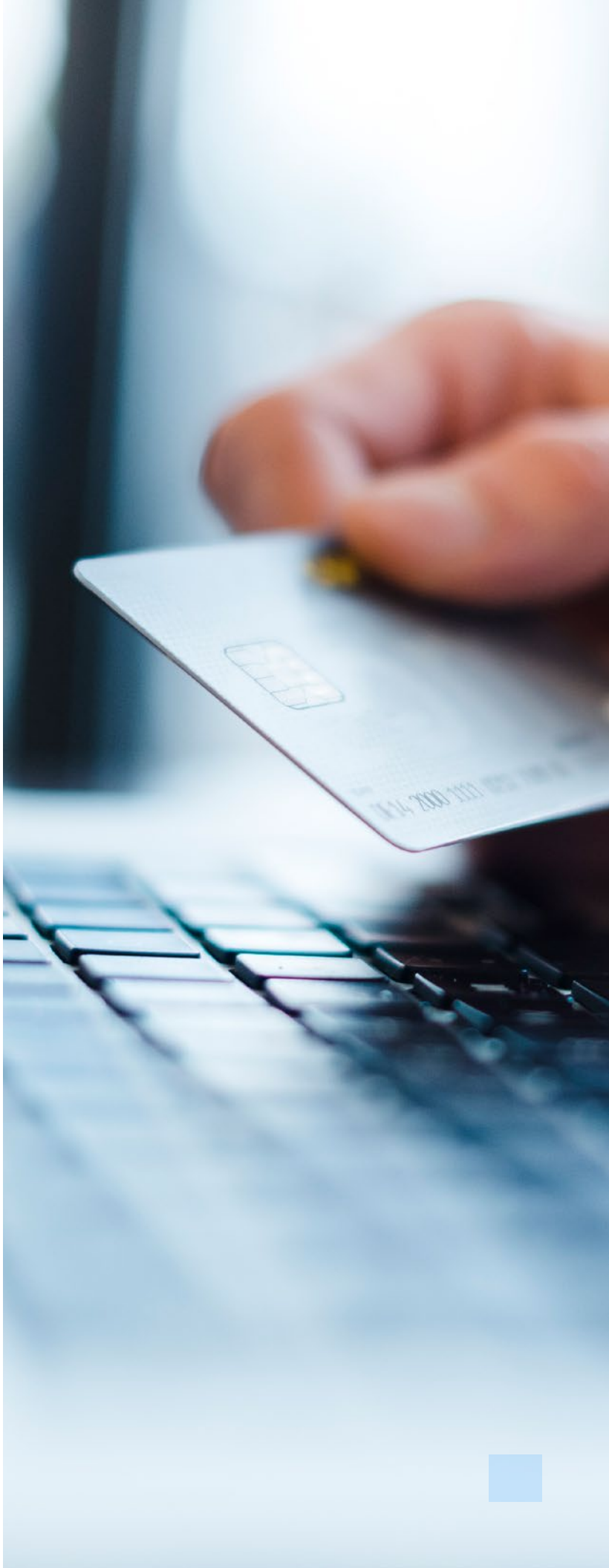

Reflecting on 2020, The Year of the IPO?

By Marc Fogarty

2020 will be remembered as the year we "stayed in place." The term "work from home" reached a new level; parents became teachers; and vacations were put on pause. Yet through it all, a vaccine for COVID-19 got started, tested and finalized within a calendar year. And none of that could have been done without the appetite for investors believing in science and giving companies the nod to spend their investment dollars on research and development. The pandemic shined a bright light on the need for therapies, and vaccines. The beneficiary of all of this was the initial public offering ("IPO") market, and more specifically, the life science IPO market.

During 2020, the IPO market was the hottest it's been in over in 20 years with more than 400 [1] offerings being completed by early December 2020. Over 75% of these IPOs occurred in the second half of 2020, when the U.S. was still learning how to do everything remotely. It is clear that the life sciences industry produced the lion share of these IPOs.[2]

"There has been $180 billion invested in the IPO market this year," said Ira Miller, CEO and chairman of Zone Capital Partners, a California-based M&A advisory firm for small- and mid-cap companies. "Life sciences is a big part of that as a percentage. The reason is that health care is 17% of the GDP so it will always play a significant part of the IPO market." The traditional IPO process can take a long time to complete. Between having a well-documented financial history and selecting board members and underwriters, the process unfortunately is built to miss peaks in the market. Private life science companies survive on fundraising in the early years and will rarely reach commercialization without access to the public market.

Having another option to become public, like a special purpose acquisition company ("SPAC"), has become a viable route for companies that seek access to the public markets, but in a less-than-traditional manner. SPACs are publically traded companies with no commercial operations. They

[1] www.stockanalysis.com

[2] www.iposcoop.com

raise money through an IPO with the sole intention of acquiring a fully operational private company, essentially allowing the private company to become public in a less traditional way. SPACs generally have two years to spend the money they raised in the IPO on a target company or they return it to the investors at the end of the SPAC term. For several years, private companies going public via a SPAC were not treated the same by the subsequent investing public; however, all that has changed in recent years and most notably 2020. The reason for the change in mindset: "The new normal." 2020 taught us that everything traditional needs to be re-evaluated and the SPAC market was no different.

"M&A is expected to grow to $300 billion next year," Miller said. "A big portion of that will be SPACs, which will be dominated by biotech and technology. Given COVID-19, SPACs have become more prevalent because they are faster to come to market, less expensive and have a redeemable feature such that if they don't come to market in a certain timeframe, investors are able to get their money back through a trust. Next year, the SPAC market will be slanted toward biotech. The bottom line is that biotech SPACS have surged 250% since 2019 with two dozen being announced since mid-October targeting more than $3.58 billion in proceeds." The pandemic year has shown us that medicine and science are important for the world to operate under normal conditions. Aside from the known players that have already developed a COVID-19 vaccine, there are several smaller companies that are actively looking for ways to improve on the delivery and effectiveness of the vaccine. These smaller companies are typically in pre-clinical or Phase I trials. Historically, most companies that are pre-clinical in nature are not IPO candidates; however, this year all that has changed. The desire from investors to get in earlier on these pre-clinical companies has become more attractive in the current period since the companies they invest in typically will touch a broader population of those than can benefit from the therapies/vaccines being developed.

The virtual nature of the current world has allowed companies and investors to meet over video and allowed many more meetings than typically would happen. The old process of getting on a plane and hopping city to city with investor presentations has been replaced with an efficient video call that allows companies to present to investors in New York at 10 a.m. and then San Francisco at 12 p.m. The virtual roadshow process for underwriters has opened many more doors than years past.

Many of the new normal ideas surrounding IPOs and target companies that were birthed in 2020 should not change in the immediate future and it is expected companies that are attractive to investors to continue to be attractive no matter the stage of development or geography. Everything has been expedited, and our work, whether performing audits or assisting companies in getting their filings done quickly, is no exception.

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