Market Trends 2018/19: Life Sciences

A Lexis Practice Advisor® Practice Note by Anna Pinedo and Ali Perry, Mayer Brown LLP

Anna Pinedo
Mayer Brown LLP

Ali Perry
Mayer Brown LLP

This market trends article examines recent trends in life sciences by addressing (1) deal trends with respect to capital markets and mergers and acquisitions (M&A); (2) disclosure trends; (3) legal and regulatory trends; and (4) an outlook for activity in the life sciences sector going forward.

For a more detailed discussion of the unique life sciences issues for transactional lawyers, see Life Sciences Industry Practice Guide, Life Sciences M&A Transactions and Life Sciences in International Jurisdictions.

Deal Trends

Growing a life sciences company is time and resource intensive, and at each stage of a life sciences company's development, its funding needs change. Companies must consider the timing of their financings in light of their announcements, such as announcements related to clinical trial enrollment, new clinical trial data, new strategic relationships or collaborations, and other corporate events, as well as their cash burn rates. Other considerations include balancing cash needs against the difficulties often associated with financing particularly when there is no news or at least no significant news, and whether the company should consider undertaking dilutive financings or waiting until other financing opportunities become available.

Before a life sciences company can undertake an IPO, in most cases it will need to establish strong investor sponsorship. Outside of the life sciences sector, a lot has been written regarding the increased availability of private capital for pre-IPO companies and the increase in the number of mega financing rounds. Private capital sources have improved for the life sciences sector, but not to the same extent as for tech companies. Life sciences companies remain dependent on committed sector investors and investors that are willing to withstand the often seven to ten year time horizon generally associated with life sciences company financings. Of course, the prospects for success are less predictable in the life sciences sector than in other sectors. As a result, while tech and fintech companies may have the option to stay private longer, rely on successive rounds of private placements, and defer their IPOs, or no longer see IPOs principally as financing opportunities, the same cannot be said of life sciences companies. Generally, life sciences companies continue to view IPOs as important capital-raising opportunities.

In 2018, most life sciences companies that conducted an IPO (approximately 36.8%) did so when they were in Phase II of clinical trials. Of the other life sciences IPOs undertaken in 2018, 22.1% of the IPO issuers were in Phase I of clinical trials, 17.6% were in Phase III of clinical trials, 14.7% were in the preclinical stage and 8.8% were in the commercial stage.

2018-2019 deal trends in the life sciences industry are discussed below in detail.

Venture Capital (VC) Activity

VC activity in the United States reached an all-time high in 2018, exceeding over $100 billion for the first time since 2000, totaling $131 billion, which is a 58% increase from 2017 (according to PitchBook-NVCA Venture Monitor as of December 31, 2018). VC activity in the life sciences sector also reached record levels in 2018, but accounted for only 16% of total VC activity. In 2018, there were 1,308 life sciences VC deals totaling $23.3 billion, with approximately 60% of such deals valued at over $50 million each. Chinese VC investment in U.S. life sciences companies also reached a record high in 2018 at 80 deals totaling $5.0 billion, a significant increase from 2017 at 54 deals totaling $3.5 billion.

Debt Financing

A notable trend in recent years has been the growth in alternative lenders that are prepared to finance life sciences companies. Participants in this market include certain commercial banks; alternative, or direct, lenders; royalty-based financing sources; and business development companies. These transactions may take various forms, from secured note issuances to bank-style draw-down financing commitments subject to repayment upon the occurrence of specified milestones or liquidity events. Often the issuance of debt-like securities will be accompanied by the issuance of warrants or another equity security as a kicker or sweetener. Particularly in the case of companies with in-licensed intellectual property, granting security interests may give rise to burdensome diligence and documentation issues. According to an investment bank survey, although the broader debt markets have shown recent signs of pulling back, lenders continue to aggressively pursue opportunities within the healthcare sector. Of the respondents in the survey, 41% of lenders surveyed identified the healthcare sector as an industry as to which their firm is proceeding more aggressively as of the fourth quarter of 2018 compared to six months prior.

Pre-IPO (or Crossover) Financing

For companies that are 12 to 24 months away from an IPO, pre-IPO private placements have become an important stepping stone. While this is generally true of most IPO issuers, for life sciences companies, it is particularly significant. The pre-IPO round not only serves to provide much-needed capital, but perhaps more importantly provides validation from sector investors. Also, there is a presumption that pre-IPO investors will be anchor investors in the IPO. Pre-IPO investors will also expect a step-up from the pre-IPO round to the IPO.

There are several considerations for life sciences companies in the context of pre-IPO financings. By their nature, investments in life sciences companies usually require more extensive and complex due diligence. The company will also need to establish a time horizon as pre-IPO investors may have a specific timeline in mind for the IPO and a target valuation. Unlike pre-IPO rounds for unicorns, generally valuations for life sciences companies' pre-IPO rounds have not been as rich. Therefore it is essential for life sciences companies to understand the milestones or other value creation events that will transpire between the pre-IPO round and the IPO.

IPOs for companies that completed at least one crossover round with public institutional investors before undertaking an IPO tend to perform better at pricing and in the aftermarket. According to an industry report, as of November 22, 2019, 28 of the last 40 biopharmaceutical company IPOs completed a pre-IPO crossover financing within 365 days of its IPO. Median step-up for crossover financings within 365 days of the IPO was 1.2x. Companies that undertook at least one crossover round prior to their IPO had, on average, a higher IPO deal value and were more likely to price their IPO within or above their initial price range than companies that did not undertake a crossover round prior to their IPO. A significant percentage of life science IPOs also have had insider participation and the insider participation may have contributed positively to the success of the deals.

IPOs

Healthcare was the most active sector in the IPO market in 2018, comprising 49% of the IPOs during the year. In 2019, through the third quarter of 2019, pharma and life sciences IPOs accounted for over a one-third of the IPOs completed. Healthcare IPO volume increased in 2018 while median proceeds raised and performance remained constant compared to 2017. According to an industry publication, there were 81 SEC-registered healthcare IPOs in 2018 raising a median of $86.3 million, with 67 of the 81 IPOs having priced within or above the initial filing range. In 2017, there were only 48 life sciences IPOs raising a median of $84.9 million. For both 2017 and 2018, approximately 82% priced within or above the IPO price range. In terms of aftermarket performance, 45.8% and 29.6% of the life sciences IPOs in 2017 and 2018, respectively were trading above issue as of November 22, 2019.

Notable IPOs in 2018 included: (1) Elanco Animal Health Incorporated (NYSE:ELAN), a subsidiary of Eli Lilly and Company (NYSE:LLY) specializing in animal medicine, raising $1.5 billion in September 2018 in an SEC-registered offering, and (2) Siemens Healthineers AG, a medical technology company and subsidiary of Siemens AG, raising $5.2 billion in March 2018 in a non-SEC registered offering in Frankfurt, Germany.

According to William Blair's November 2019 Healthcare ECM Update, as of November 22, 2019, there have been 71 healthcare IPOs in 2019 raising a median of $97.6 million. 55 of the 71 IPOs priced within or above its initial filing range. Aftermarket performance has been mixed with a weak median one-day return of 5.5%, but a stronger median current return of 18.4%, and 60.0% were trading above issue as of November 22, 2019. As of November 22, 2019, there was an active backlog of healthcare IPOs of 6 issuers with deal sizes ranging from $23.0 million to $100 million.

Notable IPOs in 2019 included: (1) Avantor Inc. (NYSE:AVTR), a provider of biomedical research products and services, raising $3.3 billion in May 2019, making it the second largest IPO of the year so far (second only to Uber's IPO, which raised $8.1 billion in May 2019), and (2) SmileDirectClub Inc. (Nasdaq:SDC), an online dental equipment company, raised $1.3 billion in September 2019.

Follow-On Offerings

The most important change in recent years in the United States is that public follow-on offerings have become less public. Due to market developments, such as changes to the shelf registration statement eligibility rules, heightened volatility and concerns about investor front-running, issuers are turning to a variety of alternatives to fully marketed, traditional underwritten public follow-on offerings. These alternatives include confidentially marketed public offerings (CMPO), private investment in public equity (PIPE) transactions, and registered direct offerings. In addition, at-the-market (ATM) offerings, which are announced, have similar attributes to these financing alternatives, including the ability to avoid investor front-running. However, in 2018 there was an increase in public marketing as deal activity increased and market conditions were strong in the pre-Labor Day period. Overall, companies that are eligible to file and maintain a shelf registration statement do so and companies were reminded of the value of a shelf registration statement during the SEC shut-down in December 2018. Having an effective shelf registration statement facilitates financings and increases issuer optionality. Most follow-on offerings are now completed as takedowns from shelf registration statements. According to William Blair's November 2019 Healthcare ECM Update, there were 236 healthcare follow-on offerings in 2018, an increase compared to 2017, which had 200 healthcare follow-ons, and as of November 22, 2019, there were 171 healthcare follow-on offerings in 2019. 2018 represented the most active year for life sciences follow-ons since 2015, both in terms of absolute dollars raised and number of deals. However, despite elevated market activity, pricing discounts for 2019 have increased as the median file/offer discount as of November 22, 2019 was 10.1% compared to 8.3% in 2018 and 7.5% in 2017.

Pre-marketed or Confidentially Marketed Public Offerings

Confidential marketing remains the most prevalent execution strategy for small/micro-cap issuers, while larger companies often choose to forego the wall-cross process. Investors required wider discounts when pricing follow-on offerings for micro-cap issuers while larger issuers saw narrower discounts and stronger after market price performance. According to William Blair's November 2019 Healthcare ECM Update, in 2018, of the 236 healthcare follow-on offerings, 37.7% were confidentially marketed, and in 2019, as of November 22, 2019, 46.8% of the 171 healthcare follow-on offerings were confidentially marketed.

PIPE Offerings

Among deal formats, generally reliance on PIPE transactions has declined significantly, although for the life sciences sector, PIPE transactions remain important. Since 2014, the healthcare industry has raised over $30.4 billion through 1,289 PIPEs. In 2018, there were 317 PIPEs completed by healthcare companies, raising $12.5 billion. As of September 30, 2019, there have been 282 PIPEs completed by healthcare companies, raising $11.9 billion.

Registered Direct Offerings

Registered directs allow an issuer to achieve public style pricing while maintaining the relative confidentiality of a private placement. A registered direct offering is a best efforts placement of registered common stock off an issuer's existing effective shelf registration statement, generally, to a limited number of institutional investors. For many life sciences companies with a shelf registration statement, a sale of additional securities to one or more existing holders may be easily structured as a registered direct offering, and may be preferable to a PIPE transaction because unlike a PIPE, investors will receive registered, freely transferable securities and therefor there is no liquidity discount. Also, because the transaction is registered, the company is not limited to sales to accredited investors.

The number of registered direct offerings have been consistent in recent years. In 2017, healthcare companies raised $1.2 billion through 125 registered direct offerings, and in 2018, healthcare companies raised $1.18 billion through 83 registered direct offerings. Notable deals in 2018 include a $150.0 million registered direct offering by Verastem, Inc. (Nasdaq:VSTM), a biopharmaceutical company focused on cancer therapies, and a $100.0 million registered direct offering by Adaptimmune Therapeutics plc (Nasdaq:ADAP), clinical-stage biopharmaceutical company focused on T-cell therapy to treat cancer. This trend of consistent registered direct offerings in the healthcare industry is expected to continue in 2019. As of September 30, 2019, healthcare companies have raised approximately $6.7 billion through 249 registered direct offerings.

ATM Offerings

ATM offerings are an offering of securities into an existing trading market at publicly available bid prices, and are commonly referred to as "equity distribution" or "equity dribble out" programs. Shares are dribbled out to the market over a period of time at prices based on the then prevailing market price of the securities and, generally, sales do not involve special selling efforts. ATM offerings can be helpful in facilitating block trades of primary shares for large institutional investors. For life sciences companies, ATMs may pose special challenges. For example, some ATM distribution agents only will offer securities of actively traded companies. Also, the volume in the stock may not allow for significant amounts of capital to be raised. For baby shelf issuers, or those with under $75 million in market capitalization, an ATM uses up the one-third primary offering capacity permitted.

M&A Activity

Recent years have been marked by strong life sciences M&A activity as companies move outside their traditional business areas to consolidate larger segments of the life sciences market. According to Ernst & Young's 2019 M&A Firepower Report, in 2018, M&A activity in the life sciences industry totaled $198 billion, an increase from 2017 of $178 billion, but a decrease from 2014 through 2016, which averaged approximately $284 billion per year. This decrease in 2018 and 2017 compared to prior years is partly due to a decrease in average deal size. Aside from the year's sole mega-deal of $62.0 billion for the acquisition of Shire plc by Takeda Pharmaceutical Company Ltd. (which closed in January 2019), other notable transactions in 2018 include Celgene Corporation (Nasdaq:CELG) acquiring Juno Therapeutics, Inc. (Nasdaq:JUNO) for $9.0 billion and Impact Biomedicines for $1.1 billion. 2018 was marked by smaller less transformative deals than in 2014 through 2016. High valuations of biotechnology and digital health companies may also have factored into the decrease in M&A activity in 2018. According to Ernst & Young's 2019 M&A Firepower Report, market valuations of biopharmaceutical companies increased 78% since 2014.

There have so far been nine major M&A deals announced in the healthcare sector in 2019:

1 Bristol-Myers Squibb Company (NYSE:BMY) announced in January 2019 that it was acquiring Celgene Corporation (Nasdaq:CELG) for $74.0 billion. The deal was completed on November 20, 2019. The combined company will have nine products with more than $1.0 billion in annual sales and six expected near-term product launches in immunology, inflammation and hematology representing revenue potential of more than $15.0 billion. In addition, in connection with the merger, on August 26, 2019, Celgene entered into an agreement with Amgen Inc. (Nasdaq:AMGN) to sell Otezla® (apremilast), an oral, non-biologic treatment for psoriasis and psoriatic arthritis, and certain related assets and liabilities, for $13.4 billion.

2 AbbVie Inc. (NYSE:ABBV) announced in June 2019 that it is acquiring Allergan PLC (NYSE:AGN) for $63.0 billion. The deal is anticipated to close by the end of the first quarter of 2020, subject to regulatory and shareholder approvals.

3 Pfizer Inc. (NYSE:PFE) announced in July 2019 that its off-patent unit, UpJohn, which distributes Lipitor and Viagra, will be merging with Mylan N.V. (Nasdaq:MYL), creating a new company to be called Viatris in an all-stock, "Reverse Morris Trust" transaction valued at $32.7 billion. The merger is expected to be completed in mid-2020.

4 Danaher Corporation (NYSE:DHR) announced in February 2019 that it is acquiring GE Biopharma, the biopharmaceutical business of General Electric Company (NYSE:GE), for $21.4 billion. GE Biopharma will join Danaher's Life Science segment as a standalone business, adding technology, equipment and supplies for biotech drug production to Danaher's current portfolio of life sciences companies. The deal is expected to be completed in the first quarter of 2020.

5 Pfizer Inc. (NYSE:PFE) announced in June 2019 that it was acquiring Array BioPharma Inc. (Nasdaq: ARRY), a U.S.-based, clinical stage, pharmaceutical company focusing on oncology medication, for $11.4 billion. The deal closed on August 1, 2019.

6 Eli Lilly and Company (NYSE:LLY) announced in January 2019 that it was acquiring Loxo Oncology, Inc. (Nasdaq:LOXO), a biotech company focused on developing cancer therapies, for $8.0 billion, broadening Eli Lilly's portfolio of medicines for patients with genomically defined cancers. The deal was completed on February 15, 2019.

7 Roche Holding AG (SIX:RO, ROG) (OTCQX:RHHBY), a Swiss pharmaceutical company, announced in February 2019 that it is acquiring Spark Therapeutics, Inc. (Nasdaq:ONCE), a Philadelphia-based pharmaceutical company, for $4.3 billion. The tender offer was extended for a tenth time on December 9, 2019 as the U.S. Federal Trade Commission and the UK Competition and Markets Authority continue their respective reviews of the transaction.

8 Merck & Co., Inc. (NYSE:MRK) announced in May 2019 that it is purchasing Peloton Therapeutics, Inc., a clinical-stage biopharmaceutical company focusing on cancer therapies, in an all-cash deal for approximately $1.1 billion. Merck also announced in December 2019 that it is acquiring ArQule, Inc. (Nasdaq:ARQL), a biopharmaceutical company focusing on cancer therapies, for approximately $2.7 billion, representing a 100% premium over ArQule's share price. The transaction is expected to close in the first quarter of 2020.

9 Sanofi SA announced in December 2019 that it is acquiring Synthorx Inc. (Nasdaq:THOR), a clinical-stage biotechnology company focusing on cancer and autoimmune disorder therapies, for approximately $2.5 billion, representing a 172% premium to Synthorx's share price. The tender offer is expected to commence in December 2019 and close in the first quarter of 2020.

In addition, earlier in the year, there was increased M&A activity in the cannabis sector:

1 In April 2019, Canopy Growth Corporation (NYSE:CGC), a Canadian cannabis company, announced that it would be acquiring Acreage Holdings, Inc., a multi-state operator of cannabis licenses and assets in the United States, in a deal valued at $3.4 billion. However, the deal is subject to U.S. federal legalization of cannabis.

2 Curaleaf Holdings, Inc. (CSE: CURA) (OTCQX: CURLF), a U.S. cannabis company, announced in May 2019 that it will be acquiring the state-regulated cannabis business of Cura Partners, Inc., a maker of oil for vape pens, for $949.0 million. Then in July 2019, Cura Holdings, Inc. announced that it is also acquiring GR Companies, Inc., a private multi-state cannabis operator, for approximately $875.0 million.

3 In April 2019, Cresco Labs Inc. (CSE:CL) (OTCQX:CRLBF), a U.S. cannabis company, announced that it had entered into a definitive agreement to purchase CannaRoyalty Corp. d/b/a Origin House (CSE:OH) (OTCQX:ORHOF), a Canadian cannabis company with a large distribution network in the United States, for $823.5 million.

4 In April 2019, Harvest Health & Recreation, Inc. (CSE:HARV) (OTCQX:HRVSF), a U.S. cannabis company, signed a definitive agreement to purchase Verano Holdings, LLC, another U.S. cannabis company, for $850.0 million. The combined company will be one of the largest multi-state operators in the United States, with up to 200 facilities across 16 states, including 123 retail dispensaries.

However, in the latter half of 2019, M&A deals in the cannabis sector have slowed or even fallen apart. Specifically, in October 2019, MedMen Enterprises (OTC:MMNFF) announced that it was shelving its previously announced $682.0 million acquisition of privately-held MSO PharmaCann, citing changing markets and the length of time regulators were taking to approve the deal. Then in November 2019, Curaleaf announced that it had amended its deal to acquire Cura Holdings, decreasing the all-stock deal value from $949.0 million to approximately $293.0 million. Also, in November 2019, Cresco Labs announced that its deal to purchase Origin House had been amended, reducing the value of the transaction from $823.5 million to approximately $263.0 million. These deal trends exemplify the volatility of this sector, as investors recognize that some companies were vastly overvalued and as the regulatory environment continues to change and evolve.

For more detailed discussion on M&A transactions in life sciences, see Life Sciences M&A Transactions.

Disclosure Trends

Cybersecurity

Cybersecurity disclosure has become increasingly important for life sciences companies as data sharing and analysis play a greater role in research and development (R&D) activities. The SEC staff has been focusing on, and providing comments to companies regarding, cybersecurity disclosure. Due to the significance of cybersecurity issues, the SEC staff monitors press reports on cybersecurity incidents and may raise questions about the sufficiency of cybersecurity disclosure in SEC reports. With heightened focus on cybersecurity by the SEC, issuers' disclosures in the risk factors section, business section, management's discussion

and analysis (MD&A) section and the financial statements of their securities offering documents and reports filed with the SEC have become more detailed. In February 2018, the SEC published an interpretative release, Commission Statement and Guidance on Public Company Cybersecurity Disclosures, to assist public companies in preparing disclosures about cybersecurity risks and incidents.

Insider Participation in IPOs

Insider participation in life sciences IPOs increased slightly in 2019 and 2018 compared to 2017. As of November 22, 2019, the median insider participation for 2019 was 28.1%. In 2018, median insider participation was 25.9%, an increase from 2017 of 24.2%. Insider participation refers to capital committed by affiliates of the issuer at IPO pricing and excludes broader participation from existing or cross-over investors. Both the Financial Industry Regulatory Authority (FINRA) and the SEC expect to see disclosures relating to insider participation in the IPO prospectus, and depending on the percentage of the IPO that will be allocated to the insiders, additional disclosures may be advisable because insider or affiliate holdings may have the effect of reducing public float and future sales by insiders may have a disproportionately negative effect on stock price.

Accounting-related Issues

Revenue recognition, R&D, business combinations and non-GAAP measures have been areas of focus by the SEC staff with regard to accounting disclosures made by companies in the life sciences industry.

Revenue recognition continues to be a key topic in recent SEC staff comment letters. In the life sciences industry, many companies rely heavily on estimates and assumptions to recognize revenues, and adjustments to prior period estimates require disclosures with regard to the magnitude and nature of such adjustments. In addition, life sciences companies commonly enter into licensing agreement to transfer intellectual property along with other services such as R&D and manufacturing. Similarly, collaborative agreements are common among biotech and pharmaceutical companies. Recognizing revenues related to licensing activities and collaborative agreements requires a company to make judgments as to the what and how the consideration for such licensing agreements should be recognized. The SEC staff continues to request companies to provide enhanced disclosures with regard to revenue recognition to describe the considerations a company made to determine its accounting treatment, including the significant judgments, estimates and assumptions.

As life science companies fuel their future product pipelines, the expenses related to such pivotal activities result in costs often classified as R&D. The SEC staff frequently asks companies with significant R&D costs to support the classification of such costs as R&D and to provide robust disclosures about capitalizing prelaunch products that has not been approved by the FDA. Specifically, the SEC staff has asked life science companies to quantify the total amount of capitalized unapproved product inventory and clarify their accounting policy for the capitalization of unapproved product inventory. In addition, the SEC staff may ask a registrant to provide disclosures that help a reader understand the comparability of cost of sales in periods before and after prelaunch products began to be capitalized.

As discussed above, mergers and acquisitions activity is prevalent in the life sciences industry as companies look to expand their pipeline of products in development and acquire commercial products. Depending on the nature and purpose of the assets being acquired, the combination will be accounted for as a business combination or an asset acquisition. Accordingly, the SEC staff often issues comments to life sciences companies inquiring as to the basis of their accounting treatment and the considerations made in determining whether the acquisition meets the definition of a business combination or an asset acquisition.

The number of SEC comments on non-GAAP measures to life sciences companies as decreased in recent years but it still continues to be a key topic of focus for the SEC staff. The SEC staff has continued to evaluate the form of non-GAAP disclosures including focusing more acutely on the appropriateness and usefulness of the metrics presented and the nature of the adjustments included therein. For example, some companies in the life sciences community make adjustments for up-front, milestone, and royalty payments made to or received from other parties to business development transactions. The SEC staff has commented on the nature and purpose of these adjustments. Life sciences companies should continue to evaluate the facts and circumstances supporting the non-GAAP metrics it presents in its SEC filings, the adjustments included therein, and the usefulness of those items to external stakeholders and the investing community.

Legal and Regulatory Trends

The regulatory environment for life sciences can be unpredictable and are driven by a variety of forces including, political shifts, changes in social norms and behaviors, and technological innovation.

Scrutiny Over Drug Pricing

Globally, there has been increasing pressure for governments to curtain healthcare spending. In May 2018, the White House and the U.S. Department of Health and Human Services released a blueprint to lower drug prices, reduce out-of-pocket costs for consumers, and make drugs more accessible by improving competition, facilitating better negotiation for Medicare and government programs, incentivizing lower list prices and reducing out-of-pocket costs. Scrutiny over drug pricing is also increasing in the United Kingdom, European Union and China.

As the life sciences sector continues to face pressure to drive prices down and demonstrate the value of their products, competition will increase and companies will need to provide consumers with greater transparency to rationalize their drug prices.

Cybersecurity

The recent rise in cybersecurity and data privacy attacks has led to greater regulation and scrutiny over data security. The risks and costs of regulatory non-compliance and reputational damage from cyber and privacy security have also increased. In the life sciences industry, data sharing and analysis have become key to innovation. One innovation of particular concern is the advent of wireless, sensor-based medical devices. Cyber criminals can target these devices to gain entry into hospital networks, access sensitive information and harm patients through device tampering. The Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) have become increasingly active in the cybersecurity space. In 2017, the FDA released its Digital Health Innovation Action Plan, which outlines the agency's efforts to modernize its policies in the face of digital innovation, and has continued to put forth draft guidance regarding its recommendations relating to digital health and cybersecurity.

In the Europe Union, the General Data Protection Regulation (GDPR), a stringent regulation related to data protection, was implemented in May 2018. While the scope of GDPR specifically pertains to EU residents, it applies to any organization that offers goods or services to EU residents or collects, processes, monitors, hosts or stores personal data of EU residents. Challenges for medical device manufacturers and healthcare companies include understanding what data they have and where it resides, implementing adequate privacy and security measures for both traditional IT systems and medical devices that may create, store, use or transmit data of EU customers, and complying with data breach reporting requirements. One of the GDPR's largest impacts is its potential penalties for noncompliance: up to four percent of annual global turnover or 20 million euros, whichever is greater.

The evolving regulatory framework and enforcement considerations in the United States and abroad, combined with increasing demands from consumers, have pushed privacy and security to the top of the corporate agenda and led many organizations to strengthen their privacy and security team and capabilities.

Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA)

In October 2018, the U.S. Department of Treasury announced a pilot program to implement part of the FIRRMA, effective November 10, 2018. The pilot program expands the jurisdiction of the Committee on Foreign Investment in the United States (CFIUS), an inter-agency committee under the U.S. Department of Treasury that is authorized to review transactions that could result in foreign control of a U.S. business and to block deals in the name of national security. One of the areas of focus under the pilot program is "research and development in biotechnology." The pilot program provides CFIUS with a longer review program of direct or indirect foreign investments in certain defined categories of U.S. companies, grants CFIUS with more power to stop acquisitions that are not voluntarily brought in front of the committee for inspection, and expands its purview to include some non-controlling investments. FIRRMA also empowers CFIUS to require certain foreign investors to make mandatory filings and to charge filing fees related to such filings. Such filings are subject to review by CFIUS.

Life sciences companies that rely on investments from foreign markets, including China, may be affected by FIRRMA.

Fundraisings that do not result in potential ownership, such as convertible notes, warrants and joint ventures are not covered by CFIUS.

Cannabis

Cannabis is an emerging frontier in the life sciences industry. 2018 was a transformative year with the legalization of marijuana in Canada in October 2018, changes to federal hemp and cannabidiol (CBD) policy in the United States under the Agricultural Improvement Act of 2018, and the growing number of U.S. states legalizing marijuana for medical and/or recreational use. Also in June 2018, GW Pharmaceuticals plc (Nasdaq:GWPH) became the first cannabinoid-based drug developer to get a cannabis-derived therapy (Epidiolex) approved by the U.S. Food

and Drug Administration for the treatment of seizures associated with two rare and severe forms of epilepsy. 2018 saw numerous U.S. cannabis companies going to Canada to list on the Canadian Stock Exchange (CSE) as well as several listings on the NYSE and Nasdaq. Tilray Inc. (Nasdaq:TLRY) was the first cannabis company to IPO on a U.S. exchange, raising $153 million in July 2018. Although marijuana remains a complex regulatory issue in the United States, this momentum continued in 2019. Sundial Growers (Nasdaq:SNDL) raised $143 million in August 2019, becoming the second cannabis company to IPO on a U.S. exchange.

The legal and regulatory landscape continues to evolve in the cannabis sector. The recent increase in vaping-related illnesses and deaths may have a chilling effect on the cannabis industry, as the federal government prepares to ban the sale of flavored e-cigarettes, which could have broader ramifications for the cannabis sector, including additional regulations targeting the sale of marijuana vaporizers. Conversely, the U.S. Congress is currently reviewing the Secure and Fair Enforcement (SAFE) Banking Act, which if enacted, will allow financial institutions to do business with state-legal cannabis companies.

Market Outlook

Global healthcare spending is on the rise and is expected to have a compound annual growth rate (CAGR) across 60 countries of 5.4% for the period from 2018 to 2022, compared to just 2.9% for the period from 2013 to 2017 (according to World Industry Outlook, Health Care and Pharmaceuticals, Economic Intelligence Unit, June 2018). The dominant therapy segment is expected to continue to be oncology, growing US$129 billion in projected worldwide sales from 2017 to 2024 and reaching US$233 billion by 2024 (according to World Preview 2018, Outlook to 2022, EvaluatePharma, ***2018***).

Decreasing returns from research and development have caused companies to look externally to source innovation. In the near term, traditional life sciences companies facing expiring patents, increased competition and weak drug pipelines are mostly likely to use alliances to acquire growth capabilities through licensing, joint venture and M&A deals. Such deals will also be attractive to the hundreds of startups currently developing next-generation therapies given the lack of manufacturing capacity that is expected to continue in the near term. As a result of the hundreds of ongoing clinical trials and projected drug launches, the contract manufacturing capacity is already taxed with wait times ranging from 12 to 24 months (according to Deloitte's 2019 Global Life Sciences Outlook).

Recent U.S. tax reform, which reduced the corporate tax rate and eliminated prior tax disincentives on the repatriation of foreign cash reserves, should help keep the U.S. M&A market strong. However, anticipation of a cyclical downturn in the U.S. economy in 2020 and continued political uncertainty could weaken the life sciences market.

Technology will continue to play an increasingly important role in the life sciences industry. As data connectivity grows, companies can access a deeper network of information, fostering collaboration and accelerating learning. New transformative technologies like artificial intelligence and advanced analytics are broadening the capabilities of life science companies and revolutionizing diagnoses, treatment planning, patient monitoring and drug discovery. Large technology giants like Apple and Google are diversifying into healthcare and life sciences, hoping to capitalize their technological expertise to broaden their service offerings. These new entrants will represent both opportunities for partnerships as wells as competitors and disrupters to the life sciences industry.

Current trends related to cybersecurity and data privacy indicate that the regulatory environment will continue to evolve both in the United States and abroad as regulators continue to provide additional guidance on implementing and enhancing data security and privacy measures. Blockchain has emerged as a potential solution to aggregate and share data securely. Other changes in the regulatory environment, driven by political shifts, innovation and social norms and behavior will require companies to continue to focus on implementing and enhancing cyber and privacy security.

Anna Pinedo, Partner, Mayer Brown LLP

Anna Pinedo is a partner in Mayer Brown's New York office and a member of the Corporate & Securities practice. She concentrates her practice on securities and derivatives. Anna represents issuers, investment banks/financial intermediaries and investors in financing transactions, including public offerings and private placements of equity and debt securities, as well as structured notes and other hybrid and structured products.

She works closely with financial institutions to create and structure innovative financing techniques, including new securities distribution methodologies and financial products. She has particular financing experience in certain industries, including technology, telecommunications, healthcare, financial institutions, REITs and consumer finance. Anna has worked closely with foreign private issuers in their securities offerings in the United States and in the Euro markets. She also works with financial institutions in connection with international offerings of equity and debt securities, equity- and credit-linked notes, and hybrid and structured products, as well as medium term note and other continuous offering programs.

In the derivatives area, Anna counsels a number of major financial institutions acting as dealers and participants in the commodities and derivatives markets. She advises on structuring issues as well as on regulatory issues, including those arising under the Dodd-Frank Act. Her work focuses on foreign exchange, equity and credit derivatives products, and structured derivatives transactions. Anna has experience with a wide range of transactions and structures, including collars, swaps, forward and accelerated repurchases, forward sales, hybrid preferred stock and off-balance sheet structures. She also has advised derivatives dealers regarding their Internet sites and other Internet and electronic signature/delivery issues, as well as on compliance matters

Ali Perry, Associate, Mayer Brown LLP

Alexandra (Ali) Perry is an associate in Mayer Brown's New York office and a member of the Capital Markets practice.

Ali earned her JD from the University of Pennsylvania Law School where she was the managing editor of the Journal of Business Law and a member of the Entrepreneurship Legal Clinic. She also received a Certificate of Management from The Wharton School of Business. She received her BBA in Accounting and Finance from Emory University's Goizueta School of Business and is a certified public accountant.