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USA: Trends & Developments

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Trends and Developments

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Ropes & Gray LLP

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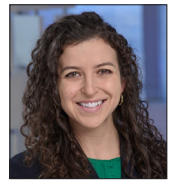

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Introduction

The life sciences industry in the USA continues to be significantly impacted by the COVID-19 pandemic. Companies experienced a record number of deals and high valuations during the biotech boom in 2020 and 2021. This past year marked the turning point – with economic instability, rising inflation, and ongoing supply chain disruptions cooling the rapid expansion and bringing uncertainty within the industry. Such market unpredictability will likely persist throughout 2023. This article will examine emerging trends and regulatory updates in the biotechnology, pharmaceutical, medical device, and digital health sectors.

Biotechnology and Pharmaceuticals

After a record-setting pace of biotech investment activity in 2021, 2022 was a relatively sobering year for the industry – particularly in comparison with the pre-pandemic economic boom. During 2022, 22 biotech companies debuted on public markets, which is less than half of the number in each of the previous four years (including 104 IPOs in 2021).

Pharma companies also faced difficulties in the bear market. Rising inflation cut into profitability and this appeared to contribute to lower deal volume. The volume of higher-value M&A deals in 2022 was lower than previous years as well, with only 17 deals topping USD1 billion in value. Concerns over a prolonged recession in 2022 were a factor in turning venture capital financing options colder, making pharma deal activity less aggressive, and significantly reducing valuations for public market biotech financing. Moreover, uncertainty around the longer-term effects of the Biden Administration's implementation of the Inflation Reduction Act (IRA) and increased enforcement of regulatory requirements have had an impact on the industry.

The wide-ranging IRA has become a point of strong interest to the biopharma industry – at least in part owing to the potential for lower profits and uncertain sales projections resulting from the IRA's enactment. The new legislation, signed into law in March 2022, gives Medicare the ability to negotiate pricing for the 50 highest-selling medications that lack competition. Under the IRA, Medicare can target "small molecule" drugs just nine years after market approval and can target "large molecule" drugs after 13 years. Some in the biopharma industry have raised concerns that, as a result, the IRA will disincentivise small molecule development. While the actual effects of the IRA on the biopharma industry will likely not be fully understood for years (or, potentially, decades), the uncertainty around pricing may depress sales projections and therefore further limit financing options for biotech companies. Also, biotech companies are increasingly expected to share in the impact of any pricing reduction related to the IRA under pharma partnerships.

Additionally, the headwinds in the regulatory space point towards the Food and Drug Administration (FDA) more strictly enforcing the requirements around the accelerated approval programme, including as reflected in the Food and Drug Omnibus Reform Act (FDORA) enacted on 29 December 2022. At a high level, the accelerated approval programme allows for expedited approvals for drugs serving unmet needs. After accelerated approval, confirmatory trials are often required. However, there has been increasing concern over the enforcement of this requirement, transparency of the conditions related to accelerated approval, and the perceived reluctance by the FDA to require a market withdrawal of a drug if such conditions are not met.

The FDORA provides the FDA with more tools to require the conduct of confirmatory trials – for example, by requiring that such trials are initiated prior to accelerated approval being granted. It also requires more public-facing information to be disclosed regarding both the conditions of accelerated approvals and the satisfaction of such conditions, as well as creating a pathway for the FDA to require more expedited mandatory market withdrawals if such conditions are not met. In 2023 and beyond, there is growing belief in the pharma industry that the FDA will move to enforce these requirements more closely for accelerated approval. This could result in increased research and development costs being baked into product budgets and lead to the negotiation of downstream economics between biotech and pharma companies.

Despite depressed biotech valuations that would seem to be attractive targets for larger pharma companies, pharma was not as active in the deal space in 2022 as might have been expected. Pharma continued to cautiously deploy cash in an uncertain market and sometimes instead relied on stock buybacks and investment in homegrown pipelines to buoy themselves through the market instability, resulting in biotech companies needing to make difficult decisions in the face of fewer funding options. For biotech companies, redirecting funds into research and development may require a temporary or permanent reduction in resources, including personnel. In 2022 alone, more than 100 biotech companies made the decision to conduct lay-offs.

Overall, there are reasons to believe that deal volume in 2023 will increase from that of 2022. By way of an example, more than 50 drugs are set to face patent expiration in 2023, including some drugs that historically have been very profitable. This may result in pharma companies evaluating the available assets of biotech companies with more intention to partially compensate for lost profits from their recently or soon-to-be off-patent drugs.

In addition, biotech valuations are already showing signs of starting to tick up – as evidenced by the benchmark biotech exchange-traded fund, XBI, experiencing a steady rise towards the end of 2022 after it hit rock bottom in June. As such, participants in the biotech industry may be ready to partner with larger pharma companies that are looking to bolster their research and development pipelines.

As described earlier, large biopharma M&A may increase. However, for any number of reasons, this will not be a viable solution for the majority of biotech companies who may be looking for financing and/or partnerships. Biotech companies looked to more unique and creative financing and partnership options in 2022, and this trend appears to be continuing in 2023.

With valuations stubbornly remaining low, royalty financings have grown in popularity. Royalty financings come in two varieties: traditional and synthetic. In a traditional royalty financing, a biotech company sells off a portion or the entirety of a royalty stream created by an existing licence. (Generally these existing licenses are with larger pharmaceutical partners to whom the biotech company licensed technology, and which are now utilising – or about to utilise – licensed technology to achieve commercial sales). In synthetic royalty deals, a biotech company with an emerging or already commercially viable drug will sell a portion of the sales of such drug for a large upfront payment. In synthetic financings, because the biotech company is still responsible for the development and commercialisation of the drug, the deals can be more complex so as

to provide more comfort to the financing partner. These transactions are attractive to cash-hungry biotech companies because they provide large, non-dilutive payments that may help keep companies afloat through the uncertain market. Continue to look for royalty financings and similar debt-style deals as biotech companies work to avoid committing equity at deeply discounted rates.

Medical Devices

Medical device M&A slowed down in 2022, with Johnson & Johnson closing out the year by completing the acquisition of Abiomed for USD16.6 billion in December. According to data from consulting and accounting firm Ernst & Young, there were only 11 mega-deals valued at more than USD1 billion in 2022 – compared with nearly double that number in 2021. Many of the deals that happened in 2022 were for assets that used the 510(k) programme created by the FDA, which lets manufacturers obtain approval by showing that the new devices are "substantially equivalent" to products already on the market. For acquiring companies, this greatly lowers the risk associated with regulatory clearance in the USA and could be a persisting trend in deal-making in 2023.

Strategic M&A buyers will continue to hunt for innovations in technology and digital health in order to strengthen their rosters, along with implementing trimming and divestment strategies. In January 2023, General Electric Company completed their spin-off of GE HealthCare, which manufactures medical diagnostics equipment and agents. Medtronic has also announced plans to spin out their patient monitoring and respiratory divisions now that the demand for ventilators has dropped below pre-pandemic levels.

On the private and venture-backed side, deal activity for medical device companies may be on the rise, despite the continued lukewarm IPO market. One effect of the pandemic, unfortunately, is a growing ageing population that faces lasting medical needs likely to benefit from long-term device monitoring. Compared with the volatility in other economic sectors, many view healthcare and medical devices as a safer investment alternative. M&A demand and deal-making for medical device manufacturers may increase alongside the growing number of elective procedures that have been steadily on the rise since the height of the pandemic. Small and mid-size companies with new technological advances could have many interested potential acquirers, with perhaps overall less market interest for larger mega-deals as potential acquirers assess their asset portfolios with greater care owing to economic instability.

Certain innovations and growing demand for hospital-to-home care may also greatly impact deal-making in the medical device space. New breakthrough technology – from AI-guided surgery to wearable devices for remote monitoring – are attractive targets for acquisitions. With hospitals overwhelmed during the height of the COVID-19 pandemic, demand for remote monitoring of vitals and other personal health information has increased rapidly during the past few years and is expected to continue in 2023. Growth in implantable medical devices, such as cardiovascular implants and intraocular lenses, is also expected to increase with the post-pandemic steady resumption of elective surgery and procedures across multiple medical specialties. The heightened global demand for COVID-19 testing is on the decline, but new variants and regional outbreaks could continue to provide steady demand for medical device and diagnostics companies in the near future.

On the regulatory side, the FDA User Fee Reauthorisation Act of 2022 was signed into law, thereby authorising the Medical Device User Fee Amendments (MDUFA V) for the next five years. MDUFA V funding will provide resources to the FDA's medical device review programmes, including the recent launch of the Center for Devices and Radiological Health's Total Product Life Cycle Advisory Programme (TAP) Pilot. TAP aims to increase predictability and reduce time from concept to commercialisation, in part by encouraging robust engagement early on with the FDA, industry and key stakeholders. The first phase of the programme launched on 1 January 2023. TAP is expected to give certain medical device manufacturers access to an advisory programme that could help identify the right level of evidence to support FDA submissions and help developers better address patient needs and anticipate reimbursement and market adoption considerations. This pilot programme, along with the Breakthrough Devices Programme and the Early Feasibility Study Programmes, will provide greater opportunities for new innovative medical devices to hit the market.

In the EU, the Medical Devices Regulation (MDR), which came into effect in May 2021, has been deemed by some as complicated to implement. The current transitional periods provided in the MDR require an estimated 23,000 devices certified under the previous directives to be re-certified by May 2024 and May 2025 under the much stricter safety criteria of the MDR. Devices that are not re-certified by this date may not lawfully be placed on the market of the European Economic Area. This has caused consternation for device manufacturers that are unable to meet certification requirements on time or bear the increased costs associated with the re-certification, which in some cases include the cost of performing one or more new clinical trials.

The European Parliament voted on 16 February 2023 to adopt a legislative proposal to extend the transition period for certain legacy devices to 2027 and 2028 in order to prevent widespread shortages of life-saving medical devices. The amendment will include staggered deadlines for re-certification, depending on the risk profile of a device if such device continues to meet certain conditions – one such condition being that there are no significant changes in the design and intended purpose. This deadline extension could provide valuable time for SMEs to keep their devices on the market while pursuing re-certification. However, certain questions – such as how these legacy devices are to be monitored for compliance during this extension – have yet to be answered.

The outlook for medical devices and technology companies is generally optimistic. Industry insiders and analysts expect to see more deal activity for small to mid-size companies, given that some economic pressures are predicted to stabilise in 2023. Technological trends and growing demands for remote monitoring and AI will be important factors driving deal-making, and the effects brought on by major regulatory changes in the USA and the EU could provide both opportunities and challenges for medical device companies to navigate.

Digital Health

Digital health innovation in 2022 was bolstered in part by the still-present COVID-19 pandemic, ongoing staff shortages of skilled healthcare workers, employee turnover in the medical field, and increasing comfort with – and awareness of – digital healthcare options for patients. Challenges in the digital health space in 2022 included economic concerns, such as inflation and less access to funding, and anticipated and enacted regulatory and legislative initiatives

that, in the aggregate, created a less predictable environment for digital health transactions and advancement. Looking ahead, the overall economic picture in early 2023 is a departure from the same period in 2022. Interest rates are up, inflation is higher, supply chain issues persist, and investors remain cautious about funding.

With regard to digital healthcare options such as telehealth, availability of these options expanded in 2022 as concern over COVID-19 variants and the perceived ease of access factored into patients' decisions to continue to seek virtual medical care and increased the likelihood that certain digital healthcare options will become a permanent feature of medical treatment in the USA and worldwide. Indeed, rates of telehealth utilisation have maintained a steady pace since the drop of usage from the height of the pandemic.

Notably, in 2022, Congress paved the way for additional digital health expansion with passage of the IRA, which was signed into law in August of 2022. The IRA extends certain pandemic-related telehealth permissions until the end of 2024 for Medicare patients, thereby enabling more patients to receive care virtually. Relatedly, the Interstate Medical Licensure Compact, which allows medical providers to become licensed in multiple states to provide interstate virtual care, continues to expand – growing from 33 states to 37 in 2022. With the reversal of Roe v Wade, virtual health is also gaining attention as a proposed avenue for patients seeking reproductive care across state lines.

One example, however, of a complicating factor in the growth of telehealth is the decision by the Biden administration to end – as of 11 May 2023 – the federal public health emergency (PHE) waiver that had previously been renewed by the US Department of Health and Human Services every 90 days during the COVID-19 pandemic. This waiver, among other things, afforded flexibilities related to telehealth, such as permitting audio-only telehealth for certain medical services and allowing more healthcare professionals to provide and bill for Medicare telehealth services. Certain exempted activities will remain permitted for a period of time – for example, audiologist and speech-language pathologists will be able to provide telehealth services until the end of 2024. However, many other telehealth waivers that have remained in place since January 2020 will end.

When the federal PHE ends, telehealth providers (including those that cover patients on Medicare) will be required to comply with the latest in regulations. As a result, anticipation of the federal PHE expiration has created hesitation for current telehealth providers who entered the market during the pandemic and barriers to entry for certain would-be telehealth providers. With almost half of all physicians in the USA currently providing some version of telehealth services, the impact of the end of the PHE waiver may be significant.

Unlike the 2021 record-setting venture funding and M&A transactions for digital health companies, economic concerns and inflation created a less predictable environment for digital health transactions in 2022. Digital health start-ups received unprecedented financing in 2021 but hit only 48% of that success in 2022. Slower and unstable market conditions have, in some instances, required venture-stage digital health companies (including in the direct-to-consumer digital healthcare sector) to seek financing through smaller M&A deals or collaboration and licensing arrangements. Larger industry players are also pivoting within their own digital health

initiatives under renewed government scrutiny in areas such as antitrust and FDA regulation.

Increasing integration between mobile apps and wearables/medical devices also continues as a popular initiative in the digital health field. With this integration comes a growing wealth of health and consumer data that digital health providers and tech players are responsible for managing in compliance with international, federal and state data privacy laws, which continue to evolve. As of 1 January 2023, California, Virginia, Colorado, Connecticut, and Utah all have new or revised comprehensive data privacy laws that digital health companies are mandated to comply with when processing patient data.

Companies producing medical devices and wearables, which are a cornerstone of the digital health industry, must also follow the FDA's Clinical Decision Support Software (CDSS) Guidance that was released in September 2022. This new guidance outlines a determination of whether technologies used in the medical care space are considered CDSS and therefore whether they are considered medical devices subject to FDA oversight. The September 2022 guidance revises existing 2019 draft guidance and, in part, these revisions result in certain software functionalities – which, previously, were exempt from FDA oversight – now being subject to such oversight. And beyond the USA, digital health players wanting to operate globally are required to comply with the ever-growing and often varied data privacy laws in various countries, including in more than 70% of all UN countries.

Conclusion

Despite continuing uncertainty and high inflation in the market, there is hope for a return to normalcy in 2023. Deal activity may remain slow for the first half of the year, but many biotech and pharma companies have adequate cash reserves to weather the storm and push potential drug candidates through clinical trials with innovative financing and partnership options. Medical device companies are looking at a slow but likely recovery, as consumer demand by an ageing population remains strong. Digital health companies will continue to innovate alongside increased emphasis on remote patient care and other wellness-monitoring trends. On the regulatory side, it is still too soon to tell how new frameworks like the IRA will impact the life sciences and healthcare industries. However, companies are updating their long-term strategies to account for repercussions on existing and future product pipelines.

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