

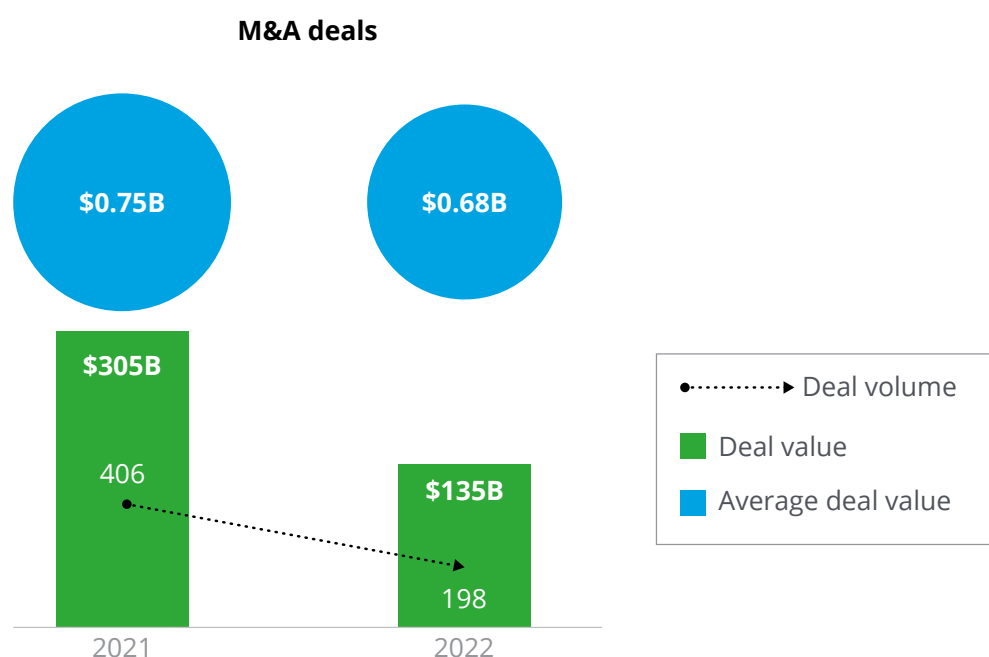
The key portfolio decisions that life sciences companies are contemplating today come at a time of contrasts. Big pharma is cash-rich enough to snap up hundreds of small to mid-cap biotech companies.<sup>1</sup> And, access to cash for biotech is compressing. Yet the mega mergers that occurred during the comparatively robust M&A era of the 2010s slowed significantly at the beginning of the current decade. Only recently have acquirers closed a handful of sizable deals, suggesting a potential uptick in M&A value in 2023.<sup>2</sup>

Furthermore, within this complex picture, with higher interest rates and lower valuations, medtech companies are mitigating uncertainty in the sector by divesting low-growth and low-margin assets. By doing so, medtech companies can free up capital, improving their financial profiles in the hopes of becoming more attractive to strategic acquirers.<sup>3</sup>

Life sciences organizations have traditionally relied on M&A to grow or diversify into new technologies and capabilities. From a defensive perspective, M&A have historically served to build resilience. As an offensive strategy, M&A serves to facilitate business transformation, ecosystem value creation, and industry disruption.

Much of this activity slowed in 2022, during the third year of the COVID-19 pandemic, as life sciences transactions surpassing US\$1 billion fell by 60% compared to 2021 (Figure 1). In total numbers, there were 406 deals totaling US\$306 billion in revenue in 2021, while that number declined to 198 deals totaling US\$135 billion in revenue in 2022.<sup>4</sup>

**Figure 1. M&A and venture activity in life sciences (2021 and 2022)**



Source: M&A Trends in Life Sciences: Deal-making in 2022, Deloitte, 2022

Notwithstanding, pharma companies with substantial cash balances have increasingly appeared ready to unleash pent-up demand. In June 2022, Bristol Myers Squibb acquired Turning Point Therapeutics in an all-cash deal focused on the experimental lung cancer candidate Repotrectinib.<sup>5</sup> In October of that year, Pfizer acquired Biohaven Pharmaceuticals, bringing two new migraine treatments into its portfolio in a transaction valued at around US\$11.6 billion.<sup>6</sup> The following month, Johnson & Johnson (J&J) acquired heart pump maker Abiomed in a US\$16.6 billion cash transaction. A month later, Amgen picked up rare disease specialist Horizon Therapeutics in a US\$27.8 billion acquisition.<sup>7</sup>

One area of potential interest for acquirers comprises multi-indication pharma products with potential applications across therapy areas. These drugs have the ability to treat several diseases, such as disorders that span immunology, oncology, and metabolic illnesses, but are linked to similar underlying causes—demonstrating how one therapy developed for a particular disease can ultimately alleviate another.<sup>8</sup> A 2022 study of pricing and value of multi-indication drugs in the United States, Germany, France, England, Canada, Australia, and Scotland, highlights how the drugs have become particularly effective for cancer treatments over the past two decades, with 75% of oncology drugs having been approved for multiple indications by 2018. The drugs can offer efficiency gains through a single cycle of research and testing.<sup>9</sup> What's more, investors value the multi-indication treatments because of the potential to provide higher returns compared to single-indication drugs.<sup>10</sup>

Prospective acquirers pay a premium for that medicinal versatility, however. A study of 311 acquisitions involving US and EU biopharma companies developing prescription drugs from 2005 to 2020 shows that acquirers paid 37% more for companies with biologics and gene therapeutics, than small-molecule drugs, and paid 12% premium for multi-indication products.<sup>11</sup>

## Researching the path to new revenue

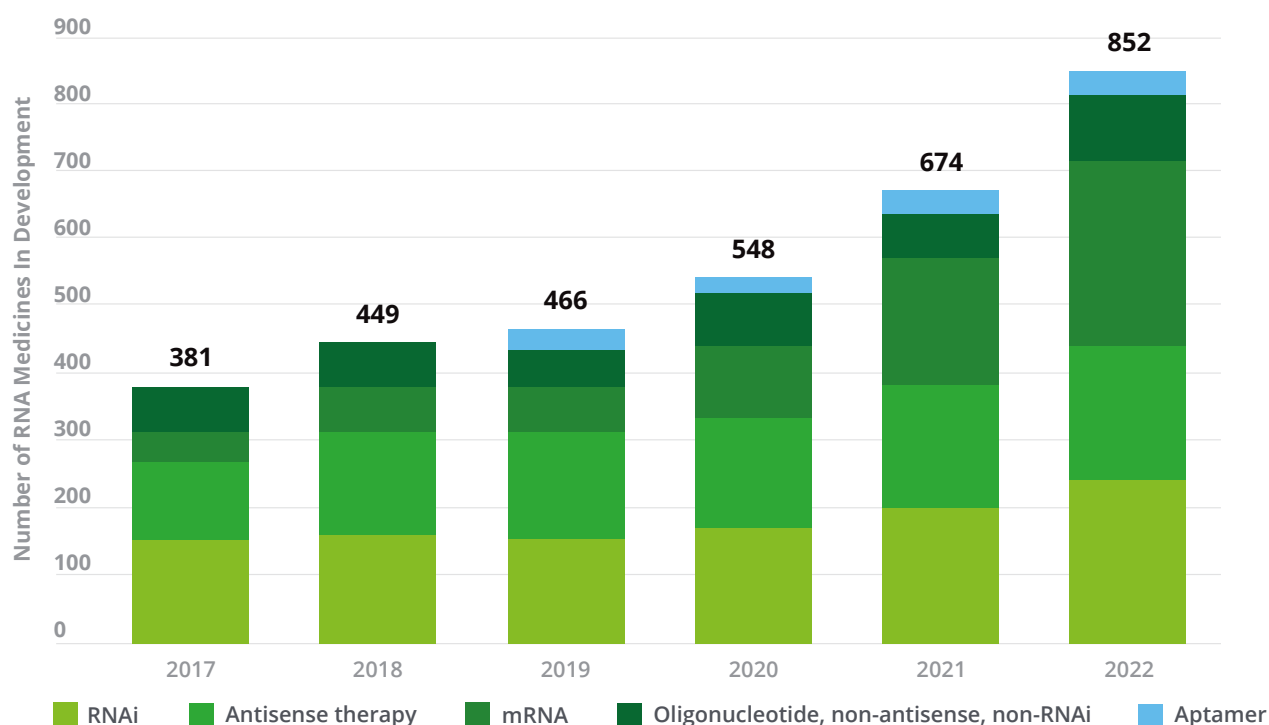
Life sciences executives surveyed by Deloitte appear to be actively preparing for a promising, if turbulent, year ahead in regard to portfolio growth. In a Deloitte US Center for Health Solutions survey of 60 C-suite executives from life sciences companies, 95% of respondents say they intend to focus on the development of innovative products; 91% say they plan to invest in R&D innovation; and 87% say they plan to invest in digital innovation, underscoring the push to adapt portfolios and operations in response to external disruption.<sup>12</sup>

One set of developments that have invigorated pharmaceutical portfolios involve the emergence of mRNA technology. Unlike traditional vaccines, which use weakened or inactivated viruses to elicit an immune response, mRNA vaccines use genetically engineered molecules that teach cells to make a harmless protein, which then triggers the production of antibodies to attack and destroy the protein. What's more, mRNA technology can be quickly designed and scaled as needed.

Many scientists view mRNA technology as the future of medicine. In the United States, the Vaccines National Strategic Plan 2021-2025 lists its primary goal as fostering innovation in vaccine development and related technologies. In 2022, the US pharma and biotechnology company Pfizer announced the first volunteer recipients of its mRNA flu shot in a study involving more than 25,000 US adults. Meanwhile, Moderna announced a late-stage trial of an mRNA-based influenza vaccine. Both trials will seek FDA approval if successful.<sup>14</sup>

There were 49 deals signed involving mRNA companies or assets in 2021, with a combined potential value of US\$5.37 billion (Figure 2). One such deal is Sanofi's commitment to investing €400 million (US\$476 million) a year to develop mRNA vaccines against a wide range of infectious diseases. The company's mRNA Center of Excellence will include 400 employees in Cambridge, Massachusetts, and Lyon, France. The teams comprise professionals in R&D, digital, chemistry, manufacturing, and controls, with a goal of having at least six vaccine candidates in the clinic by 2025.<sup>15</sup>

**Figure 2. Growth in RNA pipeline has doubled since 2017**



Notes: Chart includes candidates in development from preclinical through pre-registration. Annual snapshots taken in May.

Source: Pharma Intelligence UK

Pfizer, which used mRNA in its COVID-19 vaccine, has agreed to pay as much as US\$1.3 billion to gene-editing company Beam for the advancement of novel in vivo base editing programs for a range of rare diseases. The programs will use mRNA and LNPs to deliver base editors to target organs. The four-year research alliance will focus on rare genetic diseases of the liver, muscle, and central nervous system.<sup>16</sup>

The outlook for mRNA vaccines includes research to develop vaccines against HIV, Zika, and rabies that are currently in the human trial phase.<sup>17</sup> Many of these developments and treatments have largely gone to developed countries, highlighting longstanding inequities in public health. To help combat these disparities in the global south, a South African-based vaccine technology transfer hub comprising universities and pharmaceutical companies is collaborating to make an effective mRNA vaccine against COVID-19, with plans to expand into other diseases such as the measles.<sup>18</sup>

## Exploring innovations in therapeutics

Research into next-generation therapies, including gene editing, is another area of portfolio expansion for life sciences companies as they look to augment their traditional drug portfolios. As of 2021, there were more than 6,500 active cell and nucleic-acid therapeutic R&D programs, a year-over-year increase of 20%.<sup>19</sup> Trailblazing discoveries such as the Phase 3 trials of the world's first topical gene therapy used to heal decades-old open wounds.<sup>20</sup>

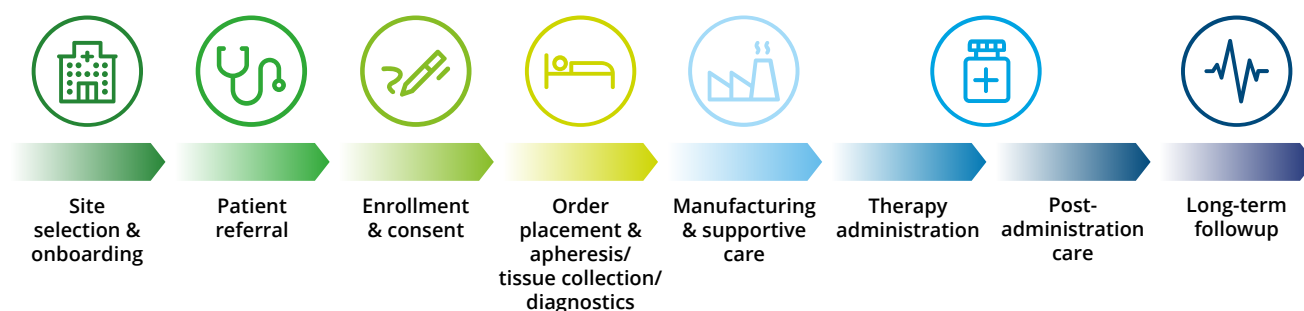
These scientific advancements have taken a significant leap forward since the discovery of CRISPR/Cas9, which could make the elimination of inherited diseases a reality. In 2020, Regeneron and Intellia Regeneron and Intellia expanded their collaboration expanded their collaboration to develop CRISPR/CAS9-based treatments. By 2025, the regenerative medicine market is predicted to be worth US\$22 billion, growing twofold over the course of a decade.<sup>21</sup>

A number of recent key drug approval are showing promise for new diagnostic and therapeutic technologies. In the United States, the FDA approved Bristol-Myers Squibb's (BMS) BCMA CAR-T cell therapy Abecma in 2021, the first cell therapy approved for multiple myeloma.<sup>22</sup>

**Figure 3. A typical CGT value chain**

*Shifting the model from supply chain to a value chain for CGT*

Supply chain refers to the integration of all activities involved in the process of sourcing, procurement, conversion, and logistics. On the other hand, value chain is the series of business operations in which utility is added to the goods and services offered by the firm to enhance customer value. Our definition of customers includes treatment sites, patients, and other relevant stakeholders. Figure 3 depicts the typical, made-to-order cell and gene therapies (CGT) value chain.



Source: Cell and gene therapies: Delivering scientific innovation requires operating model innovation," Deloitte Insights, April 17, 2020

However, major challenges persist, notably the exorbitant upfront cost to develop cell and gene therapies, which require bespoke manufacturing processes—to say nothing of the staggering price tags that can make payors hesitant to adopt the experimental therapies. As gene therapies move from ultra-rare applications to other more prevalent disease areas, manufacturing processes also need to scale. This has proven to be a challenge as a lack of manufacturing space and bottlenecks arising from the lack of equipment such as incubators has led to capacity constraints (Figure 3). In addition, CGT companies are still facing shortages of raw materials as a lingering effect of the pandemic.<sup>23</sup> As a result, we have seen pharma companies and contract development and manufacturing organizations (CDMOs) invest heavily to meet demand needs, such as the French contract development and manufacturing organization Yposkesi, which announced plans to build a US\$71 million CGT plant to boost production of the viral vectors used in gene therapy biomanufacturing.<sup>24</sup>

Life sciences organizations may need to consider alternate funding and payment models to accelerate widespread adoption of their CGTs. For example, Novartis's gene therapy Zolgensma, a one-time treatment for pediatric patients with spinal muscular atrophy, costs more than US\$2 million. To help accelerate adoption and lower the barrier to entry, Novartis is working with payors to develop outcomes-based pacts and pay-over-time options.

## Shedding noncore assets

In the current environment, companies are rationalizing their base—carving out assets that don't fit within their overall portfolios or restructuring and rebalancing their portfolios. For instance, in a deal finalized in 2021, Merck created a new drug company, Organon, after spinning off a US\$6.5 billion business to include women's health products and biosimilars. The carve out allowed Merck to not only cut costs by removing manufacturing and sales responsibilities but also focusing on growth areas such as cancer drugs and vaccines.<sup>25</sup> In 2022, Novartis announced it was spinning off Sandoz, the company's generics and biosimilars division, into a publicly traded standalone company.

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*In a news release, the company's chair Joerg Reinhardt said in part that, “A spin-off would allow our shareholders to benefit from the potential future successes of a more focused Novartis and a standalone Sandoz, and would offer differentiated and clear investment theses for the individual businesses.”<sup>26</sup>*

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Similarly, in 2022, the Austrian biotechnology company APEIRON Biologics announced it would demerge its pre-clinical and clinical development activities to form a new fully separate holding company, invIOs Holding AG (invIOs). The new company would continue to focus on developing novel immuno-oncology treatments for difficult-to-treat cancers, enabling the company to access funding from investors to build its immuno-oncology pipeline.<sup>27</sup>

Also in 2022, Danaher Corporation, the global science and technology company, spun off its Environmental & Applied Solutions (EAS) segment to create an independent, publicly traded company. This follows significant growth in the company's diagnostics and life sciences area, thanks to tailwinds from the pandemic, whereas the EAS had been the company's weakest.<sup>28</sup>

Economic conditions make many of the deals more attractive. Though debt is more expensive because of rising interest rates, valuations slipped during the first three quarters of 2022. In addition, 11 mega-blockbuster medicines with sales exceeding US\$5 billion per year are set to lose global patent protection over the coming decade, setting up fierce competition through the manufacturing of generic products.<sup>29</sup>

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*“When it doesn't make sense in the portfolio, you move it out,” says Keith Boettiger, President, Abbott Heart Failure. “You look at the landscape, how it fits into your long-term strategy, and ultimately you make hard decisions.”*

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## Value creation considerations for life sciences organizations

- How are you filling your growth gaps?
- Where can you seek adjacencies to bolt on technologies you don't currently possess?
- How are you balancing diversity in development of a portfolio with focus in a given platform or therapeutic area and how can you avoid becoming too fragmented or too focused?
- How can multi-indication products enhance your portfolio?
- How do next-generation therapeutics fit into your portfolio?

## Contacts

### Chris Caruso

Deloitte Global Financial Advisory Leader

[chcaruso@deloitte.com](mailto:chcaruso@deloitte.com)

### Prateep Menon

Principal

Deloitte United States

[pmenon@deloitte.com](mailto:pmenon@deloitte.com)

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## Acknowledgements

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