

Navigating legal obstacles in life sciences restructurings

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The life sciences industry continues to grapple with market forces bearing down on available growth capital, which is challenging traditional business models in the sector. Such pressures will only continue in the pharmaceutical sector with the enactment of the Inflation Reduction Act (IRA) and the Federal Trade Commission's (FTC) scrutiny of pharmacy benefit managers' (PBMs) drug pricing tactics.

Whether it's terminating or divesting non-core programs, winding down unprofitable operations, or outsourcing, companies are exploring various restructuring strategies and focusing on core capabilities in order to create value.

Simultaneously, beleaguered biotechs continue to struggle through the IPO downturn and compete for limited private funding. In these difficult market conditions, many development-stage pharmaceutical and biotech companies are running out of cash.

As a result, an increasing number of affected companies are resorting to restructurings in order to extend their cash runways. Whether it's terminating or divesting non-core programs, winding down unprofitable operations, or outsourcing, companies are exploring various restructuring strategies and focusing on core capabilities in order to create value. However, such restructuring is not without its risks, and it's essential for these companies to carefully navigate a multitude of legal considerations, including the following.

Employment law considerations

One of the most widely applied strategies is to downsize the existing workforce. However, companies must be mindful of the legal obligations associated with mass layoffs, both contractual and statutory, and should conduct a comprehensive review of existing employment contracts and federal and state laws. For example, individual employment contracts may require companies to pay severance or provide advance notice of an impending layoff.

In addition, the federal Worker Adjustment and Retraining Notification Act (WARN Act) requires certain employers to provide 60-days' notice to employees and local governments before implementing a mass layoff or a plant closure. Numerous states, such as California and New Jersey, also have their own WARN Act corollaries, some of which include a severance payment obligation. Therefore, when planning a workforce reduction, employers should account for all potential financial obligations and coordinate any notices required contractually or on a state or federal level.

Employers also must be mindful of potential employer liability for employment discrimination and retaliation. For instance, it may appear financially prudent to lay off the highest-earning employees, but these individuals are often the most senior and are likely older than other employees in the organization. This could potentially lead to age discrimination claims under the Age Discrimination in Employment Act (ADEA) and corresponding state law. When restructuring, companies must ensure layoff decisions are based on legitimate business needs and not on factors protected under employment law.

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Companies will also want to ensure that departing employees are reminded of any existing obligations not to use or disclose confidential information and trade secrets. Before seeking to enforce existing restrictive covenants, employers should check current law to ensure such covenants are still valid, as the law has been evolving quickly in this area.

Clinical trial and contractual commitments

Life science companies may seek to streamline their operations and reduce financial expenditures by divesting non-core assets and programs. However, this strategy brings a complex set of considerations, especially with respect to obligations related to ongoing clinical trials.



Whether these companies collaborate with a contract research organization (CRO) or lead collaboration efforts, they must thoroughly review their agreements to understand any ongoing obligations. This review should include determining if the current agreements allow the company to exit the program and/or return IP licenses. If the contract does not include such options, the company will need to approach the counterparty and negotiate an exit or termination.

Privacy protections

Life sciences companies should also carefully consider privacy law and contractual privacy obligations during any restructuring that involves the divestiture of clinical programs or assets, especially when acting as the clinical sponsor. As the sponsor, it's common for the organization to collect and store patient research data from investigators or delegate this task to the sponsor's CRO. When involvement in the clinical trial concludes, this data may need to be clawed back from the CRO, transferred to the appropriate parties, and/or retained consistent with applicable law and contractual obligations.

To the extent that the patient research data includes protected health information regulated by HIPAA (Health Insurance Portability and Accountability Act), or if the sponsor is performing services as a business associate for research sites, additional HIPAA obligations and potential liability exposure could arise. Other global privacy and data protection laws such as the General Data Protection

Regulation (GDPR) and U.S. state-specific privacy laws may also be applicable and must be evaluated when exiting or winding-down any clinical program.

Real estate matters

Beyond clinical divestitures, companies may look to reduce unnecessary overhead costs through downsizing their real estate assets. Real property leases, however, rarely permit early termination, and, given the current market conditions, landlords may be less willing to accommodate early termination requests.

The shift to remote work and existing market dynamics have made finding tenants to lease or purchase facilities challenging. This situation could potentially leave a cash-strapped company paying for unused space. It is crucial for companies to carefully review their lease agreements to find the best possible outcome for real estate assets and liabilities.

Conclusion

Restructurings in the life sciences sector require companies to carefully navigate various legal considerations, ranging from employment law to contractual commitments. Therefore, it is essential for companies to conduct a thorough review of their existing contracts, legal obligations, and potential liabilities. By doing so, they can make informed decisions that will help them extend their cash runways and ultimately create value in a rapidly evolving industry landscape.

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