Insight

The Long-Term Investment Opportunity in Healthcare R&D

Contract research organizations (CROs) are companies that operate in research, development and testing of new drugs and medical devices.

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Contract research organizations (CROs) are companies that operate in research, development and testing of new drugs and medical devices. CROs are independent companies whose clients are typically in the pharmaceutical, biotechnology (biotech) and medical device industries. These sponsor companies pay CROs to provide services to help in the R&D process when developing a new drug, therapy or medical device.

These are often functions that were previously undertaken in-house by the sponsor or where the sponsor lacks the capacity or expertise to undertake the function internally. Sponsors also often outsource aspects of product development to CROs to reduce fixed costs as part of their cost structure mix and to reduce the heavy capital requirements of maintaining development capabilities internally.

The clinical and regulatory experience of CROs can often reduce the cost of development and time-to-market for a new healthcare product. This is because CROs can leverage their expertise in specialist fields and specific phases of the R&D process. Large CROs have been operating for decades and often have deeper knowledge and experience in specific fields of research than sponsor companies. This has made CROs in many cases indispensable in the R&D process for new drugs and therapies.

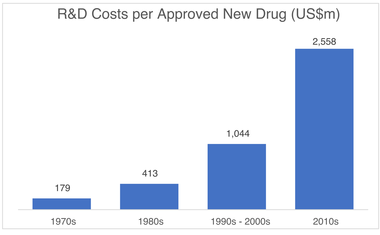
In an age of increasing drug development costs, where cash costs and R&D timelines on new drugs are increasing, and when the probability of successful approval of new drugs is declining, CROs have emerged as critical providers of specialized services for healthcare companies. Today CROs play a critical role in the drug development process. Growth in the market for CROs is driven by the increase in spend on healthcare product research & development by sponsors, which itself is driven by improving technology and an ageing population.

As the difficulty and expense of drug and medical device development continue to rise, the demand from pharma and biotech sponsors to outsource R&D functions to specialists is continuing to rise too. In the case of big pharma and biotech, once they make the decision to outsource a function in the drug R&D process, it is very difficult for those services to be brought back in-house. This is a strength of the CRO business model and a barrier that becomes stronger as outsourcing penetration rates rise.

Increasingly CROs are also working with governments, academic institutions and other research entities on new drug R&D. These services cover all stages of the drug development process, beginning with compound selection, discovery, preclinical (pre-human in vitro and in vivo) research, clinical (in-human) testing, as well as post approval functions such as commercialization, safety assessment and monitoring. CROs are able to undertake functions more effectively and faster than in-house research and development teams at these non-profit institutions. These non-profit sources of R&D funding are increasingly important in new healthcare 'breakthroughs', with many seen as 'discovery engines' which can be leveraged to develop new treatments for diseases. As these institutions become more important, the demand for outsourced expertise from CROs will also rise, given that these institutions by their nature lack the internal infrastructure of big pharma or larger biotech firms to undertake major drug R&D work internally.

CROs were first started in the 1970s with small companies offering relatively basic and un-differentiated services, serving as a capacity resource to large pharma companies. CROs later increased their capabilities and offerings to encompass increasingly complex aspects of the drug development process, like preclinical research and development, clinical trials monitoring and management, data management and analysis, study design, bio-statistical analysis, post marketing surveillance, consulting, regulatory and safety assessment, resourcing and functional services, communications, outcomes, and other commercialization services.

Increasing healthcare R&D, rising complexity of development, and the need of biotech and pharma companies to reduce costs and decrease time-to-market are the critical drivers for demand for CRO services. Out of every 10,000-15,000 experimental compounds tested, only 5 enter preclinical trials that advance to human testing, and out of those 5 only 1 gets to the regulatory approval stage to then be commercialized. This is driving costs up. The average cost of drug development have increased 1400% since the 1970s (see chart below).



Source: WHO, UN, McKinsey

Average R&D costs per new approved drug have increased from $179m in the 1970s to $2.6bn today.

This trend makes it financially impractical to maintain teams of developers and researchers at biotech and pharma companies, teams which may become redundant quickly. Biotech and pharma companies are increasingly becoming reliant on CROs and their expertise in this increasingly expensive and complex process of discovering and testing new drugs and healthcare products.

This confluence of trends (ageing population, rising global demand for healthcare, improving medical technology, rising costs of developing new medicines) are driving long-term structural demand growth for CRO companies. This makes these businesses an exciting investment opportunity. The Dominion Global Trends Managed Fund has exposure to CRO businesses, which have been important contributors to fund performance for many years and remain core investments.

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