ROIS Reflects on 2025

Innovation & Investment

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For ROIS, the last few years have been defining in their evolution as a pure play CDMO – and 2025 has proved no exception.

Specializing in complex, high-value sterile injectables, the Spanish based CDMO has embarked on an ambitious growth plan built around major investments in state-of-the-art filling technology, new facilities, additional production, device assembly and packaging lines as well geographic expansion into the US through a major strategic acquisition.

This has transformed ROIS into a global contract development and manufacturing partner. In fact, the Madrid-based company now counts itself among the leading CDMOs worldwide for injectable drug product manufacture.

From Family Roots to Global Leadership

Built on the stable foundations of a century of family ownership and management, ROIS has moved swiftly to meet the shifting global market demands. Its parent company, ROVI Pharmaceuticals, received a number of offers to purchase its dedicated contract manufacturing arm. However, following a strategic review that highlighted strong market tailwinds across the CDMO sector, the decision was taken to restructure the CDMO arm into a company in its own right with a new and focused service company brand: ROIS.

This decision affords ROIS the independence to operate as a dedicated and focused CDMO and to chart its own path as a global service and solution provider. ROIS now has the freedom and flexibility to adapt to meet the needs of its partners and the wider biotech/pharma industries, while still being able to draw on its parent company's deep expertise, technology and innovation.

The new ROIS brand has a distinct value proposition focused on the contract manufacturing, filling, device assembly and packaging of high-value injectables, a message underscored by a recent website revamp and relaunch. Its concerted drive to increase specialist manufacturing capacity is urgently needed, particularly as the industry scrambles to meet the explosion in GLP-1, biosimilar and high potent ADC filling demand.

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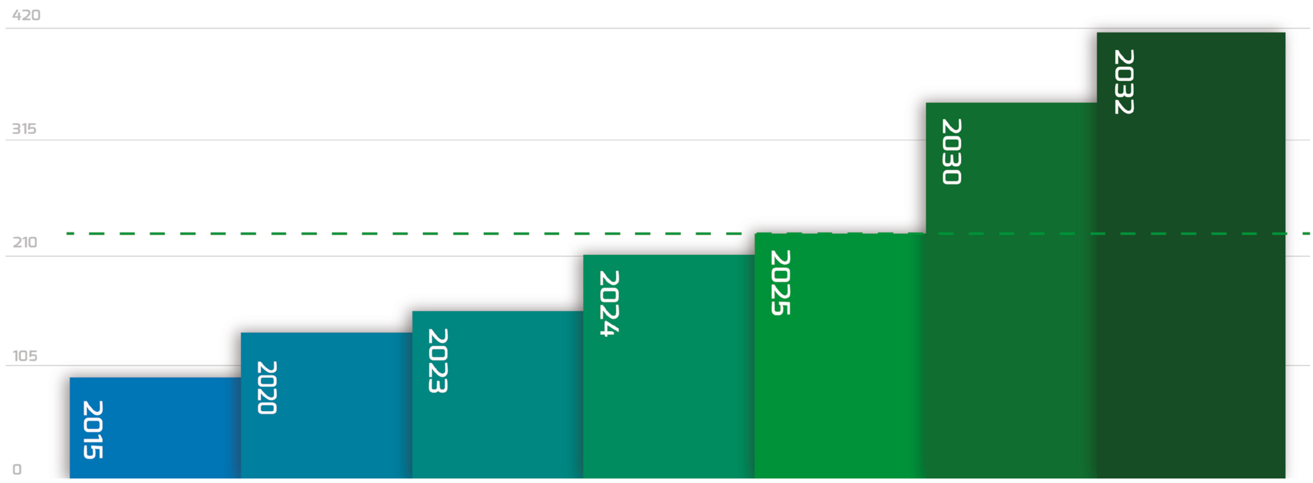


Global CDMO market forecast to double by 2032 (Market size in US Billions)

Ambitious Investment Campaign Goes International

While ROIS is a publicly traded company, it takes great pride in its heritage, where it successfully combines a family-centred identity with a strong commitment to innovation, investment and internationalisation.

As major biotechs worldwide pivot to outsource specialist manufacturing processes and refocus their internal efforts and capital on R&D and Sales, reliable CDMOs who are ready to partner and meet this supply demand will stand to benefit. Fortune Business Insights, for example, forecasts that the global CDMO market will double between 2024 and 2032 to exceed USD 465 billion.

The goal for ROIS is to double down and expand its position as a world-leading injectable CDMO. A deal announced in October 2025, between ROIS and Bristol Myers Squibb (BMS) exemplifies this ambition: In addition to acquiring the facility in Phoenix AZ from BMS which has commercial-scale fill-finish capacity for vials and Prefilled Syringes (PFS), including capabilities on high potent and lyophilization with FDA, EMA and Japanese regulatory approvals already in place, ROIS also signed a 5 year Toll Manufacturing Agreement (TMA) with BMS worth at least $250 million.

This acquisition represents a key strategic move for ROIS, expanding from its EU base to secure a first foothold on American soil. This US-based production will ensure proximity to key partners and provide supply chain security for US customers in the context of heightened global geopolitical tensions.

The decision to secure this US based manufacturing asset aligns with a wider strategic recalibration: according to Manufacturing Today, 15 of the world's largest pharma companies have collectively announced $270 billion of investment in US research and manufacturing in recent years.

Javier López-Belmonte Encina, Vice-Chairman of the Board and CFO at ROVI, described the agreement as emblematic of the ROIS approach. "This acquisition is a strategic step in building ROIS as a global CDMO for high-value injectables," he said. "The Phoenix site adds significant sterile fill-finish and high-potent capability, enabling us to better serve partners on US soil while continuing to invest across our network."

ROIS in numbers

80M+ Vials per year

40M+ Cartridges per year

3B+ Tablets annually

600M+ Syringes annually

12 Aseptic filling lines

15 Injectable packaging lines

Pen & autoinjector assembly lines launching
Manual line in 2025, semi-automatic in 2026 with 7M unit capacity

Global Regulatory Approvals
FDA, EMA, PMDA, KFDA, ANVISA, MHRA, and more

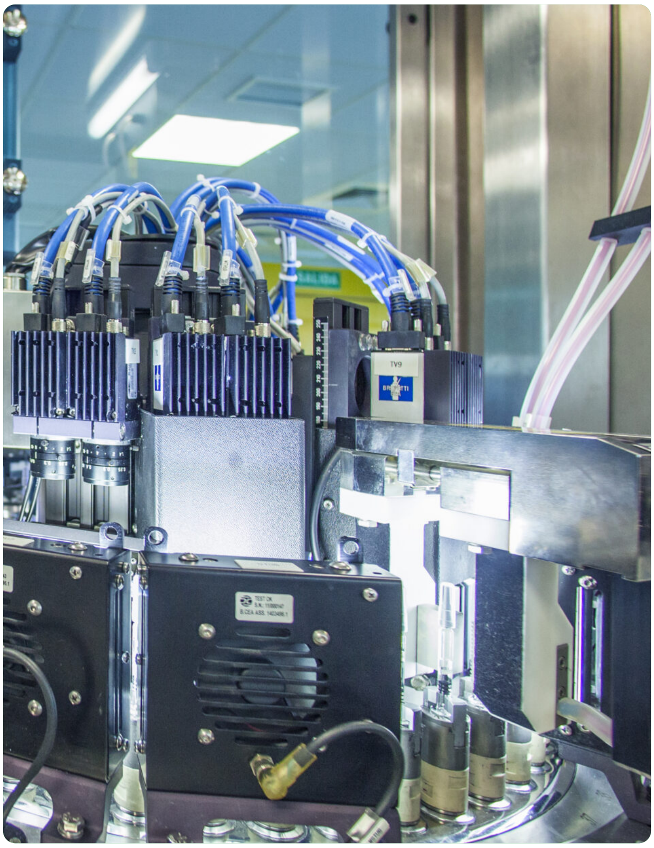
75+ Markets served globally

Collaborations Continue with Pharma Industry Giants

ROIS combines a wealth of industry experience with strategic investment in manufacturing infrastructure and a proven history of securing approvals from regulatory agencies in major jurisdictions. Taken together, this provides the foundations for strong, sustaining supply partnerships with key industry players for their critical products.

ROIS can already look back on a strong M&A track record in this regard. Its supply partnership with Merck Sharp and Dohme (MSD), for example, dates back to 2010 and has been renewed several times since. The original agreement to manufacture and market some important products for MSD also included the incorporation of an existing facility, complete with production lines and employees – which bodes well for integration into ROIS of the BMS plant in Phoenix.

During the pandemic, ROIS, like many other CDMOs who stepped up to the plate, played a major role in partnering with Moderna for manufacture and supply of its Spikevax COVID vaccine. This partnership played a material role in fuelling the company's rapid growth in the first half of this decade and the agreement with Moderna has since been expanded to include production for both their Respiratory Syncytial Virus (RSV) and influenza vaccines.



The vision to expand technical capabilities and capacities also paved the way for a new agreement in April 2024 with a global pharmaceutical company , which is expected to have a positive impact on revenue – ranging between +20% to +45% over 2023 sales by 2027, the first full year of recurrent manufacturing – and strengthened ROIS's track record of partnerships with industry giants. This momentum continued in October 2025, when an agreement with Swiss pharma giant Roche was announced where ROIS will use high-speed filling line capacity at its San Sebastián de los Reyes (Madrid) site for an important, novel Roche drug currently in late-stage clinical development. ROIS forecasts that this deal alone will contribute to a 20–25% increase in its sales revenue by 2030, compared with 2024 figures.

Juan López-Belmonte Encina, Chairman and CEO at ROVI, expressed his delight at the agreement: "We are delighted to become Roche's strategic partner in the manufacture of this innovative product to be distributed globally and its potential to contribute to enhancing the quality of life of millions of people."

Tellingly, however, Mr López-Belmonte Encina's remarks referenced both the company's domestic ties and its international ambitions. "We take special pride in positioning ROIS among the leaders in latest-generation pharmaceutical production," he said. "Over recent years, guided by our growth strategy, our company has made significant investments in increasing its capacities and incorporating innovative technology to make us one of the largest contract manufacturing companies for sterile injectables in the world."

Disclaimer: The opinions expressed in this article are solely those of the author and do not necessarily reflect the views or positions of the Company (Rovi Industrial Services).

The Best is Yet to Come

There is little doubt that 2025 marked a key milestone for ROIS. From its strong, family-owned base and deep Spanish roots, the CDMO division has seized on its new-found autonomy to chart an ambitious growth course. However, it remains fundamentally focused on reliably meeting its partners' need for qualified capacity and agility, especially for high-quality injectables: ROIS expects to double its CDMO turn-over by 2030.

Its ambitious yet highly targeted investments are designed to tackle the pharmaceutical industry's manufacturing bottleneck. Bringing together qualified capacity with speed, best-in-class technology and proven compliance, ROIS is committed to lead the way – serving as a robust and dependable expert partner to both pharma and biotechs around the world for years to come.

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ROIS

Over 30 global pharma clients trust ROIS to deliver compliant, high-capacity manufacturing with precision and speed. As one of the top three CDMOs for injectables worldwide, we offer end-to-end, cross-format support with approvals from major regulators. A dedicated NPI team at each of our sites ensures seamless tech transfer and rapid scale-up. Recent capacity investments align fully with the revised EU GMP Annex 1 standards, as confirmed by multiple post-enforcement inspections. At ROIS, we're ready to meet today's demand and support tomorrow's developments.

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