

From European Roots to
Ambitious International Growth

ROIS: The CDMO Making Waves in the US Market





Innovation and Investment

For ROIS, the last few years have been defining in its evolution as a pure-play CDMO. Looking forward, ROIS has set its sights on continued growth and ambitious internationalization.

Specializing in complex, high-value sterile injectables, the Spanish CDMO has embarked on an ambitious international growth plan built around major investments in state-of-the-art filling technology, increased production capacities, device assembly and packaging lines.

This has transformed the firm into a global contract development and manufacturing partner. Headquartered in Madrid, ROIS is now one of the leading sterile CDMO's worldwide for injectable drug product manufacturing, with 5 sites across the globe it possesses particular expertise in advanced fill-finish processes for vaccines and biologics.

restructure its CDMO arm into a company in its own right: ROIS.

The new ROIS brand has a distinct value proposition focused on the contract manufacturing, filling, device assembly, and packaging of high-value injectables. It combines the flexibility to adapt to industry needs with access to ROVI's deep expertise. ROIS offers urgently needed specialist filling capacity both on US and European soil in an industry scrambling to meet the explosion in demand for GLP-1s, biosimilars, and ADCs.

In March 2026, ROIS underscored its global aspirations by appointing Kimberlee Steele as its new Chief Commercial Officer. A seasoned executive with an impressive industry record, Steele is spearheading the company's global commercial strategy, bringing her experience to bear as ROIS takes its first big strides stateside. Her appointment as CCO at ROIS serves as a prime example of the Spanish CDMO's international outlook.



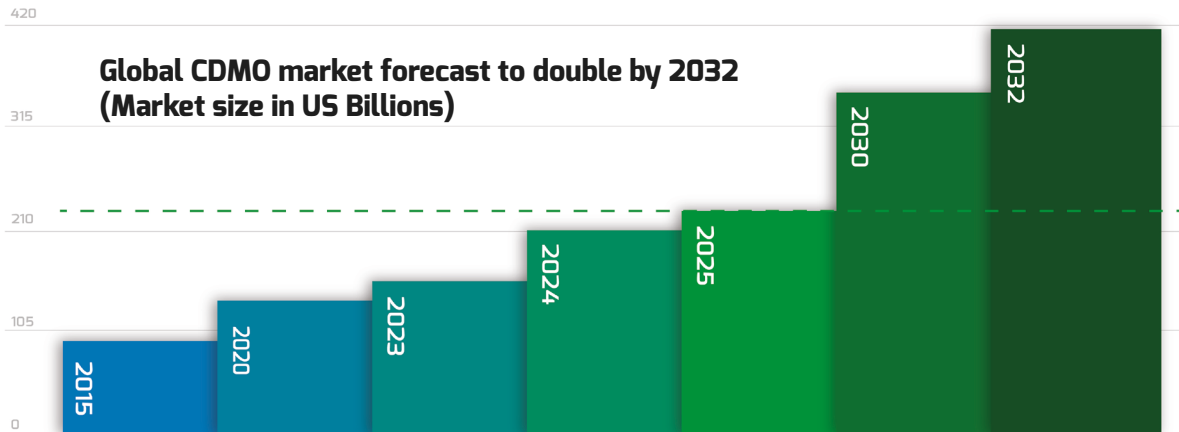
*ROIS Senior Leadership Team Launch Event
Phoenix, US - April 9, 2026*

As the next step in its impressive evolution, ROIS acquired a state-of-the-art manufacturing facility in Phoenix, Arizona. Besides signaling the company's pursuit of closer links with US partners and customers, the Phoenix facility adds key fill-finish capacity for antibody drug conjugates (ADCs) along with cytotoxic fill-finish and lyophilization.

From Family Roots to Global Leadership

ROIS is built on the stable foundations of a century of family ownership and management. Following a strategic review, its parent company ROVI opted to





Ambitious Investment Campaign Goes International

Around the world, pharma & biotech companies are pivoting to outsource specialist manufacturing processes, refocusing their internal efforts on R&D and sales. Fortune Business Insights, for example, forecasts that the global CDMO market will double between 2024 and 2032 to exceed USD 465 billion.

The recent acquisition in Phoenix is a great example of the readiness of ROIS to support this growth. The facility features commercial-scale fill-finish capacity for vials and prefilled syringes, with a segregated cytotoxic production area with four commercial-scale lyophilizers dedicated to vial filling. The site has FDA, EMA and Japanese regulatory approvals already in place with the site's existing cytotoxic capabilities making it a perfect fit for specialist cytotoxic handling, all vital additions given the double-digit growth widely forecast in this multi-billion dollar segment

Expansion is already underway for the installation of a segregated biologics area and the installation of an Optima isolator PFS line with an additional capacity of 65-70M PFS per year. Once operational this will bring the CDMO's total global sterile capacity north of 800 million units/year.

The acquisition is a major strategic undertaking for ROIS, expanding from its EU base to secure a first foothold on American soil. "This is a pivotal moment for us," commented CCO Kimberlee Steele. "It demonstrates where we're headed: We're growing, investing, and expanding capacity."

Combined with existing expertise in WFI manufacturing and the Center of Excellence in Injectable Packaging in Alcalá de Henares, the firm covers the entire injectable CDMO service spectrum.

Kimberlee Steele described the Phoenix investment as emblematic of the ROIS approach. "This acquisition is a strategic step in building ROIS as a global CDMO for high-value injectables," she 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 Capacity



800M+
PFS/VIALS/
Cartridges
annually



14
Aseptic
filling
lines



16
Injectable
packaging
lines



75+ Markets served globally



Global Regulatory Approvals

FDA, EMA, PMDA, KFDA, ANVISA, MHRA, and more

New Services with ROIS Phoenix

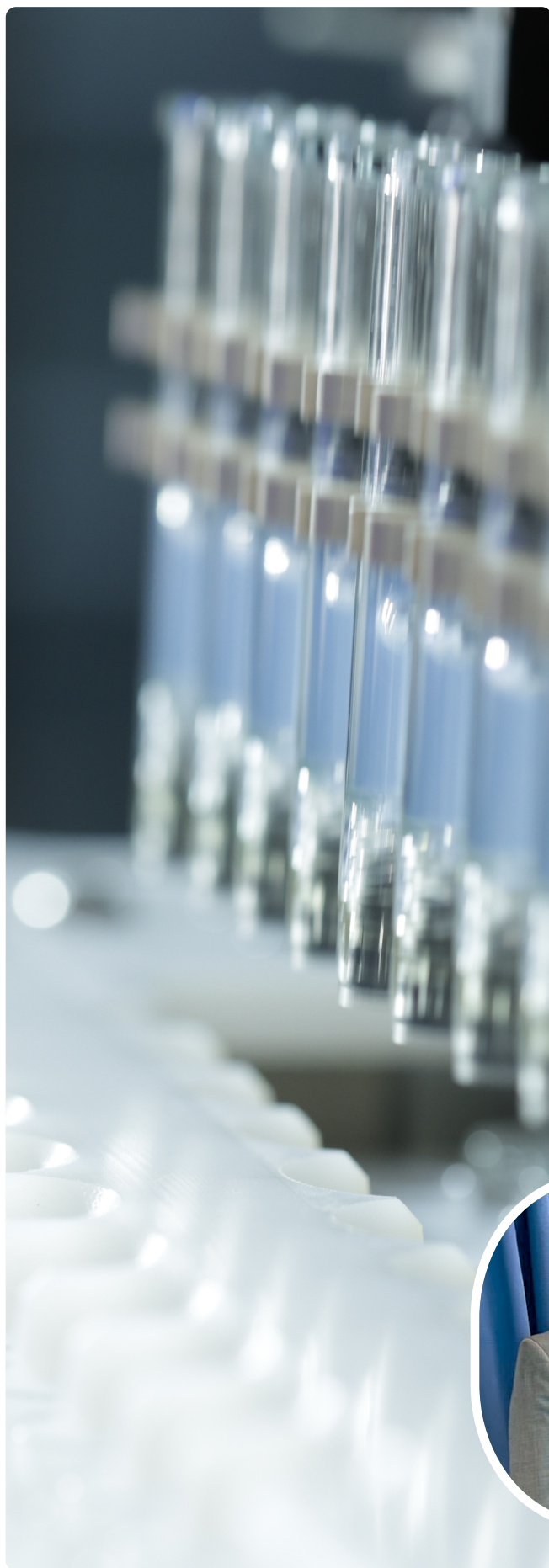
Dedicated Cytotoxic Production Area

Fill-Finish Capabilities for ADC's

Four 440 sq ft Lyophilizers

Vials up to 100ml
2.5ml - 100ml range

Segregated Optima PFS Isolator Line
(adding annual capacity of 65-70 million PFS)



Collaborations Continue with Pharma Industry Giants

ROIS has long demonstrated success with its M&A activities converting well invested big pharma sites into robust contract manufacturing operations. 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 important products for MSD also included the incorporation of an existing facility, complete with production lines and employees – which bodes well for integration of the new Phoenix facility.

During the pandemic, ROIS – like many other CDMOs – stepped up to the plate. ROIS played a vital role by partnering with Moderna to manufacture and supply its Spikevax COVID vaccine. This partnership played a material role in fueling the CDMO's rapid growth in the first half of the decade, and has since been expanded to include production of its RSV and influenza vaccines, further strengthening ROIS's expertise in mRNA-based vaccines and complex injectable manufacturing.

The company's active investment in technical capabilities and capacities also paved the way for a new agreement in 2024 with an undisclosed global pharmaceutical company. This 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. This momentum continued in October 2025, when an agreement with Swiss pharma giant Roche was announced. 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.

Javier López-Belmonte Encina, CEO at ROIS, expressed his joy 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.”



Local Mayor Kate Gallego meets with ROIS CEO Javier López-Belmonte & Nathan Trembath, ROIS General Manager, at her office. April 10, 2026



The Best is Yet to Come

Recent years have brought about seismic changes for ROIS. The CDMO is charting an ambitious growth course, through major international investments and an unwavering focus on driving capacity growth, ROIS expects to double its turnover by 2030. In this context, the Phoenix acquisition represents the next logical step forward.

Its ambitious yet highly targeted growth strategy is 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 leading the way for years to come.



This is a pivotal moment for us. We're growing, investing, and expanding capacity to meet our partners' needs worldwide.

Kimberlee Steele, CCO.



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).



ROIS is a top three Global CDMO for sterile injectable manufacturing capacity. With proven expertise, global capacity, and personalized partnerships, ROIS partners with science leaders to deliver complex injectable medicines to patients worldwide. With approvals from leading regulators – including the FDA, EMA, PMDA, KFDA, ANVISA, and MHRA – ROIS offers end-to-end support across multiple formats, including syringes, cartridges, and vials.



620 N 51st Ave, Phoenix,
AZ 85043, USA



info@roiscdm.com



roiscdm.com