

Libera Bio S.L.

Category:

Best Startup

Company Name:

Libera Bio S.L.

Turnover and/or Funding:

Turnover: USD 80,000 last year (from co-development programs)

Funding (Seed): USD 1,500.000

Funding (nondilutive): USD 1,700,000 (multiple grants after company formation)

Sub-Category:

Biotechnology

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

Founded with the mission to revolutionize the delivery of biologics through next-generation nanomedicine, Libera Bio is pioneering breakthrough solutions for difficult-to-treat targets.

Co-founded by world-renowned drug delivery scientist Prof. María José Alonso, our CSO, the company is built upon over 30 years of pioneering research in nanomedicine. A Full Professor at the University of Santiago de Compostela (Spain) and former researcher at MIT's Langer Lab, she is a member of the US National Academy of Medicine, with 300+ publications, over 41,000 citations, almost 30 patent families, and three biotech ventures to her name. Her leadership grounds the company in scientific excellence and global recognition.

Intracellular targets drive many hard-to-treat diseases and make up about 75% of all therapeutic targets yet remain largely out of reach for current drugs. Monoclonal antibodies (mAbs) are powerful, highly specific pharmacological tools, yet their use has so far been limited to extracellular targets due to their inability to cross cell membranes. Libera Bio is changing that. Our proprietary MPN Technology®

(Multifunctional Polymeric Nanocapsules) is the first nanotechnology platform to demonstrate in vivo intracellular delivery of full intact antibodies to reach these elusive targets. This represents a major leap forward in drug delivery science. To date, we have successfully validated our technology in three different mAbs, targeting distinct intracellular proteins across multiple preclinical cancer models -including breast, lung, colorectal, and pancreatic cancers- all at clinically translatable doses. This breakthrough opens the door to a new class of intracellular antibody-based therapeutics, with broad implications for oncology and beyond.

Libera Bio has received international recognition for its breakthrough innovation. The company was selected by Johnson & Johnson Innovation JLABS during the QuickFire Challenge at JP Morgan (2020) and awarded the Salisbury Award (2021) by the National Foundation for Cancer Research (US) for its pioneering intracellular delivery of mAbs. In addition, Libera Bio has been honored with numerous national-level awards in Spain -granted by leading pharma/biotech foundations and financial institutions- which underscore the strong industry support and market potential behind Libera Bio's innovation. The company has also built strategic alliances with firms in the United States, Canada, the Netherlands, Austria, and France, and collaborates with leading research groups in the US, United Kingdom, Belgium, and Spain, further validating its global scientific relevance.

Our lead MPN-mAb (LIB125) addresses the KRAS G12V oncogenic mutation that today has no treatment and is associated with 1 in 4 pancreatic, 1 in 10 colorectal, 1 in 20 lung cancers and many others. Preclinical studies are complete. The product is ready for CMC.

We have started to develop three other mAbs on our own to address poorly treated targets: STAT3 (cancer, inflammation), CRAF (cancer), and HIF-1 α /2 α (cancer, ophthalmology).

With a strong pipeline and bold scientific vision, our goal is to deliver first-in-class therapies that reshape the future of precision medicine.

History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):

Libera Bio's MPN Technology® overcomes a key limitation of mAbs by enabling their delivery inside cells, opening access to previously untreatable intracellular targets in cancer and beyond.

The MPN Technology® has demonstrated robust in vivo proof-of-concept for the intracellular delivery of mAbs, targeting cancer-associated proteins that were previously considered inaccessible. Preclinical studies have validated the platform with three different mAbs directed against key intracellular targets: Gasdermin B (a cytosolic

protein), and mutated KRAS G12D and G12V (inner membrane-associated oncogenic drivers). These were tested across breast, lung, colorectal, and pancreatic cancer models. Results consistently demonstrated that MPNs effectively deliver intact mAbs into tumor cells, achieving robust intracellular target engagement and inhibition. This led to marked tumor growth reduction with single-agent treatment, and near-complete suppression when combined with other therapies, all at clinically translatable intravenous doses (5-10 mg/kg mAb).

The nanocapsules exhibit favorable biodistribution, with active accumulation in tumors and minimal presence in off-target organs such as the liver, spleen, kidney, and heart -comparable to or lower than that observed with non-formulated mAbs. Importantly, no signs of toxicity or adverse effects were observed even at doses up to 50 mg/kg mAb (5-10x the therapeutic dose), confirming an excellent safety margin in toxicology studies.

MPN Technology® uses FDA-approved excipients for intravenous administration and is built on a solvent-free, heating-free simple and mild process that preserves 100% of the active mAb during manufacturing. It is scalable, with pilot-scale production up to 5 liters already demonstrated in an industrially relevant environment.

The formulation is stable in suspension, frozen, and lyophilized formats, supporting flexible logistics and long-term storage. Furthermore, MPNs enable co-delivery of small molecules within their oily core, opening the door to synergistic combination therapies that target multiple cancer pathways simultaneously.

Together, these milestones validate the MPN Technology® as a first-in-class intracellular mAb delivery platform with strong translational potential and industrial readiness.

Libera Bio has established a second pipeline of strategic collaborations across the U.S., Canada, and Europe, some of which already revenue-generating. These partnerships not only validate the versatility and appeal of our MPN Technology® platform but also extend our impact to a range of intractable biomedical challenges. Current joint development efforts include repeated systemic delivery of mRNA for hormone replacement therapies, long-acting release of mAbs from implantable devices, efficient crossing of the blood-brain barrier to make therapeutic mAbs reach the brain; and cytosolic delivery of protein degraders for targeted cancer treatment. These alliances enhance our innovation pipeline and accelerate the translation of our technology into clinical applications.

Libera Bio holds a robust and strategically structured IP portfolio covering composition of matter, methods of use, and manufacturing processes related to its proprietary MPN Technology®. The platform is protected by three internationally filed patent families, with key patents already granted in the U.S. and EU. In 2025, four additional patent

applications will be filed to further strengthen IP protection - two focused on expanding the platform's scope for delivering mAbs and other biologics (e.g., mRNA), and two targeting specific product innovations.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Intracellular targets play a key role in many of the world's most challenging diseases - from cancer to neurodegeneration- yet they remain out of reach for conventional biologics. Libera Bio's MPN Technology® represents a major scientific breakthrough: the first nanotechnology platform that enables safe, in vivo delivery of intact monoclonal antibodies (mAbs) into cells. This unlocks a new class of intracellular biologics and opens a vast new therapeutic frontier.

Traditional mAbs are too large and too polar to cross cell membranes, limiting their use to extracellular targets. Despite multiple efforts - including conjugation with cell-penetrating peptides and advanced antibody engineering - no approach has achieved safe and effective intracellular mAb delivery at clinically translatable therapeutic doses. Libera Bio's proprietary MPN nanocapsules overcome this barrier by encapsulating numerous mAbs per particle, shielding them in circulation, and delivering them into the cells in an active form.

Our lead candidate, LIB125 - an MPN-delivered mAb targeting the KRAS G12V mutation - has demonstrated preclinical efficacy in pancreatic, lung and colorectal cancer models, and it is ready for CMC and positioned for a capital-efficient Phase 1/2a trial.

What sets Libera Bio apart isn't just the technology, but how we're accelerating its refinement. Years of formulation work using design of experiments and quality-by-design approaches have generated a rich, diverse dataset. This solid foundation now enables the reliable use of AI to uncover how formulation parameters influence key product attributes, define optimal conditions, and streamline feasibility assessments. The result: faster, sharper decision-making and more effective collaborations - all driving therapies forward with greater speed and confidence.

Importantly, the implications of the MPN Technology® extend far beyond mAbs or oncology. The platform is adaptable to a wide range of biologics, including peptides, proteins, and nucleic acids - enabling new solutions for diseases that have resisted conventional approaches.

Examples of transformative applications in progress:

- Deep tissue delivery: A repurposed biosimilar mAb encapsulated in MPNs showed superior efficacy in liver fibrosis compared to its commercial counterpart, due to improved tissue penetration and targeted cell uptake.

- Crossing the BBB: While MPNs do not naturally cross the BBB - a key safety advantage - methods such as focused ultrasound and ligand-functionalization are being explored to enable more efficient mAb brain delivery. Two collaborative programs are underway to develop MPN-based therapies for glioblastoma (HIF-1 α /2 α mAbs) and Parkinson's disease (anti-synuclein mAbs).

- Implantable devices: A leading medtech partner has selected MPNs to solve the long-standing challenge of delivering stable antibodies from implantable devices, leveraging our proven long-term stability.

- Repeatable mRNA therapies: An MPN-mRNA encoding Klotho - a protein linked to aging-related diseases - shows potential for repeated dosing without triggering immune responses. Unlike traditional LNPs, MPNs offer minimal toxicity, extrahepatic delivery, and prolonged plasma stability leading to more sustained transfection levels.

By redefining the boundaries of what biologics can achieve, Libera Bio's MPN Technology® has the potential to reshape the future of precision medicine - expanding the druggable landscape and improving outcomes for millions worldwide.

Please provide appropriate references (PubMed, Abstract, Website):

Website

<https://www.liberabio.com>

Publications by our team

(1) Teijeiro-Valiño C et al. (2018) A multifunctional drug nanocarrier for efficient anticancer therapy. Journal of controlled Release.
<https://doi.org/10.1016/j.jconrel.2018.12.002>

(2) Molina-Crespo A et al. (2019) Intracellular Delivery of an Antibody Targeting Gasdermin-B Reduces HER2 Breast Cancer Aggressiveness. doi: 10.1158/1078-0432.CCR-18-2381
<https://aacrjournals.org/clincancerres/article/25/15/4846/264902/Intracellular-Delivery-of-an-Antibody-Targeting>

(3) Dacoba T.G. et al. (2021) Nano-Oncologicals: A Tortoise Trail Reaching New Avenues. <https://doi.org/10.1002/adfm.202009860>

(4) Paul Joyce, Christine J. Allen, María José Alonso, Marianne Ashford, Michelle S.

Bradbury, Matthieu Germain, Maria Kavallaris, Robert Langer, Twan Lammers, Maria Teresa Peracchia, Amirali Popat, Clive A. Prestidge, Cristianne J. F. Rijcken, Bruno Sarmiento, Ruth B. Schmid, Avi Schroeder, Santhni Subramaniam, Chelsea R. Thorn, Kathryn A. Whitehead, Chun-Xia Zhao & Hélder A. Santos. A translational framework to DELIVER nanomedicines to the clinic. *Nat. Nanotechnol.* 19, 1597-1611 (2024).
<https://doi.org/10.1038/>

(5) A. M. López-Estévez, P. Lapuhs, L. Pineiro-Alonso, M. J. Alonso, Personalized Cancer Nanomedicine: Overcoming Biological Barriers for Intracellular Delivery of Biopharmaceuticals. *Adv. Mater.* 2024, 36, 2309355.
<https://doi.org/10.1002/adma.202309355>

(6) Laura Pineiro-Alonso, Inés Rubio-Prego, Alexandra Lobyntseva, Eva González-Freire, Robert Langer, María José Alonso, Nanomedicine for targeting brain Neurodegeneration: Critical barriers and circadian rhythm Considerations, *Advanced Drug Delivery Reviews*, Volume 222, 2025, 115606, ISSN 0169-409X,
<https://doi.org/10.1016/j.addr.2025.115606>

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