IRAZÚ ONCOLOGY

First-in-class OMV Immunotherapy: tumor antigens, self-adjuvant, and immunosuppressive-cell targeting in one

Series A: $30M | Preclinical | IND Submission 2027 | Phase 1 FIH Q3 2028

Jeffrey Strovel, PhD, CEO | (301) 580-9858 | jstrovel@irazuoncology.com

$2.2B	100%	2027	Q3 2028
Addressable Market	**IRZ-01 Durable Response**	**IND Submission**	**Phase 1 FIH**
NSCLC, MSS CRC, PDAC ($15B TAM)	n=17, 5 mo post 2nd rechallenge	FDA Pre-IND aligned	CEA/MUC-1⁺ solid tumors

THE PROBLEM

Checkpoint inhibitors fail 60–70% of patients with solid tumors. Patients with "cold" tumors — lacking immune infiltration — derive virtually no benefit. No approved therapy simultaneously kills tumor cells and reprograms the immunosuppressive tumor microenvironment (TME).

IRZ-03: FIRST-IN-CLASS MULTIMODAL IMMUNOTHERAPY

IRZ-03 displays **CEA and MUC-1** (tumor antigens) plus **PD-L1** (targeting PD-L1⁺ immunosuppressive cells — TAMs, MDSCs, suppressive DCs — for vaccine-induced cytolytic elimination, *distinct from checkpoint blockade*). Built on a proprietary OMV platform with 15+ years of optimization at the UMD Vaccine Center.

- **Self-adjuvanted.** Intrinsic lymph node targeting via TLR2/4 self-adjuvanticity — no exogenous adjuvant required
- **Multimodal.** Simultaneous tumor + TME targeting in a single compound — unique among competing modalities
- **Plug-and-play.** Modular SpyCatcher/SpyTag antigen display enables rapid pipeline expansion
- **Manufacturing.** Low COGS, scalable bacterial fermentation vs. >$100K/patient for mRNA-LNP
- **External validation.** IO Biotech's Cylembio (IO102-IO103) demonstrates clinical activity targeting the same PD-L1⁺ immunosuppressive cell population

PRECLINICAL PROOF OF CONCEPT (IRZ-01)

- **Monotherapy efficacy.** Tumor elimination as monotherapy with durable memory response
- **Durability.** 85% tumor-free at 1st rechallenge (n=20); 100% tumor-free 5 months post 2nd rechallenge (n=17)
- **Combo + anti-PD-1.** Statistically superior survival vs. either agent alone ($p<0.01$)
- **Antigen prevalence.** CEA and MUC-1 expressed in 80–100% of CRC, NSCLC, gastric, and pancreatic tumors (NCI-prioritized antigens)

FDA PRE-IND: KEY ALIGNMENTS ACHIEVED

✓ **Species model accepted:** mice as single tox species; leverages prior OMV & S. typhi safety data
✓ **Safety testing approved:** MAT assay accepted — non-animal, human-relevant pyrogenicity approach
✓ **Dosing approach supported:** KDO–antigen ratio validated as OMV dosing metric
✓ **PK/BD simplified:** standalone PK/BD studies not required — accelerates IND readiness

CLINICAL STRATEGY

Phase 1a/1b (n≈30, BOIN design): 2L/3L **NSCLC, MSS CRC, and PDAC** — CPI-refractory, CEA/MUC-1 selected. Phase 1a budget ~$9.5M external; 9-month FPI-to-LPLV.

- **PD-L1-rich tumors:** ORR uplift target 10→25% in combination with CPI
- **PD-L1-poor tumors:** Projected ORR 20–40% — largely unserved population (MSS CRC, PDAC)
- **Clinical candidate nomination:** Q1 2026 → IND submission 2027 → FIH Q3 2028

PLATFORM COMPARISON

Feature	Irazú OMV	mRNA-LNP	Peptide Vaccine
Lymph node targeting	**Intrinsic**	Moderate	Poor
Self-adjuvanted (TLR2/4)	**Yes**	Partial	No
Simultaneous tumor + TME targeting	**Yes**	No	No
Cost per patient (est.)	**Low COGS**	>$100K	Moderate
Plug-and-play antigen swap	**Yes (SpyCatcher/SpyTag)**	Partial	Yes

FINANCING & MILESTONES

Series A (2026): $30M → Series B (2028): $45–50M

- **Use of proceeds:** IND-enabling tox, CMC clinical lot manufacture, IND filing, Phase 1a execution, Phase 1b initiation
- **Runway:** Through IND submission (2027), FIH (Q3 2028), and Phase 1a interim data

TEAM & ADVISORS

Jeffrey Strovel, PhD (CEO) — 25+ yrs, co-founder Veralox Therapeutics ($50M+ raised). **Marco Chacon, PhD** (Chairman) — founder of Paragon Bioservices ($1.2B Catalent sale). **Marcio Chedid, PhD** (CSO). **Elizabeth Smith, PhD, MBA** (SVP IP & Corporate Strategy). **Kevin Chen, PhD** (Director of Research). **Eric Lutz, PhD** (Director of Immunology). CMC and program leads from JHU, Charles River, and NCI experience. KOL advisors: JHU, UMB, Harvard T.H. Chan; industry affiliations with Lilly, MSD, Catalent, Celsion.