Market Pulse

September 2025

Northern BioStrategies

Executive Insights

- Biotech equities rebounded sharply (small-cap index +75% since April) as trial wins, FDA approvals, and M&A restored confidence.
- Capital is flowing again but selectively – mega-rounds (Isomorphic Labs $600M) coexist with leaner A/B raises. IPO window reopened with LB Pharma’s $285M Nasdaq debut.
- Innovation pipeline remains rich: CRISPR therapies, mRNA 2.0, bispecifics and ADCs advancing.
- Regulators supportive: FDA approvals (paltusotine, imlunestrant, subQ Keytruda) highlight momentum; EU pharma law reform looms, with shorter exclusivity tied to wider access.

Capital Flows & Deals

- VC: ~$18B H1 funding (–16% YoY). Concentration in AI, gene therapy, oncology.
- M&A: Big Pharma filling gaps (J&J $14.6B Intra-Cellular, Merck $10B Verona, Sanofi $9.5B Blueprint).
- IPO: Market reopening – LB Pharma raised $285M, largest biotech IPO of 2025.

Regulatory & Policy

- FDA approvals accelerating – oncology, rare disease, next-gen modalities.
- EU Pharma Package reform: exclusivity down to 9 years baseline, extendable with access commitments.
- US: Medicare drug price negotiations to affect biologics post-2030; payers demanding stronger value data.

Sector Spotlight – AI in Drug Discovery

- 400+ startups globally; full-stack vs. platform models.
- Landmark deals: Isomorphic Labs $600M Series A; Takeda $4B buyout of Nimbus’ AI-designed TYK2 inhibitor.
- Challenge: No AI-discovered drug approved yet; Phase 2/3 outcomes in next 2 years critical.
(Visual: landscape map – small molecules vs. biologics, platform vs. pipeline.)

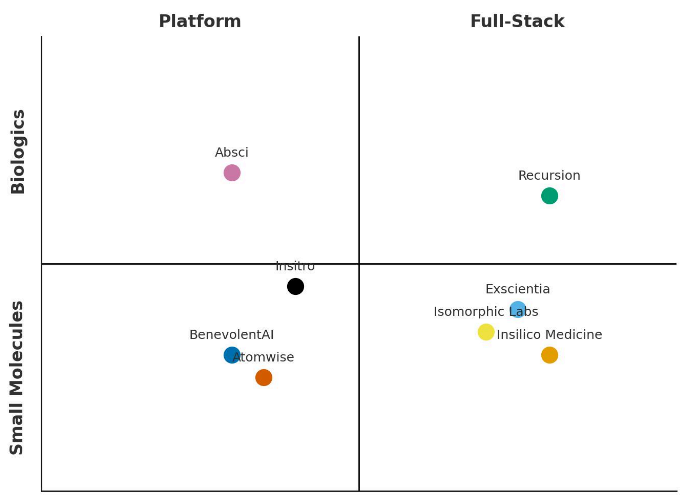
Innovation & Pipeline

- Gene Editing: CRISPR and base-editing trials expanding; first approvals (Casgevy) set precedent.
- mRNA 2.0: Moderna/Merck cancer vaccine in Phase 3; new delivery tech expanding scope.
- Clinical Milestones: Alzheimer’s therapy, bispecific antibodies, gene therapies showing strong efficacy.

Investor & Market Sentiment

- Public markets: recovery driven by trial wins and M&A speculation; valuations improving but selective.
- VC: capital available but terms tougher, focus on quality platforms/late-stage assets.
- Outlook: cautious optimism – “smart money” flows to differentiated, de-risked science.

AI Drug Discovery Competitive Landscape (2025)



Strategic Outlook (Q4 2025)

- Be deal-ready: M&A tailwinds strong; ensure data/IP packaged for partners.
- Adapt to regulation: model EU exclusivity reforms and US pricing shifts into planning.
- Seize funding windows: prepare for opportunistic IPO/secondary raises while market is open.
- Differentiate: focus resources on assets with unique mechanisms and strong data credibility.