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Biotech's New Rules: Data, Discipline and the Return of Capital

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David H. Crean, Chief Business Officer of MediciNova, discusses biotech financing, cross-border dealmaking, regulatory strategy, and why neuroscience may offer some of the industry's most compelling value creation opportunities.

After several years of volatility, biotechnology financing has returned—but under very different rules. Investors are increasingly focused on data, defined catalysts, and disciplined execution, while cross-border partnerships and strategic transactions are playing a larger role in value creation. **David H. Crean, Chief Business Officer of MediciNova, discusses the changing investment landscape, regulatory influences, and emerging opportunities in neuroscience and rare disease development in this conversation with BioSpectrum Asia at BIO International Convention 2026.**

How would you characterize the current biotech financing environment for clinical-stage companies?

The window has reopened, but it reopened with conditions. After the 2022 reset, capital returned to clinical-stage biotechnology through 2025 and into 2026, and the clearest signal sits in the secondary market. Follow-on equity issuance ran to roughly $56 billion in 2025, with demand concentrated in companies carrying credible clinical data. IPOs are coming back, but the bar has moved. Close to 90 percent of life sciences IPO issuers last year were in Phase 2 or later. The market is looking for de-risk stories, buying proof, not promise.

Underneath the recovery sits a split that every clinical-stage leader should read carefully. Late-stage, de-risked assets attract large sums of capital and premium valuations. A long tail of small-cap companies trades at or below cash, with negative enterprise value, unable to convert good science into investor conviction. The same index (XBI) that fell to an 18-month low after the April 2025 tariff announcement rose roughly 75 percent by December. That is recovery and dispersion at the same time.

What clears the bar now is specific. Blue-chip and insider support. A defined value catalyst inside 12 to 18 months. A mechanism a generalist can underwrite without a PhD. Generalist investors have started to re-engage, and certain therapeutic areas, neurology and cardiometabolic among them, have drawn fresh capital after a decade on the margins.

For a company like MediciNova, the discipline writes itself. Capital efficiency is not a buzzword. It is a financing strategy. We run a lean operating structure and advance a meaningful share of our clinical work through investigator-sponsored trials funded by government and institutional grants. Our large-scale Expanded Access Program in ALS, the SEANOBI study, is supported by an NIH and NINDS grant under the ACT for ALS initiative, which lets us generate real-world clinical and biomarker data while limiting dilutive equity financing. A small-molecule pipeline with manageable cost of goods and clear inflection points is easier to fund than a capital-intensive platform selling optionality. The companies that raise well in 2026 are the ones that can name the catalyst, name the date, and show why the data will move the price.

What dealmaking and partnership trends are shaping biotech growth strategies in 2026?

Business development has moved from optionality to a requirement. Two forces explain it. Large pharma faces a loss-of-exclusivity wall on the order of $200 billion in branded revenue this decade, and the cash to fill it is sitting on the balance sheet. The result is the most active dealmaking environment since before the pandemic, and the shape of it is instructive.

The mega-merger is out of favor. Buyers have settled on bolt-on acquisitions, generally in the $1 billion to $5 billion range, aimed at one or two assets with validated biology and a clear regulatory path. Smaller deals integrate faster, clear antitrust more easily, and let acquirers buy science rather than franchises. Structure has evolved alongside size. Contingent value rights and milestone-weighted terms are now standard, a way to bridge the gap between what a seller believes and what a buyer will underwrite before the next readout.

The second force is geographic, and it should command everyone's attention. China has moved from manufacturing hub to innovation source. Cross-border out-licensing from Greater China reached roughly $138 billion in 2025, close to ten times the 2021 figure, and 2026 is on pace to surpass it. China now accounts for something near 30 percent of the global clinical pipeline. AstraZeneca, GSK, Roche, and Merck have all signed multi-billion-dollar agreements with Chinese biotechs. The NewCo structure, which pairs an Asia-origin asset with Western capital and management, has become a repeatable model rather than an experiment.

The rest of Asia-Pacific is building deliberately. South Korea is landing blood-brain-barrier and ADC licensing deals and scaling translational funding. Japan's Sakigake designation and bioventure programs shorten the road for promising therapies. For MediciNova, which carries a dual presence on the NASDAQ Global Market and the Standard Market of the Tokyo Stock Exchange, cross-border financing and partnering are a native part of strategy, not a bolt-on. Regional partners can contribute more than capital. In neurology and rare disease, where trial execution is hard and patient populations are dispersed, a high-quality regional partner brings investigator networks, regulatory engagement, and patient identification. The discipline is the same everywhere. Partner from a position of data, not desperation, and structure the deal so the value follows the result.

How are regulatory dynamics influencing investment and development decisions across the sector?

Regulation has become a primary input to valuation, not a downstream formality. Investors now price the regulatory path and the agency as directly as they price the science, and 2026 has given them reasons in both directions.

The constructive signal is the continued application of the accelerated approval pathway to serious rare disease. In April 2026, the FDA cleared Denali's tividenofusp alfa for the neuronopathic form of Hunter syndrome on a biomarker surrogate, a reduction of roughly 90 percent in cerebrospinal fluid heparan sulfate, with clinical confirmation to follow. For developers of brain-penetrant therapies in rare neurological disease, that decision matters beyond the single drug. It signals that a well-qualified surrogate, tied credibly to clinical benefit, can still carry an approval. The June 2026 rare disease roundtable framed the question correctly. The issue is not whether uncertainty exists in a small trial. It is whether the remaining uncertainty is acceptable given the severity of the disease and the absence of alternatives.

The countervailing signal is unpredictability itself. Leadership turnover at the FDA, debate over the future of advisory committees, and inconsistent benefit-risk calls have introduced risk that appears on no term sheet. Capital does not flee risk. Capital flees risk it cannot price. When the standard for a given endpoint can shift between meetings, every program touching that endpoint carries a wider discount.

Alongside that caution, there is real openness to better methods. Regulators are increasingly receptive to Bayesian and adaptive designs and to validated biomarkers such as neurofilament light as a measure of axonal injury, provided they are prospectively justified and transparent. That openness is opportunity and obligation at once. Innovative design has to be grounded in the disease biology, not bolted on for effect.

The development response is consistent across the companies doing this well. Engage the FDA early and document everything. Build biomarker strategy into the protocol from first dosing rather than retrofitting it at the end. Choose endpoints regulators have accepted before, where the biology allows it. For MediciNova, that logic runs straight through our lead program. MN-166 (ibudilast) holds Orphan Drug and Fast Track designations from the FDA and Orphan designation from the European Commission in ALS, and we built COMBAT-ALS, our Phase 2b/3 trial, to produce the controlled evidence a full approval requires. Our NIH-funded SEANOBI Expanded Access Program runs alongside it, capturing neurofilament and clinical data in patients ineligible for the randomized trial. Together, those programs bring both controlled and real-world evidence to the regulatory discussion. Regulatory strategy does not begin at the pre-NDA meeting. It is a design choice made at the moment of first dosing, and increasingly it is the variable that decides whether an asset is financeable at all.

What are the key challenges in advancing therapies for neurological and rare diseases through late-stage clinical development?

The hardest problems in neurology and rare disease are not commercial. They are evidentiary. Three challenges separate the programs that reach approval from those that stall.

The first is the endpoint. Neurological diseases often progress slowly, vary widely between patients, and inflict damage that is irreversible by the time of diagnosis. In conditions such as ALS and progressive MS, functional scales like the ALSFRS-R carry real variability, progression rates differ substantially across patients, and a clinical endpoint built on slow functional decline can require large trials over long horizons. That is expensive and slow in common disease and close to impossible in rare populations. This is why biomarker-driven development has moved from preference to necessity. A surrogate that regulators accept as reasonably likely to predict benefit, interpreted in the context of clinical outcomes, can be the difference between a feasible trial and one that cannot be run.

The second is the patient population, and the operational burden that comes with it. Rare disease trials compete for small, geographically scattered cohorts, often against multiple sponsors pursuing the same indication. Patients frequently travel to specialized centers, and participation places a real burden on families and caregivers, which restricts compliance and retention. Design choices follow directly. A patient-centric protocol minimizes unnecessary visits and favors accessible routes of administration. An oral small molecule carries a clear logistical advantage here over a biologic or gene therapy that requires institutional infusion infrastructure. The patient advocacy ecosystem has become essential infrastructure, not a courtesy. Advocacy organizations build registries, accelerate recruitment, and articulate the lived benefit-risk tradeoff that a statistical table cannot convey. Sponsors who treat that community as a late-stage marketing exercise rather than a development partner pay for it in time.

The third is translation across regions. A late-stage neurology program increasingly runs as a multi-regional trial, which raises real questions of endpoint harmonization, ethnic sensitivity, and acceptance of foreign data by the FDA, EMA, NMPA, and PMDA. For Asia-Pacific sponsors and partners, this is both opportunity and obligation. Designing a trial that satisfies several regulators from the outset is harder than designing for one. It is also far cheaper than discovering the gap after database lock.

Underlying all three is capital intensity. Late-stage neurologic trials are long, expensive, and difficult to finance, which is why companies must advance only those programs where mechanism, preclinical evidence, clinical data, endpoint strategy, and regulatory path support continued investment. Running an expanded access program such as SEANOBI alongside a randomized trial such as COMBAT-ALS lets a sponsor serve patients ineligible for the pivotal study while systematically capturing real-world outcomes and long-term safety data. None of this is solved with capital alone. It is solved with trial design that respects the biology, a biomarker strategy agreed with regulators early, and an advocacy partnership built years before the pivotal readout. For a small-molecule developer in this space, those choices, made early, are what carry an asset through the stage where most fail.

Where do you see the greatest opportunities for value creation in biotechnology over the next few years?

Value will concentrate where unmet need, scientific tractability, and a financeable path intersect. Four areas stand out right now.

Neuroscience is the clearest. After years on the periphery of investor interest, the field is drawing capital again, helped by approvals that validate brain-penetrant mechanisms and by biomarkers that finally let developers measure central nervous system engagement. Conditions such as ALS, progressive multiple sclerosis, Alzheimer's disease, and the broader neurodegenerative set carry enormous unmet need and, increasingly, tractable endpoints. The failures in neurology are

well known, and those failures have made the field more rigorous. Small molecules retain a structural advantage in the brain, where crossing the blood-brain barrier remains the gating problem for many modalities. There is also leverage in a single compound that addresses shared drivers of disease, such as neuroinflammation, glial activation, and fibrotic pathways, across related indications. That pipeline-in-a-product approach mitigates the binary risk inherent to single-asset models.

Rare disease is the second. The regulatory framework, for all its current noise, still rewards well-designed programs in severe conditions with no alternatives, and the biomarker toolkit that makes those programs feasible continues to improve. The opportunity is not limited to genetic medicines. Small molecules, reformulated or repurposed agents, and anti-inflammatory or disease-modifying approaches can all play a role when matched to the right indication. The economics favor focused developers who can run efficient trials and command durable pricing for genuine benefit.

The third is the corridor between Asian innovation and Western capital. The asset flow out of China, Korea, and Japan is no longer a curiosity. It is a structural feature of the industry. Value accrues to the parties who can bridge the two systems, sourcing high-quality science in one geography and financing, regulating, and commercializing it in another. That intermediation skill, executed while managing regulatory, geopolitical, and operational complexity, is itself a scarce and valuable asset.

The fourth is the capital-efficient operating model. The reset taught a lesson the boom obscured. Companies that convert each dollar into clear de-risking milestones, rather than diffuse optionality, will out-raise and out-last those that do not. A focused pipeline with defined catalysts is not a penalty imposed by a hard market. It is the durable way to build.

The thread connecting all four is discipline. The next several years will reward developers who pick problems where the science is ready, design programs regulators can endorse, and fund them against catalysts that move conviction. For MediciNova, that perspective is shaped by the realities of developing therapies for serious diseases where patients have limited options and where clinical development demands patience. The opportunity in biotechnology is not to chase what is fashionable. It is to advance programs where the science is credible, the need is real, and the development strategy can withstand scrutiny from regulators, partners, investors, physicians, and patients. Capital is available again for that kind of company.