

Partnering and Preparedness Prospectus

What we are looking for from governments, funders, manufacturers and endemic-country investigators.

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Owner	Business Development
Applies to	Prospective partners and funders

Baxtra Research Labs is looking for partners who treat preparedness as a public capability rather than a normal commercial launch. This prospectus describes the assets, operating models and boundaries we will use in diligence conversations.

The problem statement

Countermeasures for high-consequence pathogens are not commercially self-sustaining. Demand is episodic, procurement is uncertain, and the people who need access may not be the people who can pay for discovery, trials, manufacturing readiness and stockpiles. The funding therefore has to come from preparedness budgets, governments, philanthropic or other public-interest funders, and structured commitments that recognise the value of readiness before an outbreak.

Saying this plainly is better than pretending otherwise. A product plan that assumes ordinary volume-based sales will support an intermittent emergency portfolio will fail at the point when readiness matters. Baxtra is seeking agreements that pay for evidence, capacity and access conditions, not only doses after an event.

What Baxtra brings

Asset	Current public description
Clinical-stage medicines	12 disclosed Phase 1 programmes; one further real clinical-stage Phase 1 programme withheld as Programme 9. None approved anywhere.
Maximum containment	Palm Coast BSL-4 suit laboratory; commissioning completed July 2026.
Discovery capability	Select-agent-registered discovery capability, with discovery and containment-level-3 laboratories opened August 2025.
Surgical technology	Lumavue™ real-time tissue perfusion imaging; SealWeave™ bioresorbable staple-line sealant; Axion OR™ robotic soft-tissue instrument platform.
Operating base	Founded March 2025 in the United States; 412 headcount, including 268 in research and development.

Partnership models offered

Model	What it is	What Baxtra expects in return
Co-development	Shared development plan, governance and funding for a named programme or platform.	Committed capital, defined decision rights, specialist expertise and an access plan.
Regional licensing	Rights in a defined geography with local regulatory, medical and commercial responsibility.	Regulatory and manufacturing capability, transparent access commitments and pharmacovigilance support.
Stockpile supply agreements	A preparedness purchase or option covering product, release criteria, replenishment and expiry management.	Budgeted demand, agreed specifications, forecast discipline and a route to replenish readiness stock.
Outbreak-activated trial partnerships	Pre-agreed sites, investigators and operational triggers for a trial that activates when an outbreak meets defined criteria.	Standing funding, site readiness, data standards and authority to start without rebuilding the network.
Contract access to maximum containment	Agreed access to the Palm Coast BSL-4 suit laboratory for qualified work under a defined scope.	Cost recovery, qualified staff, scheduling, biosafety compliance and clear ownership of data and materials.

What a good partner contributes

- Governments contribute predictable preparedness funding, procurement clarity and the authorities needed to connect research with public-health action.
- Funders support the unglamorous interval between discovery, validation, trial readiness and manufacture, not just a press-ready milestone.
- Manufacturers bring process development, analytical control, fill-finish, cold-chain or room-temperature assessment as appropriate, and a willingness to reserve capacity.
- Endemic-country investigators bring local clinical knowledge, epidemiology, site leadership and a voice in questions that affect their communities.

Diligence begins with scope

Baxtra will not describe withheld Programme 9 information in an initial prospectus. Under agreement, diligence is staged: first the public portfolio and governance record, then programme-specific scientific, clinical, quality and financial material appropriate to the proposed model. Access to sensitive information is not permission to publish it.

The clinical portfolio spans nine therapeutic areas and has 27 clinical trial sites across the United States. Every programme is under a cleared US Investigational New Drug application. Most use the FDA Animal Rule; BX-733, BX-1140 for mpox and BX-1620 have feasible conventional 505(b)(1) routes.

Outbreak-activated trial partnerships

The central operational argument is simple: being ready before an outbreak is better than beginning readiness after it. An outbreak-activated trial partnership establishes the people, sites, contracts, data standards, investigational product logistics and decision rules while there is time to do the work carefully.

Before an outbreak

1. Select the pathogen, population, candidate and comparator question; agree what constitutes an activation trigger with public-health and regulatory partners.
2. Qualify sites and investigators, including laboratory, pharmacy, data, safety and infection-control capability. Maintain training and contact details rather than storing a dormant list.
3. Agree a master protocol or adaptable platform structure, endpoints, statistical assumptions, specimen handling, authorship, data ownership and reporting expectations.
4. Reserve manufacturing, packaging, shipping and temperature-monitoring capacity. Define release tests and the replenishment or expiry plan for any readiness stock.
5. Run a tabletop exercise with the sponsor, authorities and endemic-country partners. Record failure points and fund their correction.

At activation

1. Confirm that the trigger is met, that the investigational product and comparator are available, and that the protocol remains ethically and scientifically appropriate to the event.
2. Open sites in a planned sequence, with local investigators leading patient-facing implementation and a central team supporting supply, monitoring, safety and data quality.
3. Use pre-agreed interim review and stopping rules. A small outbreak is not an excuse to lower evidentiary standards; it is a reason to make every observation count.
4. Share information rapidly under the agreement, including negative or inconclusive results, while protecting participant confidentiality and site safety.

After the event

Close the trial with a public account of the design, enrolment, protocol deviations, safety findings and limits of inference. Reconcile stock, samples and data. Update the model for the next event. The partnership is a preparedness capability, not a one-off emergency purchase.

Readiness is an operational deliverable. A memorandum that does not fund site maintenance, manufacturing reservation, data governance and exercises is not an outbreak-activated trial partnership.

Endemic-country partnership principles

A pathogen may be high consequence globally while being a recurring reality in a particular country or region. Baxtra will not treat endemic-country investigators as a source of samples or a recruitment channel only. The partnership must shape the protocol, the interpretation and the benefits of the work.

Principle	Commitment
Technology transfer	Build a practical plan for methods, training, quality systems and, where agreed, manufacturing or fill-finish know-how to move with the programme.
Local authorship	Recognise endemic-country investigators in authorship and leadership in proportion to their scientific and operational contribution, agreed before the work begins.
No sample export without agreement	No sample leaves the country without a data-sharing agreement that states permitted use, custody, return or destruction, access and publication.
Fair data access	Provide participating investigators timely access to data needed for local analysis, safety oversight and public-health action, subject to privacy and security.
Local value	Budget for site capability, training, diagnostics, clinical care interfaces and other durable capacity rather than extracting a single study result.

Manufacturing and stockpile readiness

Preparedness requires more than a molecule and a positive assay. Baxtra is seeking manufacturers that can develop a reproducible process, define critical quality attributes, qualify analytical methods, plan comparability after changes, and document a release pathway that regulators and procurers can inspect. For biologics, this includes cell-line, expression, purification and stability decisions; for small molecules, it includes route, impurity control, solid form and scale-up decisions.

Stockpile agreements should state who owns inventory, who pays for replenishment, how expiry and rotation are handled, which presentation is held, and what happens when the clinical or regulatory evidence changes. A stockpile is not evidence of efficacy and should not be represented as approval or prescription availability.

Quality, safety and transparency

Every programme is under a cleared US Investigational New Drug application, but that status does not establish safety or efficacy. Partnering discussions will use the Disclosure Review Board process and will distinguish cleared public facts from confidential diligence material. The site's "Statement on a containment failure", 29 August 2026, ref BXRA-PS-2026-08, confirms only that an event occurred, was found by Baxtra's own staff, that work stopped, an independent review is open, and authorities were notified. It declines to name the programme, suite, material, quantities, dates or individuals, and states there is no identified risk outside the facility.

What Baxtra will not do

- We will not grant exclusive rights that block endemic-country access or make a region dependent on a single commercial channel.
- We will not withhold an effective therapy as a trial comparator. Comparator decisions must be ethically and scientifically defensible and agreed with the relevant investigators and authorities.
- We will not describe a Phase 1 programme as approved, proven, available on prescription or established to work.
- We will not export samples without a data-sharing agreement or treat a partner's contribution as a waiver of local governance.
- We will not promise an outbreak timetable, a regulatory outcome or a manufacturing capacity that has not been contracted and qualified.

How to make contact

Prospective governments, funders, manufacturers, hospitals, health systems and endemic-country investigators may contact Business Development through disclosure@baxtra.pages.dev with the proposed geography, pathogen or platform, partnership model, intended contribution and preparedness objective. Please do not write to ask for withheld Programme 9 information; there is no timetable for publication.

Disclosure queries disclosure@baxtra.pages.dev

Website baxtra.pages.dev

Business scope Investigational medical countermeasures and surgical technology

Data date 31 August 2026

Diligence pack available under agreement

Pack	Indicative contents
Scientific	Target rationale, mechanism-of-action package, assay qualification, cross-pathogen scope, resistance work and model limitations.
Clinical	Protocol synopsis, investigator and site plan, endpoints, statistical approach, safety oversight and regulatory correspondence appropriate to the model.
CMC and quality	Process description, critical quality attributes, analytical methods, stability, release plan, manufacturing capacity and change-control approach.
Preparedness operations	Stockpile assumptions, shelf-life and rotation, shipping lanes, activation triggers, site readiness, tabletop exercise outputs and escalation contacts.
Governance and access	Disclosure Review Board record, data-sharing template, sample governance, authorship principles, technology-transfer plan and access conditions.
Financial and legal	Use of funds, development budget, milestone assumptions, background and foreground IP, licence territory, indemnity and termination principles.

A practical next step

The first meeting should end with a narrower question than it began with: which pathogen, which population, which evidence gap, which partner contribution and which access obligation can be funded now. That is how a preparedness conversation becomes a plan.

Important. Baxtra Research Labs develops investigational medicines and investigational medical devices. No Baxtra investigational medicine has been approved by any regulatory authority in any country, and the safety and efficacy of none of them has been established. This document is published for information. It is not medical advice, not biosafety or biosecurity guidance, not an offer to sell or a solicitation to buy securities, and not a forecast that any programme described in it will succeed. Forward-looking statements about timing, enrolment, regulatory interactions and intended indications are subject to change without notice.

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