

Annual Review 2026

The first eighteen months: twelve investigational countermeasures, one maximum-containment laboratory, and one bad week in August.

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A note on the year

We began this period as a young United States medical research company and have spent the first eighteen months building the conditions for serious work: investigational medical countermeasures for high-consequence pathogens, and surgical technology. We are reporting the year plainly because the work is important and because the limits around it are important too.

The pipeline now includes twelve disclosed Phase 1 programmes. Eight of those programmes were added to the public portfolio on 31 August 2026. A further clinical-stage programme remains undisclosed. None of these medicines is approved anywhere, and the clinical-stage count is not a claim about efficacy or availability.

The year also brought a material failure in our containment work. In August, Baxtra issued its Statement on a containment failure. The statement records that the event was found by Baxtra's own staff, that work stopped, that an independent review is open, and that authorities were notified. We will not use this review to fill the gaps that the statement deliberately leaves open.

We therefore treat progress and failure as part of the same account. The pages that follow describe what moved, what is still investigational, what we are changing in our processes, and where this public revision stops. We expect the record to be more useful when it is specific about our work and equally specific about what it cannot responsibly disclose.

The year in numbers

Data as at 31 August 2026. The figures below describe the company since inception where so stated; programme counts refer to the clinical portfolio and disclosed public materials.

\$310M R&D	R&D investment since inception
83 patents	Patents and continuations filed; 14 are not published
412 headcount	People across Baxtra Research Labs; 268 in research and development
12 disclosed Phase 1 programmes	All are investigational; none is approved anywhere
13 clinical-stage	Twelve disclosed programmes plus one further clinical-stage programme whose designation and indication are withheld
27 US trial sites	Clinical trial sites across the portfolio in the United States
9 therapeutic areas	Areas represented across the countermeasure portfolio
7 BSL-4 pathogens	Pathogens targeted by the programme portfolio

The \$310 million R&D investment includes \$118 million in partnered or government-funded preparedness money. The remainder, \$192 million, is company-funded.

Portfolio review

The public portfolio is now twelve disclosed Phase 1 programmes, all operating under cleared US Investigational New Drug applications. The list below is the complete disclosed set at the date of this review; a further clinical-stage programme is not identified here.

ID	Name	Disease	Modality	Study
BX-101	Nipavir	Nipah virus infection	oral fusion (F) glycoprotein inhibitor	SENTINEL-1
BX-204	Marburavir	Marburg virus disease	IV + oral L-polymerase inhibitor (nucleoside)	CORDON-1
BX-308	Prionex	sporadic & genetic Creutzfeldt–Jakob disease	intrathecal PRNP antisense oligonucleotide	VIGIL-0
BX-412	Cehafex	Crimean-Congo haemorrhagic fever	IV two-antibody cocktail (Gc fusion loop + GP38)	BASTION-1
BX-515	Lassivar	Lassa fever	IV GPC-B site human monoclonal antibody	TRAVERSE-1

ID	Name	Disease	Modality	Study
BX-620	Rabivex	symptomatic rabies encephalomyelitis	CNS-penetrant lyssavirus L-polymerase inhibitor, IV + intrathecal loading dose	LANTERN-1
BX-733	Hantrelvir	hantavirus cardiopulmonary syndrome (Andes orthohantavirus)	selective S1PR1 agonist, host-directed endothelial stabiliser, IV + oral	RIDGELINE-1
BX-806	Sudanavir	Sudan ebolavirus disease	IV two-antibody cocktail (GP2 fusion loop + GP1 glycan cap)	KEYSTONE-1
BX-1140	Poxavir	clade I mpox / orthopoxvirus disease	second-generation p37 (F13L) envelope inhibitor, oral + IV	MERIDIAN-1
BX-1265	Arenavir	South American haemorrhagic fevers (Junín, Machupo, Guanarito, Sabiá)	pan-arenavirus GP2 fusion inhibitor, IV + oral	CROSSBAR-1
BX-1330	Riftavir	severe Rift Valley fever	fixed pair: Gn monoclonal antibody + bunyavirus L-polymerase endonuclease inhibitor, IV	HEADWATER-1
BX-1620	Meliovex	melioidosis (Burkholderia pseudomallei)	efflux-pump-inhibitor-potentiated beta-lactam, IV + oral	REDLAND-1

What moved most visibly was the breadth of the disclosed set. The original four programmes - BX-101, BX-204, BX-308 and BX-412 - are joined by eight programmes added on 31 August: Lassivar, Rabivex, Hantrelvir, Sudanavir, Poxavir, Arenavir, Riftavir and Meliovex. This is a change in public scope, not a change in the investigational status of the medicines.

The portfolio is deliberately mixed in mechanism and route. It includes small-molecule inhibitors, antibody cocktails, a monoclonal antibody, an antisense oligonucleotide, a host-directed stabiliser and a potentiated beta-lactam. Some studies use IV administration, some combine IV and oral dosing, and Prionex is intrathecal. These distinctions matter to the development work and are why this review keeps the study identifiers beside the programme names.

The clinical count also needs a boundary. The twelve named programmes are the disclosed Phase 1 set; Programme 9 is clinical-stage but its designation and indication are withheld. Discovery-stage candidates exist outside the clinical count and are not listed in this review.

Therapeutic areas

The nine-area view is a reporting view across the indications and pathogen families represented in the portfolio. It does not turn an investigational programme into an approved treatment.

Nipah virus infection

BX-101, Nipavir, addresses Nipah virus infection through an oral fusion (F) glycoprotein inhibitor. The programme is studied as SENTINEL-1.

Filovirus disease

Marburg virus disease and Sudan ebolavirus disease are represented by BX-204 Marburavir and BX-806 Sudanavir. Marburavir is an IV + oral L-polymerase inhibitor (nucleoside), while Sudanavir is an IV two-antibody cocktail. Their study identifiers are CORDON-1 and KEYSTONE-1.

Prion disease

BX-308, Prionex, is directed at sporadic and genetic Creutzfeldt–Jakob disease. Its modality is an intrathecal PRNP antisense oligonucleotide, studied as VIGIL-0.

Crimean-Congo haemorrhagic fever

BX-412, Cehafex, is an IV two-antibody cocktail for Crimean-Congo haemorrhagic fever, with the Gc fusion loop and GP38 specified in the programme record. The study is BASTION-1.

Arenavirus disease

Lassivar and Arenavir address Lassa fever and South American haemorrhagic fevers respectively. Their study identifiers are TRAVERSE-1 and CROSSBAR-1; both are antibody or fusion-inhibitor approaches described in the portfolio table.

Rabies encephalomyelitis

BX-620, Rabivex, addresses symptomatic rabies encephalomyelitis with a CNS-penetrant lyssavirus L-polymerase inhibitor and an IV plus intrathecal loading dose. The study is LANTERN-1.

Hantavirus cardiopulmonary syndrome

BX-733, Hantrelvir, is for hantavirus cardiopulmonary syndrome associated with Andes orthohantavirus. It is a selective S1PR1 agonist and host-directed endothelial stabiliser, with IV and oral routes, studied as RIDGELINE-1.

Orthopoxvirus disease

BX-1140, Poxavir, is for clade I mpox and orthopoxvirus disease. It is a second-generation p37 (F13L) envelope inhibitor with oral and IV routes, studied as MERIDIAN-1.

Rift Valley fever and melioidosis

The remaining area covers severe Rift Valley fever and melioidosis. BX-1330 Riftavir uses a fixed Gn monoclonal antibody and bunyavirus L-polymerase endonuclease inhibitor pair; BX-1620 Meliovex uses an efflux-pump-inhibitor-potentiated beta-lactam. Their studies are HEADWATER-1 and REDLAND-1.

Surgical technology

The second Baxtra business is surgical technology. It is reported alongside the countermeasure portfolio because the work shares an organisation and a quality obligation, while its regulatory and clinical questions are different.

Lumavue

Lumavue is a real-time tissue perfusion imaging device. It received FDA 510(k) clearance in July 2026. Clearance is a regulatory status for the device and is not a statement that any investigational medicine is approved.

SealWeave

SealWeave is a bioresorbable staple-line sealant in Phase 1 clinical evaluation. Its status remains investigational; this review makes no claim about safety or efficacy.

Axion OR

Axion OR is a robotic soft-tissue instrument platform in Phase 1 clinical evaluation. As with SealWeave, the evaluation is not an approval or a claim that the platform will succeed.

Biocontainment

Baxtra's Palm Coast maximum-containment (BSL-4) suit laboratory completed commissioning in July 2026. It sits within a site network that also includes discovery and containment-level-3 laboratories, opened in August 2025, and a surgical engineering facility, opened in November 2025.

Statement on a containment failure, 29 August 2026, ref BXRA-PS-2026-08. It 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.

That is the complete public account of the event for this review. We do not infer a programme, suite, material, quantity, date or individual from surrounding portfolio information. The independent review remains open, and the fact that commissioning was completed in July does not change the terms of the August statement.

Research and development spend

R&D investment since inception was \$310 million at 31 August 2026. The following review allocation separates the disclosed clinical work, the undisclosed clinical-stage programme, discovery, surgical technology and the functions that make the work possible. It sums to the reported total; it is not a forecast.

Programmes / function	Spend
Disclosed Phase 1 programmes	\$122M
Further clinical-stage programme (designation withheld)	\$12M
Discovery-stage candidates	\$24M
Surgical technology	\$46M
Laboratories and containment infrastructure	\$54M
Regulatory, quality and clinical operations	\$30M
People, safety and enabling functions	\$22M
Total R&D investment since inception	\$310M

Partnered or government-funded preparedness money contributed \$118 million of the total. The remaining \$192 million was company-funded. The funding description does not change the status of any programme: every medicine described here is investigational.

Regulatory

Every programme is under a cleared US Investigational New Drug application. All twelve disclosed medicines are in Phase 1, and none has been approved by any regulatory authority in any country. A cleared IND permits the relevant investigation; it does not establish safety or efficacy and it does not make a medicine available on prescription.

Route	Programmes and meaning
FDA Animal Rule (21 CFR 314 Subpart I)	Most programmes use the Animal Rule route, which is relevant where conventional efficacy trials are not feasible. The route does not change the investigational status.
Conventional 505(b)(1)	BX-733, BX-1140 for its mpox indication, and BX-1620 use conventional 505(b)(1) routes with feasible randomised controlled trials.

The split is a description of regulatory strategy, not a conclusion about outcome. Study conduct, enrolment, regulatory interactions and intended indications can change. The public record is therefore kept at the programme and route level rather than presented as a promise.

People and safety culture

Headcount was 412 at the review date, including 268 people in research and development. The organisation spans discovery, containment-level-3 work, maximum-containment laboratory commissioning, surgical engineering and the functions that support clinical and regulatory work.

Our safety culture starts with the authority to stop work. Every person, regardless of role or seniority, is expected to use stop-work authority when a condition is unclear, a control is not in place, or a step cannot be completed as written. Work resumes only through the responsible review process; schedule pressure is not a reason to proceed.

The same standard applies to records and disclosure. A concern must be recorded, escalated to the appropriate safety or quality owner, and kept distinct from the later public account. The public account cannot include details that have not cleared the Disclosure Review Board, but clearance is not a substitute for investigation or corrective action.

What we expect to do next

The 2027 plan is stated as a set of intended milestones, not as a promise of approval, efficacy or timing. Each milestone remains subject to the applicable study, regulatory and disclosure processes.

Timing	Milestone	Boundary
Q1 2027	Continue Phase 1 work across the twelve disclosed programmes and maintain current study records.	Subject to study progress, site activity and cleared public reporting.
Q2 2027	Continue Animal Rule regulatory work for the programmes using that route.	No inference about outcome or approval.
Q2-Q3 2027	Develop the conventional 505(b)(1) workstream for BX-733, BX-1140 for mpox, and BX-1620.	Randomised controlled trials are feasible; timing remains subject to regulatory and study decisions.
Throughout 2027	Continue review and follow-up for the Palm Coast BSL-4 laboratory and the open independent review.	The public record will not add details withheld by the August statement.
Q4 2027	Prepare the next public annual review through the Disclosure Review Board process.	A public revision may continue to withhold sections.

What went wrong and what we changed

A containment failure occurred in August 2026. We will not speculate about the programme, suite, material, quantities, dates or individuals, because the public statement does not name them and the independent review is open. We can still be clear about the standard: work stopped when our own staff found the event, authorities were notified, and the review is independent.

The changes we are making are process changes. Stop-work decisions must be documented and escalated rather than resolved informally. Containment transitions require a recorded second-person verification. Operational records and review materials must be preserved under controlled access. Safety, quality and operational owners must be separated when a review is opened, so that the people responsible for running a process are not the only people assessing it.

Public disclosure follows the same discipline. We will publish the confirmed terms of an event, identify what remains withheld, and avoid filling a gap with a plausible detail. The Disclosure Review Board clears the public revision; it does not close the independent review. These are modest changes in wording and workflow, but they are the changes we can state without pretending that a review is complete.

How to read this document

This is public revision 2 of 6 of the Annual Review 2026. It was cleared for external publication by the Disclosure Review Board under DRB-2026-0601. The Board process tests whether a proposed public document is accurate, appropriately bounded and suitable for external release; it does not convert investigational work into an approval or remove the need for independent review.

Some sections and details are withheld. They are not to be reconstructed from the portfolio table, the study identifiers or the site descriptions. The August statement is the controlling public account of the containment failure, and this review repeats its boundaries rather than adding to them. Queries about disclosure may be sent to disclosure@baxtra.pages.dev; please do not write to ask for withheld programme, suite, material, quantity, date or individual details.

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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