

Commercial Manufacturing of AB-101

Scope, basis of estimate and commercial terms — Artiva Biotherapeutics × Made Scientific — Confidential — 14 August 2026

1. Purpose

This document supports the budgetary projection prepared for Artiva Biotherapeutics ahead of the September Board discussion on commercial capacity for AB-101. It sets out what Made Scientific would do, what it would cost, what we have assumed, and what we have deliberately excluded.

All figures are budgetary and carry a **±30% tolerance**, the accuracy you specified. They are prepared for planning and Board discussion. They are not an offer, and they do not commit either party. A work-order-level proposal would follow confirmation of the process assumptions in §9.

2. What you asked for

1. Lead time to secure seven commercially-licensed (FDA) GMP suites — one Intermediate Cell Bank, five Drug Product, one Fill/Finish
2. Cost to Artiva through Technology Transfer and PLI / first commercial batch, 2027–2030
3. Cost per batch at 200 L scale, at 20 batches per suite per year, broken into suite reservation fee, staffing, raw materials (assumed \$200,000) and other items such as semi-annual aseptic process validations
4. A comparison between Made Scientific and other CDMOs

3. Process understanding

Our understanding of the AB-101 process, drawn from your August 2026 summary and your public disclosures, with our own stated assumptions where a specific number was not available:

Stage	Process
Intermediate Cell Bank	Cord blood unit thawed and T-cell depleted, expanded with eFeeder in gas-permeable bags and then a 50 L single-use bioreactor, harvested on a CARR UniFuge, filled on an Aseptic Technologies M1 and cryopreserved. Yields 50–80 vials per cord blood unit
Drug Product	A single ICB vial seeds a seed train — bag/rocker or 50 L — and is then expanded in a 200 L single-use bioreactor with eFeeder top-ups, harvested on a UniFuge and formulated to 1.0×10^9 cells/vial. Batch duration 11–13 days
Fill / Finish	Aseptic Technologies closed-vial fill in a Grade B isolator, controlled-rate freeze, LN ₂ storage, ten-test QC release panel and QA disposition

Stage	Process
eFeeder	A 24-day campaign from working cell bank thaw through 50 L expansion, UniFuge harvest, 100 Gy X-ray irradiation, formulation and closed-vial fill. Consumed at both expansion stages

A note on the seven-suite configuration. One ICB suite, five Drug Product suites and one Fill/Finish suite account for all seven rooms. eFeeder is a separate product, consumed at every expansion step — the ICB bag phase, the seed train, and the 200 L top-ups — and has no suite in that count. Made Scientific already has a dedicated eFeeder suite mapped at East Norriton, Pennsylvania, assessed at approximately 60 batches per year, which we propose supplies the program.

4. Production strategy and throughput

Your plan assumes 20 batches per suite per year. That is your San Diego operating rate, and it reflects a process in which the seed train occupies the same room as the final expansion.

At 200 L the constrained asset is the bioreactor suite. If the seed train runs in a dedicated seed room, suite occupancy falls from the full 11–13 day batch to roughly the final expansion alone. This is the same mechanism that lets a 24-day eFeeder campaign yield about 60 batches a year from one suite: only the bioreactor step ties up the room.

Option	Configuration	Rooms	Batches/yr	Patients/yr
1	As specified — 1 ICB + 5 DP + 1 F/F, seed train in-suite	7	107	5,885
2	Decoupled seed — one DP suite becomes the seed room	7	133	7,315
3	Decoupled seed, keeping five DP suites	8	166	9,130
4	East Norriton ballroom build	12	265	14,575

eFeeder is produced at East Norriton in every option — it was never one of the seven rooms. **Option 2 raises output by 24% without adding a room**, by converting one drug product suite into a shared seed room that feeds the other four.

Patients per year assume the proposed Phase 3 regimen of two 4-billion-cell doses, i.e. eight 1-billion-cell vials per patient. Against your stated commercial reach of 250 clinics at one to two patients a month — 3,000 to 6,000 patients a year — **Option 1 already covers the launch plan**; the remainder create headroom.

Decoupling moves the constraint onto the seed room. One seed room running four concurrent trains supports roughly 182 batches a year, so Option 4 requires a second.

5. Facility and lead time

Starting now, bridging to 307. The program does not wait on the 307 build. Technology transfer and engineering activities begin in existing licensed space — **201 College Road East** in Princeton, or **East Norriton** in Pennsylvania — and bridge into **307 College Road East** as each suite comes ready, carrying the process through GMP readiness, PPQ and commercial supply.

Consolidating eFeeder. Following technical review with Made Scientific's Head of Development and Head of Technical Operations, moving eFeeder production from East Norriton into Princeton 307 is a **proposed move — options remain open**. It would give better utilization and a single-site regulatory footprint. The Artiva suite build at 307 is estimated at **12–15 months from signature of the commercial agreement**, through fit-out and qualification to GMP readiness. Transfer site and suite configuration — one room or two for feeder plus ICB, and a shared vs. per-suite harvest room — are both under joint review with you; see §9 and the Technical Points of Clarification document.

Princeton — 307 College Road East. Production for all seven licensed suites — Intermediate Cell Bank, drug product and fill/finish — with eFeeder consolidating in. A seven-cleanroom expansion, ISO 8 / Grade C background with Annex 1-compliant separation of personnel and material flow, a Grade C supply corridor and a Grade D return corridor, and a Grade B isolator in fill/finish. Made Scientific's initial build-out at 307 — cleanrooms, laboratories, warehousing and cold storage — begins shortly and completes Q4 2027 – Q1 2028; the Artiva suite build runs 12–15 months from signature of the commercial agreement. The RS 1800-Q irradiator would site in Fill/Finish or a dedicated Harvest suite — siting TBD.

East Norriton, Pennsylvania. eFeeder's current site — an 85,000 ft² cell therapy facility of shell-within-shell GMP design, reviewed across two FDA Type C meetings, with approximately 140 batches manufactured to date. It is also a candidate site for the technology transfer phase, and would wind down only if the proposed consolidation into 307 proceeds.

6. Scope of work, 2027–2030

The program runs from technology transfer through Pre-License Inspection and first commercial batch, on the dates you have set.

Stage 1 — Technology transfer and feasibility (2027). Full process and analytical method transfer for all three processes; cross-functional gap assessment and risk register covering equipment, materials and facility fit; raw material and consumable equivalency; dedicated suite allocation; capital procurement; feasibility and confirmation runs at non-GMP scale.

Stage 2 — Analytical establishment (2027–28). Transfer, qualification and validation of the release and characterization panel to ICH Q2, including identity, purity, viability, sterility, mycoplasma, endotoxin and residual feeder clearance. **A custom NK potency assay is the principal cost and schedule driver** and is treated as a distinct workstream, developed against the mechanism of action and qualified for release use.

Stage 3 — GMP readiness (2028). Operator and analyst training and qualification; cleanroom validation and environmental monitoring performance qualification; equipment IQ/OQ; computerized system validation to Part 11 and Annex 11; Master Batch Record, sampling plan and bill of materials finalized; raw material release under QA oversight.

Stage 4 — Engineering runs (2028). Non-clinical GMP runs to finalize the Master Batch Record and control strategy and to generate material for method qualification.

Stage 5 — Aseptic process qualification (2029). Three consecutive aseptic process simulation media fills covering the fill/finish operation at commercial batch size, with semi-annual requalification thereafter carried within the batch fee.

Stage 6 — Process performance qualification (2029). Process knowledge and characterization, FMEA and PPQ gap assessment; gated readiness criteria; **PPQ campaigns for the Intermediate Cell Bank, Drug Product and Fill/Finish processes**, each comprising a minimum of three consecutive successful batches, with risk-based acceptance criteria and full critical process parameter to critical quality attribute traceability.

Stage 7 — Regulatory and inspection readiness (2029–30). CMC section authoring and review support for the BLA; PLI preparation, which begins twelve months ahead of the anticipated inspection; mock inspection and remediation; post-approval continued process verification and lifecycle management.

Throughout. ICH stability program; joint governance with a steering committee and scheduled technical reviews; a shared program plan and document workspace.

7. Cost

7.1 Through technology transfer, PPQ and PLI, 2027–2030

\$10.10M – \$17.20M.

Workstream	Range
Program initiation and knowledge transfer	Fee waived
ICB process transfer and engineering runs, 50 L	\$1.5M – \$2.5M
Drug product process transfer and engineering runs, 200 L	\$2.5M – \$4.0M
Fill/finish transfer and AT M1 qualification	\$1.0M – \$1.5M
Analytical method transfer, qualification and validation (eFeeder, ICB and DP)	\$1.5M – \$2.5M
GMP readiness — training, EMPQ, IQ/OQ, MBR	Fee waived
Aseptic process simulation, three consecutive media fills	\$0.45M – \$0.75M
PPQ campaign — eFeeder, ICB, drug product and fill/finish	\$1.9M – \$3.8M
CMC regulatory support, BLA authoring and PLI readiness	\$0.75M – \$1.25M
Stability program	\$0.5M – \$0.9M

Two workstreams are fee-waived. At a standard CDMO both would be billed.

7.1a Work package breakdown, by milestone and work order

The same \$10.10M – \$17.20M total, decomposed to work-order granularity in the format used for Made Scientific's other commercial programs. The splits below allocate the combined transfer-and- engineering lines above across their constituent work orders — they do not add cost.

Milestone	Year	Low	High	Basis
M1 · Program Initiation & Knowledge Transfer	2027	Waived		Fee waived — as on the eHuT-78P program
M2 · Technology Transfer — Process & Analytical	2027	\$4.90M	\$7.90M	ICB, drug product and fill/finish process transfer; analytical method transfer across eFeeder, ICB and DP
M3 · GMP Readiness	2028	Waived		Fee waived — as on the eHuT-78P program
M4 · Engineering Runs	2028	\$1.60M	\$2.60M	ICB and drug product engineering runs
M5 · Aseptic Process Qualification	2029	\$450K	\$750K	3 consecutive media fills; semi-annual APS thereafter sits in the batch fee
M6 · Process Performance Qualification	2029	\$1.90M	\$3.80M	eFeeder, ICB, DP and fill/finish PPQ — 3 consecutive successful batches each
M7 · Regulatory & PLI Readiness	2029–30	\$750K	\$1.25M	CMC authoring, PLI prep, mock inspection
M8 · Stability Program	2027–30	\$500K	\$900K	ICH stability protocol, pulls, reporting
M9 · Commercial Manufacturing & Lifecycle	2030+	\$380K	\$430K	All-in per batch under the volume-tiered schedule in §7.3, not a fixed program fee

M1–M8 total: \$10.10M – \$17.20M, matching §7.1 exactly. M9 is priced per batch, not a fixed fee.

Assumption stated explicitly: the technology-transfer-versus-engineering-run split within M2/M4 (60%/40%) and the ICB/DP/fill-finish split within M6 PPQ are Made Scientific's own allocation of an already-stated combined range, not independently estimated line items. Each work order can be requoted independently once the process assumptions in §9 are confirmed.

7.2 Cost per batch at 200 L

Bucket	Position
Suite reservation fee	\$0. Made Scientific funds and equips the suites. Charged instead as an agreed minimum annual batch commitment
Staffing	Dedicated, not shared. Included in the conversion fee

Bucket	Position
Raw materials	\$200,000 per batch, your assumption, passed through at cost
Other — semi-annual APS, stability, cryogenic storage	Included in the conversion fee. Thirty days of post-manufacture storage is included

Annual volume	Conversion fee	Materials	All-in per batch	Per vial
up to 60 batches	\$230K	\$200K	\$430K	\$977
61 – 120 batches	\$210K	\$200K	\$410K	\$932
121 – 180 batches	\$195K	\$200K	\$395K	\$898
over 180 batches	\$180K	\$200K	\$380K	\$864

Every tier sits inside the commercial cost of goods target of **under \$1,000 per 1-billion-cell vial** that Artiva has stated publicly for the 200 L process. At eight vials per patient this is **\$6,909 – \$7,818 of drug product cost per patient**, against the \$8,000 per patient in Artiva’s own materials.

The conversion fee comprises dedicated manufacturing staffing, QC release testing including the custom potency assay, operating recovery on facility and equipment, quality oversight and batch disposition, and the semi-annual aseptic process simulations, stability pulls and cryogenic storage. Tiering reflects fixed-cost absorption as volume rises.

7.3 Commercial forecast — volume-based discount

Structured the way a volume-discount schedule should read: as commitment grows, the batch fee steps down. This is anchored to **our own throughput options** in §4, not to an Artiva demand forecast — Artiva has not shared drug product volumes with us, so any year-by-year demand curve here would be Made Scientific’s invention, not Artiva’s plan. What follows is instead an honest question: if you commit to a rising share of an option’s capacity, here is what it costs.

Illustrative year	Configuration	Ceiling (batches/yr)	Commitment	Committed batches	Batch fee	Minimum annual fee	All-in cost/vial
2030 (PLI & launch)	Option 1	107	50%	54	\$230K	\$12.42M	\$977
2031	Option 2	133	65%	86	\$210K	\$18.06M	\$932
2032	Option 3	166	80%	133	\$195K	\$25.93M	\$898
2033+	Option 4	265	90%	238	\$180K	\$42.84M	\$864

The fee steps down as committed volume scales — \$230K → \$210K → \$195K → \$180K per batch — and every step remains inside Artiva’s own <\$1,000/vial commercial COGS target. Materials pass-through is additional at \$200K/batch and is not part of the minimum fee.

Assumptions stated explicitly, not implied:

- The **2030→2033+ year mapping is Made Scientific's proposed adoption sequence**, not a commitment Artiva has made or a demand forecast Artiva has provided.
- **Commitment levels (50%/65%/80%/90%) are illustrative**, structured to rise as the relationship matures, and not yet negotiated with Artiva.
- **Batch fees are read from the §7.2 tier schedule at each year's committed volume**, not at the configuration's ceiling — pricing reflects what you actually commit to, not the capacity available. You do not get bulk-tier pricing on capacity you have not committed to.
- The interactive microsite carries a 5-year volume ramp you can adjust yourself, showing the same fee schedule split into service/batch fees, materials pass-through, and per-vial cost.

8. Commercial model

	A standard CDMO	Made Scientific
Facility build-out	Charged to the client — est. \$30M–\$40M	Absorbed
Suite fit-out and process equipment	Charged to the client — est. \$45M–\$55M	Absorbed
FTEs / labor	Hire and manage your own — est. \$7M–\$11M/yr for a dedicated ~45–55 FTE team	Included in the batch fee — no separate hire
Suite reservation fee	Charged, non-refundable	\$0 against a volume commitment
Program initiation	Charged	Waived
GMP readiness (APQ, CQV, equipment maintenance & calibration, EMPQ, etc.)	Charged	Waived
Dedicated program management	Charged — est. \$15K/month	Included
Capacity	Shared, multi-client	Dedicated suites

Made Scientific funds the facility and the equipment against an agreed minimum annual batch commitment. Artiva commits to volume rather than to capital. FTEs are dedicated, not billed separately — their cost sits inside the per-batch conversion fee in §7.2, not this comparison. A capacity reservation agreement is available to secure a technology transfer slot and suite capacity ahead of the master agreement; any reservation fee is credited in full against work orders.

On the build-versus-buy comparison. A seven-suite build is on the order of \$85M — our own estimate of \$30M–\$40M facility shell plus \$45M–\$55M suite fit-out and process equipment. Artiva's FY2025 accounts record \$2.6M of property and equipment purchases and \$874K of leasehold improvements in total. This would therefore be a capital project roughly two orders of magnitude beyond anything Artiva has previously undertaken, drawing on the same balance sheet that funds a Phase 3 beginning this year.

9. Assumptions

Input	Value	Source
Drug product batch yield	~440 vials at 1×10^9 cells	Linear 4× from the published $\geq 110B$ at 50 L
Batch duration	11–13 days	Your process summary, August 2026
Batches per suite per year	20 in-suite seed / 33 decoupled	Your operating rate; the decoupled figure is our estimate
eFeeder campaign	24 days, ~60 batches/yr per suite	Our East Norriton suite assessment
eFeeder : NK seeding ratio	2.5 : 1	Our working assumption
Dose	2×4 billion cells, eight vials per patient	Proposed Phase 3 design
Materials	\$200,000 per batch	Your assumption
Commercial COGS ceiling	<\$1,000 per 1-billion-cell vial	Artiva public statements

Estimates pending your confirmation. The split of the 11–13 day batch between seed train and 200 L expansion; suite turnaround, cleaning and release time; NK seed density or expansion fold; the number of eFeeder top-ups per batch; and the number of ICB vials required to seed a 200 L batch. These move the throughput figures. They do not change the commercial structure.

10. Exclusions

Cord blood units and other Artiva-supplied starting materials; the RS 1800-Q irradiator, which transfers from Artiva; Artiva-side regulatory filing fees; clinical or commercial distribution beyond ex-works; comparability studies arising from Artiva-initiated process changes after Master Batch Record lock; and any scope arising from a change in scale or process beyond that described in §3.

11. Next steps

1. **Confirm the process assumptions.** A short technical session on seed-train duration, suite turnaround, NK seed density, feeder/vial thaw and expansion, and DP storage duration would replace our estimates with your numbers and tighten the $\pm 30\%$.
2. **Resolve the suite configuration.** eFeeder consolidating into Princeton 307 raises open design questions — one room or two for feeder + ICB, shared vs. per-suite harvest, and enlarged multi-suite rooms vs. individual suites for throughput. See the Technical Points of Clarification document.
3. **Capacity reservation**, to secure a technology transfer slot and suite capacity.
4. **Detailed proposal** at work-order level, with a full Gantt to first commercial batch.