ImmunityBio, Inc. — $50m a quarter. One decisive readout. $3 or $46.

NASDAQ: IBRX · ~$8.00 · ~1.06bn shares · market cap ~$8.5bn · enterprise value ~$9.8bn

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STANCE	FY26E REVENUE	FY27E REVENUE	FY28E REVENUE	CASH-FLOW BREAKEVEN
Speculative Buy Multi-year horizon; size for the tails, not the point estimate	**$217m** Consensus ~$222m	**$420m** Consensus ~$436m	**$890m** Consensus ~$1.1bn	**Q1 '28** Trough cash ~$138m

01 SUMMARY

ANKTIVA is a genuine commercial product — eight consecutive quarters of growth to $50.7m[1], roughly 99% gross margin, a permanent J-code, NCCN listings in two settings, and a narrowing operating loss. The investment question is not whether the product works. It is how fast it can scale, and against what.

Three conclusions from this work differ from both the standard bull and bear framings of the name.

First, the binding constraint is evidence and timing, not BCG supply. Supply is real and it shapes the business ANKTIVA has today: "BCG-unresponsive" is a status that requires documented adequate prior BCG, so the shortage constricts the eligible pool for every second-line agent. But it does not gate the growth thesis. ANKTIVA in the BCG-naive setting rides on the *same* BCG schedule a high-risk patient already receives — it adds no incremental demand — and urologists already prioritise high-risk naive patients for BCG during shortages. What actually decides 2028 is whether QUILT-2.005's full readout holds up and how fast FDA moves.

Second, IMFINZI's head start is weaker than it appears. AstraZeneca reached the BCG-naive market first, in May 2026, with randomised Phase 3 data ANKTIVA cannot match. But it requires intravenous infusion every four weeks for thirteen cycles in a disease managed by community urologists who cannot administer it. Pembrolizumab was approved in NMIBC in 2020 with no locally administered competitor and drew 126 patients[27] in two years. Site of care may matter more here than trial data.

Third, the company is closer to self-funding than its going-concern[41] language implies. Operating cash flow turns positive in Q1 2028 with a cash trough near $123m — tight but not forced. The larger issue is the $480m convertible maturing 31 December 2027[36], one quarter ahead of that trough.

A fourth point deserves more weight than it usually receives. ANKTIVA's subcutaneous approvals for lung cancer in Saudi Arabia and the UAE are not merely a small lung-cancer opportunity. They put an injectable, systemically-administered vial on a pharmacy shelf in jurisdictions where off-label prescribing is lawful — which makes every future NSCLC approval a lawful supply channel for immune reconstitution in a far larger population. That is examined in Section 07a.

02 THE BUSINESS AS IT STANDS

ANKTIVA (nogapendekin alfa inbakicept) is an IL-15 superagonist approved April 2024[3] for BCG-unresponsive NMIBC with carcinoma in situ, administered intravesically *in combination with BCG*. That combination requirement is the most consequential fact

about the franchise and recurs throughout this report.

QUARTER	NET PRODUCT REVENUE	SEQUENTIAL Δ$	SEQUENTIAL %	OPERATING CASH BURN	CASH & SECURITIES
Q1 2025	$16.5m	—	—	$(85.9)m	—
Q2 2025	$26.4m	+9.9	+60%	$(79.7)m	—
Q3 2025	$31.8m	+5.4	+20%	—	—
Q4 2025	$38.3m	+6.5	+20%	—	$242.8m
Q1 2026	$44.2m	+5.9	+15%	$(75.4)m	$380.9m
Q2 2026	**$50.7m**	**+6.5**	**+15%**	**$(66.5)m**[35]	**$357.4m**

Table 1 · Reported quarterly performance, SEC-filed. All revenue is US-sourced; no ex-US product revenue has been recognised to date despite approvals spanning roughly 34 countries.

The pattern that matters: percentage growth decelerates while absolute dollar adds hold flat near $6m. That is the signature of a business adding patients at a constant rate into a constrained pool, not one compounding. Operating burn — derived on a quarter-standalone basis — improved $13.2m year-on-year while operating expenses grew — the improvement is revenue-driven operating leverage, which is the healthy version.

Unit economics

WAC is $35,800 per 400mcg dose[15], unchanged since launch — FY2025[2]'s growth was volume, not price. At the reported ~17% gross-to-net, net realisation is approximately **$29,714 per dose**. The label permits up to 30 doses over 37 months (roughly $891k net lifetime), but QUILT-3.032 persistence implies an expected **12.8 doses, or about $380k net per patient**. Q2 2026 revenue therefore represents roughly **1,700 doses** and, in quasi-steady state, on the order of **130–200 new patient starts per quarter** — 550–800 annually against a BCG-unresponsive addressable pool of roughly 12,000–16,000. Penetration is 10–15%, and the runway inside the current label is real.

The gross margin, and why it persists

ANKTIVA reports cost of sales of $0.298m against $50.7m of revenue in Q2 2026 — a gross margin above 99%. No commercial biologic sustains that on normal economics, and the reason matters for the cost line in this model.

Manufacturing costs incurred before FDA approval were expensed to research and development rather than capitalised, because inventory was not yet probable of future economic benefit. ImmunityBio completed and released drug substance sufficient for **170,000 doses** in May 2024.[48] At the current consumption rate of roughly 1,700 doses a quarter, that is on the order of twenty-five years of bulk supply carried at essentially zero cost. Reported cost of sales therefore reflects fill-finish and packaging, not drug substance.

The practical consequence is that a model normalising cost of goods to the 10–15% typical of large biologics would be wrong. ANKTIVA is dosed at 400 micrograms against a $35,800 list price; the protein mass is trivial and the substance behind it is already expensed. Product cost of sales should stay in the low single digits as a percentage of revenue for years, and this model holds it there.

The offsetting consideration is that the fixed cost of the manufacturing base is not in cost of sales at all. The Dunkirk fill-finish facility spans 400,000 square feet with capacity for a million vials annually[48] against current demand of roughly 7,000 doses a year — utilisation below one percent. Under ASC 330-10-30-7 abnormal idle capacity must be expensed currently rather than capitalised, so that burden sits in research and development and selling, general and administrative expenses. Bring-up and validation costs will roll off as the facility reaches commercial status, but idle-capacity charges replace them. The model treats this as approximately neutral and does not credit an opex reduction.

03 COMPETITIVE LANDSCAPE

Cross-trial comparison in this field is unreliable. Every pivotal study is single-arm with different eligibility, biopsy protocols, response definitions, and follow-up. The tables below present the data with those differences visible rather than ranked, and flag BCG dependency — the axis on which ANKTIVA is structurally disadvantaged. Both ImmunityBio and Johnson & Johnson have published sponsor-funded indirect comparisons favouring their own product; these are marketing-adjacent and should not be treated as evidence.

AGENT	STATUS	COMPLETE RESPONSE	DURABILITY	GR ≥3 TRAE	BCG?	ADMINISTRATION
ANKTIVA + BCG ImmunityBio	APPR APR'24	62% 95% CI 51–73[8] (n=77)	51% probability maintaining CR ≥45mo; 84% cystectomy-free at 36mo; DSS 99% at 36mo	~3%	REQUIRED	Intravesical, weekly ×6 + maintenance to 37mo
INLEXZO (TAR-200)[6] Johnson & Johnson	APPR SEP'25	82.4% 95% CI 72–90 (n=85)	51% maintained ≥12mo; median DOR 25.8mo	12.9%	None	Indwelling device, q3wk then q12wk, up to 14 cycles
ADSTILADRIN Ferring	APPR DEC'22	51% 95% CI 40.7–61.3 (n=98)	Median DOR 9.7mo; 46% of responders ≥12mo; 25.5% at 3yr	3.8%	None	Intravesical, once every 3 months
KEYTRUDA Merck	APPR JAN'20	~41% at 3 months	12-mo DFS 43.5%; 24-mo 34.9%	Systemic	None	Intravenous q3–6wk
Cretostimogene CG Oncology	BLA Q4'26	75.5%[7] 95% CI 66.3–83.2 (n=110)	12-mo DOR 64.2%; 24-mo 60.1%; median ≥27.9mo and ongoing; 3.6% MIBC progression	**0%**	None	Intravesical monotherapy, office-based
Detalimogene (EG-70) EnGene	BLA 2H'26	62–63% at 6 months	Immature	Low	None	Intravesical non-viral gene therapy

Table 2 · BCG-unresponsive NMIBC with carcinoma in situ. Follow-up durations differ materially. ANKTIVA's long durability figures rest on the longest follow-up in the group (median 29.3 months), which mechanically flatters them.

AGENT	REGULATORY	EFFICACY	DURABILITY / BLADDER PRESERVATION	NCCN
ANKTIVA + BCG	PDUFA 6 JAN 2027	58.2% 12-mo DFS 95% CI 46.6–68.2 (n=80)	83.1% cystectomy-free at 36mo; disease-specific survival 96%	Cat 2A (Mar'26)
Cretostimogene	COHORT P, N=56	HG-EFS 95.7% / 84.6% / 80.4% at 3 / 6 / 9 months	No cystectomies, no MIBC progression at 6.0mo median follow-up — immature	Not yet
ADSTILADRIN	OFF-LABEL	72.9% HG recurrence-free at 3 months (n=48)	31.4% at 3 years	Cat 2A (Mar'26)

Table 3 · BCG-unresponsive papillary-only disease (Ta/T1 without CIS). No agent yet holds an FDA label specific to this population; NCCN Category 2A listings already enable reimbursed use, which is why the January 2027 approval is an acceleration of existing demand rather than a discrete new market.

AGENT	STATUS	DESIGN	RESULT	BCG?
IMFINZI + BCG[5] AstraZeneca	APPROVED 28 MAY 2026	POTOMAC — randomised Phase 3, n=1,018	DFS HR **0.68** 95% CI 0.50–0.93 · p=0.0154	REQUIRED
ANKTIVA + BCG ImmunityBio	BLA TARGET Q4'26	QUILT-2.005 — randomised, n=366 enrolled[9]; interim analysis	6-mo CR 85% v 57% · **p=0.0536 (NS)** 9-mo CR 84% v 52% · p=0.0455	REQUIRED
TAR-200 ± cetrelimab Johnson & Johnson	SUNRISE-3[26] ONGOING	Randomised Phase 3 vs BCG, n≈1,050	Readout pending	None
Cretostimogene CG Oncology	CORE-008 PHASE 2	Single-arm, n=54	CR 83.7% (95% CI 70.3–92.7) 88% with optimised admin; follow-up only 4.6mo	None
Pembrolizumab + BCG Merck	KEYNOTE-676 COHORT B	Randomised, ~975 patients	Readout pending	REQUIRED

Table 4 · BCG-naive high-risk NMIBC — the setting underwriting consensus 2028 estimates. This is the only table containing randomised controlled evidence, and ANKTIVA does not lead it.

Reading Table 4. Three points follow. AstraZeneca reached this market first with a larger randomised dataset and will have roughly eighteen months of prescriber relationships before ANKTIVA could arrive. QUILT-2.005's headline significance rests on the nine-month durability endpoint; the six-month complete-response comparison did not clear conventional significance, and full topline on all 366 patients is unreleased. And both IMFINZI and ANKTIVA are BCG-dependent, so they compete for the same rationed input — while TAR-200 and cretostimogene do not.

03A THE BCG-NAIVE SHARE QUESTION

The single most consequential assumption in this model is how much of the BCG-naive population ANKTIVA captures. Two structural factors drive it, and neither is the one usually cited.

Site of care decides more than data does. BCG-naive high-risk NMIBC is managed almost entirely by community urologists. IMFINZI requires intravenous infusion every four weeks for up to thirteen cycles — which most urology practices cannot deliver, forcing a referral to medical oncology and the loss of both the patient relationship and the revenue. ANKTIVA is instilled in the same visit as the BCG the patient is already receiving, by the same staff, and bills under J9028[10] with buy-and-bill margin retained, plus CMS pass-through status through September 2027.

The precedent is unusually clean. Pembrolizumab was approved in BCG-unresponsive NMIBC in January 2020 with no locally administered on-label competitor at the time. A claims analysis of Optum Clinformatics data covering January 2020 to December 2021 identified just **126 patients** initiating treatment over two years, median age 80, median time on therapy 6.8 months. An intravenous systemic agent essentially failed to penetrate a urology-managed setting despite having the field to itself. IMFINZI faces the same structural obstacle, which materially devalues its eighteen-month head start.

DIMENSION	ANKTIVA + BCG	IMFINZI + BCG	EDGE
Evidence	QUILT-2.005 interim, n=43 evaluable; 9-mo maintained CR 84% v 52% (p=0.0455); 6-mo not significant (p=0.0536)	POTOMAC randomised Phase 3, n=1,018; DFS HR 0.68[5] (95% CI 0.50–0.93, p=0.0154); 60.7-month median follow-up	IMFINZI
Grade 3/4 TRAE	Low single digits; no systemic immune toxicity	21% with induction + maintenance; any-grade immune-mediated 27%, grade 3–4 8%; 45% of imAE patients needed high-dose steroids	ANKTIVA
Discontinuation	~7% (second-line data)	18% permanent discontinuation; 32% serious AEs	ANKTIVA
Route and site of care	Intravesical, same visit as BCG, urologist-administered	IV every 4 weeks ×13 cycles; needs infusion capability or referral out	ANKTIVA
Practice economics	Buy-and-bill under J9028, margin retained, pass-through to Sep 2027	Referral out; urology practice earns nothing	ANKTIVA
Course cost	$750k–$1.1m list	~$170k–$200k drug acquisition	IMFINZI

Table 5 · Competitive position in BCG-naive high-risk NMIBC. Safety and workflow favour ANKTIVA; evidence maturity and cost favour IMFINZI.

Safety carries more weight here than it would elsewhere. This is a curative-intent, bladder-preservation population of otherwise-well patients. A 21% grade 3/4 rate and 27% immune-mediated AEs — thyroid dysfunction, hepatic events, dermatitis, with 45% of affected patients requiring high-dose corticosteroids — reads very differently in first-line organ preservation than in metastatic disease. The evidence nonetheless indicates safety is a secondary driver behind workflow, not the primary one.

TWO ARGUMENTS THE MODEL DOES NOT CREDIT

Durability read-across from second line. ANKTIVA's second-line durability (median duration of complete response 45.4[8] months, 84% cystectomy-free at 36 months) was measured against a population that had already failed BCG and had essentially no effective alternative. In the naive setting the comparator is BCG itself, which delivers roughly 60% five-year recurrence-free survival with maintenance. A durability edge over failed BCG does not transfer to an edge over working BCG. The direct QUILT-2.005 naive data is the correct evidence base, not extrapolation across lines.

The interim effect size at face value. The 84% versus 52% gap rests on 43 evaluable patients, and the six-month comparison did not reach significance. Interim analyses in oncology systematically overstate final effects — one published series found interim progression-free survival effect sizes ran a median of 31% larger than final overall survival effects. We apply a 20–35% haircut to the interim gap when modelling the full 366-patient readout.

How the penetration assumption is built. It is constructed as two factors rather than one blended rate: the fraction of eligible patients who receive *any* branded add-on, multiplied by ANKTIVA's share *of that add-on pool*. ANKTIVA likely wins a high share of the second factor on workflow and economics. The first factor stays modest, because most BCG-naive patients will remain on BCG alone — it is cheap, familiar, effective for the majority, and payers facing a $750k–$1.1m add-on across 30,000-plus first-line patients will impose prior authorisation and probable step-through.

The base case therefore carries roughly **4.5% of the eligible pool in launch year 2028**, within the 3–6% band the launch analogs support and above its low end on the strength of the workflow advantage. ANKTIVA's own BCG-unresponsive launch — same company, salesforce, call point and J-code — reached mid-single-digit to low-double-digit penetration in its first full year, and the naive setting is a harder first-line add-on sale offset by a larger addressable pool. Years two and three ramp toward 7–12% and 12–20%, gated on a clean full readout, guideline inclusion and coverage. The bull case assumes 8–10% in launch year and 25–35% by year three.

04 SECOND-LINE NSCLC — THE LARGER PRIZE AND THE HARDER FIGHT

ANKTIVA holds accelerated approvals for metastatic NSCLC in Saudi Arabia (January 2026)[31] and the UAE (July 2026)[32] via the subcutaneous route — the first subcutaneous IL-15 superagonist approvals anywhere. There is no US or EU approval. The confirmatory Phase 3, ResQ201A[23] (ANKTIVA + tislelizumab + docetaxel versus docetaxel, 2:1, target ~462 patients, overall survival primary), began October 2025 with estimated primary completion September 2028 — implying a realistic US approval window of **2029–2030**.

The TAM argument is sound: 2L+ NSCLC is worth multiples of the entire BCG-unresponsive bladder market, and a 15% share would exceed ANKTIVA's total current opportunity. The difficulty is what will already be established by 2029.

AGENT	CLASS	STATUS	KEY RESULT
Docetaxel ± ramucirumab Standard of care	Chemo ± VEGFR2	ESTABLISHED	Median OS 10.5 v 9.1mo (REVEL, n=1,253) HR 0.857, 95% CI 0.751–0.979, p=0.0235; docetaxel alone ~7–9mo
Ivonescimab Summit / Akeso	PD-1/VEGF bispecific	PDUFA 14 NOV 2026	1L squamous OS 27.89 v 23.69mo (HARMONi-6) HR 0.66, 95% CI 0.50–0.87, p=0.0017 — first to beat PD-(L)1+chemo on OS
Datroway (Dato-DXd) Daiichi / AstraZeneca	TROP2 ADC	APPR JUN'25, EGFR ONLY	TROPION-Lung01 **missed OS overall** (12.9 v 11.8mo, HR 0.94) Nonsquamous 14.6 v 12.3mo; broad BLA withdrawn
Emrelis AbbVie	c-Met ADC	APPR MAY'25	ORR 35% (95% CI 24–46), median DOR 7.2mo c-Met-high nonsquamous only
Enhertu Daiichi / AstraZeneca	HER2 ADC	APPR AUG'22	ORR ~49–58%, PFS 9.9mo, OS 19.5mo HER2-mutant only
Trodelvy Gilead	TROP2 ADC	FAILED	EVOKE-01 **missed OS** 11.1 v 9.8mo HR 0.84, 1-sided p=0.0534
Patritumab deruxtecan Daiichi / Merck	HER3 ADC	WITHDRAWN	CRL Jun'24; BLA withdrawn May'25 after HERTHENA-Lung02 missed OS
Tusamitamab ravtansine Sanofi	CEACAM5 ADC	DISCONTINUED	CARMEN-LC03 failed; PFS 5 v 6mo, HR 1.14
ANKTIVA + CPI ImmunityBio	IL-15 superagonist	PH3 ENROLLING	Single-arm QUILT-3.055[33] median OS 14.1–14.6mo 21.1mo in high-ALC subgroup; vs cross-trial historical docetaxel 7–9mo

Table 6 · Second-line and later checkpoint-refractory NSCLC. Note the pattern: no agent has yet won on overall survival in the broad, biomarker-unselected population. Success has come only in biomarker niches — which is both the unmet need ANKTIVA targets and a measure of how high the bar is.

THREE SPECIFIC RISKS TO THE NSCLC THESIS

The control arm may be obsolete by readout. ResQ201A compares against docetaxel monotherapy. By 2029, with ivonescimab and multiple ADCs established, a statistically positive result against docetaxel may not translate into adoption.

The ALC biomarker may be prognostic rather than predictive. The survival advantage in ALC-responders (16.2 v 11.8 months, HR 0.52) is vulnerable to reverse causation — healthier patients maintain higher lymphocyte counts and live longer regardless of treatment. Only a randomised result resolves this.

The checkpoint partner is not a market leader. Tislelizumab has US approvals in oesophageal and gastric cancer but no NSCLC indication, adding access friction versus a pembrolizumab or nivolumab pairing.

The more realistic commercial path may be combination rather than competition. ANKTIVA's mechanism — restoring NK and T-cell competence — is logically complementary to ADCs and bispecifics rather than rivalrous with them. ImmunityBio is not currently running such a registrational combination, and that is a strategic gap worth watching.

On the claim that ANKTIVA is the best approved option in this setting

It is worth stating precisely why this cannot yet be asserted, because the reasoning matters more than the conclusion. QUILT-3.055 is single-arm, n≈79–86, with median overall survival of 14.1–14.6 months. The comparators it is measured against are randomised: docetaxel plus ramucirumab produced median overall survival of 10.5 months in REVEL (n=1,253). A single-arm median cannot be set against a randomised median and read as superiority.

The reasons are structural rather than technical. QUILT-3.055 enrolled patients who had *responded* to prior checkpoint therapy and then progressed with no intervening treatment — a favourable-prognosis, checkpoint-sensitive group, not REVEL's all-comers. Single-arm designs additionally carry performance-status enrichment, eligibility restriction, and era effects: supportive care has improved since REVEL enrolled in 2010–2013. The oncology methods literature is consistent that single-arm results systematically overestimate benefit relative to the randomised trials that follow.

The ALC-responder analysis has the same problem in sharper form. Responders showed median overall survival of 16.2 months against 11.8 months for non-responders. But patients well enough to mount a lymphocyte response are patients well enough to live longer, and they are also on treatment longer. That is reverse causation, and only randomisation separates it from drug effect.

None of this says the drug does not work. It says the magnitude is unknown, and that ResQ201A exists precisely to find out. The defensible position is that ANKTIVA is a promising, plausibly differentiated option in a setting with genuinely poor alternatives — not that it is demonstrably the best.

05 MECHANISM, AND WHAT THE DURABILITY DATA CAN AND CANNOT PROVE

ANKTIVA is an IL-15 mutant (IL-15N72D) bound to a dimeric IL-15 receptor-α sushi domain fused to IgG1 Fc. It mimics physiological trans-presentation of IL-15, driving proliferation of NK cells and CD8+ memory T cells through the IL-2/IL-15 receptor βγc complex. Its genuine differentiator versus IL-2 is that IL-15 does not support regulatory T cells — it expands cytotoxic effectors without expanding immunosuppression.

The hypothesis that this "trains" durable antitumour immunity is plausible and is consistent with the long response durations observed. But two qualifications matter for valuation.

There is no published human immune-monitoring data from the QUILT bladder trials demonstrating memory T-cell generation, epitope spreading, or trained-immunity markers. The mechanistic backbone is a rat NMIBC model and systemic-setting data in other diseases. Durable clinical responses are consistent with immune training but do not prove it.

Intravesical administration produces no measurable systemic exposure. The FDA label states systemic concentrations were below the limit of quantitation[3] (<100 pg/mL) in all patients. A bladder-cancer patient receiving ANKTIVA is therefore not receiving a body-wide immune benefit, and prescribing on that rationale would have no scientific basis. The systemic thesis lives entirely in the *subcutaneous* programme — a different route, a different set of trials, and a different risk profile.

Finally, the framing that chemotherapy "wears out" while immunotherapy trains is too clean. Gemcitabine is a recognised inducer of immunogenic cell death, depleting myeloid-derived suppressor cells and enhancing antigen cross-presentation — which is why J&J is testing TAR-200 with a checkpoint inhibitor. Neither agent has proven durable immune memory in human bladder tissue.

06 WHAT BCG SUPPLY DOES AND DOES NOT CONSTRAIN

Merck is the sole US supplier of TICE BCG, allocating a global capacity of 600,000–870,000 vials[14] annually on the basis of historical purchasing patterns — a formula that structurally excludes small and newer practices regardless of patient need. A company-cited survey found 57% of US urologists unable to treat patients for want of it. The question is what that actually constrains.

It constrains the second-line funnel. "BCG-unresponsive" is a definitional status[28] requiring documented adequate prior BCG — generally five of six induction instillations plus two of three maintenance. Patients who never receive enough BCG never enter the category, so the shortage constricts the eligible pool for every second-line agent, including the BCG-free ones. This is the correct reading of ANKTIVA's linear ~$6m quarterly adds: it is partly a market-wide phenomenon, not solely company-specific execution.

It does not constrain the BCG-naive opportunity. This is the point most easily got wrong, and getting it wrong distorts the entire 2028 forecast. In the naive setting ANKTIVA is administered alongside the *same* BCG schedule the patient receives as standard of care — six weekly induction instillations, then three-week maintenance courses, identical to the control arm of QUILT-2.005. Adding ANKTIVA adds no incremental BCG. Moreover, AUA/SUO shortage guidance directs that scarce BCG be prioritised for exactly these high-risk naive patients, and dose-splitting lets one vial treat three. Even at an aggressive 2,500 naive patients a year, ANKTIVA-associated BCG use is a low single-digit percentage of current global supply — and that BCG is consumed with or without ANKTIVA.

One residual friction survives in the second-line setting: because ANKTIVA there *does* consume BCG for a patient who has already failed it, a rationing urologist has a real argument for withholding scarce supply from that combination. That pressure does not apply to first-line use.

Why TICE relief is modelled as an unlock rather than a wash

The instinctive reading is that ImmunityBio has already solved its BCG problem through the recombinant BCG expanded-access programme, so Merck's Durham capacity changes little. The billing mechanics say otherwise, and they are worth setting out because they govern the largest single upward revision in this model.

A urology practice administering TICE bills two components: the instillation procedure under CPT 51720, and the drug itself under J9030 at a national Medicare rate of $2.821 per milligram, or roughly $141 for a 50mg vial.[46] Under an expanded-access programme rBCG is investigational, carries no J-code, and is supplied free or at cost recovery — so the drug line disappears. The procedure fee survives: reporting of 51720 at full value is appropriate regardless of dose.[47]

So the direct economic loss is small — roughly $141 of gross billing per instillation, and at ASP plus 6% only single-digit dollars of margin. **That is precisely what makes the friction decisive.** To preserve a $141 line item a practice must accept IRB review, informed consent, adverse-event reporting to the sponsor and FDA, live-biologic storage and handling, and staff training. The cost-benefit is indefensible for any practice with an alternative.

The conversion data confirms it. ImmunityBio reported nearly 200 urology practices registering for the rBCG programme in May 2025.[42] By early 2026 the programme had roughly 58 active sites. Three-quarters of registering practices did not proceed.

> **The asymmetry this creates.** rBCG is not a substitute for TICE; it is a last resort for practices that would otherwise treat nobody. Which means the shortage functions as a handicap borne by ANKTIVA alone — INLEXZO, cretostimogene and ADSTILADRIN require no BCG at all and are unaffected by it.
>
> Durham relief therefore does two things at once: it widens the second-line funnel for every agent, and it removes a prescribing constraint that binds only one. The first effect is shared; the second is not. On balance the asymmetry favours ANKTIVA, and this model now reflects that.

The US core line accordingly decays through Q2 2027 as the current niche saturates, then re-accelerates from Q3 2027 as relief arrives — sequential adds returning to roughly $7m rather than fading toward $2m. FY2028 US core moves from $364m to **$413m**, and the FY2028 total from $841m to **$890m**.

The risk to this is timing rather than direction. Merck's guidance is that supply increases "gradually over time following local market review and approvals," and the gating sequence — prior-approval supplement, pre-approval inspection, a manufacturing cycle exceeding three months, then lot release — could push relief into 2028. A one-year delay removes most of the FY2028 benefit without changing the terminal picture.

The commercial ramp is behind the company, not ahead of it

A related assumption deserves the same treatment. It is tempting to model acceleration as the salesforce matures — the natural reading of a young commercial organisation against a competitor that arrived with an established urology field force. The evidence says that catch-up has already happened.

ANKTIVA's inflection came with reimbursement, not headcount. The first quarter carrying the permanent J-code delivered revenue of $16.5m against $7.2m the quarter before, a 129% increase, with unit volume up 150% and a single quarter's units exceeding all of the prior fiscal year.[43] By late 2025 the company described adoption spanning leading research centres and community urology clinics including rural areas.[44]

The J-code has now been effective for eighteen months and the field organisation is built. If commercial immaturity were still suppressing demand, sequential adds would be rising. They have held between $4.9m and $6.5m for six consecutive quarters. That flat line is the post-buildout run rate, not a suppressed one — which is why no catch-up acceleration is modelled.

SOURCE	MECHANISM	GATING MILESTONES	REALISTIC RELIEF	CONFIDENCE
Merck Durham expansion	Capacity expansion of an approved product; triples TICE output	Construction → prior-approval supplement → pre-approval inspection → site approval → 3-month manufacturing cycle → lot release	**Mid-2027 to 2028**, phased	High
ImmunityBio rBCG[25]	Serum Institute of India; expanded access today	No BLA filed. Uptake stalled near 580 patients across ~58 sites — investigational product carries no J-code, so practices earn no drug margin	**Available now, immaterial**; approval 2028+	Moderate
Tokyo-172[18] **strain**	Japan BCG Laboratory, exclusive US rights May 2026; SWOG S1602[37] non-inferior to TICE (HR 0.82)	NCI data-use agreement unexecuted → full BLA → foreign facility inspection → bridging CMC	**2029–2031**	Low

Table 7 · Supply relief pathways. Relief widens the second-line funnel by allowing more patients to reach documented BCG-unresponsive status. It does not gate the BCG-naive opportunity, which consumes no incremental BCG.

07 REVENUE MODEL

We build from Q2 2026 actuals using a cohort and penetration approach rather than extrapolated dollar adds: $29,714 net per dose, 12.8 expected doses per patient, and a new-start ramp modulated by BCG availability. Papillary is treated as acceleration of an existing trend rather than a discrete new market, because NCCN Category 2A already permits reimbursed use. BCG-naive enters late, small, and supply-gated. NSCLC contributes nothing before 2029 and is excluded from the base case entirely.

QTR	US CORE	PAP	NAIVE	MENA BLADDER	MENA NSCLC	LYMPHO	EU	ROW	REVENUE	OPEX	BURN	CASH	PRINCIPAL DRIVER
Q3'26	58.0	—	—	—	—	—	—	**58.0**	115.4	61.9	295.5	US CIS plus reimbursed papillary use under NCCN 2A	
Q4'26	62.9	—	—	0.3	0.5	—	—	**63.7**	117.9	58.9	236.6	First Gulf private-pay doses; BCG-naive BLA filed	
Q1'27	68.0	7.5	—	0.8	1.0	0.5	1.5	**79.3**	120.5	46.1	190.5	Papillary approved 6 Jan; Germany free-pricing launch	
Q2'27	73.0	13.0	—	1.5	2.0	0.7	5.0	**95.5**	123.2	32.7	157.8	EU broadens; France early access if enrolled	
Q3'27	79.0	18.0	—	2.5	3.0	0.9	9.0	**112.9**	125.9	18.2	139.6	**TICE relief begins:** ANKTIVA prescribable without EAP friction	
Q4'27	86.0	22.0	3.0	3.5	4.0	1.1	12.0	**132.4**	128.6	1.6	138.0	Prescriber base widens. **Convertible matures 31 Dec.**	
Q1'28	93.0	25.0	18.0	4.5	5.0	1.5	16.0	**164.2**	131.5	**(27.2)**	165.2	**Cash-flow positive.** Naive launch into an unshackled channel	
Q2'28	100.0	28.0	38.0	5.5	6.0	2.0	21.0	**202.1**	134.4	**(62.0)**	227.2	Buy-and-bill economics drive community adoption	
Q3'28	107.0	30.0	62.0	6.5	7.0	2.5	26.0	**243.0**	137.3	**(99.8)**	327.0	Italy/Spain reimburse; naive scales	
Q4'28	113.0	32.0	85.0	7.0	8.0	3.0	30.0	**280.5**	140.3	**(134.2)**	461.2	Self-funding; FY28 revenue $890m	

Table 8 · Base case quarterly build, $m. H1 2026 actual. MENA is split into bladder and NSCLC private-pay following the Gulf analysis in Section 07a. Operating expenses grow 2.2% per quarter; interest $20–25m per quarter; $16–19m per quarter of non-cash addbacks reconcile to filed operating burn.

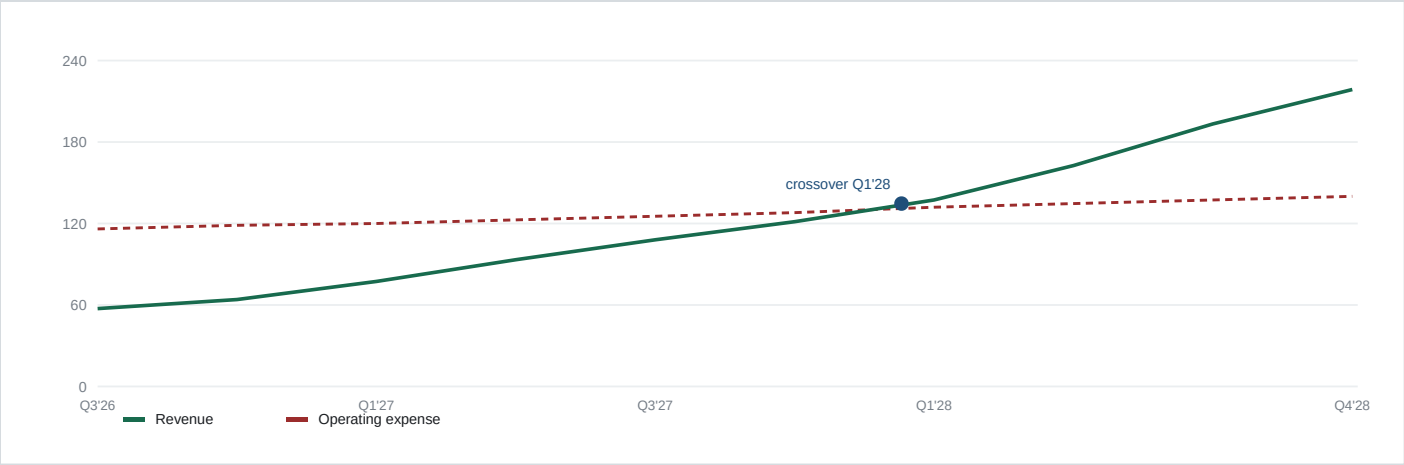

Figure 1 · Revenue closing on operating cost. The lines cross in Q1 2028, one quarter earlier than in the prior draft, on the added Gulf private-pay contribution.

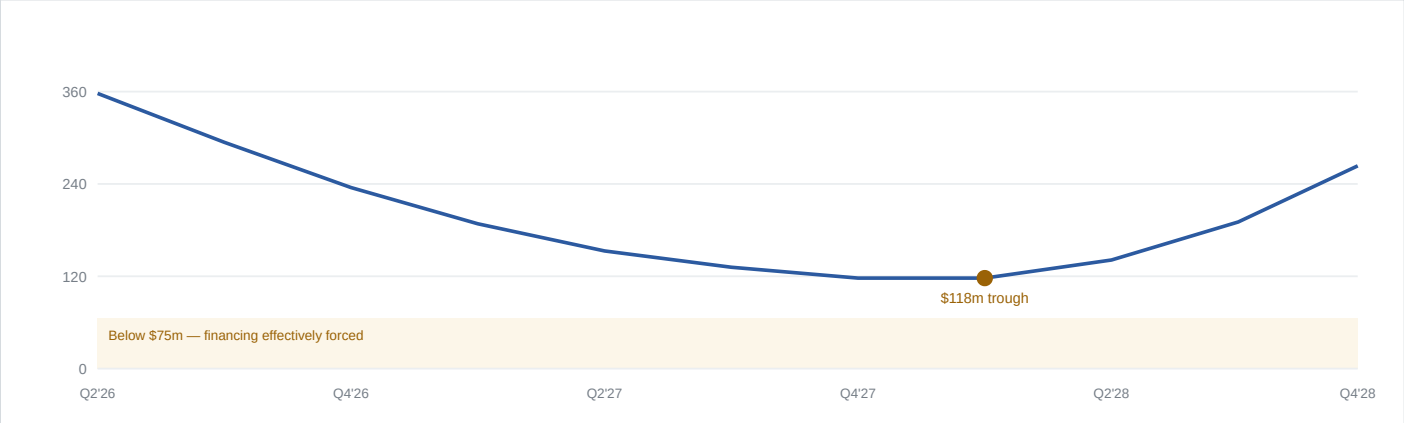

Figure 2 · Cash balance assuming no ATM issuance, warrant exercises or further Oberland draws. The trough at ~$121m in Q4 2027 coincides with the convertible maturity — the reason a financing is likely regardless of what the model says.

SCENARIO	FY26	FY27	FY28	GOVERNING ASSUMPTION	PROB
Bear	$214m	$360m	$590m	QUILT-2.005 full readout ambiguous or effect size collapses; standard review pushes approval to late-2028; payers impose BCG-alone step-through; INLEXZO and cretostimogene take CIS share	30%
Base	$217m	$420m	$890m	Papillary approved Jan'27; QUILT-2.005 holds; naive approved Q4'27; ~4.5% penetration in launch year on workflow advantage	45%
Bull	$223m	$495m	$1.36bn	Clean QUILT-2.005 topline; supply resolves on schedule; rBCG approved; Germany scales; ANKTIVA differentiates on durability versus IMFINZI	25%

Table 9 · Scenario brackets. The bear case is not a stress test — it is what happens if the QUILT-2.005 full readout disappoints or review runs long. Probability-weighted FY28 is approximately $917m.

Consensus at roughly $1.1bn for FY28 now sits level with our bull case rather than above it. The Street reaches that figure principally through the BCG-naive opportunity, modelled with an approval arriving on time and a launch curve that assumes the full readout confirms the interim. We reach a similar number by a different route — a slower bladder ramp offset by the lymphopenia and Gulf channels. The agreement on the total conceals a real disagreement about composition, and the two paths carry different risks.

07A THE GULF PRIVATE-PAY OPPORTUNITY

ANKTIVA holds the only NSCLC approvals anywhere — Saudi Arabia (January 2026) and the UAE (July 2026). The question is whether affluent patients with checkpoint-refractory disease, facing few remaining options, will fund treatment themselves. The arithmetic is seductive: at Gulf pricing, a few hundred patients would exceed a quarter of current US revenue. The channel deserves testing rather than dismissal.

Two distinct opportunities sit inside it, with very different feasibility.

Domestic and regional private pay

Wealthy Gulf residents and regional patients already in the catchment, treated at private hospitals, paying cash. This bypasses the NUPCO tender system entirely and is the more realistic near-term channel. The constraint is not wealth — Saudi Arabia hosts 350,000-plus millionaires and the UAE was the world's leading destination for relocating millionaires in 2025. The constraint is disease arithmetic.

MARKET	LUNG CANCER	NSCLC	ADVANCED	RECEIVE 1L CPI	PROGRESS & FIT
Saudi Arabia	913[38]	~780	~600	~300	**150–200**
UAE	449	~380	~290	~150	**60–90**
Rest of GCC	—	—	—	—	**40–70**
Combined eligible pool	—	—	—	—	**250–350**

Table 10 · Checkpoint-refractory metastatic NSCLC funnel, annual. Lung cancer incidence from GLOBOCAN[38] 2024; downstream percentages are modelled from NSCLC literature and Saudi Cancer Registry staging data, not from Gulf-specific treatment registries.

Against that pool, the self-pay-capable and clinically-willing subset is perhaps 15–25%, and real-world persistence is short — median overall survival in this population is roughly 14 months, so most patients receive well under the 24-month maximum. Insurance will not close the gap: UAE mandatory plans cap at AED 150,000–250,000 and Saudi CCHI-mandated cancer cover at SAR 500,000, both below a six-figure course. This is a cash market or nothing.

Why travel is genuinely necessary for NSCLC

Patients with money and a terminal diagnosis do relocate for treatment — that much is not in doubt. The question is whether they must, and for this indication the answer is closer to yes than is generally assumed.

The obvious workaround would be for a US oncologist simply to prescribe ANKTIVA off-label — it is already FDA-approved here, and off-label prescribing of approved drugs is legal under 21 U.S.C. § 396. We tested that route and it is foreclosed on formulation grounds.

ATTRIBUTE	US PRODUCT (BLA 761336)	GULF NSCLC PRODUCT
Presentation	400 mcg / 0.4 mL — **1 mg/mL**	1.2 mg / 0.6 mL — **2 mg/mL**
Route	Intravesical only	Subcutaneous injection
Label language	"For Intravesical Use Only[3]. **Do NOT administer by subcutaneous or intravenous or intramuscular routes.**"	
UAE registration	78609-45860-260486 (0.4 mg)	78609-1572-260487 (1.2 mg)
J-code J9028	Defined as "…**for intravesical use**, 1 microgram" — the reimbursement code itself is route-specific	

Table 11 · The two ANKTIVA presentations are not interchangeable. This is the single most consequential technical finding for the NSCLC access question.

A US physician cannot pool three intravesical vials to reconstruct the Gulf dose: the concentration differs, the US product is not filled or tested for injection, and the label affirmatively prohibits the route. Nor is there reimbursement — ANKTIVA appears in no CMS-

recognised compendium for NSCLC, so Medicare's off-label anticancer rule under Social Security Act §1861(t)(2)(B) is not satisfied. Self-pay would run roughly **$1.87m a year** at three vials per dose every three weeks, using the wrong product by a prohibited route with no liability cover. No documented case of independent US off-label use exists.

> **What this means.** For NSCLC there is no domestic substitute: the correct subcutaneous product exists only in Saudi Arabia and the UAE, and importing an unapproved-in-the-US presentation for an unapproved indication is materially harder than importing an approved drug. A US or European patient who wants the studied regimen has three options — a clinical trial, the lymphopenia expanded-access[24] programme, or travel. That is a narrow funnel, and it is the reason the Gulf NSCLC line deserves real weight rather than dismissal.
>
> The binding constraint is therefore not willingness to travel. It is that the checkpoint-refractory pool is small, the drug must be given every three weeks for up to two years, and the evidence supporting it is single-arm.

The label-expansion mechanism — why NSCLC approvals matter more than lung cancer

There is a structural consequence of the Gulf NSCLC approvals that the lung-cancer framing obscures. The subcutaneous 1.2 mg presentation is now a registered, priced, stocked product in Saudi Arabia (registration 78609-1572-260487 in the UAE; SFDA registration certificate with pricing issued in Saudi Arabia). Off-label prescribing is a lawful physician prerogative in both jurisdictions — peer-reviewed surveys describe it as common practice in the Kingdom, and nothing in the UAE framework prohibits it for a registered biologic.

The consequence: a physician in Riyadh or Dubai can lawfully purchase an injectable ANKTIVA vial and prescribe it off-label to raise the lymphocyte count of a patient who does not have lung cancer. That is impossible in the United States, where only the intravesical presentation exists and the label forbids the route. **Every jurisdiction that approves subcutaneous ANKTIVA for NSCLC therefore simultaneously creates a lawful supply channel for off-label immune reconstitution.** The NSCLC filing footprint is the gating variable for a much larger addressable population.

POPULATION	BASIS	SCALE	WILLINGNESS TO TREAT
Chemo/radiation-induced lymphopenia	Strongest rationale; 40–70% of treated patients develop it	Low tens of thousands GCC-wide	Moderate — oncologist-driven, adjunctive
Transplant & chronic immunosuppression	Persistent lymphopenia, high infection risk	Thousands	Low — competing immunosuppression logic
Immunosenescence / elderly	Age-related lymphocyte decline	Large but undefined	Low — no accepted treatment paradigm
Wellness & longevity self-pay	DHA-licensed longevity clinics in Dubai and Abu Dhabi already market immune-boosting protocols; Hevolution Foundation budgeted up to $1bn/yr for ageing science	Small but very high value per patient	High willingness, low clinical justification

Table 12 · Populations reachable through off-label prescribing where the subcutaneous presentation is on-market. GCC cancer incidence 42,475 (2020, GLOBOCAN), projected to ~104,000 by 2040.

Dosing follows the expanded-access protocol — roughly 1.0 mg subcutaneously every two to three weeks, about one vial per dose. At an assumed Gulf net price of $20,000–$40,000 per vial, chronic use runs $350,000–$700,000 per patient-year; a several-month adjunctive course runs $100,000–$250,000. Those are plausible luxury-medicine numbers for a small number of patients, and the self-pay argument holds here in a way it does not in the United States: where the product is purchasable, money genuinely does solve the access problem.

THREE CONSTRAINTS THAT CAP THIS

The Gulf price is unknown. Neither the SFDA nor the UAE authorities have published a registered price for the subcutaneous presentation. Every figure above rests on an inference from US WAC and reference-pricing norms. This is the single largest gap in the model.

No off-label use has been observed. Extensive searching found no Gulf clinic offering ANKTIVA, no physician commentary, and no patient reports. The thesis rests on legal permissibility and market structure, not documented practice.

The company cannot promote it. Demand would have to be generated physician-to-physician or by hospitals, not by ImmunityBio, which already holds an FDA warning letter for off-label messaging. Worse, visible off-label wellness use would amplify exactly the narrative the FDA is policing — and the US bladder franchise it could jeopardise is worth far more than the incremental Gulf revenue.

The regulatory foothold that distinguishes this from prior attempts

One fact deserves more weight than the off-label framing gives it. In February 2025 the FDA granted Regenerative Medicine Advanced Therapy designation to ANKTIVA plus PD-L1 t-haNK for *reversal of lymphopenia in patients receiving standard-of-care chemotherapy or radiotherapy*. RMAT is available only for conditions the agency accepts as serious or life-threatening. In granting it, FDA implicitly acknowledged lymphopenia — in that defined population — as a serious condition worth treating.

That is materially more than any prior entrant in this space achieved. Interleukin-7 programmes from NeoImmuneTech and RevImmune spent more than a decade demonstrating they could raise lymphocyte counts without ever securing a comparable regulatory foothold or reaching market. ANKTIVA arrives with an approved product, a manufacturing base, commercial infrastructure, and an FDA designation that carries rolling review, intensive agency interaction, and eligibility for accelerated approval.

The condition also has an unusual profile for category creation: it is measured on every routine complete blood count, so no new diagnostic is required; its prognostic harm is documented across a dozen tumour types; and no approved therapy exists anywhere. A recognised serious condition with a validated biomarker, a free universal test, and no competitor is a genuinely rare configuration.

What RMAT does not do is solve the endpoint problem. It accelerates the path; it does not change the requirement that ImmunityBio demonstrate a clinical benefit — fewer serious infections, fewer treatment delays, or improved survival — rather than ALC correction alone. Nor does it extend beyond the designated population and combination. The bull case below therefore assumes RMAT converts into an approval in a defined chemotherapy- or radiotherapy-induced lymphopenia population, not a broad immune-reconstitution label.

SCENARIO	2027	2030	2032	REQUIRES
Bear	1	4	8	10–40 patients/yr; niche word-of-mouth use only; no indication granted
Base	3	12	25	Low hundreds of patients; oncology-adjacent adoption plus small wellness cohort; off-label throughout
Bull	10	60	130	RMAT-enabled US approval in a defined lymphopenia population, or a formal Gulf indication, converting off-label use to reimbursed on-label prescribing

Table 13 · Off-label and on-label lymphopenia revenue scenarios, $m per year. The bull case assumes RMAT-enabled approval converts off-label use into a reimbursed indication.

On demand dynamics. Physicians do not currently treat lymphopenia — no NCCN, ASCO or ESMO guideline recommends it, and ALC is reported on every blood count but acted on by almost no one. Neutropenia became a multi-billion-dollar market because it causes acute, visible, life-threatening infection and because filgrastim gave oncologists something to do about it. Lymphopenia has neither driver: its harm is a statistical survival decrement visible only in retrospect. This is a demand-push market, and adoption will be slower than the epidemiology alone suggests.

The exception, and the logical beachhead, is radiation oncology. That community already modifies practice at real cost — proton therapy, reduced field size, vertebral-body sparing — specifically to protect lymphocytes. Clinicians who spend money on technique to

preserve ALC are clinicians who believe the problem is worth solving. A pharmacological option would be new to them, and the conviction should transfer.

The base case is included in the model from 2027 as a separate line. It is not material to 2028 — but it compounds, it requires no US regulatory event, and a formal Gulf lymphopenia indication would convert the whole thing from off-label to on-label. That last item is the catalyst worth watching: ImmunityBio has stated it is pursuing label expansion for chemotherapy-induced lymphopenia and has opened discussions with both Gulf regulators about indications beyond lung and bladder.

07B THE NK CELL PLATFORM AND THE SEPSIS PROGRAMME

Two programmes sit behind the lymphopenia thesis and deserve separate treatment, because they are where ImmunityBio's platform claim either becomes real or does not.

The NK cell assets

ASSET	TYPE	STAGE	NOTES
PD-L1 t-haNK	Off-the-shelf NK-92-derived CAR-NK; high-affinity CD16, IL-2, anti-PD-L1 CAR	PHASE 1/2	Targets PD-L1+ tumour cells and myeloid-derived suppressor cells; backbone of the QUILT-88 pancreatic regimen; RMAT designation with ANKTIVA for lymphopenia reversal (Feb 2025)
M-ceNK	Memory cytokine-enriched NK, autologous or cord-blood allogeneic, expanded with ANKTIVA	PHASE 1/2	Single apheresis yields 10–20 doses of 0.5–1bn cells (>3,000% expansion); studied with ANKTIVA in QUILT-3.076
aNK / haNK	Parental NK-92 line	LEGACY	Foundation of the platform

Table 14 · ImmunityBio cell therapy platform.

The scientific logic is sound and is the strongest version of the platform argument. IL-15 is the dominant survival and proliferation cytokine for NK cells. Infused NK cells characteristically fail because they do not persist. Pairing an IL-15 superagonist with an NK infusion to sustain those cells in vivo is a coherent design, and ANKTIVA drives roughly 20-fold NK expansion with increased cytotoxicity in preclinical work.

The economics are also better than CAR-T. An off-the-shelf NK-92-derived product follows a one-donor-to-thousands-of-doses model. Autologous CAR-T lists at $370,000–$530,000 with cost of goods around $48,000–$115,000 per dose; allogeneic estimates run near $40,000 falling toward $10,000–$20,000 at scale. ImmunityBio holds GMP capacity in El Segundo and Dunkirk, New York.

> **THE SECTOR BASE RATE IS POOR**
>
> Fate Therapeutics discontinued its core NK programmes in 2023 after Johnson & Johnson exited the partnership. Nkarta abandoned oncology NK development for autoimmune indications after weak AML data. The field has struggled repeatedly to convert mechanistic elegance into durable clinical benefit. We model the NK platform as an adjunct that strengthens the ANKTIVA combination narrative, not as a standalone revenue line, and assign it no revenue through 2028.

Sepsis — the most endpoint-friendly indication in the pipeline

Sepsis-induced immunoparalysis is driven by apoptotic depletion of T and NK cells, and late-phase sepsis deaths are dominated by secondary infection in immunosuppressed patients. Persistent lymphopenia on day four[30] independently predicts 28-day and one-year mortality. The global burden is 48.9m cases and 11.0m deaths[29] annually — roughly a fifth of all deaths worldwide.

ImmunityBio has registered NCT07578558[22], a randomised open-label Phase 2 of ANKTIVA plus standard of care versus standard of care alone in critically ill adults with sepsis and persistent lymphopenia. Roughly 50 patients, estimated start July 2026, primary completion August 2027.

This matters disproportionately for one reason: **sepsis supplies a hard clinical endpoint that the lymphopenia indication lacks.** Twenty-eight-day mortality is unambiguous, FDA-acceptable, and fast to read out. It sidesteps the surrogate-endpoint problem that makes an oncology lymphopenia approval so difficult. A biomarker-enriched population — patients selected for persistent lymphopenia — also addresses the heterogeneity that sank previous immunomodulatory sepsis trials.

Against that: sepsis is a graveyard. Interleukin-7, GM-CSF, interferon-gamma and checkpoint blockade have all been trialled with equivocal results. And there is a specific negative signal — an IL-15 superagonist in burn-wound sepsis expanded lymphocytes but failed to improve bacterial clearance or survival. Expanding cells is not the same as improving outcomes, and that study is the most directly relevant preclinical datapoint available.

> **Why this is the readout to watch.** The August 2027 primary completion falls inside the forecast window and is cheap for the company to run. A statistically significant mortality or secondary-infection benefit would validate the immune-reconstitution thesis with the kind of evidence the oncology programmes cannot generate, and would open a genuinely large indication. A null result should discount the entire immunoparalysis franchise, including the lymphopenia opportunity that depends on the same biological premise.

Would the Saudi state pay?

If state health programmes fund treatment rather than individuals, the binding constraint shifts from household wealth to state budget — a materially larger and faster-moving opportunity. We tested this and the evidence came back thinner than the narrative suggests.

ELEMENT	STATUS	ASSESSMENT
Cancer BioShield MOU[19] MISA, KFSHRC, KAIMRC · May 2025	NON-BINDING	ImmunityBio's own disclosure states it "is non-binding and does not create any legal or financial obligations of the parties"
US–Saudi Biotech Alliance Summit January 2026	HELD	Co-chaired by a Saudi princess and the NGHA chief executive. Relationship-building, not procurement
SFDA approvals January 2026	GRANTED	World-first NSCLC approval. Real regulatory achievement
Commercial launch April 2026	LIVE	Via private distributors Biopharma and Cigalah. **No payer named**
NUPCO tender / MOH purchase	NONE FOUND	No tender, no formulary listing, no managed-entry agreement
Saudi sovereign equity stake	NONE	No PIF or Sanabil position in SEC ownership filings
Hevolution funding	NOT APPLICABLE	Funds ageing research and early-stage investment; grant terms exclude clinical treatment

Table 15 · The ImmunityBio–Saudi relationship: executed versus aspirational.

The state-funding pathway also has gates. A high-cost drug must clear SFDA pricing (done), mandatory health technology assessment, CCHI formulary listing, and NUPCO tender adoption — a process that since 2026 applies a "Made in Saudi" scoring weight favouring local manufacture. Saudi Arabia has funded high-cost novel therapies before: KFSHRC has treated more than 200 CAR-T patients and localised manufacturing, cutting cost per treatment from roughly SAR 1.3m to SAR 250,000. But those therapies carried US or EU approval.

> **THE DECISIVE GAP**
>
> We found **no documented case of Saudi state funding for a therapy lacking US or EU approval** — which is precisely ANKTIVA's status in NSCLC. The indication rests on single-arm, surrogate-endpoint data with a confirmatory trial still recruiting. That, not household wealth, is the binding constraint on the state-funding thesis.

What we have modelled, and what we have not

The base case now carries an explicit Gulf private-pay NSCLC line, building from $0.5m in Q4 2026 to $8m per quarter by Q4 2028 — roughly $26m across 2028, on the order of 25–40 patients on therapy at any time at Gulf reference pricing. Combined with MENA

bladder revenue, the region contributes about $60m across the forecast window. That lifts FY28 from $700m to $722m: real, but 1.8%, not a re-rating.

We have *not* put state funding in the base case. Sized separately: if the Saudi state funded the full eligible NMIBC and NSCLC population under a managed-entry agreement at a 40–60% discount to US list, it would plausibly add $40–80m annually from 2028 — more than private pay, because volume at a discount beats a handful of patients at list. That is the upside case, and it is a call option with identifiable triggers rather than a forecast.

> **Triggers that would move Gulf revenue into the base case:** ANKTIVA appearing in a NUPCO tender or the CCHI Unified Drug List; an announced managed-entry agreement with the Ministry of Health; a disclosed MENA geographic revenue line above $5m in any quarter; an executed local manufacturing or technology-transfer agreement converting the MOU into binding terms; or positive confirmatory NSCLC data from ResQ201A.

07C EUROPE AND THE REST OF THE WORLD

Ex-US contributes roughly $159m of FY2028, about 19% of the total. Three structural facts govern that line, and the first determines whether it should be modelled at all.

How European revenue is recognised

The decisive question is whether ImmunityBio books end-market sales in Europe or a thin royalty from a licensee. The evidence points to the former. Accord Healthcare is described as a distribution partner[20] deploying an 85-person sales force within 100-plus commercial, medical and marketing staff across the UK, EU and EFTA — a services model, not a licence. ImmunityBio simultaneously opened a Dublin subsidiary in February 2026 explicitly to support European distribution, and post-authorisation EMA records list ImmunityBio Ireland Limited[12].

On that structure, European revenue should be modelled at ImmunityBio-captured net sales — end-market price less a distributor margin, plausibly 25–35% — rather than a royalty of a few percent. That is a large multiple of the alternative, and it is why the EU line carries real weight here.

> **THE ONE FACT THAT WOULD CHANGE THIS**
>
> Serum Life Science Europe GmbH was named as the CHMP applicant in December 2025, while post-authorisation records point to ImmunityBio Ireland. The marketing-authorisation holder of record in the final EPAR Annex I would resolve it. If a Serum out-licence exists, the booked European figure would be a fraction of what is modelled here and should be reclassified as royalty revenue. This is the largest single modelling uncertainty in the ex-US line.

Two structural advantages Europe has that the US does not

BCG supply is materially better. The US depends on a single supplier. Europe has access to six approved BCG substrains[13], including Medac's Danish 1331, Serum Institute's, and the Japanese Tokyo strain. Since ANKTIVA is dosed with BCG, the constraint that suppresses US uptake is substantially absent in Europe. This is an under-appreciated positive and argues for a faster European penetration curve than the US launch produced.

The competitive field is far emptier. ANKTIVA is the first and currently only authorised therapy in the EU for BCG-unresponsive NMIBC with CIS. ADSTILADRIN received a CHMP positive opinion only in March 2026 and is not yet authorised; INLEXZO is not EU-approved; cretostimogene is earlier still. That is a first-mover window of perhaps twelve months or more in a market where the US equivalent is already crowded with four agents.

MARKET	STATUS	MECHANISM	REVENUE TIMING
Germany	EC AUTHORISED	Free pricing at launch, AMNOG negotiation after 6–12 months	2027, earliest
France	EARLY ACCESS POSSIBLE	Accès précoce at company-set price ahead of HAS/CEPS — enrolment unconfirmed	2027 if enrolled
Italy, Spain	AIFA / AEMPS	National then regional negotiation	2028–2030
Nordics, Benelux	PENDING	National HTA	2028–2029
UK	NICE TERMINATED	MHRA approved Jul 2025, but NICE terminated appraisal 4 Jun 2026[11] on non-submission — no routine NHS funding	Private-pay only

Table 16 · European market access by country. Germany's free-pricing window and France's early-access programme are the two channels capable of producing revenue ahead of formal reimbursement.

The UK outcome is a genuine negative and worth stating plainly. A NICE termination for non-submission means the product is not routinely funded in England and Wales. Whether that reflects a strategic sequencing decision or an evidence gap is not disclosed, but the practical effect is that the UK contributes almost nothing until a resubmission.

Asia — modelled near zero, but not worthless

ANKTIVA's only Asian approval is Macau, granted March 2026. No filings have been disclosed for Japan, China, Korea, Taiwan, Australia or ASEAN, so a near-zero 2028 assumption is correct.

One disclosure is worth flagging for the terminal value. The Oberland revenue-interest agreement is defined on worldwide net sales *excluding China*, with China defined to include the PRC and Hong Kong. A carve-out of that specificity implies China economics are structured separately and may sit with a partner or affiliate outside the main entity. Asian bladder-cancer incidence is roughly 215,700 cases a year, about 35% of the global total, with China near 92,800 and Japan near 34,600 — and Japan has both the region's highest incidence and the deepest BCG-use tradition.

The model carries a small rest-of-world line rising to $2.5m a quarter by end-2028, reflecting Macau and opportunistic named-patient revenue. The honest position is that 2028 is right and the terminal number is understated: an activated Japan filing or an identified China partner would be worth materially more than anything else in this section.

08 BALANCE SHEET AND FUNDING

Cash and marketable securities were $357.4m at 30 June against a derived quarter-standalone operating burn of $66.5m[35] — roughly five quarters standalone. On the base case, cumulative burn to breakeven is about $224m, troughing near **$138m in Q4 2027**. Tight, but not forced. Non-operating capital is ample: approximately $132m of in-the-money warrants (13.5m at $3.101, 27.96m at $3.240) and $349m of remaining ATM capacity.

The complications are structural rather than immediate. Total liabilities are $1.67bn against a stockholders' deficit of $1.05bn. The going-concern footnote persists, mitigated explicitly by the Founder's stated intent to fund operations — a dependency with no analogue among peers. The Oberland revenue interest[16] skims 5.625–12.50% of ex-China net sales, so the top line converts to cash less efficiently as it scales. And the **$480m related-party convertible matures 31 December 2027**, one quarter before the cash trough. That is the largest dilution event in the forecast window.

09 THE PLATFORM QUESTION

The case for valuing ImmunityBio as more than a bladder-cancer company rests on the subcutaneous programme: NSCLC, and beyond it the lymphopenia concept — restoring absolute lymphocyte count in patients depleted by chemotherapy, radiation, age, or infection. The population is genuinely large, and low ALC is robustly associated with worse outcomes across settings.

The regulatory obstacle is that ALC is a biomarker, not a clinical outcome. FDA accepts surrogate endpoints for accelerated approval only where they are reasonably likely to predict clinical benefit, and ALC has not been validated as such. Approving "treatment of lymphopenia" as an indication would in practice require demonstrating a clinical benefit — fewer infections, fewer chemotherapy delays, improved survival — in a defined population. No registrational lymphopenia trial with a clinical endpoint has been disclosed. This is a multi-year, high-risk endeavour, and the probability of a standalone approval on ALC restoration alone is low.

The wider pipeline — pancreatic (QUILT-88), glioblastoma, HPV-positive head and neck, the M-ceNK cell-therapy platform, hAdV5 vaccine vectors — is broad on paper but largely Phase 1/2, single-arm, or not yet enrolling. Against $66.5m quarterly burn and a going-concern footnote, breadth is as much a risk as an asset: it spreads scarce capital across programmes that may all end up underpowered.

Worth noting for context: systemic IL-15 has a difficult history. Sotio discontinued its programme for insufficient efficacy, Novartis halted NIZ985 short of enrolment, and the broader cytokine field was chastened by the bempegaldesleukin failure. ANKTIVA's success has come precisely in the local, intravesical setting where systemic toxicity is avoided. The subcutaneous ambition moves it back into the arena where the class has repeatedly failed.

10 CATALYSTS

DATE	EVENT	WHY IT MATTERS	IMPACT
Q4 2026	QUILT-2.005 full topline and BCG-naive BLA	The 366-patient result either validates or breaks the largest component of consensus. Watch whether significance holds beyond the nine-month durability endpoint	Very high
6 Jan 2027	Papillary sBLA PDUFA	Converts NCCN-enabled off-label use to label. Incremental rather than transformative — some revenue is already booked	High
Late 2026 →	Merck Durham operational	Widens the second-line funnel by letting more patients reach documented BCG-unresponsive status. Watch for supplement approval and first lot release, not the ribbon-cutting	Moderate
2026–27	J&J SunRISe-3 readout	Randomised, BCG-free, versus BCG in the naive setting. A positive result substantially devalues ANKTIVA's naive thesis	High (neg)
14 Nov 2026	Ivonescimab PDUFA	Establishes the PD-1/VEGF class in NSCLC three years before ANKTIVA could arrive	Moderate (neg)
31 Dec 2027	Convertible note maturity	$480m principal, one quarter before trough cash	High (dilution)
2028–29	ResQ201A overall survival readout	Determines whether the NSCLC platform thesis is real. Primary completion estimated September 2028	Very high
Ongoing	First ex-US revenue recognition	Approvals across ~34 countries have produced zero recognised revenue. A first non-US line validates the international thesis	Moderate

Table 17 · Ranked by impact on the model.

11 VALUATION — A SUM-OF-THE-PARTS

A single revenue multiple cannot value this company, and forcing one produces a systematically low answer. The reason is visible in a comparable: **CG Oncology carries roughly $4.5–5bn of enterprise value on essentially no revenue**, entirely for cretostimogene's pre-commercial NMIBC optionality. If the market pays that for one unapproved asset in this indication, then running all of ImmunityBio's value through a multiple on approved-indication revenue assigns near-zero worth to BCG-naive, NSCLC, lymphopenia and sepsis. That is not a conservative assumption; it is an incorrect one.

What follows separates the two. The commercial franchise — approved indications, generating revenue — takes a revenue multiple. Unapproved programmes are valued separately against the CGON benchmark and folded into the commercial line only when approved.

Where the commercial multiple belongs

The historical record is unambiguous about where multiples sit during the scaling phase, and it is far above where a mechanical discount would put them.

COMPANY	LAUNCH PHASE	~$500M REVENUE	~$1BN REVENUE	MATURE
Neurocrine[34] (Ingrezza)	~56x (2017, $116m)	~18x (2018, +252%)	~10x (2020, +32%)	4.6x (2025, +21%)
Vertex (CF franchise)	~48x (2014, $580m)	~29x (2015)	~13x (2016)	~9–10x today
Alnylam (RNAi)	~72x (2019, $194m)	~30x (2020, +154%)	~23x (2021–22)	~15x (2024)
Krystal (Vyjuvek)	~40x (2023, $51m)	~12–13x (2024, +473%)	~13–16x (2025–26) — compression paused by profitability	

Table 18 · Historical EV/Sales through the scaling phase. Pre-2021 figures are interpolated from quarterly market-cap snapshots (±10–15%); later figures exact.

At $200m of revenue the range is 40–72x. At $500m it is 12–30x. At $1bn, 10–23x. Mature franchises with durable economics and high gross margins settle at 9–15x, not the 4.6x of the single weakest observation. Vertex is the better mature analog for a 99%-gross-margin franchise with patent protection to 2036.

The commercial multiples used below sit in the *middle* of that historical range: 20x in 2026 falling to 9x at maturity in the base case. IBRX-specific discounts — going-concern language, 62–66% insider control[3917], the Oberland revenue interest, the FDA warning letter — are real and are reflected in that positioning, applied once rather than compounded.

Pipeline optionality, benchmarked to CGON

PROGRAMME	BEAR	BASE	BULL	BASIS
BCG-naive NMIBC	900	**2,200**	3,800	TAM of 30,000+/yr against 12–16k for BCG-unresponsive. Earlier data than cretostimogene (43-patient interim) and IMFINZI already approved — so 40–60% of CGON's value
NSCLC (US/EU)	200	**700**	1,600	ResQ201A reads out 2028, approval 2029–30. Large TAM but single-arm support and docetaxel-comparator risk. Roughly 30–35% probability
Lymphopenia (US)	100	**500**	1,400	RMAT granted, no registrational trial, ALC surrogate unresolved. Very large TAM if solved. Roughly 15–20%
Sepsis	50	**300**	900	Phase 2, n=50, reads out August 2027. Hard mortality endpoint sidesteps the surrogate problem. Cheap option against a poor sector base rate
NK platform + rBCG	50	**250**	600	Fate and Nkarta both retreated from NK oncology. rBCG and Tokyo-172 carry real strategic value as supply independence
Total pipeline	**1,300**	**3,950**	**8,300**	Base case is roughly 0.8x one CG Oncology, across five programmes

Table 19 · Risk-adjusted pipeline value, $m. CG Oncology's ~$4.75bn enterprise value for one pre-commercial NMIBC asset is the reference point.

Share count and financing, built rather than assumed

Two mechanics govern the denominator, and both are frequently mishandled. The first is that dilution and its proceeds are a single transaction. The 41.5m in-the-money warrants appear in every fully diluted count, but they also deliver roughly $132.5m of cash on exercise. The $480m convertible produces 88.4m shares, but extinguishes $480m of debt in the same motion. Counting one side without the other understates equity value twice over.

The second is that ATM issuance is a function of need and price, not a fixed schedule. A company generating cash does not draw it; a company burning cash draws it at whatever price the market offers — which is lowest precisely when the need is greatest.

COMPONENT	BASE / BULL	BEAR	CONTINGENCY
Outstanding, 31 July 2026	1,060.0m	1,060.0m	Per 10-Q cover page
Convertible conversion	88.4m	**137.1m**	$480m at $5.427[36]. Converts voluntarily only above that price. Below it the holder will not convert and the company cannot repay — a renegotiated conversion at roughly $3.50 produces *more* dilution, not less
Warrants	41.5m	**—**	13.5m at $3.101 and 27.96m at $3.240, expiring 2030. Both strikes sit above the bear price path, so they expire unexercised
Options and RSUs	32.0m	32.0m	Historically excluded as anti-dilutive
Fully diluted base	**1,221.9m**	**1,229.1m**	Similar totals, opposite composition

Table 20 · Fully diluted share count. Every component except outstanding stock and equity awards is price-contingent, so the count differs by scenario rather than being a single figure.

The composition matters more than the total. In the bear case the warrants deliver no shares and no cash, while the convertible delivers 48.7m *additional* shares because it must be restructured at a distressed price. Dilution does not disappear when the stock falls — it changes form and gets worse.

SCENARIO	WARRANT CASH	CASH PRE-ATM	ATM DRAWN	ISSUE PRICE	ATM SHARES	2028	2030	2032
Bear	**nil**	$138m	$550m	**~$3.00**	183.3m	1,433m	1,563m	1,653m
Base	**$132.5m**	$271m	$100m	~$9.00	11.1m	1,253m	1,271m	1,289m
Bull	**$132.5m**	$271m	**none**	—	—	1,242m	1,260m	1,278m

Table 21 · Financing requirement and resulting share count. Warrant proceeds are credited only where the scenario's own price path clears the strikes.

THE WARRANTS FAIL EXACTLY WHEN THEY ARE NEEDED

Both tranches strike at $3.101 and $3.240. The bear price path runs $2.92 to $3.19 — below or barely at those levels — so the $132.5m of proceeds does not arrive in the one scenario where the company is short of cash. Treating that money as available regardless of price would flatter the downside by roughly $132m of liquidity and understate the ATM draw required to replace it.

The same conditionality governs the convertible. At $5.427 it converts comfortably in the base and bull paths; in the bear path it is deep out of the money, and the resolution is a distressed restructuring rather than a clean conversion.

The asymmetry is the point. Base and bull differ by only 11m shares, because once operating cash flow turns positive the ATM is a buffer rather than a lifeline — and at $9 a share, $100m costs almost nothing in dilution. The bear case issues 183m shares for $550m because it must raise at $3, and must raise more besides because the warrants deliver nothing. Between bear and bull the share count differs by 375m, or 29%, and essentially all of that gap is created by whether the company needs the money — which is also, unhelpfully, when the cheapest sources of it stop working.

Share growth beyond the ATM is equity compensation at roughly 1.5% a year on the outstanding base — 18m shares per two-year step. No buyback is assumed in any scenario.

FY	OBERLAND	OPERATING CASH	WARRANT PROCEEDS	ATM	NET
2026	**($415m)**	$357m	—	—	**($58m)**
2028	**($350m)**	$265m	$132m	$100m	$148m
2030	**($250m)**	$700m	$132m	$100m	$682m
2032	**($120m)**	$1,500m	$132m	$100m	**$1,612m**

Table 22 · Net cash and debt, base case. Warrant proceeds are credited here because the base price path clears both strikes; the bear case carries none. The Oberland liability amortises as revenue scales; the convertible converts to equity rather than being repaid.

The sum-of-the-parts

FY	COMMERCIAL REV	MULT	COMMERCIAL EV	PIPELINE	TOTAL EV	NET	EQUITY	SHARES	PRICE
2026	$217m	20.0x	$4,340m	$3,950m	$8,290m	**($58m)**	$8,232m	1,222m	**$6.74**
2028	$638m	12.0x	$7,656m	$3,400m	$11,056m	$148m	$11,204m	1,253m	**$8.94**
2030	$1,800m	9.0x	$16,200m	$2,400m	$18,600m	$682m	$19,282m	1,271m	**$15.17**
2032	$2,650m	9.0x	$23,850m	$2,000m	$25,850m	$1,612m	$27,462m	1,289m	**$21.30**

Table 23 · Base case sum-of-the-parts. Commercial revenue covers approved indications only; BCG-naive moves from the pipeline line into commercial revenue on approval.

FY	BEAR COM REV	MULT	BEAR SHARES	BEAR PRICE	BULL COM REV	MULT	BULL SHARES	BULL PRICE
2026	$215m	12.0x	1,229m	**$3.11**	$222m	30.0x	1,222m	**$12.19**
2028	$475m	7.0x	1,433m	**$3.19**	$900m	18.0x	1,242m	**$18.87**
2030	$800m	4.5x	1,563m	**$2.92**	$3,000m	12.0x	1,260m	**$34.01**
2032	$1,050m	4.0x	1,653m	**$3.07**	$4,600m	11.0x	1,278m	**$46.39**

Table 24 · Bear and bull sum-of-the-parts.

> **Why the two buckets must be separated.** Collapsing this into a single revenue multiple would value the unapproved programmes at zero by construction. Against a market that pays roughly $4.75bn for one pre-commercial NMIBC asset, that is not a conservative simplification — it is a structural error, and it understates the base case by roughly $11 a share in 2032.
>
> The construction here remains restrained. It carries share-count growth in every scenario, assumes the Oberland revenue interest throughout, and values five programmes at less than one CG Oncology in aggregate.

What this says about the current price

On base assumptions the 2026 sum-of-the-parts is **$6.74** against a market price near $8.00 — so the market is paying roughly a 19% premium to a mid-range valuation of today's business plus a risk-adjusted pipeline. That is a premium, not a bubble, and it is smaller than the dispersion in the inputs. Push the commercial multiple to 25x — still inside the historical range at this revenue level — and the 2026 figure moves to roughly $8.00, precisely the current price.

The forward picture is what matters more. The base case compounds to **$21.30 by 2032**, roughly 2.7x from here, with a bull case at **$46.39** and a bear at **$3.07**. The distribution remains wide and the downside remains severe, but the central case is no longer dead money — it is a mid-teens annualised return with a large upper tail, which is a materially different proposition from what the single-multiple framework implied.

12 RISKS

- **Regulatory conduct.** FDA issued a warning letter on 13 March 2026[4] — its first full OPDP warning letter of that year — following two untitled letters to subsidiary Altor. It cited a television advertisement that never aired and a podcast appearance. The company implemented new promotional controls in April. The distinction the company would draw is fair: FDA adjudicates what is provable for promotion, not whether a claim might eventually prove true, and aspirational commentary from a founder is not the same as a marketing claim. But one cited item was a route-of-administration error, and with two applications under review the compliance bar is now materially higher.
- **Litigation.** *Douglas v. ImmunityBio*[21] (C.D. Cal.), class period 19 January to 24 March 2026. Lead plaintiff appointed 15 July 2026. Consolidated derivative suits stayed pending the motion-to-dismiss phase.
- **Competitive erosion.** INLEXZO is ramping faster than ANKTIVA did from an equivalent launch point, aided by BCG independence and J&J's installed infrastructure. Cretostimogene's profile — 75.5% CR, median DOR ≥27.9 months[7], zero grade ≥3 treatment-related events, BCG-free — is the most credible medium-term threat in CIS.
- **Governance.** Roughly 62–66% insider control, a related-party convertible held by an affiliate, CVRs partly held by the Founder, and a going-concern mitigation resting on his continued support. Directors have sold consistently under 10b5-1 plans; no open-market insider buying identified.
- **Payer risk in the naive setting.** Layering a ~$380k net regimen onto near-free generic BCG across tens of thousands of first-line patients invites step therapy and net-price concession. Bull models hold per-patient net price flat at scale; that is unlikely to survive a pharmacy benefit committee.

13 CONCLUSION

ANKTIVA is a real product with real durability data in a niche it has penetrated only 10–15% of. The operating loss is closing, cash flow turns positive in Q1 2028 on the base case, and the company is closer to self-funding than its going-concern language suggests. Behind the commercial franchise sits an unusual configuration: a recognised serious condition with no approved therapy, a biomarker measured on every routine blood count, and an FDA designation that accepts the premise.

The sum-of-the-parts puts today's business plus a risk-adjusted pipeline at roughly $6.74 against a market price near $8.00 — a premium of about 19%, smaller than the dispersion in the inputs, and one that closes entirely at a commercial multiple of 25x, which remains inside the historical range for this revenue and growth stage. The base case compounds to $21.30 by 2032, roughly 2.7x from here, or mid-teens annualised.

That is the case for ownership. The case for care is the shape of the distribution rather than its centre. The bull path reaches $46.39 and the bear $3.07 — a fifteen-fold spread across six years, driven by a small number of binary events. QUILT-2.005's full readout rests on a 43-patient interim in which the six-month comparison did not clear significance. The convertible matures one quarter before the cash trough. Three-fifths of the equity sits with one holder whose promotional conduct has already drawn a warning letter.

None of that argues against owning it. It argues that position size should be set against the bear case rather than the base — because a $3.07 outcome is not a drawdown to be waited out, and the events that would produce it are knowable in advance. The catalysts in Section 10 are, in effect, the schedule on which this thesis will be settled.

On the platform question: the ambition is real and the science is not fanciful, but it is unproven where it counts. Sepsis in August 2027 and ResQ201A around 2029 are the two readouts that convert optionality into franchise. Until then ImmunityBio is a bladder-cancer company with credible options attached — and, on this construction, priced at roughly the value of the business with those options only partly counted.

What would move us to Buy: a clean QUILT-2.005 topline with significance beyond the durability endpoint; confirmation of Merck's supplement approval and first lot release; two consecutive quarters of accelerating sequential adds; or a first recognised ex-US revenue line.

What would move us to Sell: a further FDA promotional action; a complete response letter on papillary; a positive SunRISe-3; or a dilutive financing at a discount ahead of the December 2027 maturity.

14 APPENDIX — SOURCES

Every identifier below was checked against SEC EDGAR, FDA.gov, EMA.europa.eu, NICE.org.uk, ClinicalTrials.gov and DOI resolvers on 5 August 2026. Where a source carries a residual limitation it is flagged in amber at the point of citation. Nothing in the analysis rests on an unverified identifier. Footnote numbers mark the first point in the text at which each claim is made.

1 **ImmunityBio, Inc., Form 10-Q, quarter ended 30 June 2026**
SEC EDGAR, accession 0001326110-26-000079, filed 4 Aug 2026. Net product revenue $50,672K; cash $75,670K + marketable securities $281,701K; total liabilities $1,674,265K; stockholders' deficit $(1,046,629)K; 1,053,221,645 shares issued at 30 Jun, 1,059,836,273 outstanding at 31 Jul 2026; convertible note fair value $774,350K; revenue interest liability $415,086K.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000079/ibrx-20260630.htm

2 **ImmunityBio, Inc., Form 10-K, FY2025**
SEC EDGAR, accession 0001326110-26-000030, filed 23 Feb 2026. File No. 001-37507.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000030/

3 **ANKTIVA (nogapendekin alfa inbakicept-pmln) Prescribing Information**
US FDA, BLA 761336, approved 22 Apr 2024. §2 Dosage and Administration: "For Intravesical Use Only. Do NOT administer by subcutaneous or intravenous or intramuscular routes." §12.3: systemic exposure below the limit of quantitation.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf

4 **FDA OPDP Warning Letter to ImmunityBio, Inc.**
MARCS-CMS 725468, dated 13 Mar 2026, posted 24 Mar 2026. Cites TV advertisement US-ANK-250065-v1 and a podcast aired 19 Jan 2026. Follows untitled letters of 9 Sep 2025 and 7 Jan 2026.
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/immunitybio-inc-725468-03132026

5 **FDA approval of durvalumab (IMFINZI) with BCG for high-risk NMIBC; POTOMAC**
FDA announcement 28 May 2026. Trial publication: De Santis M, Palou Redorta J, Nishiyama H, et al. Lancet. 2025;406:2221–2234. DOI 10.1016/S0140-6736(25)01897-5. NCT03528694; n=1,018; DFS HR 0.68 (95% CI 0.50–0.93, p=0.0154). Presented ESMO 2025, Abstract LBA108.
https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-durvalumab-combination-bacillus-calmette-guerin-high-risk-non-muscle-invasive-bladder

6 **FDA approval of gemcitabine intravesical system (INLEXZO); SunRISe-1**
FDA announcement 9 Sep 2025, Janssen Biotech. Publication: Daneshmand S, Van der Heijden MS, Jacob JM, et al. J Clin Oncol. 2025;43(33):3578–3588. DOI 10.1200/JCO-25-01651. PMID 40737582. NCT04640623.
https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-gemcitabine-intravesical-system-non-muscle-invasive-bladder-cancer

7 **BOND-003 Cohort C (cretostimogene grenadenorepvec)**
Tyson MD, Nam JK, Joshi SS, et al. Lancet Oncol. 2026;27(8):983–993. DOI 10.1016/S1470-2045(26)00194-4.
https://doi.org/10.1016/S1470-2045(26)00194-4

8 **QUILT-3.032 pivotal trial (ANKTIVA + BCG, BCG-unresponsive NMIBC)**
Chamie K, Chang SS, Kramolowsky E, et al. NEJM Evid. 2023;2(1). DOI 10.1056/EVIDoa2200167 (online 10 Nov 2022). NCT03022825.
https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167

9 **QUILT-2.005 (ANKTIVA + BCG vs BCG alone, BCG-naive NMIBC)**
ClinicalTrials.gov NCT02138734. Randomised open-label phase 1b/2b; Cohort A enrolment completed at n=366, Feb 2026. Interim data (43 evaluable) presented at AUA 2024 Annual Meeting, 3–6 May 2024.
https://clinicaltrials.gov/study/NCT02138734

10 **HCPCS J-codes**
J9028 (nogapendekin alfa inbakicept-pmln, for intravesical use, 1 mcg) effective 1 Jan 2025. J9183 (gemcitabine intravesical system) effective 1 Apr 2026.
https://immunitybio.com/immunitybio-announces-permanent-j-code-j9028-for-anktiva-is-now-effective/

11 **NICE technology appraisal TA1163 — terminated**
Terminated 4 Jun 2026. Not recommended because the company did not provide an evidence submission.
https://www.nice.org.uk/guidance/ta1163

12 **ANKTIVA EU conditional marketing authorisation**
European Commission conditional MA announced 18 Feb 2026; CHMP positive opinion 11 Dec 2025. Marketing authorisation holder **ImmunityBio Ireland Limited** per EMA List of Medicinal Products under Additional Monitoring. Marketing authorisation number **EU/1/25/2002/001** per EPAR Annex I §8. Commission Implementing Decision **C(2026) 1197 final**, 16 February 2026, addressed to ImmunityBio Ireland Limited, verified against the EU Community Register. EMA product number EMEA/H/C/006622; batch release by Bilthoven Biologicals.
https://www.ema.europa.eu/en/documents/additional-monitoring/list-medicinal-products-under-additional-monitoring_en.pdf

13 **European BCG substrain availability**
Reported in urology trade press: Europe has access to six approved BCG substrains against one in the US. **Secondary source; not confirmed against an EAU or national regulator document.**
https://www.urologytimes.com/

14 **Merck TICE BCG capacity and Durham facility**
Merck corporate statement, "Addressing the global shortage of TICE BCG": investment of more than $650 million, expected fully operational by late 2026, capacity to triple. Vial capacity of 600,000–870,000 annually reported by Fierce Pharma.
https://www.merck.com/stories/addressing-the-global-shortage-of-tice-bcg/

15 **ANKTIVA wholesale acquisition cost**
The Medical Letter, "In Brief: Anktiva for Bladder Cancer," article 1705e, June 2024: "The wholesale acquisition cost (WAC) for one dose of Anktiva is $35,800."
https://secure.medicalletter.org/TML-article-1705e

16 **Oberland Capital Revenue Interest Purchase Agreement, Second Amendment**
ImmunityBio Form 8-K, event date 30 Mar 2026. $75.0M Third Payment; tiered rate increased to 5.625%–12.50% of worldwide net sales excluding China, Hong Kong and controlled territories (4.5%–10.0% before the Third Payment); steps down to 2.8125% if cumulative payments reach $375.0M by the 31 Dec 2029 Test Date.
https://www.sec.gov/Archives/edgar/data/1326110/000119312526133363/d139829d8k.htm

17 **Beneficial ownership — Soon-Shiong affiliates**
Schedule 13D/A filed by Cambridge Equities, LP, received 25 Feb 2026: 745,576,456 shares, 66.3%, calculated on 1,028,111,456 shares outstanding as of 19 Feb 2026, including 93,053,252 shares issuable to Nant Capital on note conversion within 60 days.
https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001326110&type=SC+13D&dateb=&owner=include&count=40

18 **Japan BCG Laboratory Tokyo-172 supply agreement**
ImmunityBio Form 8-K, event date 14 May 2026. Exclusive development and supply agreement for the Tokyo-172 strain[37] for the US and its territories; initial ten-year term from FDA approval.
https://www.sec.gov/Archives/edgar/data/0001326110/000119312526229153/d75270d8k.htm

19 **Cancer BioShield Memorandum of Understanding**
ImmunityBio press release, 27 May 2025. MOU with the Ministry of Investment of Saudi Arabia, KFSHRC and KAIMRC. Verbatim: "the MOU is non-binding and does not create any legal or financial obligations of the parties."
https://www.businesswire.com/news/home/20250527707769/en/

20 **Accord Healthcare European distribution partnership**
ImmunityBio press release, 19 Feb 2026. Accord to deploy an 85-person sales force across 30 countries; Dublin subsidiary opened to support the European launch.
https://secure.businesswire.com/news/home/20260219914846/en/

21 **Securities class action**
Douglas v. ImmunityBio, Inc., No. 2:26-cv-03261 (C.D. Cal.). Class period 19 Jan – 24 Mar 2026. Lead-plaintiff deadline 26 May 2026; motions filed and pending.
https://www.ktmc.com/ibrx-immunitybio-inc-class-action-lawsuit/

22 **Sepsis trial**
ClinicalTrials.gov NCT07578558. Phase 2, randomised, open-label; NAI + standard of care vs standard of care in critically ill adults with sepsis and persistent lymphopenia. Org ID ResQ2204-SEPSIS. Estimated start 6 Jul 2026; primary completion 3 Aug 2027.
https://clinicaltrials.gov/study/NCT07578558

23 **ResQ201A (NSCLC Phase 3)**
ClinicalTrials.gov NCT06745908; EU CTIS 2025-521221-32-00. NAI + tislelizumab + docetaxel vs docetaxel monotherapy in checkpoint-resistant advanced NSCLC. Primary endpoint overall survival; enrolment target ~460.
https://clinicaltrials.gov/study/NCT06745908

24 **Lymphopenia Expanded Access Program**
ClinicalTrials.gov NCT06956547. Expanded access for NAI in lymphopenia in refractory or relapsed solid tumours. FDA authorisation announced 2 Jun 2025.
https://clinicaltrials.gov/study/NCT06956547

25 **Recombinant BCG Expanded Access Program**
ClinicalTrials.gov NCT06810141, "ResQ132EX-NMIBC." Expanded access, status available.
https://clinicaltrials.gov/study/NCT06810141

26 **SunRISe-3**
ClinicalTrials.gov NCT05714202. Phase 3, open-label, randomised; TAR-200 ± cetrelimab vs intravesical BCG in BCG-naive high-risk NMIBC. Actual enrolment 1,135; primary endpoint event-free survival.
https://clinicaltrials.gov/study/NCT05714202

27 **Pembrolizumab real-world utilisation in NMIBC**
Squires P, et al. "Real-World Pembrolizumab Utilization Patterns for High-Risk Non-Muscle Invasive Bladder Cancer." Society of Urologic Oncology 23rd Annual Meeting, 2022, Poster 86. Optum Clinformatics Data Mart; 126 patients. Conference abstract, not a peer-reviewed article. See also

KEYNOTE-057: Balar AV, et al. Lancet Oncol. 2021;22(7):919–930. DOI 10.1016/S1470-2045(21)00147-9.
https://doi.org/10.1016/S1470-2045(21)00147-9

28 **BCG-exposed treatment patterns**
Giatsoglou M, et al. "Clinical Outcomes in Bacillus Calmette-Guérin–Exposed Non–Muscle-Invasive Bladder Cancer." JAMA Netw Open. 2026;9(4):e267470. DOI 10.1001/jamanetworkopen.2026.7470. Retrospective cohort, 26,876 patients.
https://doi.org/10.1001/jamanetworkopen.2026.7470

29 **Global sepsis burden**
Rudd KE, Johnson SC, Agesa KM, et al. Lancet. 2020;395(10219):200–211. DOI 10.1016/S0140-6736(19)32989-7. PMID 31954465.
https://doi.org/10.1016/S0140-6736(19)32989-7

30 **Persistent lymphopenia and sepsis mortality**
Drewry AM, Samra N, Skrupky LP, et al. Shock. 2014;42(5):383–391. DOI 10.1097/SHK.0000000000000234. PMID 25051284.
https://doi.org/10.1097/SHK.0000000000000234

31 **Saudi SFDA approvals**
ImmunityBio Form 8-K, event date 14 Jan 2026, accession 0001326110-26-000004. SFDA accelerated approval for metastatic NSCLC with checkpoint inhibitors and for BCG-unresponsive NMIBC CIS.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000004/ibrx-20260114.htm

32 **UAE Emirates Drug Establishment authorisation**
ImmunityBio Form 8-K, event date 29 Jul 2026, accession 0001326110-26-000071. Exhibit 99.1 states verbatim: ANKTIVA 0.4 mg intravesical registered under **No. 78609-45860-260486**; ANKTIVA 1.2 mg subcutaneous under **No. 78609-1572-260487**; first registration July 2026, validity through July 2031; Modern Pharmaceutical Company as local agent. **Company-reported; a public Emirates Drug Establishment register entry was not independently retrieved.**
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000071/ibrx-20260729.htm

33 **QUILT-3.055 (ANKTIVA, checkpoint-resistant NSCLC)**
ClinicalTrials.gov NCT03228667. Median OS 14.1 months presented at IASLC World Conference on Lung Cancer 2024; 14.3 months (95% CI 11.7–17.4) in the company release of 8 Sep 2025.
https://clinicaltrials.gov/study/NCT03228667

34 **Comparable company multiples**
Historical and current EV/Sales derived from company filings and market data via stockanalysis.com. **Pre-2021 figures are interpolated from quarterly market-capitalisation snapshots and carry approximately ±10–15% error. Sell-side estimates and the Guggenheim[40] NMIBC report referenced in the text could not be verified against a publisher source and are treated as directional.**
https://stockanalysis.com/stocks/ibrx/

35 **Operating cash flow — basis of the quarterly figure**
ImmunityBio Form 10-Q, quarter ended 30 June 2026. The Condensed Consolidated Statement of Cash Flows reports net cash used in operating activities of **$(141,853) thousand for the six months** ended 30 June 2026. The $66.5m quarterly figure used throughout this report is **derived** (six-month $141.9m less Q1 $75.4m) and is not a line item presented in the statement.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000079/ibrx-20260630.htm

36 **Nant Capital convertible promissory note**
Originating terms: Form 8-K filed 11 Dec 2024, accession 0001193125-24-274871, Item 1.01, Exhibit 1.2 (Second Amended and Restated Promissory Note, dated 10 Dec 2024). Verbatim: "a consolidated $505.0 million note… due December 31, 2027, bearing interest at 3-month Term Secured Overnight Financing Rate ('SOFR') plus 8.0% per annum… convertible in full (and not partially) at the holder's option, at a price per share equal to $5.427." Partial-conversion amendment: Form 8-K filed 26 Jan 2026, accession 0001326110-26-000014. Step-down to $480.0m: Form 8-K filed 31 Mar 2026, accession 0001193125-26-133363 — "converted $25.0 million… into 4,606,596 shares… the principal amount outstanding… is $480.0 million."
https://www.sec.gov/Archives/edgar/data/1326110/000119312524274871/0001193125-24-274871-index.htm

37 **SWOG S1602 (PRIME) — Tokyo-172 versus TICE BCG**
Svatek RS, Tangen C, Meeks JJ, et al. J Clin Oncol. 2026;44(suppl 4), Abstract LBA629. DOI 10.1200/JCO.2026.44.7_suppl.LBA629. Presented at the ASCO Genitourinary Cancers Symposium, 26–28 Feb 2026. NCT03091660. Non-inferiority HR 0.82 (95.8% CI 0.63–1.08); 5-year high-grade recurrence-free survival 64% (Tokyo-172) vs 58% (TICE); 5-year PFS 79% vs 79%; intradermal priming no benefit (HR 1.0, 95% CI 0.76–1.33). **Efficacy figures confirmed via named ASCO Daily News, UroToday and Urology Times coverage; the JCO abstract itself sits behind ASCO's subscriber wall.**
https://ascopubs.org/doi/10.1200/JCO.2026.44.7_suppl.LBA629

38 **Lung cancer incidence, Saudi Arabia and UAE**
IARC Global Cancer Observatory, **GLOBOCAN 2024 (v1.0, released July 2026)** — supersedes GLOBOCAN 2022. Saudi Arabia: 913 new lung cancer cases, both sexes, 2024 (rank 6, 3.7% of all cancers). UAE: 449 new cases (rank 5, 5.1% of all cancers; leading cancer cause of death in males). Underlying: Sung H, et al. CA Cancer J Clin. DOI 10.3322/caac.70090.
https://gco.iarc.who.int/media/globocan/factsheets/populations/682-saudi-arabia-fact-sheet.pdf

39 **Insider ownership — proxy record date**
ImmunityBio DEF 14A, accession 0001326110-26-000049 (document ibrx-20260429). Verbatim: "Dr. Patrick Soon-Shiong… and his affiliates owned, in the aggregate, approximately 62.5% of the company's outstanding common stock as of the Record Date." The 66.3% figure cited elsewhere derives from the Schedule 13D/A and is a broader measure including shares acquirable within 60 days.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000049/ibrx-20260429.htm

40 **Guggenheim Securities NMIBC industry report**
Divan V. "Biopharma: The NMIBC Revolution — Innovation Finally Starting to Flow in Bladder Cancer, Setting the Stage for Multiple New Mega Blockbusters." Guggenheim Securities, LLC, 22 September 2025. Verbatim: ANKTIVA "~$1.1Bn in PoS-adjusted global peak sales"; cretostimogene "$3.0Bn in WW probability-adjusted peak sales potential"; Inlexzo "WW PoS-adjusted peak sales potential of ~$4.6Bn."
https://www.guggenheimsecurities.com/getattachment/cc009dff-e00f-4705-9a62-7489e22b8d52/Biopharma-The-NMIBC-Revolution.pdf

41 **Going-concern disclosure — mitigated**
ImmunityBio Form 10-Q, quarter ended 31 March 2026, accession 0001326110-26-000059, filed 7 May 2026. Verbatim: "we believe that substantial doubt exists regarding our ability to continue as a going concern without additional funding or financial support," followed immediately by the alleviation statement resting on existing liquidity, product sales, equity offerings, and "our Founder… intent and ability to support our operations with additional funds, including loans from affiliated entities, as required, which we believe alleviates such doubt." This is a qualified/mitigated disclosure, not an unmitigated warning.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000059/ibrx-20260331.htm

42 **rBCG expanded access as a shortage-era differentiator**
ImmunityBio press release, 12 May 2025 (Form 8-K Exhibit 99.1). Verbatim: "We are seeing a steady growth in revenue as urologists increase their use of ANKTIVA to treat NMIBC carcinoma in situ (CIS) patients, particularly since we addressed the BCG shortage with the launch of our rBCG EAP in February… Nearly 200 urological practices are in early stages of implementation or have already begun administering rBCG to patients, many of them in rural areas where patients otherwise would not have access to this treatment."
https://www.sec.gov/Archives/edgar/data/1326110/000132611025000069/ibrx-2025512x8kexhibit991.htm

43 **J-code inflection**
ImmunityBio press release, 12 May 2025. Verbatim: "For the three months ended March 31, 2025—marking the first quarter with a permanent J-code that streamlined billing and reimbursement for prescribing providers—ImmunityBio achieved net product revenue of approximately $16.5 million, representing a 129% increase over $7.2 million in Q4 2024." Unit volume grew 150% over Q4 2024, with Q1 2025 volume exceeding all of fiscal 2024.
https://www.sec.gov/Archives/edgar/data/1326110/000132611025000069/ibrx-2025512x8kexhibit991.htm

44 **Prescriber breadth**
ImmunityBio Q3 2025 results. Richard Adcock, President and CEO: unit sales "grew nearly 6X year-to-date compared with full-year 2024, reflecting adoption both at leading research centers and in community urology clinics, including rural areas." Q3 2025 product revenue $31.8m, a 434% increase over Q3 2024.
https://immunitybio.com/driven-by-strong-demand-immunitybio-reports-467-year-to-date-unit-growth-and-75-million-in-sales-year-to-date-up-434-from-q3-2024/

45 **INLEXZO launch trajectory**
Johnson & Johnson Q2 2026 earnings call, 15 July 2026. Jennifer Taubert: INLEXZO "is outperforming recent competitive launches, with one in three eligible patients[45] starting on the regimen." CFO Joseph Wolk attributed the $400m operational sales guidance increase primarily to pharma, "particularly due to the strong performance of products like ICOTYDE, INLEXZO, and TREMFYA." J&J does not break out INLEXZO revenue as a separate reported line.
https://www.investor.jnj.com/investor-news/news-details/2026/Johnson--Johnson-reports-Q2-2026-results-raises-2026-outlook/default.aspx

46 **BCG reimbursement mechanics**
HCPCS J9030, "BCG live intravesical instillation, 1 mg," effective 1 July 2019, replacing J9031. National Medicare fee rate $2.821 per milligram; a ~50mg vial yields $141.05 under the Part B fee schedule. Practices bill the instillation separately under CPT 51720.
https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56754

47 **Instillation fee independent of dose**
Urology coding guidance on the J9031-to-J9030 transition: "Reporting of code 51720 at full value is appropriate regardless of dose." The procedure fee therefore survives substitution of free investigational product for billable TICE; only the drug line is lost.
https://info.prsnetwork.com/prs-alert-bcg-update-7-1-19/

48 **Pre-approval drug substance and manufacturing capacity**
ImmunityBio press release, 7 May 2024: drug substance "completed and successfully qualified for fill finish… sufficient for 170,000 doses of 400mcg ANKTIVA," with the El Segundo site to have "capacity to manufacture drug substance sufficient for a million doses of ANKTIVA a year" and the Dunkirk, New York fill-finish facility — 400,000 square feet — "on track to be completed in 12-18 months with capacity to produce a million vials annually."
https://ir.immunitybio.com/news-releases/news-release-details/immunitybio-completes-gmp-drug-substance-manufacturing

Residual limitations. Two items remain short of full independent confirmation and are flagged in place. The UAE registration numbers are company-reported via SEC exhibit; no public Emirates Drug Establishment register entry was retrievable. The SWOG S1602 efficacy figures are confirmed

through named ASCO Daily News, UroToday and Urology Times coverage of the presentation, because the JCO abstract sits behind ASCO's subscriber wall — the abstract number, author, DOI and conclusions are nonetheless verified. Pre-2021 comparable-company multiples are interpolated from quarterly market-capitalisation snapshots and carry approximately ±10–15% error. Every other identifier in this appendix was retrieved from the originating document.

AUTHOR, POSITION DISCLOSURE AND IMPORTANT NOTICES

Author. This report was researched and written by Edwin P. Jacques (X/Twitter: @EdwinPJacques). It represents the author's own analysis and opinions and is not issued by, endorsed by, or affiliated with ImmunityBio, Inc., any broker-dealer, investment adviser, or research firm.

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Basis of preparation. Financial figures are drawn from ImmunityBio's Form 10-Q for the quarter ended 30 June 2026 (filed 4 August 2026) and prior filings. Clinical data are from FDA labels, pivotal trial publications, and conference presentations. Cross-trial efficacy comparisons involve studies with differing eligibility criteria, response definitions, biopsy protocols, and follow-up durations; they are presented for orientation and are not evidence of comparative efficacy. Sponsor-funded indirect comparisons and cost-effectiveness models published by ImmunityBio and Johnson & Johnson reach opposing conclusions by construction and are excluded from our analysis. Revenue projections are the author's model, not company guidance — ImmunityBio does not issue financial guidance. Analyst consensus derives from a coverage universe of roughly three to five contributing estimates and should be treated as directional. This is analysis, not investment advice; every input in the model is an assumption open to revision.