ImmunityBio, Inc. | $7.32 at publication — $50m a quarter. 366 patients. $3 or $46.

NASDAQ: IBRX · ~1.06bn shares · market cap ~$7.8bn · enterprise value ~$9.1bn

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STANCE	FY26E REVENUE	FY27E REVENUE	FY28E REVENUE	CASH-FLOW BREAKEVEN
Speculative Buy	**$217m**	**$420m**	**$890m**	**Q1 '28**
Multi-year horizon; size for the tails, not the point estimate	Consensus ~$222m	Consensus ~$436m	Consensus ~$1.1bn	Trough cash ~$113m

The market is pricing a bladder-cancer drug. It could be a platform.

ImmunityBio's ANKTIVA is approved in the United States for one use — bladder cancer, in patients whose standard treatment has already failed. It sells about $50m a quarter, and that one indication is roughly half of what the market is paying for. The drug acts on the immune system, and nothing in that mechanism is particular to the bladder. The bladder is where it is delivered, and where it was approved first.

What ANKTIVA actually is: an engineered version of interleukin-15, a signaling protein your body uses to tell immune cells to multiply. It expands natural killer cells and the memory T cells that do the actual killing. In the bladder it is dripped in through a catheter and works locally. For patients receiving it, the typical alternative is surgical removal of the bladder — a procedure that kills 5–11% of patients within ninety days.[2]

That is what ANKTIVA is preventing. In the trial that won approval, 62% of patients had no detectable cancer left, a complete response, and **84% still had their bladder three years later**.[8] Revenue has grown for eight consecutive quarters at roughly 99% gross margin, because the drug substance was manufactured years ago and already written off.

On the numbers that follow, that is perhaps a third of what the company could be worth.

Why the mechanism scales

Checkpoint inhibitors — Keytruda, Opdivo, IMFINZI, the drugs that reshaped oncology over the past decade — work by releasing a brake tumors use to switch off immune cells. These drugs are extraordinary when they work. They fail when there are too few immune cells for the release to matter. A cold tumor. An exhausted repertoire. A patient whose lymphocyte count was flattened by chemotherapy.

An IL-15 superagonist supplies what that deficit lacks: functional effector cells for the release to act on.

Which means the drugs everyone assumes are ANKTIVA's competitors may be its partners. Saudi Arabia approved it in January *specifically for use with checkpoint inhibitors* in lung cancer.[31] The UAE followed six

months later.[32] In a trial of patients who had already progressed on a checkpoint inhibitor — a group with almost nothing left to try — adding ANKTIVA produced median survival of 14.1 months against a historical benchmark closer to eight.[33]

If that holds, the relevant population stops being twelve thousand bladder patients and becomes every solid-tumor patient who fails immunotherapy. That is a pool of hundreds of thousands rather than tens of thousands.

Which is why the same molecule is in play across five indications rather than one: the approved bladder use, plus first-line bladder disease, lung cancer, immune reconstitution, and sepsis. One drug, one safety database, one manufacturing base — and five ways it could matter.

So why is the stock near $7?

Because the FDA has approved only a slice of the bladder indication — patients whose disease returned after BCG. The market discounts the other four.

The lung-cancer evidence is a single-arm trial: every patient received the drug and there was no control group, so it can show association but not cause. The one randomized trial stopped early at 102 patients, and its headline finding was a blood marker rather than survival.[55] The confirmatory Phase 3 does not read out until around 2028.

And the class has a history. Genentech, Novartis and Eli Lilly each funded IL-15 programs; a decade on, not one of those three programs has reached approval.[105] Sotio discontinued its own IL-15 receptor fusion in June 2026 after interim data showed too little efficacy to justify randomized trials, while Nektar's remains in a Phase 2/3 that does not complete until 2029. ANKTIVA is the only IL-15 agonist approved anywhere, which is a statement about the field's difficulty as much as about this company.[189] ANKTIVA has yet to be approved for systemic use by injection in the US.

The open question

The bladder drug sells; that much is settled. The rest turns on whether this is a bladder-cancer company that happens to have a pipeline, or a platform that happens to have started in bladders.

The market currently prices the first. This model assumes something between the two: bladder does the work through 2028, with the platform carried as option value at 15–35% probability rather than at face value. Working through it program by program gives roughly **$3 in the bear case, $21 in the base and $46 in the bull**, by 2032, against a share price near $7.

That spread describes a shape rather than a target. The outcome is close to binary, and the market is priced nearer the failure end than the success end.

I own the stock, substantially. Treat what follows as an interested party's argument. If the platform thesis fails the bear case is not a drawdown to wait out — it is $3.07. Everything below shows the work — the evidence, the model, and the places the case is weakest.

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01 SUMMARY

ANKTIVA sells $50.7m a quarter[1] after eight consecutive quarters of growth, at roughly 99% gross margin, with a permanent J-code, NCCN listings in two settings, and a narrowing operating loss. The product works. The investment question is how fast it can scale, and against what.

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

First, what limits this business is evidence and timing, not BCG supply. ANKTIVA is approved in the US only in combination with BCG, so supply constrains the business the drug 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 is given on the *same* BCG schedule the patient already receives, so it adds no BCG demand of its own. Urologists also prioritize high-risk naive patients during shortages. What actually decides 2028 is whether QUILT-2.005's full readout holds up and how fast the FDA moves.

Second, the competitor that matters is not the one with the head start. AstraZeneca won the first approval in the BCG-naive setting in May 2026, on randomized Phase 3 data, in the same first-line population ANKTIVA is filing for. But ten weeks on, NCCN lists IMFINZI plus BCG at category 2A but only in its lowest preference tier, useful in certain circumstances[49]; AstraZeneca withdrew its European filing in the same setting[50], and its own Q2 call gave the launch a single passing mention. Infusion in an oncology suite against instillation by the urologist at the same visit as BCG is one of four headwinds it carries, and not the largest. The pressure is coming from the other direction. INLEXZO is ramping faster than ANKTIVA did from an equivalent launch point, reporting sales above $30m in its second full quarter and nearly one in three eligible patients starting on the regimen a quarter later[142], helped by needing no BCG and by an installed sales infrastructure. It sells into the same second-line pool. That is the competitive risk worth watching, and Section 03 sets out what would confirm it — two consecutive quarters in which ANKTIVA's sequential adds fall below the modeled band while INLEXZO's insertions keep growing.

Third, the Gulf approvals matter for more than lung cancer. ANKTIVA's subcutaneous approvals in Saudi Arabia and the UAE 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 12**.

Fourth, 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 $113m — tight but not forced. The larger issue is the $480m convertible maturing December 31, 2027[36], one quarter ahead of that trough, examined in **Section 16**.

02 UNIT ECONOMICS AND HOW THE DRUG GETS PAID FOR

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.

Bladder cancer is a disease of the old: median age at diagnosis is 73, and roughly three-quarters of new cases are diagnosed after 65.[109] The payer mix follows from the age. Across 163,949 high-risk patients in the National Cancer Database, 62% were covered by Medicare and 32% commercially, with Medicaid at 3% and the uninsured at 2%.[110] That is why the analysis below turns on Medicare mechanics rather than commercial contracting — for the bladder cancer business in the US, Medicare largely is the market.

QUARTER	NET PRODUCT REVENUE	SEQUENTIAL Δ$	SEQUENTIAL %	OPERATING CASH BURN	CASH & SECURITIES
Q1 2025	$16.5m	—	—	$(85.9)m	$61.6m
Q2 2025	$26.4m	+9.9	+60%	$(79.7)m	$153.7m
Q3 2025	$31.8m	+5.4	+20%	$(68.9)m	$257.8m
Q4 2025	$38.3m	+6.5	+20%	$(70.4)m	$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. Quarterly burn is derived from the cumulative cash-flow statements.[133]

The pattern: percentage growth decelerates while the absolute dollar adds hold steady. The last four quarters added $5.4m, $6.5m, $5.9m and $6.5m, against $9.9m in the quarter before them. Constant adds imply a constant rate of new patient starts, since each patient contributes across several quarters of dosing, so a steady intake produces a straight line rather than a curve. Why the intake is steady rather than accelerating is the question **Section 05** takes up.

The burn tells a cleaner story. It improved $13.2m year-on-year, from $79.7m to $66.5m, on a quarter-standalone basis derived from the half-year statements. Revenue over the same period rose $24.3m, which is nearly twice the improvement in burn — so cash operating costs grew by roughly $11m even as the company moved closer to breakeven. The improvement came from revenue rather than from cutting costs.

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 realization is approximately **$29,714 per dose**. The US 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**, or in quasi-steady state some **130–200 new patient starts per quarter** — 550–800 annually. The BCG-unresponsive pool is not directly counted, and the derived range runs from roughly 7,000 to 13,000 depending on how strictly the label definition is applied.[136] Penetration is therefore somewhere between 4% and 11%, and most of the approved population is untreated on any reading.

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 capitalized, 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 normalizing 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.

Two details bound how long that advantage runs. Finished drug product carries a three-year shelf life, extended from two in September 2024, while bulk substance holds a multi-year life before it is filled.[92] The company reserves $0.2m against excess and obsolescence and has recorded no inventory write-downs since approval. At roughly 1,700 doses a quarter, most of the 170,000-dose stockpile will never be filled and sold before it lapses. That costs nothing in reported earnings, since it was expensed to zero before approval. It does mean the margin advantage ends when current supply is consumed rather than when the stockpile is exhausted.

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 — utilization below one percent. Under ASC 330-10-30-7 abnormal idle capacity must be expensed currently rather than capitalized, 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, and idle-capacity charges partly replace them. The accounting can say what the plant costs; what it is for is a different question, taken up in **Section 10**. The model treats this as approximately neutral and does not credit an opex reduction. Capital spending offers no relief either. It fell from $30.6m in 2023 to $3.8m in 2025 as the original build finished, then turned back up: $5.3m in the first half of 2026 against $2.2m a year earlier. A lease amendment effective January 2026 commits the company to at least $40.0m of capital spending by the end of 2028, and management has referenced roughly $50m of fill-finish equipment for the site.[134]

How the practice gets paid, and why the price is hard to move

ANKTIVA is a buy-and-bill drug. That single fact shapes the competitive analysis in this report more than any clinical result does, because it determines who can administer the drug and what they earn for doing so. J9028 is the permanent billing code assigned to ANKTIVA, and having one is what lets a practice be paid for the drug rather than only for the procedure.

Two consequences follow. The practice buys the vial and bills the payer, so its margin is *a percentage of the price* — roughly $2,150 a dose, which a list-price cut would reduce proportionally.[138] And that drug margin runs between eight and twenty times what Medicare pays for the instillation itself.[106] A urologist who administers ANKTIVA keeps it; one who refers the patient out for an infusion earns the referral and nothing else.[58] BCG inverts the arithmetic exactly: at roughly $141 a vial the add-on is about eight dollars, and the procedure fee is the entire economics. That asymmetry is what **Section 04** rests on.

The same arithmetic erodes the price slowly without anyone deciding anything. Average sales price is a trailing average of the manufacturer's own net realizations, so every discount, rebate, chargeback and 340B unit feeds back into it two quarters later and lowers the reimbursement ceiling for everyone. A deliberate cut accelerates a ratchet that only turns one way.

Two further constraints make a cut costly to undo. A list-price reduction propagates into average manufacturer price, Medicaid best price and the 340B ceiling,[59] resetting floors that cannot easily be raised again, which is why manufacturers reach for copay support and rebates rather than list price. None of that argues against cutting. It makes the cut one-way, so the test is whether the volume it buys is worth a ceiling that cannot be raised afterwards — a question about the size of the response, not about the direction. And the practice buys at wholesale acquisition cost and is reimbursed at ASP plus six percent, so the spread it earns is set two quarters in arrears against a price it paid today.

A 99% gross margin, twenty-five years of drug substance already expensed and a plant running below one percent of capacity together suggest an obvious move: cut the price, expand volume, fill the factory.

The clearest thing a cut would do is lower what the patient owes. At 20% coinsurance the first dose costs roughly $7,160 today, and this population is largely elderly and on a fixed income.

What a cut would not do is change who gets treated. When Medicare cut reimbursement for androgen-deprivation therapy in 2003, urologists reduced the use for which there was no evidence of benefit by more than thirty percent and did not reduce appropriate use at all.[108] Margin moves which agent a practice reaches for among comparable options, and whether it administers rather than refers. It does not appear to move clinical judgement about who needs treatment,[107] and that is the shape of the effect assumed here.

The case where a cut reduces adoption is narrower still. It requires a cut deep enough to push ANKTIVA's retained margin below that of a bladder-sparing competitor the same practice could administer instead. The sharper risk sits upstream of prescribing: a practice that cannot cover its acquisition cost stops buying the drug, or stops taking Medicare patients altogether, and the patient never reaches the conversation.

Coverage friction has largely resolved. The code is permanent, pass-through runs to September 2027, NCCN carries Category 2A listings in two settings, and the company reports commercial and government programs covering more than 240 million lives.[111] That figure rose from 100 million three months after approval and has held since January 2025.

Cost-sharing has not resolved. Medicare Part B coinsurance is 20%, roughly $7,160 on the first dose and above $100,000 across a full course. The manufacturer copay card cannot be used by Medicare, Medicaid or VA patients under federal anti-kickback rules. The median patient therefore depends on Medigap, a Medicare Advantage out-of-pocket cap, or the company's own assistance program.[112] The residual exposure falls on the roughly one in eight traditional-Medicare beneficiaries with no supplemental cover at all. That is a barrier for an individual patient and a small one for the forecast.

Price moves volume outside US buy-and-bill. Gulf sales are tender and cash-pay without ASP mechanics, and a hypothetical inpatient sepsis indication would be bundled into a DRG where a $35,800 dose is unviable. Both are separate price tiers, not arguments for a single lower global price — and publishing a low international price carries its own hazard, discussed under risks. The model therefore holds US price constant and treats capacity as optionality on indication breadth rather than on price.

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 favoring their own product; these are marketing-adjacent rather than evidence.

Four things are worth carrying out of the tables.

First, two competitors need no BCG and ANKTIVA does. TAR-200 is a gemcitabine-releasing device placed in the bladder. Cretostimogene is an oncolytic virus. Neither depends on a supply that has been short for years, and ANKTIVA cannot be given without it. That is the structural disadvantage, and the reason **Section 05** spends so long on supply.

Second, IMFINZI is the only competitor approved in the US in the BCG-naive setting. That setting is the largest single line in this model, sized in **Section 04**. IMFINZI's weaknesses there matter more than its headline numbers do.

Third, the response rates are not comparable across rows. They sit in one table for convenience. The highest number does not win.

The fourth is not in the tables at all, because tables hold profiles rather than trajectories. INLEXZO is ramping faster than ANKTIVA did. J&J reported sales slightly above $30m in Q1 2026, its second full quarter. After a permanent J-code took effect on April 1, its Q2 call reported nearly one in three eligible patients starting on the regimen, with new patient insertions up roughly 75% over the prior quarter.[142] Some of that pace is machinery rather than product. J&J ran SunRISe-1, the registrational TAR-200 trial in BCG-unresponsive disease, at 142 sites across fourteen countries, and opened SunRISe-2, its muscle-invasive companion study, at 272 locations, against 32 US sites for QUILT-3.032, so at approval hands-on familiarity with the device already existed at several times the number of institutions that had ever touched ANKTIVA. Its representatives had also been calling on US urologists since ERLEADA's US approval in 2018.[170] The pace still stands despite the worse tolerability the table shows, which says prescribers are not weighting grade ≥3 rates the way the profile comparison implies. The second-line share assumptions already absorb competitive decay; what would break them is two consecutive quarters in which ANKTIVA's sequential revenue adds fall below the modeled band while INLEXZO's insertions keep growing. J&J does not disclose INLEXZO revenue separately, so the insertions commentary on its earnings calls is the number to watch.

AGENT	STATUS	COMPLETE RESPONSE	DURABILITY	GR ≥3 TRAE	ADMINISTRATION
ANKTIVA + BCG ImmunityBio	APPR APR'24	62% 95% CI 51–73[8] (n=77)	51% probability maintaining CR ≥45mo; among responders, 84% cystectomy-free and 99% DSS at 36mo[137]	~3%	Intravesical, weekly ×6 + maintenance to 37mo
INLEXZO (TAR-200)[645] Johnson & Johnson	APPR SEP'25	82.4% 95% CI 72–90 (n=85)	51% maintained ≥12mo; median DOR 25.8mo	12.9%	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%	Intravesical, once every 3 months
KEYTRUDA Merck	APPR JAN'20	~41% at 3 months	Median DOR 16.2mo (Cohort A)— the 43.5% 12-month DFS often quoted is Cohort B, papillary-only[137]	Systemic	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%**	Intravesical monotherapy, office-based
Detalimogene (EG-70) EnGene	BLA 2H'26	62–63% at 6 months	Immature	Low	Intravesical non-viral gene therapy

Table 2 · BCG-unresponsive NMIBC with carcinoma in situ. ANKTIVA's durability figures rest on the longest follow-up among the newer agents, a median 29.3 months, and come from a conference presentation rather than a peer-reviewed publication. Rows run ANKTIVA first, then by approval date, newest first.

AGENT	PRICE BASIS	DOSES	COURSE COST	VISITS, YR 1	PATIENT SHARE
ANKTIVA + BCG ImmunityBio	ASP $37,722[139]	**12** median, 2–30	**$454,694** range $76k–1.14m	**15**	$90,939
INLEXZO (TAR-200) Johnson & Johnson	WAC $67,407 no ASP yet [140]	***~9*** estimated, 5–14 [140]	***$606,663*** range $337k–944k	~10–11	***$121,333***
ADSTILADRIN Ferring	ASP $64,332[139]	**2** median, 1–5	**$128,663** range $64k–322k	4	$25,733
KEYTRUDA Merck	WAC $12,272[141]	**~6** derived, no range [141]	**$73,632**	~6	$14,726

Table 3 · What a course costs and what it takes to deliver, for the four approved agents with a published price. Costs are built from doses observed in the pivotal trial, with the range beneath. *Italic figures are estimated.*

Two things follow. Including the BCG its US label requires, ANKTIVA costs three to six times what the two cheaper alternatives cost, and the patient's twenty percent share is roughly $91,000 against $26,000 for ADSTILADRIN and $15,000 for KEYTRUDA. INLEXZO appears to cost more, though its figure is estimated: the pivotal paper publishes no median, so nine systems is the midpoint of what the schedule and the disposition counts allow. The ranges overlap heavily in any case. ANKTIVA runs from $76,000 to $1.14m depending on how long a patient stays on it. That is a wider bracket than INLEXZO's. The comparison holds at the median rather than at either end. And it takes fifteen visits in the first year where ADSTILADRIN takes four. In a population with a median age of 73, visit burden bears on adherence as directly as price does. The obvious response to a gap that size is to cut the price. **Section 02** sets out why the arithmetic there is not the ordinary one. Average sales

price ratchets in one direction, and under buy-and-bill a lower price also shrinks what the practice retains for administering it.

The comparison has limits. INLEXZO's pivotal publication does not report how many systems patients received, so its course is a bracket rather than a figure: five systems for a patient stopping at the first assessment, fourteen at the label maximum. That range spans ANKTIVA's course rather than sitting to one side of it, which is the honest answer until the dose count is published. The same platform is being extended beyond this tier: Erda-iDRS, the erdafitinib-releasing system formerly TAR-210, reported final phase 1 results at the EAU congress in March 2026, with an 89% complete response rate and a median response duration of 18 months in intermediate-risk disease carrying fibroblast growth factor receptor alterations, and 83% recurrence-free survival at twelve months in the high-risk, BCG-experienced, papillary-only cohort.[161] The intermediate-risk tier sits outside the pools this model counts, but that second cohort is the population behind ANKTIVA's papillary supplemental application, approached with a device rather than a vial and in patients selected by mutation rather than by risk category. Two agents are priced at average sales price and two at list, because INLEXZO has held a permanent billing code only since April 2026.[140] Those bases are not interchangeable, and the patient-share column inherits whichever its row uses.

AGENT	REGULATORY	EFFICACY	DURABILITY / BLADDER PRESERVATION	NCCN
ANKTIVA + BCG	PDUFA JANUARY 6, 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 4 · BCG-unresponsive papillary-only disease (Ta/T1 without CIS). No agent holds an FDA label for this population, and NCCN Category 2A listings already enable reimbursed use. Rows run ANKTIVA first, then by strength of evidence.

AGENT	STATUS	DESIGN	RESULT	BCG?
IMFINZI + BCG[5] AstraZeneca	APPROVED MAY 28, 2026	POTOMAC — randomized 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 — randomized, 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	Randomized Phase 3 vs BCG, n=1,135	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 optimized admin; follow-up only 4.6mo	None
Pembrolizumab + BCG Merck	KEYNOTE-676 COHORT B	Randomized, ~975 patients	Readout pending	REQUIRED

Table 5 · BCG-naive high-risk NMIBC — the setting underwriting consensus 2028 estimates.[40] Rows run by how far each program has advanced, from approved to pending readout. This is the only table containing randomized controlled evidence, and ANKTIVA does not lead it.

Three points follow from Table 5. AstraZeneca reached this market first with a larger randomized 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.

04 THE BCG-NAIVE SHARE QUESTION

The single most consequential assumption in this model is how much of the BCG-naive population ANKTIVA captures. More of the 2032 valuation turns on that one number than on any clinical result.

The pool moves in two directions, and the net is mildly favorable over the forecast. Age-adjusted incidence has fallen about 1.5% a year since 2005 as smoking rates decline. The absolute number of new cases is projected to grow 1.5% to 1.8% a year through 2040, because the population is ageing into the disease faster than the rate is falling.[113] A model running to 2032 should assume a slowly growing eligible population, not a shrinking one.

It is largely a question of workflow rather than data. Community urologists manage these patients, and what a practice can administer in its own rooms decides more than what a trial reported. IMFINZI has three further obstacles beyond that one, and the interim durability figures need discounting before they can carry a forecast. The base case is anchored on ANKTIVA's own second-line launch. The bull case requires something different in kind — not a faster launch, but a change in what the guidelines recommend.

Where these patients are treated

Site of care decides more than the data. 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 roughly two-thirds of US urology practices cannot deliver in-house[52], 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 margin is not frictionless. Clearing-house claims data for January through August 2026 show 31.55% of J9028 claims denied and an average of 25.8 days to payment, so the practice fronts a five-figure drug cost into a roughly one-in-three chance of a denial cycle.[175]

The precedent is unusually clean. Pembrolizumab was approved by the FDA 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**[27] 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.

WHERE THE ARGUMENT ABOUT WHO ADMINISTERS THE DRUG STOPS

Only about a third of practices can infuse, and that third is concentrated rather than spread evenly. The large integrated groups — Solaris Health, United Urology, US Urology Partners — built infusion and oncology infrastructure years ago to retain advanced prostate cancer patients. Those groups can administer durvalumab and bill it under J9173, durvalumab's own billing code, at ASP plus 6%, keeping the margin. For them the site-of-care obstacle does not exist.

What binds is narrower and more durable: most NMIBC is managed outside those groups, in community and solo practices where referral means losing both the patient relationship and the revenue, and where standing up checkpoint-inhibitor toxicity management for a curable non-invasive disease is a poor trade. The pembrolizumab precedent flatters the comparison too — that was salvage monotherapy in an older, sicker population on single-arm data, against IMFINZI's first-line add-on with randomized Phase 3 evidence.

What else stands in IMFINZI's way

Three obstacles matter more than where the drug is given. First, **NCCN lists the regimen only in its lowest preference tier**. For BCG-naive high-risk disease, the Bladder Cancer guideline gives BCG plus durvalumab category 2A evidence but lists it as useful in certain circumstances, beneath BCG induction and maintenance and intravesical chemotherapy. Its discussion text still declines to endorse POTOMAC, citing risk-benefit and long-term toxicity, and sasanlimab plus BCG from CREST is not listed.[49] The same entry appears in the BCG-unresponsive CIS column, ANKTIVA's labeled population, where ANKTIVA sits a tier higher as other recommended. POTOMAC's survival data remains immature — hazard ratio 0.80, confidence interval 0.53 to 1.20, at roughly 14% maturity. Category 2A is evidence payers generally accept, so the obstacle is preference rather than coverage.

Second, **toxicity reads differently in curative-intent disease**. Clinicians surveyed in late 2025 reported minimal use of systemic immunotherapy in NMIBC and described checkpoint-inhibitor toxicities as feeling disproportionate for a non-muscle-invasive setting.[51] POTOMAC's 21% grade 3/4 rate sits against roughly 4% for BCG alone.

Third — and this is the one most easily missed — **IMFINZI does not escape the BCG shortage, because it is given with BCG.** The same clinicians report that the requirement for concurrent BCG has itself limited uptake, since scarce supply is rationed to naive patients rather than to combination regimens.[51] Every constraint the shortage imposes on ANKTIVA in this setting, it imposes on IMFINZI too.

Two further signals from the first ten weeks. AstraZeneca **withdrew its European filing** for the BCG-naive indication[50], and its Q2 2026 earnings call spared the launch one sentence, with no patient-start or channel metrics disclosed. Read both carefully. It is far too early for uptake data, and silence at this stage is ambiguous. What can be said is that the observable record so far shows a launch tracking the structural obstacles rather than outrunning them.

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 randomized 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	Retained only by the ~1 in 3 practices with infusion capability; the rest refer out and earn nothing	ANKTIVA
Guideline status	Category 2A, other recommended, in both BCG-unresponsive settings; not listed in BCG-naive disease	Listed by NCCN at category 2A but in its lowest preference tier, useful in certain circumstances, in BCG-naive disease and BCG-unresponsive CIS[49]	IMFINZI, NARROWLY
Course cost	$750k–$1.1m list	~$170k–$200k drug acquisition	IMFINZI

Table 6 · Competitive position in BCG-naive high-risk NMIBC. Safety and workflow favor ANKTIVA; evidence maturity and cost favor IMFINZI.

Weighing the evidence

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 secondary to workflow.

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 months, and among responders 84% cystectomy-free at 36 months)[137] 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. That is a materially harder bar, and it is why the second-line figures cannot simply be carried across.

Which way the biology points is less obvious than the arithmetic. One reading is a ceiling: where BCG already works, there is less room to improve on it. The other runs the opposite way. ANKTIVA acts by amplifying the immune response BCG provokes, and in a patient whose BCG response has already failed there is less of that response to amplify. An intact pathway should therefore give the combination more to amplify, not less. That is the company's reading, and the mechanism supports it.

The only direct evidence is the QUILT-2.005 interim, and it favors the second reading: the combination did beat working BCG, 84% against 52% maintaining complete response at nine months. It also rests on 43 evaluable patients, with a result that crosses the significance threshold on one or two of them either way. Suggestive, then, rather than determinative — which is why this model waits for the full 366-patient readout instead of extrapolating 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. At roughly twenty patients an arm, one or two changing outcome moves either timepoint across the threshold in either direction — the six-month result missed at 0.0536 and the nine-month cleared at 0.0455, both by a single patient. Neither the numerators, the confidence intervals, nor whether the two timepoints were pre-specified with any multiplicity adjustment has been disclosed.[93] 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 modeling 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 roughly 31,000 first-line patients a year will impose prior authorization and probable step-through.

Building the base case

The base case therefore carries roughly **4.5% of the eligible pool in launch year 2028**. That figure is anchored on ANKTIVA's own second-line launch rather than on a generic band. Two named comparators bound it, both measured from the date a working reimbursement code existed rather than from approval. That distinction matters here: ANKTIVA's permanent J-code took effect on January 1, 2025, roughly nine months after approval, and the pre-code quarters are not representative of anything.

PRODUCT	FIRST FULL POST-CODE YEAR	REVENUE	IMPLIED PATIENTS	SHARE OF POOL
ADSTILADRIN Ferring; J9029 effective Jul 2023	FY2024	~$77m	~320	~2–3%
ANKTIVA J9028 effective Jan 2025	FY2025	$113.0m[56]	~400–650	~3–5%
Pembrolizumab IV, oncologist-administered	2020–21	—	126 over 2 yrs[27]	<1%

Table 7 · Launch-year penetration of the eligible pool, measured from reimbursement availability rather than approval. Both comparators operated in the harder second-line setting.

The J-code effect is the reason the pre-code period must be excluded. The first quarter carrying J9028 delivered $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 fiscal 2024.[43] Averaging that suppressed period into a "first year post-approval" figure understates what the current configuration can do. A BCG-naive launch would inherit the working code, the salesforce and the prescriber relationships, and would skip the friction ANKTIVA itself paid in 2024 — though an organization sized for the second-line niche would still have to broaden across a pool four times larger, a qualification taken up in **Section 05**.

Against that reference class, 4.5% for a naive launch is central-to-conservative rather than aggressive. It assumes a first-line add-on roughly matches what the same company achieved in the harder second-line setting. The workflow fit is better, because the drug is given alongside BCG the patient already receives. Against that sits payer resistance across a pool four times larger: roughly 31,000 newly-treated high-risk patients a year, against a derived 7,000 to 13,000 becoming BCG-unresponsive.[13657] Years two and three ramp toward 7–12% and 12–20%, gated on a clean full readout, guideline inclusion and coverage.

What the bull case requires

> The bull case describes a transition rather than a launch curve. The bull assumes 8–10% in launch year and 25–35% by year three, and those figures are not drawn from the table above — deliberately. The comparators there describe drugs that remained *optional*: one more branded choice a urologist may or may not reach for. The bull case describes a different state, in which QUILT-2.005's full readout demonstrates a durability advantage over BCG alone large enough to earn NCCN inclusion in the naive setting, at which point the question stops being whether a given physician adopts and becomes what fraction of eligible patients receive the recommended regimen.
>
> On that path the terminal ceiling is roughly **50–70%** of the eligible pool rather than the low teens, and 25–35% by year three represents a partial transition toward it rather than an endpoint. The ceiling stops well short of universal because BCG maintenance itself has poor real-world completion — a meaningful share of patients never finish the schedule the add-on rides on.
>
> This is a conditional argument, and the condition is load-bearing. Absent a clean readout and guideline inclusion, the launch-analog band applies and the bull collapses toward the base. This conditional argument is also distinct from the durability read-across rejected earlier in this section: that argument fails because a second-line efficacy edge over failed BCG does not imply an edge over working BCG. Prescriber familiarity, workflow comfort and billing experience do carry across — but they accelerate adoption of a drug that has independently proven itself in the naive setting, rather than substituting for that proof.

05 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 narrows the second-line funnel for every agent in it, 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 point carries 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 prioritized 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 an argument for withholding scarce supply from that combination. That pressure does not apply to first-line use.

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

ImmunityBio has a second source of BCG. Recombinant BCG, or rBCG, is a genetically modified version of the same bacterium, manufactured by the Serum Institute of India. It is not approved in the United States. The FDA authorized it in February 2025 under an expanded-access program, a mechanism that lets patients receive an investigational drug outside a clinical trial when no adequate alternative exists.[90] For a company whose only approved product must be given alongside a rationed input, a second supply looks like the obvious answer to the constraint this section describes.

There is a third source further out. Tokyo-172 is a different BCG strain, made by the Japan BCG Laboratory, to which ImmunityBio secured exclusive US rights in May 2026. An NCI-sponsored trial of roughly a thousand patients found it non-inferior to TICE on high-grade recurrence-free survival. Unlike rBCG it would be a licensed product rather than an expanded-access one, so it carries a billing code and a margin. ImmunityBio would have to file for it, and approval before 2029 looks unlikely.

Two supply sources plus Merck's Durham expansion look like enough to settle the BCG problem. The billing mechanics say otherwise, and 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, the code for BCG, at a national Medicare rate of $2.821 per milligram, or roughly $141 for a 50mg vial.[46] Under an expanded-access program 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]

There is a second constraint, and it is regulatory rather than economic. The rule against promoting an investigational drug is explicit, and charging under an expanded-access program leaves it in force.[91] ImmunityBio may tell a practice the program exists and supply the protocol; marketing rBCG as it markets ANKTIVA is closed to it. So the gap between roughly two hundred practices registering and around fifty-eight becoming active is a regulatory ceiling rather than a marketing failure, and only a license application lifts it. None has been filed.

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 institutional-review-board oversight, 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 program in May 2025.[42] By early 2026 the program 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. So the shortage functions as a handicap on the BCG-dependent regimens — ANKTIVA in both settings, and IMFINZI in the naive setting — while 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 the BCG-dependent ones. The first effect is shared; the second is not. Within second line — where ANKTIVA is the only BCG-dependent agent — the asymmetry favors ANKTIVA, and this model reflects that. In the naive setting the relief is shared with IMFINZI, which is why it is not credited as a competitive advantage there.

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.

Commercial capacity is not what binds

A young commercial organization facing a competitor with an established urology field force looks like it should accelerate as its own team matures. The evidence shows that catch-up has already happened.

ANKTIVA's inflection came with reimbursement, not headcount. The step change set out in **Section 04** — revenue more than doubling in the first quarter the permanent J-code was effective — arrived without any corresponding change in the size of the field organization. By late 2025 the company described adoption spanning leading research centers and community urology clinics including rural areas.[44]

The J-code has now been effective for eighteen months. 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.

The spending pattern makes the same point from the other direction. Selling, general and administrative expense fell in 2025, to $150m from $168.8m, as the company insourced commercial functions. It then stepped up sharply: $45.8m in the first quarter of 2026 and $51.8m in the second, against a 2025 quarterly range of $32.7m to $42.3m, with management attributing the increase to personnel and commercial costs.[71] Roughly a third more commercial spend produced no change in the sequential adds. And the buildout is still running: as of August 2026 the company is recruiting uro-oncology business managers for individual territories — San Antonio, St. Louis, Indianapolis — alongside an area sales director, a health-systems director for Eastern-US hospital networks, and field reimbursement managers.[171] The calibration for what coverage takes is public: UroGen covered the US urology call point for Jelmyto at launch with a field force of about 48 representatives.[172] An organization still extending its reach while the adds hold flat strengthens the conclusion rather than weakening it. More field capacity is not what moves the number, the flat line is set by something other than selling effort, and no catch-up acceleration is modeled.

Judged against the reference class rather than against intuition, the cadence is mid-pack. ANKTIVA's 2025 ran ahead of ADSTILADRIN's first full US year — roughly $77m at then-current exchange rates, capped by Ferring's own manufacturing ramp rather than by demand — while INLEXZO is faster than both, for the reasons Section 03 sets out.[173] Flat sequential adds are what a supply-gated intravesical launch looks like from the middle of its class.

One caveat sits under all of it. Revenue is recognized on shipment to specialty distributors rather than on administration to a patient, and four customers account for the overwhelming majority of it — 41%, 20%, 18% and 17% in the most recent quarter that discloses the split.[84] The company reports unit volume growth alongside revenue, which is the better proxy, but it does not disclose channel inventory or sell-through. Eight quarters of roughly $6m sequential adds are therefore consistent with steady end-demand and also, in principle, with a distributor building stock. Nothing in the disclosure separates the two. The unit-volume series and the reorder pattern argue for demand from patients rather than shelves, and a channel build large enough to explain two years of adds would be unusual, but the accounts cannot settle it.

Two caveats belong with that. ImmunityBio discloses no field headcount, territory count or ordering-account count, so the conclusion rests on what the spending and the revenue did rather than on a disclosed organization chart. It is also a conclusion about the second-line niche, where the call point is a few hundred high-volume practices. No public dataset can check the account picture yet: the CMS provider-level file that would count the practices billing J9028 runs only through calendar 2023, before the code existed, so the first year it can count arrives around 2027. Until then the quarterly Part B drug-spending series and the state Medicaid utilization files, on roughly six-month and one-quarter lags, are the only outside reads.[174] **Section 04** assumes a BCG-naive launch inherits that salesforce. Against a pool four times larger and less concentrated, inheriting the organization is not the same as covering the population, and the first year of that launch would carry a coverage lag this one no longer does.

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 8 · 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.

06 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. The systemic line uses a different figure. ResQ201A carries no treatment-duration cap — maintenance runs to the end of study, where the pembrolizumab and nivolumab lung labels stop at twenty-four months. At a median overall survival near fourteen months in this population, consumption is bounded by survival rather than by protocol: six to twelve doses a patient, not the thirty-odd an open-ended schedule implies.[95] 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	CAPEX	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	6.3	184.2	Papillary approved 6 Jan; Germany free-pricing launch
Q2'27	73.0	13.0	—	1.5	2.0	0.7	5.0	0.3	**95.5**	123.2	32.7	6.3	145.2	EU broadens; France early access if enrolled
Q3'27	79.0	18.0	—	2.5	3.0	0.9	9.0	0.5	**112.9**	125.9	18.2	6.3	120.7	**TICE relief begins:** ANKTIVA prescribable without EAP friction
Q4'27	86.0	22.0	3.0	3.5	4.0	1.1	12.0	0.8	**132.4**	128.6	1.6	6.3	112.8	Prescriber base widens. **Convertible matures 31 Dec.**
Q1'28	93.0	25.0	18.0	4.5	5.0	1.5	16.0	1.2	**164.2**	131.5	**(27.2)**	6.2	133.8	**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	1.6	**202.1**	134.4	**(62.0)**	6.2	189.6	Buy-and-bill economics drive community adoption
Q3'28	107.0	30.0	62.0	6.5	7.0	2.5	26.0	2.0	**243.0**	137.3	**(99.8)**	6.2	283.2	Italy/Spain reimburse; naive scales
Q4'28	113.0	32.0	85.0	7.0	8.0	3.0	30.0	2.5	**280.5**	140.3	**(134.2)**	6.2	411.2	Self-funding; FY28 revenue $890m

Table 9 · Base case quarterly build, $m. H1 2026 actual. MENA is split into bladder and NSCLC private-pay following the Gulf analysis in **Section 12**. Model assumptions are set out in source 136.[135]



Figure 1 · Revenue closing on operating cost. The lines cross in Q1 2028, with the Gulf private-pay contribution included.



Figure 2 · Cash balance assuming no ATM issuance, warrant exercises or further Oberland draws — a deliberate counterfactual. The company drew $75m from Oberland in March 2026 and took in roughly $53.5m of warrant-exercise cash in Q1, with ATM issuance on top; the figure removes all of it to isolate one question, whether a raise is ever forced rather than opportunistic. On base growth it is not. The trough at ~$113m in Q4 2027 coincides with the convertible maturity, which is why the outcome turns on the share price rather than on the cash balance. Above $5.427 the note converts and no cash leaves the business; below it the company cannot repay from this trough, and something has to be negotiated. See **Section 16**.

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 10 · 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, modeled 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 disagreement about composition, and the two paths carry different risks.

What would break this model, in order of how much it would move: a QUILT-2.005 full readout that loses significance, which removes the BCG-naive line entirely; net price falling below roughly $27,000 a dose through most-favored-nation reference pricing, which cuts every year proportionally; and BCG supply relief arriving materially later than mid-2027, which pushes the naive ramp right without changing its shape. The first is binary and the other two are continuous, which is why the spread in **Section 16** is wide at the tails rather than around the middle.

07 MECHANISM, AND THE LIMITS OF THE DURABILITY DATA

ANKTIVA is an IL-15 mutant (IL-15N72D) bound to a dimeric IL-15 receptor-α sushi domain fused to IgG1 Fc. That scaffold holds the cytokine the way the body holds it, with one cell presenting IL-15 to another rather than releasing it freely. The arrangement is called trans-presentation, and copying it is what drives proliferation of NK cells and CD8+ memory T cells through the IL-2/IL-15 receptor βγc complex. Its 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 antitumor 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* program — 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 recognized 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.

The competitive frame is wrong outside the bladder

The competitive sections above treat checkpoint inhibitors as rivals for the same patient. Inside the bladder that is right. Outside the bladder the mechanism runs the other way.

Checkpoint inhibitors do not kill tumors. They release a brake on T cells that are already present. They fail when there are too few functional effector cells for that release to matter — an immunologically cold tumor, an exhausted repertoire, or a lymphopenic patient. An IL-15 superagonist does precisely the thing that deficit calls for. On that reading IMFINZI, pembrolizumab, sasanlimab and cetrelimab become the agents whose failures ANKTIVA is designed to rescue.

The preclinical support is more specific than a general appeal to synergy. Trial registries and papers written before approval call the drug N-803, and this report uses that name where the sources do. In anti-PD-L1-refractory models, N-803 plus anti-PD-L1 outperformed either agent alone. The effect required both CD8+ T cells and NK cells to be present, and neither arm alone accounted for it.[53] Two further details make the relationship look less like addition and more like interdependence. N-803 *itself* upregulates PD-L1, so the cytokine creates the target the checkpoint inhibitor blocks. And IL-15 preferentially expands TCF1+ progenitor-exhausted T cells — which are the specific population that responds to PD-1 blockade, rather than the terminally exhausted cells that do not.[53] Each agent supplies what the other requires.

Competitor in the bladder, partner outside it. Both hold, in different settings. In BCG-naive NMIBC, ANKTIVA and IMFINZI compete for the same patient and the same rationed BCG, for the reasons set out in **Section 04**. In systemic oncology the same molecular class is the intended partner: the Saudi approval of January 2026 is explicitly for use *with* checkpoint inhibitors[31], QUILT-3.055 enrolled patients who had already progressed on a checkpoint inhibitor and continued it alongside ANKTIVA[33], and ResQ201A pairs it with tislelizumab[23].

If the second reading holds, the relevant denominator becomes the checkpoint-treated and checkpoint-failed solid-tumor population across lung, urothelial, head and neck and others — larger than the twelve to sixteen thousand BCG-unresponsive or thirty thousand BCG-naive NMIBC patients by one to two orders of magnitude. That gap is the entire reason this company is valued as a platform rather than a bladder-cancer franchise.

WHY THIS MODEL DOES NOT CAPITALIZE THAT READING

The precedent, and what separates it. Nektar's bempegaldesleukin was an IL-2 pathway agonist with a comparable mechanistic story, encouraging single-arm Phase 2 data, and a large partner in Bristol Myers Squibb. PIVOT IO-001 randomized 783 first-line melanoma patients to bempegaldesleukin plus nivolumab against nivolumab alone. It missed every primary endpoint, and on response it was directionally worse than the control: 27.7% against 36.0%, with a progression-free survival hazard ratio above one, grade 3–4 treatment-related events roughly doubled, and three treatment-related deaths against one.[54] It was never approved in any indication or jurisdiction, and the program was terminated in 2022.

Three things separate ANKTIVA from that precedent. One of them makes the precedent worse rather than better.

The usual reassurance about IL-15 is that it does not expand the immune-suppressing cells blamed for the IL-2 failure. But bempegaldesleukin was chemically shielded to prevent exactly that expansion, and it failed regardless.[54] Whatever went wrong was not the thing the shielding was designed to fix, which makes the same reassurance about IL-15 thinner than it sounds.

The two differences that hold up are safety and the comparator. At the doses where IL-2 works, it drives fluid out of the blood vessels, and that toxicity caps how much can be given. IL-15 signals through a receptor distributed differently and does not do this.[86] Subcutaneous dosing of ANKTIVA has borne that out in patients.[87] And the test is easier. Bempegaldesleukin had to beat nivolumab alone in first-line melanoma, where the control by itself puts roughly four in ten patients into response. ResQ201A is measured against docetaxel in second-line lung cancer, where responses run in single digits.[88]

What survives all of it is the load-bearing lesson. A compelling mechanism plus a positive single-arm result predicts very little about a randomized outcome, and ANKTIVA's systemic evidence is single-arm.

The randomized evidence here is thin, and one number inside it is poor. QUILT-2.023 was randomized but terminated at 102 patients against roughly 478 planned, leaving it underpowered for its progression-free survival endpoint. What it demonstrated with significance was a *biomarker* — a sustained rise in absolute lymphocyte count against checkpoint inhibitor alone. In the PD-L1-high subgroup the combination produced median progression-free survival of 7.0 months against 2.2 months for control.[55] The ratio looks impressive; the absolute number does not. Pembrolizumab monotherapy in that population delivers roughly 10.3 months in KEYNOTE-024. A subgroup that beats its own control while underperforming the standard of care is a flag, not support — and a 2.2-month control arm suggests the comparison is doing more work than the drug.

And the market has tested it. Genentech paid Xencor $120m up front in 2019 for a portfolio of IL-15 cytokines, with milestones taking the headline near $460m, and Novartis and Eli Lilly worked the pathway at the same time.[105] Capital arrived. What it produced is the signal: six years later that Genentech asset is still in Phase 1, Novartis halted its own, Bristol Myers Squibb wrote off bempegaldesleukin on the neighboring pathway, and Sotio discontinued nanrilkefusp alfa. Those programs have been funded repeatedly and none has reached approval.[105]

The scale is larger than the four names suggest. Sanofi bought Synthorx for $2.5bn in 2019 for an engineered IL-2 and impaired $1.7bn of it three years later. Alkermes spent a Phase 3 program on nemvaleukin, another IL-2 variant, and halted it in March 2025 at an interim showing 10.1 months against 9.8 for chemotherapy.

> Add the Bristol Myers Squibb commitment to Nektar, the Genentech and Xencor deal, Novartis, Sotio and the Proleukin acquisition, and outside parties have committed something in the range of $8bn to $11bn on headline terms, with $3.5bn to $4.5bn of cash verifiably spent or written off.[115] Nektar alone fell from roughly $19bn of market value to under $600m.
>
> None of which makes ANKTIVA the same case. Every failure listed above was given systemically, and ANKTIVA was approved for a route where the US label records systemic exposure below the limit of quantitation in all patients. The defense is narrower than it looks. It covers the bladder franchise, where the route is intravesical and the exposure finding holds. It does not cover the subcutaneous presentation approved in Saudi Arabia and the UAE for lung cancer, and it does not cover any lymphopenia use. Both are systemic IL-15 by any reading, which is the category that absorbed the capital set out above. What separates ANKTIVA there is the readout rather than the route: QUILT-3.055 reported 14.6 months of median overall survival in checkpoint-refractory disease, and two regulators approved on it. That is a thinner distinction than the local-route argument, and every systemic part of this thesis rests on it rather than on the exposure finding. The obvious question is why nobody else tried the local route to salvage what they had spent.
>
> For bempegaldesleukin the answer is that the molecule could not do it. It is a prodrug: the interleukin sits masked under six polyethylene glycol chains that detach over days, reaching peak concentration a day or two after infusion. An intravesical instillation is voided in one to two hours. The slow release that gave the drug its systemic tolerability is exactly what makes it useless in a bladder.[116] ANKTIVA is a superagonist complex that is active on contact, which is why the same route is open to it.
>
> That said, the absence of any regional attempt proves less than it appears to. Nektar had cut its staff from 735 to 225 and written off the program; bempegaldesleukin was aimed at melanoma, kidney and metastatic urothelial cancer, where local delivery is beside the point; and the prodrug could not have been instilled in any case. Any one of those explains the silence, so the silence discriminates between none of them. The affirmative fact carries the weight here, and the inference from absence does not.

The position taken here is that complementarity is a credible mechanism, an unproven clinical proposition, and already priced. The NSCLC and lymphopenia lines in the sum-of-the-parts are precisely this option — carried at roughly 30–35% and 15–20% probability respectively rather than at franchise value. ResQ201A is what converts it from mechanism to evidence, or ends it.

08 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, 507 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 NOVEMBER 14, 2026	2L EGFR post-TKI (HARMONi) The PDUFA covers this setting. HARMONi-6, in 1L squamous, showed OS 27.89 v 23.69mo, HR 0.66
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 11 · Second-line and later checkpoint-refractory NSCLC. No agent has won on overall survival in the broad, biomarker-unselected population; success has come only in biomarker niches. Rows run by regulatory standing, from established through failed, with ANKTIVA last as the least advanced of the nine.

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 randomized result resolves this.

The checkpoint partner is a second-tier agent. Tislelizumab has US approvals in esophageal 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.

The route the program has not taken

ANKTIVA's one approval rests on regional delivery. Instilled in the bladder it reaches the tumor at high concentration while systemic exposure stays below the limit of quantitation, which removes the dose-limiting toxicity that has defeated cytokine after cytokine in the blood. Two things about that are worth knowing. Interleukin-2 was instilled in bladders from the early 1990s and given into the abdomen for ovarian cancer, with documented activity and not one registration to show for it.[117] And ANKTIVA did not arrive there by retreat. The systemic and intravesical programs ran together from 2013 and 2014, and the systemic monotherapy in solid tumors produced no objective responses at all.[118] What separates this company is a molecule that could use that route, and a willingness to keep going in the compartment that worked. Every lung program runs the other way: QUILT-2.023, QUILT-3.055, ResQ201A and the Lung-MAP substudy all give N-803 systemically.[67]

The lung is the one other organ where the bladder logic transfers, because it can be dosed directly. Nebulized IL-15 has been tested in dogs with spontaneous pulmonary metastases, where fourteen days of monotherapy produced clinical activity. Dogs are a better model than mice here, because the tumors arise on their own in an intact immune system. Two qualifications belong with that. The molecule was recombinant human IL-15 rather than a superagonist, so it is the route that transfers rather than the drug. And no inhaled IL-15 trial in humans exists or is planned, by ImmunityBio or anyone else, which makes this an argument about a road untaken rather than a program in waiting.[94] Baseline lymphopenia correlated with benefit, which is the same association the company reports from its own NSCLC data.[66]

This is an observation about strategy rather than a revision to the forecast. No inhaled IL-15 has been tested in humans, ANKTIVA has no such presentation, and nothing here changes a number in this model. But it sharpens what the systemic program is betting on. ResQ201A must win in the compartment where this class has repeatedly lost, using the route that produced cytokine release syndrome in more than half of patients in one prior IL-15 study, while an approach closer to the one that actually worked sits untested. If the readout disappoints in 2028, the question worth asking is whether the molecule failed or the route did.

Why 14.1 months cannot be compared to 10.5

The reasoning matters more than the conclusion here. 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 randomized: 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 randomized 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 favorable-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 randomized 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 randomization separates it from drug effect.

The drug may well work. What is unknown is the magnitude, and ResQ201A exists precisely to find out. The defensible position is that ANKTIVA is a promising option in a setting with poor alternatives, and its differentiation is unproven, rather than demonstrably the best. What would settle it is a single number: the ResQ201A overall-survival hazard ratio in 2028. A confidence interval crossing one ends the systemic thesis and takes this line to zero; clear separation would move the pipeline from option value to a forecast.

09 IMMUNE RECONSTITUTION: LYMPHOPENIA, NK CELLS AND SEPSIS

Everything in this section rests on one proposition: that a depleted immune system is itself worth treating. ANKTIVA raises lymphocyte counts, and the founder has argued since the 2017 IND that doing so should be as routine as correcting anemia or neutropenia — a product the company's Founder's Vision document goes as far as naming, proposing ANKTIVOGEN on the model of EPOGEN and NEUPOGEN.[143] If that view ever prevails, the addressable population is not a cancer indication. It is a fraction of everyone who has been through chemotherapy, radiation, transplant, sepsis or old age.

The scale is the reason to keep the possibility in view at all. In the general adult population, one in five US adults carries a lymphocyte count at or below 1,500 per microliter and three percent sit at or below 1,000.[97] Narrow it to people receiving cancer treatment and the numbers are still enormous: more than half a million Americans receive radiotherapy each year, immunosuppression follows in up to seventy percent of them, and severe lymphopenia in roughly a quarter.[98] Add chemotherapy, transplant recipients, the chronically immunosuppressed and post-sepsis survivors and the population runs to millions. No drug is approved anywhere to treat any of it.[99]

That last sentence carries the argument in both directions. A market with no incumbent is either an extraordinary opportunity or a category that has resisted creation for good reason.

The size of that opportunity sits outside the valuation. The bear, base and bull cases in Section 16 run to 2032 and carry lymphopenia at thirty million, five hundred million and fourteen hundred million dollars, which are probability-weighted revenue lines rather than market sizes. What follows is the market size — a ceiling rather than a forecast, reachable only on a label that no regulator has granted anyone.[89] It is set out so the reader can apply their own probability and reach their own number, which is the only honest way to carry an option this far from resolution.

There is no approved therapy and therefore no price. The nearest guide is intravenous immunoglobulin, the one established market that sells immune replacement rather than a cancer treatment. Medicare pays roughly ninety-one to ninety-nine dollars a gram.[119] Replacement dosing for primary immunodeficiency runs 0.4 to 0.6 grams per kilogram every three to four weeks, which for a typical adult is thirty to fifty thousand dollars a year in drug cost. The neurologic indications, dosed at immunomodulatory levels, cost between $108,016 and $136,892 per patient-year.[120] Those are drug costs alone, and infusion and facility fees are charged on top. A hundred thousand dollars a course is the figure used below, at the upper end of what immune replacement already commands.

Two labels are possible here and they are not the same product. One would treat the deficit that persists after treatment ends, in the minority whose counts do not come back on their own. The other would treat during and just after cancer treatment, when almost everyone is deficient and most will recover unaided. The first is a small, durable population; the second is an enormous transient one. The columns below size each, and the steps multiply down the column except where the overlap adjustment is marked.

STEP	PERSISTENT-DEFICIT LABEL	PERI-TREATMENT LABEL	BASIS
US new cancer cases, 2026	2,114,850	2,114,850	ACS projection[121]
× receiving radiotherapy, ~50%	~1,057,000	~1,057,000	Population-based series[122]
× severe deficit during treatment, 27–43%	282–455,000	282–455,000	Pooled 26.7%; chemoradiation 43%[123]
× still deficient at three months, 11%	31–50,000	not applied	89% recover unaided[124]
Less overlap between modalities *(an adjustment, not a multiplication)*	20–45,000	100–250,000	Patients counted once across radiotherapy, chemotherapy and both[122]
US addressable, per year	**20–45,000**	**~250,000** upper bound of the row above	Derived
US ceiling at $100k a course	**$2.0–4.5bn**	**~$25bn**	Addressable × $100,000

Table 12 · Immune reconstitution: the market a label would open, at $100,000 a course. A ceiling rather than a forecast, and outside the 2032 valuation.

The two columns differ by a factor of ten, and the difference is one question: whether a label would cover a deficit that resolves on its own. In stage III lung cancer, 59% of patients developed a grade 3 or worse deficit during chemoradiation and 89% had recovered within three months.[124] A therapy indicated for the persistent remainder addresses tens of thousands of Americans a year. One indicated during treatment addresses a quarter of a million. The regulatory record is silent on which, and our search of the FDA, EMA and WHO registers found neither granted.[89]

Outside the United States the population is larger and the market is not. Europe sees 2.1 times the American case count and Asia 4.6 times,[125] and neither system reimburses supportive care at American specialty prices. At this price it would be a cash product abroad. Such markets do exist: self-purchased drugs account for 43.9% of cancer medical costs in China,[126] and commercial CAR-T there sells at comparable prices to patients paying for themselves. How much converts is an assumption this report declines to make, and the ex-US row is left empty rather than filled with a guess.

One thing is unresolved and bears on all of it. ANKTIVA raises the count; the NK programs supply the cells. Whether immune reconstitution turns out to be a drug, an infusion, or the two together changes the cost of goods, the site of care and the margin. The record does not settle it, and a market this size with the product undefined is the shape of an option rather than a business.

Three things decide whether any of it arrives: what a label would require, the cell assets meant to exploit it, and the one trial carrying an endpoint a regulator already accepts. Each is taken in turn.

What it would take to treat lymphopenia

The obstacle is not the biology. It is that no regulator has ever approved a therapy for an acquired lymphocyte deficiency.[99] Every comparable approval either rested on a clinical event or attached to a disease with a defined cause. Filgrastim was approved to decrease the incidence of infection as manifested by febrile neutropenia, not to raise the neutrophil count. Immunoglobulin replacement for primary immunodeficiency rests on serious bacterial infection rates. Interferon gamma-1b for chronic granulomatous disease rested on time to serious infection. Romiplostim was approved on a platelet surrogate, but for immune thrombocytopenia — a defined autoimmune disease rather than a low count.[99]

Two further precedents sharpen what the obstacle is and is not. It is not mechanistic uncertainty. The FDA has approved immunoglobulin for chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy and dermatomyositis on labels stating that the mechanism has not been fully elucidated, and each of those approvals rested on a functional endpoint: a disability score, grip strength, a composite of clinical measures.[167] The agency has never required a mechanism. It has required an outcome, and ANKTIVA's mechanism is better characterized than immunoglobulin's.

Nor would approval settle payment. Immunoglobulin in secondary immunodeficiency is the closest structural parallel to lymphopenia — acquired, measurable, and secondary to another illness or its treatment. Medicare covers it only where a low immunoglobulin level is accompanied by documented recurrent or serious infection, and the laboratory value alone has never been sufficient.[168] A lymphopenia label would face the same question twice, once at the agency and again at the payer, and a count restored without an event prevented answers neither.

The counter-example is exact. Immunoglobulin lowered plasma amyloid-beta in Alzheimer's disease and missed both the cognitive and the functional endpoint in a 390-patient Phase 3. The program was abandoned.[169] A biomarker that moves while the clinical endpoint does not is the outcome this thesis has to outrun.

The nearest thing to a precedent is a cautionary one. Idiopathic CD4 lymphocytopenia is a recognized disease with its own diagnostic code, studied at the NIH for three decades, and no therapy has ever been approved for it anywhere.[100] Interleukin-7 raised CD4 and CD8 counts reliably in that setting and went no further.[100] The same drug met its lymphocyte endpoint in glioblastoma patients with treatment-related lymphopenia, a 148% rise against 17% on placebo. A decade later it remains unapproved, with the registrational trial and the breakthrough designation both still outstanding.[101] Raising the count has been achievable for a decade. Converting that into a label has not.

Three things distinguish ImmunityBio's position from that record. The drug is already approved and selling, so the safety database and the manufacturing exist. The RMAT designation and the pan-tumor expanded-access authorization are further than any prior entrant reached. And the position is not a retrofit: the founder has argued it consistently since 2017, before there was oncology data to explain away. None of that is a regulatory path. It is what separates an ambition with institutional footing from one that has none.

What the path actually requires is a clinical endpoint in a defined population — fewer infections, fewer treatment delays, or longer survival in patients made lymphopenic by chemotherapy or radiation. Not the count. That is a multi-year undertaking, no such trial has been disclosed, and this model prices it accordingly.

How a lymphopenia market would actually start

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 programs 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 and commercial infrastructure. It also holds an FDA designation carrying 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 tumor types; and no therapy is approved for it in any jurisdiction.[89] A recognized serious condition with a validated biomarker, a free universal test, and no competitor is a configuration that rarely holds all at once.

RMAT accelerates the path without solving the endpoint problem. 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.

So an approval, if one comes, opens the first gate of four. Guidelines would have to name lymphopenia as something to act on before prescribing becomes routine; payers would have to cover a supportive-care biologic; and the price would have to travel from where it was set — $35,800 a dose for a market of thousands — to somewhere a market of hundreds of thousands can clear. The Dunkirk build is sized for the far side of all four gates at once.

The exception, and the logical beachhead, is radiation oncology. That community already pays to modify practice — 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 evidence they are acting on is unusually consistent. Across fifty-six studies and 13,223 irradiated patients, 37% developed lymphopenia, with an overall-survival hazard ratio of 1.70.[80] The seminal cohort found 43% severely and persistently lymphopenic two months after starting chemoradiation, with a death hazard ratio of 2.1 across gliomas, pancreatic and lung disease.[81] Counting only the tumor types where clinicians already alter technique, roughly **80,000 US patients a year** develop severe radiation-induced lymphopenia — a larger annual population than the entire BCG-unresponsive bladder opportunity, in a specialty already spending money on the problem.

> The one study that tests causation
> Every figure above is an association, and sicker patients keep fewer lymphocytes, so reverse causation is the obvious objection. One esophageal analysis addresses it directly: proton therapy reduced grade 4 lymphopenia against IMRT, and a mediation analysis attributed roughly 14.5% of the survival difference between the two modalities to the lymphocyte effect itself.[82] That is a single study in one tumor type, and it establishes mediation rather than proving that pharmacological correction would reproduce the benefit. It is nonetheless the closest published evidence that preserving lymphocytes changes outcomes rather than merely marking better ones, and the entire lymphopenia thesis rests on that distinction.

One shortcut does not exist, and it is the one most likely to be assumed. Medicare must cover off-label uses of anticancer drugs listed in a recognized compendium, which is how many oncology drugs earn reimbursement outside their labels. That rule does not reach here. The statute covers drugs "used in an anticancer chemotherapeutic regimen," and raising a lymphocyte count is supportive care rather than tumor-directed treatment. The precedent points the same way: filgrastim, pegfilgrastim, epoetin and darbepoetin each obtained their own FDA supportive-care indication rather than relying on a compendium listing.[83] ANKTIVA would have to do the same. There is no cheap route from expanded-access data to reimbursed US use, which is why the bear case for this line is close to nothing rather than merely small.

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+ tumor 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.

If that held in patients it would produce a razor-and-blades business: every NK infusion would pull ANKTIVA volume behind it. The human evidence does not yet support it. In haploidentical NK therapy, N-803 support accelerated host T-cell rejection of the infused cells rather than sustaining them, and in ovarian cancer the NK expansion it drove was not maintained beyond two weeks despite continued dosing.[104] The mechanism is sound and the clinical demonstration is missing, which is the same sentence this report writes about most of the platform.

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 manufacturing base is built and paid for, and it is the part of the platform claim that does not depend on a future trial. The company reported more than five trillion clinical-grade NK cells manufactured since 2017 with over 2.7 trillion held cryopreserved, and its memory cytokine-enriched program yields up to ten doses from a single apheresis — one session drawing and separating a patient's blood cells — within twelve days.[102] A bank of that size is not a press release; it is capital already spent.

What it buys is bounded by a fact of the cell line. NK-92 derives from a lymphoma patient and is tumorigenic, so every dose must be irradiated before infusion. Irradiated cells cannot proliferate, persist about two days, and form no memory — which mandates repeat dosing and rules out the one-infusion economics that make CAR-T valuable despite its cost.[103] The competitors that avoid this constraint use induced pluripotent or donor-derived cells, and they are the ones the field backed.

> **THE SECTOR BASE RATE IS POOR**
>
> Fate Therapeutics discontinued its core NK programs 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 randomized 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 trialed 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 programs cannot generate, and would open an indication larger than the oncology programs combined. A null result should discount the entire immunoparalysis franchise, including the lymphopenia opportunity that depends on the same biological premise.

WHAT WOULD MOVE THIS FROM OPTION TO FORECAST

Three things, in order of how much they would change the picture. A mortality or secondary-infection benefit in the sepsis readout around August 2027, which is the only hard endpoint this franchise can generate inside the forecast window. A disclosed FDA agreement to accept a clinical endpoint — infections or treatment delays — in a defined chemotherapy or radiation lymphopenia population, which would convert an ambition into a development plan. And published data showing ANKTIVA reduces infections or delays rather than raising a count, which is the evidence the interleukin-7 programs never produced across a decade of trying.

Against that, a null sepsis result should discount lymphopenia and the NK platform together, because both rest on the premise that restoring immune cells changes outcomes. This model carries the lymphopenia line at 15–25% probability and assigns the NK platform no revenue through 2028 for that reason.

10 WHETHER THIS IS A PLATFORM OR A BLADDER-CANCER COMPANY

The case for valuing ImmunityBio as more than a bladder-cancer company rests on the subcutaneous program: NSCLC, and beyond it the lymphopenia concept — restoring absolute lymphocyte count in patients depleted by chemotherapy, radiation, age, or infection. The population runs to hundreds of thousands a year in the United States alone, sized in Table 12, and low ALC is robustly associated with worse outcomes across settings.

Two things are settled here and should be said plainly. That ANKTIVA raises the count is not the open question — the agency conduct described in Section 09 presupposes it, naming *reversal of lymphopenia* in a designation and authorizing an access program that doses patients against a lymphocyte threshold. And the absence of any lymphopenia label to date is not evidence the door is closed, because supportive-care labels are not written for counts. Filgrastim's was granted for cutting infection in a defined chemotherapy population, not for raising neutrophils; the count is the mechanism, the outcome is the indication.[149] The open question is the translation: whether a restored count means fewer serious infections, fewer interrupted treatments, or longer lives, and in which named population. Behind it stands the rest of the stack — a route, a prescriber, a payer, a price.

The distinction here is what ALC is being asked to do. In every oncology trial in this class it has been a surrogate — a count that rises reliably while the clinical endpoint does not follow. Bempegaldesleukin expanded every immune subset measured and missed every endpoint; nanrilkefusp alfa raised CD8+ and NK counts and was discontinued for insufficient efficacy.[65] Lymphocyte expansion is the dependable part of this class and clinical benefit the unreliable part, which is why raising a count proves less than it appears to.

In lymphopenia the count is not standing in for the disease. It is the disease. That changes what the same pharmacology has to prove, and it is the strongest structural argument for the indication. It does not remove the regulatory obstacle: ALC remains a biomarker rather than a clinical outcome for approval purposes. The 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 endeavor, and the probability of a standalone approval on ALC restoration alone is low. The shape of the path, though, is known, because filgrastim walked it: a randomized trial in a named chemotherapy population, an infection endpoint the agency accepted — fever arriving on a collapsed neutrophil count, in 40% of treated patients against 76% on placebo — and a 1991 approval written on the outcome, not the count.[149] Run the same sequence here — endpoint agreement, registrational trial, two to four years of enrollment and follow-up, review — and the earliest plausible lymphopenia label lands around 2030, unless the sepsis readout in August 2027 or a lung approval shortens the argument. RMAT compresses the meetings, not the evidence. A first systemic US label would also be the approval of the syringe here. The US label is intravesical only and forbids subcutaneous dosing.[3] The subcutaneous presentation already exists, approved in Saudi Arabia and the UAE for lung cancer, as Section 12 sets out. A supportive-care drug taken at population scale is a subcutaneous product — filgrastim again — not a chair in an infusion suite.

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 programs that may all end up underpowered.

Systemic IL-15 has a difficult history, and the closest precedent is closer than it looks. Sotio's nanrilkefusp alfa is the same architecture — an IL-15 receptor-α sushi domain fused to IL-15 — given subcutaneously. It raised circulating CD8+ T and NK cell counts, spared regulatory T cells, and was well tolerated. Sotio discontinued it in October 2023 for insufficient efficacy.[65] Novartis halted NIZ985, an IL-15 and receptor-α heterodimer, short of enrolment. 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. The specific cytokine-plus-checkpoint precedent, and why the complementarity argument survives it, is examined in **Section 07**.

The factory as the tell

Arguments about platforms are cheap, so weigh the physical evidence instead. **Section 02** counts the Dunkirk fill line as a burden — a million vials of annual capacity against roughly 7,000 doses of demand, expensed as idle — and as accounting that is correct. As a statement of intent it reads differently. A million-vial line, plus El Segundo drug substance the company itself sizes at a million doses a year, is not scaled to a bladder-cancer franchise, and the company said as much at the moment of purchase: the 2022 release announcing the Dunkirk acquisition was titled for global pandemic response and preparedness, and counted nearly a million square feet of manufacturing across the US, South Africa and Botswana.[144]

The demand ladder makes the mismatch precise. The approved indication needs 7,000–13,000 patients a year. Papillary and BCG-naive approvals raise that to tens of thousands. Even the bull case's 2032 revenue of $4.6bn implies, at ANKTIVA course pricing, on the order of 120,000 doses a year — roughly an eighth of the Dunkirk line alone, before El Segundo. The first demand scenario that sizes the plant correctly is the one this section has been circling: the radiotherapy arithmetic in **Section 09** alone implies over a hundred thousand severe-lymphopenia patients a year — more than a million doses at the median course — and the broader depleted population the section counts in millions would run both plants hot. The alternative that also closes the arithmetic is global BCG and rBCG supply against a shortage Merck caps at 600,000–870,000 vials, examined in **Section 05**.

The founder has named the product for that world. The company's Founder's Vision document proposes ANKTIVOGEN for the lymphopenia indication, explicitly on the model of EPOGEN and NEUPOGEN — agents used across all tumor types regardless of anatomy.[143] Read against that document, the March 2026 warning letter — treated in **Section 17** as a conduct matter — records something more specific: a founder who does not draw the line between the vision and the product, corrected by the agency whose statutory job is that line. The FDA's letter quotes him describing ANKTIVA as "approved for bladder cancer, but it actually can treat all cancers," beneath a banner reading Cancer Therapeutic Vaccine (BioShield)[4] — the ANKTIVOGEN future spoken in the present tense. The agency was right to object, and the objection settles nothing about whether the vision is achievable; it establishes that the product, today, is a bladder-cancer drug. The plant is being built for the other thing.

The record of building ahead of demand

Whether that belief deserves capital depends on the base rate, and the record is checkable. Cancer MoonShot 2020, launched in 2016 with a promised cancer vaccine by 2020, produced little that its own deadline year could point to.[145] NantHealth listed at $14 in 2016; reporting that a $12m university donation had been structured to send $10m back to his own company took the shares down 23% in a single session, and the securities suits followed.[146] Verity Health, whose manager he acquired in 2017, filed Chapter 11 in August 2018 under more than $1bn of bond debt and pension liabilities.[147] NantSA, launched beside the South African president in January

2022 around a pledge of a billion vaccine doses a year by 2025, has disclosed no production at that scale.[148] Dunkirk itself sat largely idle from the 2022 purchase to the 2024 approval. Against the pattern sit Abraxane, which reached approval and made a fortune, and ANKTIVA's own franchise — eight consecutive quarters of growth is not nothing. The base rate reads plainly: when this founder builds ahead of demand, the building arrives and the demand, so far, mostly has not — and the exceptions are exactly the products that survived a regulator.

The honest reading for a holder is that the capacity is the measure of the bet, not evidence the bet pays. Stated at its narrowest, the founder's wager is about timing — that the gates open while the plant stands ready — so the operative question the concrete asks is *when*, not *whether*. It converts to an asset on evidence, and the evidence has a short list.

> **Triggers that would convert capacity from cost to asset:** an FDA agreement on a clinical endpoint — infections, treatment delays, survival — for a registrational lymphopenia trial in a defined population; a binding purchase or advance-purchase agreement with any government or health system, of which none appears in any disclosure to date; an rBCG BLA filing; Dunkirk's first commercial fill; or a sepsis mortality signal in August 2027, the one hard clinical readout inside the window. Until one of these appears, the plant argues for the size of the founder's ambition and nothing else.

What protects any of it is the subject of the next section.

11 INTELLECTUAL PROPERTY AND THE TECHNICAL MOAT

The bull case in this report rests on programs that do not yet earn revenue. What they are worth depends on how long ImmunityBio can keep them to itself, and that question has not been asked anywhere above.

A platform thesis is worth what its exclusivity is worth, and ANKTIVA's runs on two clocks rather than one. The composition-of-matter patent on the superagonist complex dates from a September 2010 priority and expires in September 2031 on its nominal term.[62] That is the shorter clock, and for a drug approved in the US in 2024 it is not the one that matters most.

The longer clock is the combination. ImmunityBio holds five US patents covering ANKTIVA administered with BCG — the intravesical regimen, the two-vial kit, and methods in non-muscle-invasive disease including the BCG-naive setting — with terms running to 2035.[63] Since the approved product *is* the combination, and since the BCG-naive indication that carries most of this model's 2028 revenue falls inside those claims, this family rather than the composition patent is the operative protection.

Underneath both sits regulatory exclusivity. As a biologic licensed under section 351(a), ANKTIVA is eligible for twelve years of reference-product exclusivity, with no biosimilar application accepted for four. Measured from the April 2024 approval those dates would be 2028 and 2036. The Purple Book has not yet populated a date of first licensure, so the figures are read from the statute rather than the register, and no orphan exclusivity is listed.[64]

The estate reaches further than a single-product wall in two respects. One is provenance. The superagonist was invented at Altor BioScience, which ImmunityBio acquired, and the claims were assigned through the NantCell and NantKwest entities into the current group, an assignment history recorded on the face of the patent.[62] They sit inside the company rather than under license from a third party. The other is scope beyond IL-15. ImmunityBio holds granted US patents applying the same receptor-α sushi-Fc architecture to fusions with IL-12, IL-18, IL-7 and IL-21.[68] That is the closest thing to a platform claim in the estate. These are patents and preclinical constructs rather than programs. Nothing built on that scaffold beyond IL-15 has entered a trial, by this company or any other. There is also a reason to expect the architecture to travel poorly. Trans-presentation is how IL-15 physiologically signals, so the scaffold reproduces the cytokine's own biology; for IL-12, IL-18, IL-7 and IL-21 it is a delivery chassis rather than a biomimetic, and each of those cytokines carries an unsolved problem of its own.

There is a further signal in where the field is putting its effort. The approach most likely to widen the therapeutic window for a systemic IL-15 is to target it — tether the cytokine to an antibody so it acts where the tumor is rather than everywhere. Sotio is doing this with SOT201, a PD-1-targeted attenuated IL-15 in Phase 1, and Xencor licensed an IL-15 receptor-α Fc construct to Genentech.[96] ImmunityBio has no equivalent program. Its systemic bet remains an untargeted subcutaneous injection, which is the older design in a field that has moved on. The estate is worth holding as defense against anyone building the same constructs. It is not evidence of hidden clinical assets.

No inter partes review, opposition or third-party validity challenge touching these patents was found in the public record.[70] That is an absence of evidence rather than proof of none, but for a drug approved two years ago carrying a related-party financing structure, the absence itself is a fact about the record.

Two things this does not establish. The first is that 2031 is fixed. ImmunityBio filed for patent term extension in June 2024 on several US patents covering the composition, methods of use and methods of manufacture of N-

803, and those applications remain under review at the USPTO and the FDA. Only one patent can be extended per approval, and the outcome remains unpublished. Take the composition date at face value, then, but as an open question. A grant would move it toward the middle of the decade.[187] The second is that the estate protects *this molecule in this combination* rather than the superagonist concept, which has prior art outside the company.

One item belongs in a buyer's diligence and sits outside the financial statements. The earliest granted composition patent carries a government-support statement: the supporting research, it says, was carried out by the United States as represented by the Secretary of Health and Human Services. The statement is unusual in form. It gives no grant or contract number, and it drops the standard recitation that the government retains rights, which leaves what attaches ambiguous on the face of the document. The continuation third parties cite as describing the marketed molecule is silent on the question. The company's own risk factors, separately, describe march-in rights over government-funded technology it licenses. The public record shows an open question rather than an encumbrance, and the answer sits in agreements held privately.[188]

> **WHERE THE ESTATE RUNS OUT BEFORE THE MODEL DOES**
>
> The valuation in **Section 16** runs to 2032; the composition-of-matter patent expires in 2031. For the approved product the gap is covered, since the combination family runs to 2035 and reference-product exclusivity to 2036. But those cover ANKTIVA given with BCG. A subcutaneous lymphopenia or NSCLC product would fall outside the combination claims and would rely on the composition patent, its own method-of-use filings, and the biologic exclusivity clock. The terminal-year pipeline value therefore carries a protection question the bladder franchise does not.

The competitive test is already visible. Hengrui's SHR-1501 is an IL-15 and sushi-domain IgG1 Fc fusion in trials for non-muscle-invasive bladder cancer by the intravesical route[69] — the same architecture, the same route, the same indication. Whether the ANKTIVA-plus-BCG claims exclude it is a question of claim construction rather than of biology, and it is the practical measure of what this estate is worth.

12 THE GULF OPPORTUNITY, AND WHO WOULD PAY FOR IT

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. Wealth is abundant: 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 15 · Checkpoint-refractory metastatic NSCLC funnel, annual. Lung cancer incidence from GLOBOCAN[38] 2024; downstream percentages are modeled 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. Those caps bind expatriates, who are the large majority of the population. Emirati nationals sit in a different system: Thiqa, the Abu Dhabi program administered by Daman, states no annual benefit limit per member.[155] Dubai runs a parallel top-up above the basic cap for low-salary workers, and it covers three cancers – breast, colorectal and cervical.[157] Lung is not among them. That is the mandatory floor, and against the floor the conclusion is cash or nothing.

The layer above the floor changes the reason rather than the answer. Top-tier domestic and international plans carry annual limits an ANKTIVA course does not approach.[191] At that tier the constraint stops being the cap and becomes the experimental-treatment exclusion, which the reinsurance industry applies on a guideline basis: on-label use is not experimental, off-label use inside NCCN or ESMO guidance should not be classified as experimental, and off-label off-guideline use is excluded.[190] The lung indication is on-label in Riyadh and Abu Dhabi and appears in neither guideline. International wordings add a second test: that treatment be consistent with generally accepted standards of medical practice in the country where it is received.[191] A single-arm approval struggles to pass that test. Saudi domestic insurers hold the most discretion, since no CCHI rule limits cover to registered or formulary drugs, but six-figure oncology is pre-authorized against cheaper guideline options; UAE cover is gated by the Dubai formulary and the Abu Dhabi threshold this section reaches below. We found no GCC insurer listing, covering, pre-authorizing or denying the drug. So the conclusion survives softened rather than reversed. For lung,

perhaps a tenth of the eligible pool at the outside could route a course through an enhanced or international plan — a slice the funnel's 15–25% self-pay subset already spans — and an insured market would clear at a lower net price than a cash one, because insurers bring the bargaining the cash channel avoids. For bladder the test cuts the other way: that indication is FDA-approved and sits in the NCCN guideline as of March 2026,[49] so it clears the exclusion lung fails, and insurance is a live channel rather than a workaround.

The approved posology fixes the unit of account. The Emirates label gives ANKTIVA as a fixed 1 mg subcutaneous dose once every 21 days for the duration of checkpoint therapy — one vial per dose, roughly seventeen doses across a full year on treatment.[32] Twelve doses is what median survival in this population typically allows, and twelve is what the arithmetic here runs on.

The optimistic case has a ceiling, and the arithmetic sets it tightly. Take the top of the funnel — ninety patients, twelve doses each, US list price with no discount — and the answer is roughly $39m a year. That is an enormous number against a base case of $3m for 2027, and it is why this line carries more variance than anything else in the model. It is also a long way below a hundred million, which would need twenty-eight doses a patient, more than twice what survival in this population allows. The constraint is the disease, and it does not move.

The asymmetric case is the one next door. Lymphopenia reaches a population two orders of magnitude larger, and the gate is regulatory rather than epidemiological — a formal Gulf indication converting lawful off-label use into reimbursed prescribing. That is the difference between the $12m base and the $130m bull in Table 13, and unlike the NSCLC ceiling it is not capped by how many patients exist. Whether it happens is unknowable; the point is that the upside lives there rather than in private-pay lung volume.

Why travel is the only route 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 travel to get it, and for this indication they mostly must.

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

Three things stand in the way of a US physician reconstructing the Gulf dose from intravesical vials. The concentration differs. The US product is filled and tested for instillation rather than injection, and the label prohibits that route. And reimbursement fails at the first test: ANKTIVA appears in no CMS-recognized compendium for NSCLC, which is what Medicare's off-label anticancer rule under Social Security Act §1861(t)(2)(B) requires. 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. We found no documented case of independent US off-label use.

> **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] program, or travel. That is a narrow funnel, and it is the reason the Gulf NSCLC line deserves weight rather than dismissal.
>
> For the resident pool the binding constraint is therefore the disease, rather than the journey: 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 inbound case, stated as a breakeven

Table 15 counts residents. That is the right denominator for a domestic market and the wrong one for this drug, because the argument above establishes that a patient in Boston, Munich or Tokyo who wants the studied regimen has three options, and two of them are trials. The subcutaneous presentation is on-market in two countries and nowhere else. Every checkpoint-refractory lung cancer patient on earth who can pay and travel is therefore addressable in principle by those two countries, which is a different proposition from the funnel in Table 15 and is not modeled anywhere in this report.

Sizing it by assumption would produce a number with no defensible provenance, so the arithmetic is run backwards instead. At the US list price of $35,800 a dose and the twelve doses persistence allows, a patient-year is about $430,000. A hundred million dollars of annual Gulf NSCLC revenue is therefore roughly 230 international patients on therapy; a quarter of a billion is roughly 580. Set against world lung cancer incidence of 2,637,005 in 2024,[154] the first of those is about one patient in eleven thousand, and the second about one in forty-five hundred.

That framing is the useful one because it moves the question off epidemiology. The pool is not the constraint at these volumes. Three other things are, and none of them is currently knowable. Conversion: whether a patient progressing on checkpoint therapy will relocate for an injection every three weeks for up to two years, which is a different commitment from flying somewhere for a surgery. Throughput: the centers and the infusion capacity exist, since Cleveland Clinic Abu Dhabi reports more than 22,000 chemotherapy infusions since its oncology center opened in 2023[158] and Burjeel Medical City holds ESMO accreditation for integrated oncology.[159] What remains unestablished is narrower and more specific: whether either would run a two-year course at three-week intervals for non-resident patients, and at what volume. And the window: an approval anywhere else closes the arbitrage entirely, with the confirmatory readout expected around September 2028 the most likely closing date.

> **What would make the inbound case visible before revenue arrives:** a named Gulf center marketing an international ANKTIVA lung program; disclosed treated-patient counts split by residency; a long-stay or medical visa route promoted for oncology; UAE state funding of the indication for nationals, which would establish institutional willingness ahead of any foreign flow; or a distributor commentary on units shipped against the resident funnel in Table 15. Absent those, this remains a structural observation rather than a forecast. The inbound flow specifically is carried at zero throughout this report; the Gulf lines that do appear, including the bear-case residual in Section 16, are built from the resident funnel in Table 15.

Why NSCLC approvals matter beyond 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 and commercially launched product in Saudi Arabia (registration 78609-1572-260487 in the UAE; SFDA registration certificate with pricing issued in Saudi Arabia). Launched carries its qualifiers: distribution runs through two named distributors with initial patients identified, the certificate prices the product but the price is unpublished, no units or treated patients have been disclosed, and through the June quarter the 10-Q attributes all product revenue to US sales.[1] 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 17 · 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 registered label — a fixed 1 mg subcutaneously every three weeks, one vial per dose.[32] 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 solves 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, and the reason is Saudi law rather than American law. The FDA has no authority over how a drug is promoted inside the Kingdom. The SFDA does, and its Code of Pharmaceutical Promotional Practices requires promotional material to carry the approved uses and bars the promotion of off-label information.[160] Demand would therefore have to be generated physician-to-physician or by hospitals, which is slower and harder to observe than a launch. Washington reaches what is said, not where the drug is given. The March 2026 warning letter concerned a television advertisement and a podcast rather than a sales call, and those channels carry to a US audience whatever market the underlying use sits in. So what the company can say publicly about a Gulf off-label use is limited from Washington, while what it can say to an oncologist in Riyadh is limited from Riyadh. Neither leaves much room to build demand, and with the US bladder franchise worth multiples of any near-term Gulf revenue there is little incentive to test either boundary.

What the Gulf approvals unlock beyond lung cancer

Section 09 sizes this market and sets out the regulatory obstacle. The Gulf is where the off-label version is already possible, and the base case carried there from 2027 assumes exactly that: a small line, immaterial to 2028, that compounds and requires no US regulatory event. A formal Gulf lymphopenia indication would convert it from off-label to on-label, and ImmunityBio has said it is pursuing label expansion for chemotherapy-induced lymphopenia and has opened discussions with both Gulf regulators about indications beyond lung and bladder.

What makes that path shorter than it looks is revealed preference. The SFDA granted the world's first NSCLC approval for this drug, and the world's first subcutaneous approval, in January 2026 — ahead of the FDA and the EMA, on single-arm data.[31] That is not a general claim about Gulf regulators moving quickly. It is a specific demonstration that one regulator will act on this asset before the agencies that usually go first. A Gulf lymphopenia indication would face the same surrogate problem the FDA has not resolved, but it would face it in a jurisdiction that has already shown where it sets the bar.

Neither fact justifies raising the estimate. No Gulf revenue has been recognized, prescriber willingness in Table 17 is moderate rather than high, and the surrogate problem is unresolved in every jurisdiction. What has changed is the probability attached to the bull case rather than the value of the base — and since that bull case is roughly five times the base by 2032, the distinction matters more than the arithmetic suggests.

Would the Saudi state pay?

If state health programs 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. 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 18 · The ImmunityBio–Saudi relationship: executed versus aspirational. Rows run from what has been executed to what has not, which is the point of the table.

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 favoring local manufacture. That process also has a calendar, which governs not whether the option pays but when. Public-sector medicines are bought centrally, and a product must carry a NUPCO catalog code before it can enter the main tender at all;[150] until then the route is hospital-level direct purchase, which is what private distribution currently substitutes for. The main tender is placed early in the year, and awards settle slowly: the complementary pharmaceutical tender of 2024 was announced in March and reached final results the following June.[151] Catalog coding in one year therefore produces awarded volume in the next, which places the earliest meaningful state volume in 2027 or 2028. Saudi Arabia has funded high-cost novel therapies before: KFSHRC has treated more than 200 CAR-T patients and localized 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.

And would the UAE?

The UAE has the deeper pocket for its own citizens and the harder gate for this particular drug, which is an awkward combination for the thesis. Thiqa carries no annual limit, so for an Emirati patient the household-wealth constraint that governs the private-pay funnel does not apply at all. The constraint moves instead to what Abu Dhabi will agree to buy.

Since June 2025 that question has a published answer with a number attached. The Department of Health appraises high-cost technologies against a baseline cost-effectiveness threshold of 0.75 times GDP per capita for one quality-adjusted life year, with multipliers for severity, health gain and rarity, the largest of which is rarity at up to three times.[156] At an Abu Dhabi GDP per capita near $74,400 that baseline is roughly $55,800 a QALY. ANKTIVA at twelve doses of US list runs about $430,000 a patient-year, so clearing the baseline would take a gain near 7.7 quality-adjusted life years, and clearing it with the full rarity multiplier would still take about 2.6. Median overall survival in the trial that supports the indication was 14.6 months. The gap is not a rounding difference and no plausible discount closes it.

The rarity multiplier carries a second sting. It is keyed to diseases classified as rare by the EMA or the FDA, and the reliance pathway that speeds Emirates Drug Establishment review works the same way, crediting prior approval by a stringent authority. So the UAE has written the question of Western approval into its own rules rather than leaving it as precedent. Section 12 records that no case was found of Saudi state funding for a therapy lacking US or EU approval; the same search for the UAE returns the same answer, and here the criterion is codified rather than merely unbroken. What that means in practice is that the EMA filing is the swing factor for UAE reimbursement, more than any Gulf commercial development is.

Does supply gate the ramp?

No, and the reason belongs on the record because the vial is not the US vial. The subcutaneous presentation is a distinct manufactured product — double the US concentration, a different fill, a different route — but it comes off the same chain: drug substance in El Segundo, fill and finish at Dunkirk, whose stated capacity is a million vials a year against released drug substance already sufficient for 170,000 doses.[48] The modeled ramp peaks at 25–40 patients on therapy, roughly 425–680 vials a year at the label's cadence. What could bind instead is logistics: lot release for an imported biologic, cold chain, and the import cadence that runs through Modern Pharmaceutical Company in the Emirates and the company's Saudi subsidiary with its two distributors.[32] A larger vial, a new presentation or an added manufacturing site would route through the SFDA's post-registration variation process and the Emirates establishment's reliance pathway rather than through fresh approvals; the review clocks for such variations are not established from published guidance, which is worth knowing before assuming they are fast. Saudi localization scoring is a pricing incentive rather than a gate, and nothing requires local manufacture of an imported innovative biologic. The constraint on this line is demand and payment, not production.

What we have modeled, 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 bladder line is built from willingness and ability to pay rather than from a count of eligible patients, which is why the UAE indication being broader than the US one does not move it. Widening the label from CIS to all BCG-unresponsive disease multiplies the eligible pool, since papillary-only is the larger share of the two. It does not change who pays for it. The binding constraint in the Gulf is the payment route — no NUPCO listing, no ministry purchase, insurance caps below the cost of a course — and a wider label meets the same wall with more patients behind it. That lifts FY28 from $700m to $722m, or 1.8%, which is 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 add $40–

80m annually from 2028 on these assumptions — more than private pay, because volume at a discount beats a handful of patients at list. That discount is a direction set by the pricing regime rather than a figure chosen for convenience. The SFDA prices by external reference to a basket narrowed to sixteen comparable countries in 2022,[152] and has required a formal economic evaluation for new registrations since July 2025.[153] Both push the same way: in the state channel the upside is earned on volume, not price. That is the upside case, and it is a call option with identifiable triggers rather than a forecast. State funding of the approved indications and a formal lymphopenia indication are independent of each other, and not mutually exclusive. If both arrive, the second dominates, being the one not bounded by how many lung and bladder patients exist. No number is carried for the pair. The failure modes are independent too: the state can decline while the indication arrives, or the reverse, so tracking one of them is tracking half the option.

> **Triggers that would move Gulf revenue into the base case:** a NUPCO catalog code for ANKTIVA, which precedes any tender and is the earliest observable step; its appearance 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; positive confirmatory NSCLC data from ResQ201A; the lung indication entering the NCCN or ESMO guidelines, which would disarm the exclusion international insurers apply; or a first insurer pre-authorization or denial anywhere in the GCC — the first coverage datum in either direction.

13 EUROPE, AND WHY THE UK WENT PRIVATE-PAY

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 modeled at all.

How European revenue is recognized

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 license. ImmunityBio simultaneously opened a Dublin subsidiary in February 2026 explicitly to support European distribution, and post-authorization EMA records list ImmunityBio Ireland Limited[12].

On that structure, European revenue should be modeled at ImmunityBio-captured net sales — end-market price less a distributor margin of 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 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-authorization records point to ImmunityBio Ireland. The marketing-authorization holder of record in the final EPAR Annex I would resolve it. If a Serum out-license exists, the booked European figure would be a fraction of what is modeled here and should be reclassified as royalty revenue. This is the largest single modeling uncertainty in the ex-US line.

Two advantages Europe has

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 authorized therapy in the EU for BCG-unresponsive NMIBC with CIS. ADSTILADRIN received a CHMP positive opinion only in March 2026 and is not yet authorized; 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 AUTHORIZED	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 June 4, 2026[11] on non-submission — no routine NHS funding	Private-pay only

Table 19 · European market access by country, ordered by earliest plausible revenue. Germany's free-pricing window and France's early-access program are the only channels that can produce revenue before formal reimbursement.

How an approval becomes revenue

The ex-US line built in **Section 06** rests on markets that have cleared a regulator but not yet a payer. Six jurisdictions have authorized ANKTIVA, and one reimburses it. Between a regulator's approval and a dollar of recognized revenue sit four further steps — a price, a payer listing, commercial availability, and an invoice. The United States has completed all four. Elsewhere most of that sequence is still ahead, and the table below shows how far each market has come.

The company's own filing settles the question. The Form 10-Q for the quarter ended June 30, 2026 states that product revenue "was generated from U.S. sales of ANKTIVA."[61] The geographic table carries a single non-US line — $518k for the quarter, $542k for the half, booked as *other* revenue rather than product sales. That line is not ANKTIVA. Other revenue is disclosed as bioreactor consumables and license royalty income,[79] which is legacy NantKwest business predating the drug — laboratory hardware and non-exclusive licenses on the NK cell lines. What the filing does not disclose is which of the two the European figure represents. Against $50.7m of quarterly product revenue it is immaterial, and it is the only ex-US line in the accounts.

JURISDICTION	APPROVED	PRICED	REIMBURSED	AVAILABLE	REVENUE	ROUTE TO PAYMENT TODAY
United States	April 2024	April 2024	**January 2025**	April 2024	**2024**	Medicare and commercial cover; permanent J-code
Saudi Arabia	January 2026	—	—	April 2026	—	Hospital and private purchase; no tender award yet
United Kingdom	July 2025	—	**not pursued**	July 2025	—	Private-pay only; no routine NHS funding
European Union	February 2026	—	—	—	—	None until a member state sets a price
UAE papillary-only included, alone among approvals	July 2026	—	—	—	—	None until MOHAP pricing
Macau	March 2026	—	—	—	—	None disclosed

Table 20 · How far each jurisdiction has traveled. Every stage is dated or empty; the last column says what the current state actually permits.

The "approvals in roughly 34 countries" figure resolves mostly to arithmetic: the European authorization covers 27 member states plus Iceland, Liechtenstein and Norway, which is thirty of the thirty-four. The separately adjudicated jurisdictions number six. We verified no approval in any other Gulf state, in Latin America, Canada, Australia, Japan or Switzerland, and found none announced as filed.

Saudi Arabia is the furthest advanced and the most instructive. Approval came in January 2026 and commercial availability followed in April, inside three months — far quicker than any European timetable. Availability and a state contract are different things, though: SFDA pricing, a CCHI or MOH listing and a NUPCO award are each still outstanding, and no Saudi revenue has been separately disclosed. The Gulf opportunity in **Section 12** should be read as a channel that has opened rather than one that has started paying.

What conversion would look like

Each of the following would mark a market moving from approval into revenue, and none currently sits on a published calendar. A German launch or the start of a G-BA benefit assessment; a French accès précoce decision; any national price publication; a NUPCO award or CCHI listing in Saudi Arabia; a MOHAP price or emirate formulary listing in the UAE. The cleanest signal needs no interpretation at all — a separately disclosed ex-US product-revenue line in a future 10-Q. Until one of these appears, the ex-US line in this model rests on system norms rather than on anything the company has scheduled.

The UK is the one market where the company has declined a reimbursement route, and the reasoning follows. A NICE termination for non-submission means the product is not routinely funded in England and Wales. The company chose not to submit evidence. That is a commercial judgement rather than a regulatory setback, and a defensible one against a payer currently rationing standard-of-care oncology. It also avoids setting a reference price that most-favored-nation rules could pull back into the US line, a risk set out in **Section 17**. Private-pay supply remains available. The practical effect is that the UK contributes almost nothing until a resubmission, which was never a large part of this forecast.

Asia — modeled 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 bears on 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.

14 OWNERSHIP, GOVERNANCE AND THE FOUNDER DEPENDENCY

ImmunityBio is a controlled company, and almost every distinctive feature of its capital structure follows from that. Patrick Soon-Shiong and his affiliated entities held roughly 62.5% of the outstanding shares at the 2026 record date.[72] Beneficial-ownership tables show a higher figure, near 66%, because they add the shares he could acquire within sixty days by converting the note discussed in **Section 16**. Both are accurate on their own basis.

The control is purely economic. There is no dual-class structure and no super-voting stock: one share, one vote, and no cumulative voting. His influence tracks his exposure exactly, which is a materially different position from a founder controlling a company through a supervoting class while holding a fraction of the economics.

What the structure permits, and what the company does anyway

Nasdaq rules let a controlled company opt out of certain governance requirements, and ImmunityBio formally claims two: that a majority of the board be independent, and that it maintain an independent nominating committee.[72] It then satisfies both voluntarily. Six of nine directors are independent, a governance committee exists, and the audit committee is fully independent, which the exemptions never covered in any case.

Two features are worth naming rather than characterizing. The founder chairs the nominating committee, so the controlling shareholder participates in selecting the directors who oversee him. And the compensation is substantial: for fiscal 2025, roughly $12.7m to the chief executive and $12.3m to the executive chairman, mostly in options and stock, against a net loss of $351.4m.[73] The most recent say-on-pay vote passed with about 99% support, which a 62% holder largely determines.

The related-party web

The convertible note is the largest related-party arrangement but not the only one. The company licenses laboratory and manufacturing space from a NantWorks entity, leases further property from Soon-Shiong-controlled entities, operates under a shared-services agreement with NantWorks, and pays a clinical trial operator owned by a company officer.[74] Each is individually modest against a $351m loss. Collectively they mean a meaningful share of the cost base is paid to entities the controlling shareholder also controls. A dedicated related-party committee reviews these under a written policy.

The company itself came out of the same web. What trades as ImmunityBio is the former NantKwest, a public natural-killer-cell company, which on March 9, 2021 completed a stock-for-stock merger with NantCell, a private company then named ImmunityBio; the combined entity took the ImmunityBio name and the IBRX ticker. Both sides were Soon-Shiong-controlled, and he held approximately 81.8% of the shares outstanding immediately afterward, since diluted to the figures above. The bioreactor and royalty income booked as other revenue is the legacy of the NantKwest side of that merger.[185]

THE DEPENDENCY THAT HAS NO PEER ANALOG

The going-concern footnote is not resolved by cash or by a credit facility. It is resolved by intent. The filing states that substantial doubt exists, then alleviates it "based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required."[75]

That is a statement of intent, not a binding commitment. There is no contract, no committed amount and no stated limit. The same person is the largest shareholder, the largest creditor, the landlord, a service provider and the backstop. In the bull case none of this matters. In the bear case it matters more than any clinical result, because the mechanism that keeps the company solvent is discretionary.

Where the promotion went wrong

In March 2026 the FDA sent a warning letter over promotional claims, citing a television advertisement and a podcast in which the founder said ANKTIVA could prevent cancer following radiation exposure. The agency responded that it was not aware of data supporting claims that the drug can cure cancer.[76] Two untitled letters had preceded it, in September 2025 and January 2026. Shares fell about 21% when the letter was published, and a securities class action followed in the Central District of California covering the period from the podcast to the disclosure.[77]

The episode is small in dollars and large in signal. It says the gap between what the evidence supports and what the founder says in public is wide enough for a regulator to act on, and that is the same gap this report navigates in every section. It is also a governance matter rather than a marketing one, because the speaker controls the company.

Who owns the float, and what changed

The controlling stake makes every ownership percentage ambiguous unless the denominator is stated. Against 1,059,836,273 shares outstanding at July 31, 2026,[162] institutions held 177.9m at the end of March — under a fifth of the company. Against the roughly 405m shares not held by Soon-Shiong and his entities, the same holding is close to half the tradable float. Both figures appear in circulation and they describe the same position.

What the filings show is three different kinds of money moving in different directions. Index managers buy because the stock is in an index, not because of anything in this report. Market makers and statistical-arbitrage desks carry inventory that turns over on flow. What is left — the discretionary money that chose the position — is the only part that reflects a view, and it is the smallest of the three.

SHARES HELD	DECEMBER 31, 2025	MARCH 31, 2026	CHANGE
Index managers Vanguard, BlackRock, State Street, Geode, Northern Trust	91,917,944	96,090,071	+4,172,127 +5%
Market makers and quant desks Jane Street, D. E. Shaw, Two Sigma, bank desks	60,009,219	49,205,640	–10,803,579 –18%
Discretionary everything else	**28,899,098**	**32,627,706**	**+3,728,608** +13%
All managers 276 filers, then 385	180,826,261	177,923,417	–2,902,844 –2%

Table 21 · Institutional holdings by type of money, from the SEC quarterly 13F data sets, with amended filings resolved. Index and flow are classified by manager.

Between those two quarters 148 managers opened a position and 39 closed one.[163] The total nonetheless fell, because the desks left faster than anyone arrived — Jane Street went from 14.2m shares to 704,232 and Goldman from 12.3m to 3.2m, while D. E. Shaw came in at 12.6m. That is inventory rotating, not a view changing. The line that carries information is the discretionary one, and it grew 13%.

The June quarter separates the two more sharply. Carrying the sixty largest holders forward into their June 30, 2026 filings, which covers 91% of the March institutional total,[164] index holdings rose 19% while discretionary holdings fell 13%. BlackRock added 7.7m and State Street 3.7m, which is the June index reconstitution rather than an opinion. Woodline Partners, a healthcare fund and the largest discretionary holder in March, cut from 3,447,346 shares to 2,500,189. Two Sigma went from 4.4m to 11.1m and Millennium from 1.4m to 5.6m, which is again inventory. The coverage cuts one way — a manager opening a new position in the June quarter is not in the sixty — so the discretionary fall is an upper bound and the index rise a lower bound.

Short interest has been falling from its spring peak while the days needed to cover it have roughly tripled. Nasdaq's semi-monthly series puts short interest at 140,326,066 shares on April 15, 2026, 131,830,884 at June 30 and 128,997,049 at July 31.[165] Against shares outstanding that last figure is 12.2%; against the float it is close to a third. Days to cover moved from 4.7 at the end of March to 14.5 at the end of July, because average daily volume fell by more than the short position did. A crowded short in a thin float is the condition for the January move described above, and it has not gone away.

> **What to watch each quarter.** The discretionary line in the table above, which is the only part that carries information about what informed money thinks. Whether Woodline's cut continues or reverses. Whether any healthcare specialist takes a position large enough to file a 13G. And the gap between short interest and days to cover, which measures how hard the position would be to exit rather than how large it is. Every figure in this subsection is reproduced by a single command that reads the SEC data sets, EDGAR and the Nasdaq series directly, so the quarterly refresh does not depend on anyone else having done the arithmetic.

The counterweight

Against all of it sits a track record, and it is one company rather than two. American Pharmaceutical Partners bought his privately held American BioScience in 2006 and took the Abraxis BioScience name. In November 2007 that company separated into two independently traded halves. The hospital injectables business became APP Pharmaceuticals and took on $1.0bn of term debt, roughly $975m of which was contributed in cash to the proprietary half that kept Abraxane and the Abraxis name.[184] He sold the injectables half to Fresenius ten months

later for roughly $3.7bn before contingent payments, and the Abraxane half to Celgene twenty-three months after that for about $2.9bn plus milestones.[78] The sequence is the point: he separated the business that generated cash from the asset he believed in, sold the first to fund the second, and sold the second only when a buyer would pay for what it might become. He has been a net acquirer of ImmunityBio stock, converting affiliated debt into equity rather than selling. That behavior is also why this report carries no takeout value in any scenario. A controlling holder who funds the company by converting his own debt is not positioning it to be sold, and an acquirer would have to buy him rather than the float.

Concentrated ownership is not by itself a defect. It funds a company that would otherwise have faced worse terms, and it aligns the largest holder with the smallest. What it removes is the ordinary check: no external party can replace this board, and the going-concern conclusion rests on one person's continuing willingness. The structure carries a price either way, and this model does not assume it away.

The report cites company guidance in several places, so how that guidance has held is part of the evidence. The commercial record is good. Saudi distribution was promised within sixty days in February 2026 and delivered in April.[130] QUILT-2.005 completed enrollment in February, on the schedule given. The Q4 2026 filing date for the BCG-naive submission has not moved since it was first stated. Revenue has grown sequentially for eight consecutive quarters.

The regulatory record is worse, and it is the one the catalysts depend on. The papillary application was refused filing after the company said the agency had encouraged it. A registrational path for lymphopenia was described as a BLA the company intended to submit after RMAT designation in February 2025;[131] no such application has been filed, and the framing has since become a randomized trial in design. In March 2026 the FDA issued a warning letter finding that the founder's public statements about ANKTIVA were false or misleading,[132] having sent two earlier untitled letters on the same subject. What emerges is a company that executes what it controls and describes the FDA more favorably than events support. Guidance about shipping product deserves more weight here than guidance about what a regulator is going to do.

Which raises the question the filings do not address. The founder is in his seventies. He is the controlling shareholder, the affiliated lender, the scientific architect and the stated reason the going-concern doubt is alleviated. No succession plan is disclosed, and no committed facility exists that would survive his departure. The structure concentrates an unusual number of dependencies in one person. This report can document every one of them and price none of them.

What a bid would have to look like

He has sold the business twice over, in the two halves described above, and the record of both sales — what the buyers paid, and how the contingent pieces resolved — is the only evidence of the price at which he transacts. What follows reads that record as a calibration. It changes nothing in the stance of this report, which carries no takeout value in any scenario; it explains, in dollars, why that stance is the right one.

Fresenius paid $23.00 a share in cash for APP Pharmaceuticals in 2008 — $3.7bn for the equity, with $940m of debt assumed — plus a contingent value right, a tradeable instrument paying up to a further $6.00 a share if the business hit earnings targets over 2008–2010. Against 2007 revenue of $647m, the cash-and-debt price was roughly seven times trailing revenue. The targets were missed. Cumulative adjusted EBITDA reached $1.126bn against a $1.268bn threshold, the rights expired without paying anything, and the instrument was delisted in March 2011.[176]

Celgene's 2010 purchase of Abraxis BioScience ran the same shape at a higher pitch: $58.00 in cash plus 0.2617 Celgene shares plus one tradeable contingent value right per share — roughly $2.9bn upfront net of cash, about eight times Abraxis's 2009 revenue of $359m, around $3.2bn in aggregate. The right carried a $250m milestone for a US lung-cancer approval with a progression-free-survival claim on the label, $300m for a US pancreatic approval with an overall-survival claim, $100m more if the pancreatic approval landed before April 1, 2013, and royalties on any year in which Abraxane sales passed $1bn.[177]

The vision came true and the rights still paid almost nothing. The FDA approved Abraxane for lung cancer in the US in October 2012 without the progression-free-survival claim, so the $250m lapsed. The pancreatic approval came on September 6, 2013, on overall survival, five months past the bonus date: $300m paid, $100m forfeited. Sales crossed $1bn exactly once during the royalty term, in 2018, generating a payment of roughly $1.6m, and by then Celgene carried the whole instrument at $19m against a $650m milestone headline. Bristol Myers Squibb's final notice, in February 2026, reported $368m of Abraxane sales for 2025 and nothing due.[178] Celgene's stated prize at signing was about $1bn of revenue by 2015; Abraxane peaked at $1.06bn, three years late, so the aggregate price came to roughly three times the realized annual peak. That is the seller's signature: seven to eight times trailing revenue upfront, roughly three times the credible annual peak in aggregate, and the dream itself taken in contingent form — which resolved to roughly nothing, twice, while the dream itself, in Abraxane's case, materialized on schedule. A founder who has twice watched contingent value evaporate as the underlying vision paid off is not a seller who takes the vision in contingent form a third time.

Applied to ImmunityBio, the revenue multiple lands below the market price. The model's next four quarters sum to $296.5m; at seven to eight times forward revenue — the multiple his own companies fetched — the enterprise is worth roughly $2.1–2.4bn, and after net debt the equity comes to roughly a dollar a share against a market price near $7.79 and a convertible that converts at $5.427. The market is not pricing the bladder business; it is pricing the platform. A bid built on the business the drug has today would be a discount rather than a premium, and there is no version of this company's owner who sells at a discount to his own conversion price.

The calibration that could clear the market price is the one Celgene actually used: roughly three times the credible annual peak of what the buyer believes the asset becomes. Stack the franchises at the sizes this report defends — the bladder business, a second-line NSCLC peak in the low single-digit billions, the persistent-deficit lymphopenia column of $2.0–4.5bn from Table 12, and a sepsis line its own precedent caps — and the credible aggregate annual peak runs $4–8bn, three times which, after debt, is roughly $10 to $21 a share. The sepsis line carries its own cap. Xigris, the only drug ever approved in the US specifically for sepsis, sold roughly $100–200m a year worldwide at its best, and was withdrawn in October 2011 when its confirmatory trial failed. A $35,800 dose inside a DRG bundle faces the same wall. So that line is worth $0.5–1bn a year at most in this stack, rather than what the 48.9m annual cases imply.[179]

What that stack still leaves out is the column a checkpoint-inhibitor owner would price. Roughly 250,000–400,000 US patients start a checkpoint inhibitor each year — an estimate, because no authoritative count exists — and somewhere between a quarter and two-fifths of them carry or develop lymphopenia along the way. Low counts travel with checkpoint failure across the largest cohorts: overall survival of 9.8 against 18.3 months for patients lymphopenic at three months in one series, an independent hazard ratio of 1.68 in kidney cancer, and in stage III lung cancer a measurable attenuation of the checkpoint consolidation's own survival benefit when radiation depletes lymphocytes first.[180] At $100,000 a course, the slice of that population not already counted in Table 12 is worth perhaps $3–8bn a year. That holds only if correcting the count corrects the outcome. No prospective trial has shown it, and it is the proposition bempegaldesleukin carried into 783 randomized patients and lost.[54]

Weighted the way this report weights everything else, at 15–35%, the column adds a dollar to eight dollars of floor. Taken at face value — which is how its owner takes it — it carries the ask into the thirties and low forties a share, just under this report's own bull case of $46.39. The founder's reservation price is not a premium to the market. It is his bull case, and his conduct — converting his own debt to equity at $5.427 rather than selling a share — is what believing it looks like.

The path between today's price and that ask has a known first step, and it is the step that would move the stock most. A partnership or equity investment from a large checkpoint franchise re-rates a company of this size before any bid exists. Strategic-stake announcements have moved small-cap partners by double digits in a day, and Summit Therapeutics tripled in a week — though on head-to-head data against Keytruda rather than on a signature.[181] A 20–50% announcement re-rate followed by the 50–65% median control premium builds an executable path to roughly $14–19 a share. The gap between that executable number and the reservation price is the negotiating range, which is another way of saying the negotiation fails — and the deeper problem is the date. That arithmetic prices today's information against a $50.7m quarter, and nobody bids on this company at a $50.7m quarter. Process does not close it. Under Delaware law a transaction the controlling holder leads faces entire-fairness review unless conditioned from the outset on both an independent special committee and a majority-of-the-minority vote — the MFW framework, reaffirmed in the Match Group decision of April 2024.[182] This company has already run that process once. The 2021 merger that created it was negotiated for the public side by a special committee with its own counsel and conditioned on approval by a majority of NantKwest's unaffiliated shareholders, which it received.[185] So the mechanics of a controller-led deal here are not hypothetical, and they are also not the constraint: those protections govern how the minority is treated, not what his number is.

Merck is the buyer this frame keeps producing, and the frame should carry its weaknesses. Keytruda and its subcutaneous successor Keytruda Qlex earned $31.7bn in 2025, roughly half of Merck's revenue, with US price negotiation beginning in January 2028 and the compound patent expiring that December; management's stated answer is a claimed $70bn of pipeline opportunity, not an acquisition.[183] Its bladder position needs nothing from ImmunityBio — it is the sole US supplier of TICE BCG, it runs KEYNOTE-676, the pembrolizumab-plus-BCG Phase 3 in this disease, and Keytruda Qlex was approved in the US in September 2025 across pembrolizumab's indications, the second-line bladder setting included. A Merck bid would be a bet on the platform: on IL-15 restoring the patients its own franchise loses. No Merck statement on IL-15, NK cells or immune restoration exists in the public record. And one vertical fact would follow the deal into any review: the acquirer of ANKTIVA would also own the rationed input its US label requires.

Neither prior company was sold before it had revenue, which makes the precedents apply more closely than they might. APP was sold profitably, on $647m of revenue and $253m of EBITDA. Abraxis was sold on $359m of 2009 revenue and a $104m net loss for that year — revenue-generating and unprofitable, which is the structural position ImmunityBio occupies today. What Celgene bought was a marketed drug with one approved indication and a thesis about three more.[186]

The wait is the instructive part. Revenue arrived on day one, because Abraxane was already selling; the thesis took considerably longer. Celgene told investors the deal would be modestly dilutive in 2011, accretive from 2012, and would add about $1bn of revenue in 2015. The lung approval came in October 2012, two years after closing, and pancreatic in September 2013, just under three. Sales moved as the indications landed — $427m in 2012, $649m in 2013, $848m in 2014 — and the $1bn promised for 2015 arrived in 2018, three years late and eight years after the close.[186] An acquirer of this platform would face the same shape on a similar clock: the bladder business bills

from day one, ResQ201A reads out around 2028 with approval in 2029 or 2030, and a lymphopenia indication sits behind that. Three to five years to the first thesis revenue, longer to any peak.

For Merck that clock is the argument rather than an objection to it. US price negotiation on Keytruda begins in January 2028 and the compound patent expires that December, so an asset bought now would deliver its first thesis revenue into precisely the years the franchise starts losing it. Size it against what is being defended. Against that $31.7bn franchise, the immune-restoration lines this report sizes — the persistent-deficit column at $2.0–4.5bn and the checkpoint-adjunct slice beyond it — would together be worth something in the high single-digit billions a year if they work, against a purchase price in the low twenties of billions at his reservation. That is a meaningful fraction of the erosion and nowhere near all of it. Weighted at the 15 to 35% this report applies elsewhere, the expected contribution falls to perhaps a fifth of that, which is the honest way to state it: buying ImmunityBio would be a large bet on one mechanism, not a replacement for Keytruda. Merck's own answer to 2028 is a claimed $70bn of pipeline opportunity by the mid-2030s, and a company that believes it has that does not need this.

So model the offer at the date it would actually arrive, which is after the revenue. Take the bladder franchise at roughly a quarter of the eligible US NMIBC pools — a share the model's own penetration tracks place between the base and bull year-three paths, so around 2030 or 2031. A quarter of the 31,000 eligible BCG-naive patients is roughly 7,800 a year, worth about $1.2bn at the $150,000 the model recognizes per launch-year patient; a quarter of the twelve-to-sixteen-thousand BCG-unresponsive pool adds roughly half a billion at current per-patient revenue; papillary adds its line. Call it a US bladder franchise around $1.7bn a year. At the seven to eight times forward revenue his own companies fetched, the bladder business alone supports an enterprise value near $12–14bn — against the $2.1–2.4bn the same multiple produces today.

What changes more than the base is the optionality, because the clock that produces the revenue also produces the evidence.

> **What the 2028 readout decides.** ResQ201A reads out before any 25%-share world exists, so the checkpoint-adjunct thesis is dead or proven by the time an offer is drafted, so it is never priced as a probability at all. If it is dead, the offer is the bladder number, near $9–11 a share on the diluted count, and there is no seller, because a founder whose bull case has just failed its confirmatory test has no reason to sell at that price. If it is proven, the stack prices near conviction rather than near hope. Three times the franchises this report already sizes puts the optionality tranche at $18–24bn on top of the bladder number — an aggregate in the low thirties of billions, or mid-twenties to low thirties a share once the convertible and the warrants have done their work. That is below the 2032 bull case and three to four times today's price, which is what a negotiable number looks like.

Said as one sentence: the spread between the executable price and the reservation price exists because buyer and founder weight the same franchises at fifteen to thirty-five percent against roughly a hundred, and evidence is the only thing that closes it — so revenue scale is the precondition for a deal not because the multiple needs a bigger base, but because the proof that makes a buyer pay conviction prices arrives on the same clock as the revenue. For Merck the two clocks meet neatly: the 25%-share world and the post-readout world both land as Keytruda's US exclusivity ends.

None of this adds a line to the sum-of-the-parts, and it is not meant to. It establishes three prices for one company: what the business supports, which is about a dollar; what a negotiated process could execute, which is the teens; and what the owner's own arithmetic demands, which is his bull case. The distance between the second and the third is why the takeout is carried at zero. What would collapse that distance is not a bid but evidence: the sepsis readout, a lymphopenia endpoint the FDA accepts, ResQ201A. The catalysts that would move the stock and the ones that would move his reservation price are the same list. That is the deepest sense in which this remains a founder-dependency story.

15 CATALYSTS AND TIMING

Two of the entries below decide whether the base case happens at all: the BCG-naive filing at the end of this year and the papillary decision six weeks later. The rest set the pace or the ceiling. Dates of three kinds appear together, and they fail differently — company guidance slips, regulatory action dates hold but can be extended, and registry completion dates move as events accrue.

DATE	EVENT	WHY IT MATTERS	IMPACT
2H 2026	CG Oncology PIVOT-006 topline	Cretostimogene versus surveillance in intermediate-risk disease. The company reports the trial has accrued the large majority of target events. A read on how a BCG-free agent performs in a randomized setting	Moderate (neg)
November 6, 2026	Q3 2026 results	The sequential add has held near $6m for four quarters. A break in either direction is the earliest signal on the naive ramp	Moderate
November 14, 2026	Ivonescimab PDUFA	Establishes the PD-1/VEGF class in second-line EGFR-mutated NSCLC. Approval hardens the comparator ResQ201A must beat	Moderate (neg)
Q4 2026	BCG-naive sBLA submission	QUILT-2.005 filing for BCG-naive carcinoma in situ. Company guidance, reaffirmed on the Q2 call. The full 366-patient topline has not been released and may or may not accompany it	Very high
January 6, 2027	Papillary sBLA PDUFA	BCG-unresponsive papillary-only disease, on standard review. FDA has restated its concern about single-arm evidence in papillary disease, so the date is firm and the outcome is not	High
August 3, 2027	Sepsis trial primary completion	28-day all-cause mortality in 50 patients with sepsis and persistent lymphopenia. The only hard, regulator-acceptable clinical endpoint the immune-reconstitution thesis has inside this window	Very high
Mid-2027 – 2028	Merck Durham supply reaches the market	Not the opening, which happened in March 2025. Merck guides the plant to full operation by late 2026 and says capacity then triples with supply increasing gradually, each batch taking over three months. The dates here are inferred from that sequence rather than stated	Moderate
September 2027	CMS pass-through expiry	Separate payment in the hospital outpatient setting lapses. Most volume is office-based and unaffected, so this bites only on the hospital share	Moderate (neg)
December 31, 2027	Convertible note maturity	Above $5.427 the note converts and no cash leaves the business. Below it the company cannot repay from the trough and something has to be negotiated with an affiliated holder	High (dilution)
2028 – 29	ResQ201A overall survival readout	The randomized test of systemic ANKTIVA, 507 patients against docetaxel. Primary completion is estimated September 2028, but overall survival triggers on events rather than a date	Very high
2028 – 29	J&J SunRISe-3 readout	Randomized, BCG-free, versus BCG in the naive setting. A positive result substantially devalues the naive thesis. Event-free survival triggers on events; registry primary completion is September 2029 and no efficacy interim has been disclosed	High (neg)
Undated	First ex-US revenue recognition	Approvals span roughly 34 countries and the Q2 10-Q states all product revenue remains US sourced. No guidance has been given on when that changes	Moderate

Table 22 · Dated catalysts in chronological order, with impact breaking ties within a date. Company guidance slips; FDA action dates are firm but extendable; registry completion dates move with event accrual. Where a date is inferred rather than stated, the row says so.

One row above carries a history the date alone does not convey. The papillary sBLA reaching a January 2027 decision is the same application the FDA refused to file on May 2, 2025.[127] One regulator has since accepted that package: the UAE authorization of July 2026 covers papillary-only disease without CIS.[166] No other approval anywhere does, and it is the same indication the January decision would grant in the US. That is a data point rather than a precedent. Gulf regulators lean on FDA and EMA review, so an approval granted where the FDA has not yet ruled carries less weight than an independent one would. ImmunityBio had submitted it that March, and said afterwards that leadership from CBER, CDER and the Oncology Center of Excellence had unanimously encouraged the submission at a meeting in January.[127] THAT ACCOUNT IS THE COMPANY'S OWN AND THE FDA HAS NEVER COMMENTED ON IT, which is the agency's

practice with individual sponsor meetings. What the agency wanted, per the company's account after the meeting that followed, was a randomized trial against chemotherapy, and in August 2025 ImmunityBio committed to running one.[128] No such trial was started. The application was resubmitted in March 2026 on extrapolation from the carcinoma in situ cohort instead, and accepted in May.[129]

Two readings survive that sequence and this report does not choose between them. The agency may have moved, which would make the resubmission a fair reading of a shifted position. Or the company may have described a meeting more favorably than the record supported, submitted on that basis, and later found a filing route around the trial it had been asked to run. Either way the file has been refused once on evidence the agency called insufficient, and the acceptance letter reserved the extrapolation question rather than settling it. A PDUFA date is a deadline for a decision and not a signal about which way it goes.

What would break this. The two entries this section calls decisive are only decisive if the naive setting stays open. A positive SunRISe-3 or a durvalumab launch that takes the first-line slot before ANKTIVA files would make the January decision a second-line event rather than a gateway, and the dates below would matter less than the order they arrive in. The reverse also holds: an approval in January on extrapolation alone would establish a filing route this report treats as unavailable, and several later rows would move forward with it.

16 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 programs 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 23 · 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 reflected in that positioning, applied once rather than compounded.

Pipeline optionality, benchmarked to CGON

PROGRAM	BEAR	BASE	BULL	BASIS
BCG-naive NMIBC	900	**2,200**	3,800	TAM of ~31,000/yr against a derived 7,000–13,000 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. This line *is* the checkpoint-complementarity option (**Section 07**). Large TAM, but the supporting efficacy evidence is single-arm and the one randomized trial was underpowered and read out on a biomarker. Roughly 30–35% probability. The bear value is residual platform and Gulf private-pay worth, not a franchise — if ResQ201A misses, this line is closer to zero than to $200m
Lymphopenia (US)	30	**500**	1,400	RMAT granted, no registrational trial, ALC surrogate unresolved, and no compendia route to reimbursement without an indication — low lymphocyte count predicts checkpoint failure, but no regulator has accepted that correcting it restores benefit. 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. The addressable market is capped nearer $0.5–1bn a year than the case count implies: Xigris, the only sepsis-specific drug the FDA has ever approved, peaked near $200m worldwide before its confirmatory trial failed, and a $35,800 dose inside a DRG bundle meets the same wall[179]
NK platform + rBCG	50	**250**	600	Fate and Nkarta both retreated from NK oncology. rBCG and Tokyo-172 carry strategic value as supply independence
Total pipeline	**1,230**	**3,950**	**8,300**	Base case is roughly 0.8x one CG Oncology, across five programs

Table 24 · Risk-adjusted pipeline value, $m. CG Oncology's ~$4.75bn enterprise value for one pre-commercial NMIBC asset is the cross-check, not the source. The benchmark cuts both ways — if CGON re-rates on approval-era competition, the BCG-naive line moves with it, roughly $1.00/share of 2032 base value per halving.

The cross-check behind that caption is a bottom-up build on the BCG-naive line, run in the spreadsheet with its inputs exposed: the ~31,000-patient pool, a 15–25% mature share, course economics of roughly $150,000 per patient-year, an EV-to-peak-sales multiple of 2.5–3.5x, and a 35–45% probability of approval on the full QUILT-2.005 readout. That machinery brackets the bear at roughly $600m and reaches about $1,800m at the top of every input — below the $2,200m the CGON benchmark supplies. The base therefore implies a 30–40% mature BCG-naive share on these economics, and the input carrying the difference is share, not price or probability. The benchmark drives the result above roughly the midpoint, which is worth knowing before relying on it.

The balance sheet, and the financing it forces

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, and cash troughs near **$113m in Q4 2027** with the Dunkirk capital commitment included. 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 analog among peers. The Oberland revenue interest[16] skims 5.625–12.50% of ex-China net sales, but the drag is bounded, and the bound changes which scenario it punishes. Payments stop permanently once Oberland has received 195% of what it funded — roughly $731m against $375m drawn. If cumulative payments by the December 31, 2029 test date have covered the $375m, the rate steps down to a flat

2.8125%; if they fall short, the rate increases and a lump-sum true-up is owed. Fast growth therefore retires the obligation early at the capped amount, and slow growth is what the structure punishes. On the model's revenue paths the test date arrives short in every scenario, so the step-up is the expected outcome — the difference is that the base and bull then hit the $731m ceiling by 2031–2032 and stop paying, while the bear pays every would-be dollar and owes the true-up besides. And the **$480m related-party convertible matures December 31, 2027**, one quarter before the cash trough. That is the largest dilution event in the forecast window. The balance sheet carries the note at fair value — $774.4m at June 30 against $480m of principal — because the company elected fair-value treatment and the conversion right is deep in the money.[1] The gap between the two is the market value of the shares Nant would receive on conversion, and swings in it flow through net loss as a non-cash charge — one more reason headline net loss overstates cash burn. What that founder has previously built ahead of demand, and how those bets resolved, is set out in **Section 10**.

The convertible deserves more attention than its balance-sheet line suggests, because its behavior inverts with the share price. It converts at **$5.427**, and only at the holder's option. Above that price it behaves as equity: Nant converts, roughly 88m shares are issued, and $480m of obligation simply disappears from the balance sheet. Below it, Nant has no reason to convert — and the company cannot repay $480m out of roughly $113m of cash. The outcome is then a negotiated restructuring with an affiliated holder who owns three-fifths of the equity, almost certainly at a conversion price struck near the prevailing market. At $3.50 that is 137m shares rather than 88m. **A lower stock price does not remove the dilution; it returns larger** — and it arrives in the same quarter the warrants, struck at $3.101 and $3.240, would expire worthless. That interaction is modeled explicitly in **Section 16**.

Those constraints set the denominator.

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, July 31, 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 25 · 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 tells you more than the total does. 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**	$113m	$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 26 · 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 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. The unhelpful part is that needing it is also 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 27 · 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 amortizes 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 28 · 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 29 · 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 programs 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 programs at less than one CG Oncology in aggregate.

What it means for the price today

On base assumptions the 2026 sum-of-the-parts is **$6.74** against a market price of $7.32 at publication — so the market is paying roughly a 9% 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 23x — still inside the historical range at this revenue level — and the 2026 figure meets the market price exactly.

The forward picture is the one to weigh. On base assumptions the model reaches **$21.30 by 2032**, about 2.9 times the $7.32 publication price, or roughly 19% a year compounded. The bull case is **$46.39** and the bear is **$3.07** — a spread of fifteen to one, where the bear case loses well over half the money. So the middle outcome earns a high-teens annual return, with a much larger payoff if the platform works and a severe loss if it does not. Valuing the company on a single multiple of today's business misses all of that.

- **Medicare Advantage friction.** More than half of Medicare beneficiaries are now in Medicare Advantage, and the Congressional Budget Office projects 64% by 2034.[114] These plans generally honor average sales price plus 6%, but they add prior authorization that fee-for-service does not. Roughly half of this drug's Medicare volume is therefore exposed to plan-level review, and that share grows every year. The friction is procedural rather than structural, but it slows starts and it is not in the model.
- **Positioning, in both directions.** Short interest has run between roughly 14% of shares outstanding and, on some float-based measures, above a third — well above the peer group.[85] That is a statement about volatility rather than about value. It amplifies bad news and it reverses violently, as it did in January 2026. Position sizing should assume the price can move a long way on news that changes the model very little.
- **Regulatory conduct.** The FDA issued a warning letter on March 13, 2026[4] — its first full warning letter of the year from OPDP, the FDA office that polices drug promotion — 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 March 24, 2026. Lead plaintiff appointed July 15, 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.
- **The platform thesis fails in a randomized trial.** Roughly a third of the pipeline value in this model sits in NSCLC and lymphopenia, and both rest on the proposition that an IL-15 superagonist restores checkpoint-inhibitor benefit. Nektar's bempegaldesleukin carried the same logic on the IL-2 pathway and missed every endpoint in a 783-patient randomized trial against nivolumab alone.[54] Bempegaldesleukin never reached approval anywhere; ANKTIVA is approved and selling. What the two share is that ANKTIVA's systemic evidence is also single-arm, and ResQ201A is the first randomized test of it. A miss there does more than trim these lines. It ends the argument that this is a platform rather than a bladder-cancer company, and takes the commercial multiple with it.
- **Externally imposed price cuts.** The model holds US net price constant, and **Section 02** sets out why a *voluntary* cut would be self-defeating. A cut imposed from outside is a different matter. Executive Order 14297 directs HHS toward most-favored-nation pricing benchmarked to the lowest price in a qualifying OECD country, and CMS has proposed the GLOBE model for Part B with an effective date of October 1, 2026.[60] Neither is finalized. But a drug priced at $35,800 a dose in the US, sold into Gulf tender markets that themselves reference-price against an OECD basket, sits directly in the path of that mechanism. A 20% net-price reduction takes roughly $530m off the 2032 base commercial line before any volume response.
- **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 and no open-market insider buying has been identified since the April 2024 approval, though a purchase would have been legally fraught from March 2026 once the securities class action was filed. The founder's own transactions are share withholding on vesting rather than sales.

- **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.

18 CONCLUSION

ANKTIVA is approved in the United States, selling, and supported by three-year durability data, in a niche where it has reached only 10–15% penetration. The operating loss is closing, cash flow turns positive in Q1 2028 on the base case, and the financing the company still does is opportunistic rather than forced. Behind the commercial franchise sits an unusual configuration: a recognized serious condition with no approved therapy, a biomarker measured on every routine blood count, and an FDA designation that accepts the premise.

Section 16 prices today's business plus a risk-adjusted pipeline at $6.74 a share against the $7.32 the market paid at publication — a gap that one turn of the commercial multiple closes, and smaller than the noise in its own inputs. From there the base case compounds to $21.30 by 2032, a high-teens annual return for the middle outcome.

That is the case for ownership. The case for care is the shape of the distribution rather than its center. 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 15** are, in effect, the schedule on which this thesis will be settled.

On the platform question: the ambition is large 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 it is priced at roughly the value of that business with the 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 recognized 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.

19 GLOSSARY

This report uses the vocabulary of three separate fields — urologic oncology, drug regulation and pharmacy reimbursement — and assumes fluency in all of them. That assumption is unreasonable. Terms are grouped by where they appear rather than alphabetically, and each entry says why it matters here, not merely what it stands for.

Disease and treatment

NMIBC
Non-muscle-invasive bladder cancer. The tumor sits in the bladder lining and has not grown into the muscle wall. Usually survivable, frequently recurrent, and managed for years — which is why durability of response matters more here than in advanced cancer.

CIS
Carcinoma in situ. Flat, high-grade disease spread across the bladder lining rather than a discrete lump. Harder to remove surgically, more likely to progress, and the population ANKTIVA is currently approved to treat.

papillary (Ta / T1)
Tumors that grow outward on a stalk rather than lying flat. Ta is confined to the lining, T1 has grown into the tissue just beneath it. Both can be high-grade. ANKTIVA's pending January 2027 decision covers papillary-only disease without CIS.

High-Grade (HG)
Cells that look aggressive under a microscope. High-grade disease drives the treatment decisions in this report; low-grade disease is generally watched rather than treated aggressively.

TURBT
Transurethral resection of bladder tumor. Scraping the tumor out through the urethra. The starting point for nearly every patient here, after which drug therapy aims to stop recurrence.

radical cystectomy
Removing the entire bladder. The fallback when drug therapy fails. It carries roughly 5–11% mortality within 90 days and permanently changes how a patient urinates, which is why avoiding it is the outcome patients and urologists care about most.

intravesical
Delivered directly into the bladder through a catheter. The drug acts locally and barely enters the bloodstream. ANKTIVA is intravesical in bladder cancer — central to this report, because it means a urologist administers it in their own office.

subcutaneous
Injected under the skin, so the drug circulates through the whole body. ANKTIVA's lung-cancer and lymphopenia programs use this route, which is a different drug behavior from the bladder use despite being the same molecule.

Drugs and mechanisms

BCG
Bacillus Calmette-Guérin. A live, weakened tuberculosis bacterium, originally a TB vaccine, dripped into the bladder where it provokes an immune response that attacks tumor cells. Standard care for decades, cheap, and made by a single US supplier — which is why its supply governs so much of this analysis.

TICE BCG
The specific BCG strain Merck manufactures, and the only one approved in the United States. Europe has six strains available; the US has one. That difference explains why the shortage is a US problem.

N-803
ANKTIVA under its development code. The same molecule also appears as ALT-803, from Altor BioScience where it was invented, and as nogapendekin alfa inbakicept-pmln, its generic name. Trial registries and papers written before the April 2024 approval use N-803 or ALT-803 throughout, which is why both names recur in the sources.

rBCG
Recombinant BCG. ImmunityBio's genetically modified version, supplied free or at cost under an expanded-access program while the shortage persists. Investigational, so it carries no billing code — a point the report treats as decisive.

BCG-naive
A patient who has not yet received BCG. The larger, first-line population — roughly 31,000 US patients a year — and the setting whose trial readout the entire bull case depends on.

BCG-unresponsive
A patient whose cancer returned despite adequate BCG. A formal FDA-defined status, not a judgement call, and the smaller second-line population ANKTIVA is approved in today.

IL-15 / superagonist
Interleukin-15 is a natural signaling protein that tells immune cells to multiply. A superagonist is an engineered version that does this far more strongly and lasts far longer in the body. ANKTIVA is one.

NK cell
Natural killer cell. An immune cell that kills abnormal cells without needing to be trained on a specific target first. IL-15 expands them, which is the mechanistic basis of the platform argument.

checkpoint inhibitor
A drug that releases a brake tumors use to switch off immune cells — Keytruda and IMFINZI are examples. They only work when functional immune cells are present, which is the basis of the complementarity argument in **Section 07**.

Treg
Regulatory T cell. An immune cell that suppresses immune responses. Expanding them is counterproductive in cancer, and IL-15 does not. Whether that difference is protective is examined in Section 07.

lymphopenia
An abnormally low count of lymphocytes, the immune cells that fight cancer. Common after chemotherapy and radiation, and it predicts poor response to checkpoint inhibitors. Reversing it is a potential ANKTIVA indication in its own right.

ALC
Absolute lymphocyte count. The blood measurement of the above. ImmunityBio's lung-cancer case rests substantially on raising it — but no regulator has yet accepted that raising it proves clinical benefit.[99]

ADC — antibody-drug conjugate
A tumor-targeting antibody with a chemotherapy payload attached. Much of the second-line NSCLC field is ADCs, and several have missed on overall survival.

Trial endpoints

CR — Complete Response
No detectable cancer after treatment. The endpoint used in CIS, where there is a visible lesion to clear. ANKTIVA's 62% CR rate is measured this way, against 77 evaluable patients.

DOR — Duration of Response
How long a complete response lasts before cancer returns. More important than the response rate itself: a high CR that lapses after six months is worth much less than a lower one lasting four years.

DFS / EFS
Disease-free and event-free survival. Time until the cancer returns or another defined setback occurs. Used for papillary disease, where there is no lesion to clear and therefore no complete response to measure.

OS — Overall Survival
Time until death from any cause. The endpoint regulators trust most and the one hardest to demonstrate. POTOMAC has not shown an overall survival benefit at roughly 14% maturity; NCCN lists IMFINZI in BCG-naive disease at category 2A but in its lowest preference tier.

PFS — Progression-Free Survival
Time from randomization until the tumor grows or the patient dies. The second-line NSCLC comparisons are largely fought on this measure, which can improve without anyone living longer.

TRAE — treatment-related adverse event
A side effect the investigator attributes to the drug, graded 1–5; grade ≥3 means severe enough to interfere with daily life or require intervention. The competitive tables report it because tolerability decides what an office will administer.

DSS — Disease-Specific Survival
The share of patients who have not died of this cancer, ignoring deaths from other causes. In an elderly population it runs well above overall survival, which is why it appears alongside durability rather than in place of it.

ORR — Objective Response Rate
The share of patients whose tumors shrink by a predefined amount.

Hazard Ratio (HR)
A comparison of event rates between two trial arms. Below 1.0 favors the treatment: an HR of 0.68 means roughly a 32% reduction in the rate of the measured event.

single-arm trial
Everyone receives the drug; there is no control group. Faster and smaller, but it cannot prove the drug outperformed an alternative — a caveat that applies to most evidence in this field, ANKTIVA's included.

The trials

QUILT-2.005
The randomized trial of ANKTIVA plus BCG against BCG alone in BCG-naive carcinoma in situ, 366 patients, fully enrolled February 2026. It is the single most consequential readout in this report: the BCG-naive line is the largest in the model, and this trial decides whether it arrives.

QUILT-3.032
The single-arm trial that won ANKTIVA its April 2024 approval in BCG-unresponsive carcinoma in situ. Cohort A produced the 62% complete response in the label; Cohort B, in papillary-only disease, is the basis of the supplemental application now before the FDA.

QUILT-3.055
The trial of ANKTIVA plus a checkpoint inhibitor in patients who have already progressed on one. Single-arm, so it can show what happened without showing the drug caused it, which is why the randomized ResQ201A matters more.

QUILT-2.023
The one randomized trial of systemic ANKTIVA that has reported. It was terminated at 102 patients against roughly 478 planned, leaving it underpowered for progression-free survival, and its headline result was a blood marker rather than survival. The report treats it as the weakest evidence in the systemic case.

QUILT-3.076
The trial pairing ANKTIVA with M-ceNK, the memory cytokine-enriched natural killer cells that are the company's main cell-therapy asset. Phase 1/2, so it establishes feasibility rather than benefit.

ResQ201A
The randomized Phase 3 of ANKTIVA plus tislelizumab plus docetaxel against docetaxel alone in second-line lung cancer, 507 patients, overall survival as the primary endpoint. Began October 2025. This is where the systemic thesis is settled or is not.

SunRISe-3
Johnson & Johnson's randomized Phase 3 of TAR-200 against BCG in the BCG-naive setting, 1,135 patients. A positive result would put a BCG-free regimen into the population this model depends on.

Regulation

BLA / sBLA
Biologics License Application, and the supplemental version. The application to sell a biologic drug; the supplement asks to add a new use to an existing approval. ANKTIVA has two supplements pending.

PDUFA date
The deadline by which the FDA must decide on an application. ANKTIVA's papillary decision carries a target date of January 6, 2027.

CRL — Complete Response Letter
The FDA's formal refusal to approve an application in its current form, with the deficiencies listed. ANKTIVA received one in 2023 over third-party manufacturing inspections before the 2024 approval.

EAP — expanded access program
FDA-sanctioned use of an unapproved product outside a trial for patients without alternatives, with consent and reporting obligations attached. The rBCG program runs through one, which is why prescribing it carries friction an approved product would not.

RMAT
Regenerative Medicine Advanced Therapy designation. An FDA status granting closer agency engagement and potential faster review. ANKTIVA holds one for lymphopenia — a designation, not an approval.

NCCN
National Comprehensive Cancer Network. Publishes the treatment guidelines US oncologists follow and insurers use to decide coverage. A listing here often matters more commercially than the FDA label itself.

AUA / SUO
American Urological Association and Society of Urologic Oncology. The professional bodies whose guidelines and conferences shape urology practice.

Composition of matter
A patent on the molecule itself, the strongest kind: it stops anyone making or selling that substance for any use. A method-of-use patent is narrower, covering only a stated way of using it, and is easier to work around by using the drug differently.

Patent term extension
Extra patent life granted to compensate for time lost while a drug sat in regulatory review. One patent per approval, up to five years, and it cannot run past fourteen years from approval. ImmunityBio has applied; nothing has been granted.

March-in rights
The government's power to require licensing of an invention it helped fund, if the owner fails to bring it into use or public health demands it. Rarely exercised, and it has never been used to force a price reduction.

CHMP / MAH
The European Medicines Agency committee that recommends approvals, and the Marketing Authorisation Holder — the company legally responsible for a drug in Europe. ImmunityBio Ireland Limited holds ANKTIVA's.

NICE
The body that decides which drugs England's NHS will fund. Its appraisal of ANKTIVA was terminated in June 2026 after no submission, leaving the UK private-pay only.

SFDA / EDE
The Saudi and Emirati drug regulators. Both have approved ANKTIVA, including for lung cancer in Saudi Arabia.

Payment and access

buy-and-bill
The practice purchases the drug itself, administers it, then bills the insurer. It keeps the margin between what it paid and what it is reimbursed. This is why an office-administered drug can be commercially preferable to one requiring referral elsewhere, and it recurs throughout this report.

J-code
The billing code identifying a specific drug on an insurance claim. Without a permanent one, claims are filed under a miscellaneous code and are frequently delayed or denied. ANKTIVA's (J9028) took effect January 2025 and its revenue roughly doubled in the following quarter.

ASP + 6%
How Medicare pays for office-administered drugs: average selling price plus a 6% margin, reduced to about 4.3% by budget sequestration. Because the margin is a percentage, the practice earns more in absolute dollars on a costlier drug. What a price cut would do to adoption is less obvious, and **Section 02** sets out why.

WAC
Wholesale acquisition cost. The list price before discounts. ANKTIVA's is $35,800 per dose.

gross-to-net
The gap between list price and what the manufacturer actually keeps after rebates and discounts — roughly 15–20% here. Reported revenue is already net of it.

Medicaid best price / 340B / AMP
US programs that peg discounts to a manufacturer's lowest price. Cutting a list price resets these floors permanently, which is why manufacturers prefer rebates to headline price cuts.

prior authorization / step therapy
Insurer requirements to approve a drug in advance, or to fail a cheaper option first. The main practical brake on uptake of an expensive add-on.

DRG / NTAP
Hospitals are paid a fixed sum per admission (the DRG) regardless of drugs used, so an expensive drug erodes their margin. NTAP is a temporary top-up for genuinely new technology. This is why a hospital indication such as sepsis could not support the oncology price.

MFN
Most-favored-nation pricing. A US policy proposal to peg domestic prices to the lowest paid in comparable wealthy countries. Relevant because a low price offered abroad could be imported back into the US price.

AMNOG
The German pricing law. A drug launches at whatever price the company sets, then after six months a national body assesses whether it beats existing treatment and a reimbursed price is negotiated from that verdict. The free window is the only period of unconstrained German revenue.

G-BA
The German committee that runs the AMNOG benefit assessment and decides what a drug is worth relative to standard care. Its verdict sets the ceiling for the negotiated price. No assessment of ANKTIVA has started.

accès précoce
France's early-access route. A company may supply and be paid at its own price before the formal appraisal concludes, in exchange for collecting real-world evidence. It is the one European mechanism that produces revenue ahead of a negotiated price.

NUPCO
Saudi Arabia's national procurement company. It runs the tenders through which government hospitals buy drugs, so a NUPCO award is the practical gateway to public-sector volume in the Kingdom.

CCHI
The Saudi insurance regulator. A listing with CCHI or the Ministry of Health is what makes a drug reimbursable rather than merely purchasable.

MOHAP
The UAE health ministry, which sets drug prices nationally. Individual emirates then decide separately whether to add a drug to their hospital formularies.

Finance and valuation

Enterprise Value (EV)
Market capitalization plus debt, less cash — what it would cost to buy the whole business. Used instead of market cap because it accounts for the balance sheet.

EV/Sales multiple
Enterprise value divided by annual revenue. The shorthand for how richly the market prices a company's sales. This report applies 9x to 2032 base-case revenue.

Sum-of-the-Parts (SOTP)
Valuing each part of a business separately and adding them up, rather than applying one multiple to everything. Used here because a single multiple assigns almost no value to drugs not yet approved.

risk-adjusted value
A program's potential value multiplied by its probability of success. A drug worth $2bn if approved, with a 30% chance, carries $600m.

convertible note
A loan the lender may convert into shares instead of demanding repayment. ImmunityBio's $480m note converts at $5.427 and matures December 2027. Above that price it becomes equity; below it, it becomes a problem — see **Section 01**.

warrant
A right to buy shares at a fixed price. Worthless if the share price stays below the strike, which is why this model does not credit warrant proceeds in the bear case.

ATM offering
At-the-market. Selling new shares gradually into the open market to raise cash. Flexible, but dilutive — and the worse a company's position, the lower the price at which it must sell.

dilution
Existing shareholders owning a smaller share of the company after new shares are issued. Central to the bear case here, where a falling price forces more shares to raise the same money.

revenue interest (Oberland)
A financing arrangement where an investor receives a share of future sales rather than interest. ImmunityBio pays Oberland a percentage of revenue up to a capped total.

CVR
Contingent value right. A conditional payout triggered by a future milestone, often used in acquisitions.

10-Q / 10-K
Quarterly and annual reports filed with the SEC. The primary source for most financial figures in this report.

20 SOURCES

Every identifier below was checked against SEC EDGAR, FDA.gov, EMA.europa.eu, NICE.org.uk, ClinicalTrials.gov and DOI resolvers on August 5, 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 June 30, 2026**
SEC EDGAR, accession 0001326110-26-000079, filed August 4, 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 July 31, 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 February 23, 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 April 22, 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 March 13, 2026, posted March 24, 2026. Cites TV advertisement US-ANK-250065-v1 and a podcast aired January 19, 2026. Follows untitled letters of September 9, 2025 and January 7, 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 May 28, 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 September 9, 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 November 10, 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. Randomized 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–May 6, 2024.
https://clinicaltrials.gov/study/NCT02138734

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

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

12 **ANKTIVA EU conditional marketing authorization**
European Commission conditional MA announced February 18, 2026; CHMP positive opinion December 11, 2025. Marketing authorization holder **ImmunityBio Ireland Limited** per EMA List of Medicinal Products under Additional Monitoring. Marketing authorization number **EU/1/25/2002/001** per EPAR Annex I §8. Commission Implementing Decision **C(2026) 1197 final**, February 16, 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 March 30, 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 December 31, 2029 Test Date; if they fall short, the rate increases and a True-Up Payment is owed. Payments terminate at 195% of Cumulative Purchaser Payments — $731.25M against $375.0M funded. Terms per Form 10-Q, quarter ended June 30, 2026, accession 0001326110-26-000079, Revenue Interest Purchase Agreement note.
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 February 25, 2026: 745,576,456 shares, 66.3%, calculated on 1,028,111,456 shares outstanding as of February 19, 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 May 14, 2026. Exclusive development and supply agreement for the Tokyo-172 strain 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, May 27, 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, February 19, 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 – March 24, 2026. Lead-plaintiff deadline May 26, 2026; motions filed and pending.
https://www.ktmc.com/ibrx-immunitybio-inc-class-action-lawsuit/

22 **Sepsis trial**
ClinicalTrials.gov NCT07578558. Phase 2, randomized, 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 July 6, 2026; primary completion August 3, 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 507, raised from an initial target near 460. Estimated primary completion September 2028, study completion January 2029.
https://clinicaltrials.gov/study/NCT06745908

24 **Lymphopenia Expanded Access Program**
ClinicalTrials.gov NCT06956547. Expanded access for NAI in lymphopenia in refractory or relapsed solid tumors. FDA authorization announced June 2, 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, randomized 1:1:1 to TAR-200 plus cetrelimab, TAR-200 alone, or intravesical BCG, in BCG-naive high-risk NMIBC. Study start March 23, 2023; actual enrolment 1,135 against a design target near 1,050; active and not recruiting. The primary endpoint is event-free survival, which for patients with carcinoma in situ counts persistent disease at six months as an event. Estimated primary completion September 18, 2029, stable across amendments. **A DATA MONITORING COMMITTEE EXISTS; NO EFFICACY INTERIM IS DISCLOSED** — its number, timing and event triggers appear in no public source. Johnson & Johnson has given no readout date for this trial, and the 2027 expectation in secondary commentary traces to analyst blogs rather than company guidance. The sibling SunRISe-2 stopped at a futility interim in September 2024, which shows these trials carry monitored interims without establishing an efficacy gate here.
https://clinicaltrials.gov/study/NCT05714202

27 **Pembrolizumab real-world utilization 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 January 14, 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 authorization**
ImmunityBio Form 8-K, event date July 29, 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. The exhibit also states the approved posology: “ANKTIVA is administered as a fixed 1 mg subcutaneous dose once every 21 days for the duration of checkpoint inhibitor therapy.” **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 September 8, 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-capitalization snapshots and carry approximately ±10–15% error.**
https://stockanalysis.com/stocks/ibrx/

35 **Operating cash flow — basis of the quarterly figure**
ImmunityBio Form 10-Q, quarter ended June 30, 2026. The Condensed Consolidated Statement of Cash Flows reports net cash used in operating activities of **$(141,853) thousand for the six months** ended June 30, 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 December 11, 2024, accession 0001193125-24-274871, Item 1.01, Exhibit 1.2 (Second Amended and Restated Promissory Note, dated December 10, 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 January 26, 2026, accession 0001326110-26-000014. Step-down to $480.0m: Form 8-K filed March 31, 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–February 28, 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, September 22, 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 March 31, 2026, accession 0001326110-26-000059, filed May 7, 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, May 12, 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, May 12, 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, July 15, 2026. Jennifer Taubert: INLEXZO "is outperforming recent competitive launches, with one in three eligible patients 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 July 1, 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, May 7, 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

49 **NCCN lists durvalumab + BCG at category 2A, in its lowest preference tier**
NCCN Clinical Practice Guidelines in Oncology, Bladder Cancer, v3.2026 (August 6, 2026), page BL-4. Durvalumab + BCG, added in v2.2026, is listed as useful in certain circumstances for BCG-naive high-risk disease and for BCG-unresponsive CIS, at category 2A, the page's default; its only category 2B marks are single-agent intravesical chemotherapy in the BCG-unresponsive columns and pembrolizumab in the papillary-only column. In the BCG-naive column, preferred is BCG induction followed by maintenance (category 1 absent very-high-risk features), other recommended is intravesical chemotherapy or a clinical trial, and useful in certain circumstances is BCG + durvalumab or cystectomy. Sasanlimab + BCG (CREST) is not listed. The discussion text lags the algorithm and still declines to endorse POTOMAC, citing risk-benefit and long-term toxicity. POTOMAC overall survival remains immature: HR 0.80 (95% CI 0.53–1.20), roughly 14% maturity.
https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1417

50 **AstraZeneca European filing withdrawal and Q2 2026 disclosure**
AstraZeneca withdrew its Type II variation application for durvalumab in BCG-naive high-risk NMIBC from EMA review; the US approval of May 28, 2026 is unaffected. On the Q2 2026 earnings call (July 27, 2026) the POTOMAC launch received a single passing reference from R&D head Susan Galbraith, with no NMIBC patient-start, revenue or channel metrics disclosed. Total IMFINZI Q2 revenue was $1.85bn, up 27%, against a consensus estimate of $1.91bn.
https://www.astrazeneca.com/investor-relations/results-and-presentations.html

51 **Clinician sentiment on systemic immunotherapy in NMIBC**
Urology Times Clinical Forum, December 2025. Participating clinicians reported minimal use of systemic immunotherapy for NMIBC; that checkpoint-inhibitor toxicities "feel disproportionate for a non–muscle-invasive setting"; and that the requirement for concurrent BCG "has significantly limited uptake," because scarce supply is reserved for naive patients rather than combination regimens. **Expert-opinion forum, not a quantified prescriber survey.**
https://www.urologytimes.com/

52 **Urology practice infusion capability**
De Santis M, et al. Multidisciplinary management commentary, *Oncology and Therapy*, 2025: while some urology practices can offer PD-(L)1 therapy in house, "most may have to partner with medical oncologists… including… space for infusions for IV… agents." Roughly one third of US urology practices are estimated to have infusion capability; large integrated groups (Solaris Health, United Urology Group, US Urology Partners) built infusion and oncology infrastructure to retain advanced prostate cancer patients. Durvalumab bills under HCPCS J9173 at ASP plus 6%. **The one-third figure is directional; no 2024–2026 survey quantifies it precisely.**
https://link.springer.com/journal/40487

53 **IL-15 superagonist enhancement of anti-PD-L1 therapy — mechanism**
Knudson KM, Hicks KC, Alter S, Schlom J, Gameiro SR. "Mechanisms involved in IL-15 superagonist enhancement of anti-PD-L1 therapy." J Immunother Cancer. 2019;7(1):82. DOI 10.1186/s40425-019-0551-y. PMC6429734. In anti-PD-L1-refractory 4T1 and MC38-CEA models, N-803 plus anti-PD-L1 reduced tumor burden and improved survival over either monotherapy; efficacy required both CD8+ T cells and NK cells. N-803 upregulated PD-L1 on immune cells, providing the mechanistic rationale for adding checkpoint blockade. On progenitor-exhausted (TCF1+) T cells as the PD-1-responsive population, see also the IL-2Rβ exhaustion literature — the same receptor signaling drives terminal exhaustion in chronic antigen settings, so the direction of the effect is context-dependent. **Preclinical; no human immune-monitoring dataset confirms the mechanism in ANKTIVA-treated patients.**
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6429734/

54 **Bempegaldesleukin plus nivolumab — PIVOT IO-001, the cautionary precedent**
Khushalani NI, Diab A, Ascierto PA, et al. J Clin Oncol. 2023. Randomized phase 3, 783 patients, first-line unresectable or metastatic melanoma, bempegaldesleukin + nivolumab versus nivolumab alone. Verbatim: the trial "did not meet its primary end points of ORR, PFS, and OS. Increased toxicity was observed with BEMPEG plus NIVO versus NIVO." Response was 27.7% against 36.0% for nivolumab alone; complete response 8.1% against 12.5%; progression-free survival hazard ratio 1.09; grade 3–4 treatment-related events 21.7% against 11.5%; three treatment-related deaths against one. Bempegaldesleukin was a pegylated IL-2 engineered with PEG chains masking the CD25 interface, specifically to bias signalling away from regulatory T cells; biomarker analysis found Tregs expanded over CD8 cells in later cycles regardless. It received Breakthrough Therapy designation in July 2019, was never approved in any indication or jurisdiction, and the global program was terminated in April 2022.
https://ascopubs.org/doi/10.1200/JCO.22.02203

55 **QUILT-2.023 — randomized, terminated early, biomarker endpoint**
ClinicalTrials.gov NCT03520686. Randomized first-line NSCLC, ANKTIVA + checkpoint inhibitor versus checkpoint inhibitor alone. Terminated at 102 patients against approximately 478 planned, leaving it underpowered for its progression-free survival primary endpoint. The reported significant result is a biomarker: sustained absolute lymphocyte count increase with the combination (p=0.0065). Exploratory unblinded subgroup analysis presented at ASCO 2026 reported, in PD-L1 ≥50% (n=45), median PFS 7.0 versus 2.2 months (HR 0.40; p=0.0298); pooled chemo-IO subgroup (n=36) OS 34.7 versus 20.2 months (HR 0.38; p=0.0394) with PFS not significant. For benchmark context, pembrolizumab monotherapy in PD-L1 ≥50% delivered median PFS of 10.3 months in KEYNOTE-024 (Reck M, et al. N Engl J Med. 2016;375:1823–1833. DOI 10.1056/NEJMoa1606774). **Subgroup figures taken from trade-press coverage of the ASCO abstract; not verified against the primary abstract, and no peer-reviewed randomized efficacy publication exists.**
https://clinicaltrials.gov/study/NCT03520686

56 **Launch-year penetration reference class**
ANKTIVA: ImmunityBio FY2025 results, February 23, 2026 — full-year net product revenue $113.0m, approximately 700% year-over-year growth on ~750% unit-volume growth. Permanent J-code J9028 effective January 1, 2025; the first quarter carrying it delivered ~$16.5m against $7.2m in Q4 2024. Implied patient starts (~400–650) are **derived** from net revenue divided by WAC $35,800 less a 15–20% gross-to-net, then divided by 6–12 realized doses per patient in a ramping launch year; the doses-per-patient assumption swings the estimate by roughly ±60%.
ADSTILADRIN: Ferring FY2024 US sales of €70m (reported in trade press as approximately $77m) at a course price near $240,000, implying roughly 320 patients. J-code J9029 effective July 1, 2023; ASP established April 1, 2024.
Denominator: the annual BCG-unresponsive figure is a **derived estimate** — high-risk NMIBC incidence multiplied by a BCG-failure rate of roughly 30–40% — not a directly sourced epidemiological count. Source 137 sets out the range and why this report now uses 7,000 to 13,000. **Patient counts in this table are reconstructions, not company-disclosed figures. ImmunityBio reports ANKTIVA only as net revenue and percentage unit growth, never absolute patient or account counts.**
https://ir.immunitybio.com/news-releases/news-release-details/immunitybio-reports-record-q1-2026-results-net-product-revenue

57 **BCG-naive high-risk NMIBC population — incidence versus prevalence**
AstraZeneca US press release, May 28, 2026 (IMFINZI approval in BCG-naive high-risk NMIBC): "In 2024, over 31,000 people in the US were treated for high-risk NMIBC." A separate AstraZeneca release accompanying ESMO 2025 cites "an estimated 125,000 patients" treated for high-risk NMIBC in 2024. The two figures come from the same company and are not reconcilable as a single quantity: the ~31,000 figure represents the **incident or newly-treated flow** entering curative-intent TURBT plus BCG, whereas ~125,000 represents **prevalence** — all patients under management including those on multi-year maintenance from prior years. For a launch-year add-on administered at the start of BCG induction, the incident flow is the correct denominator. This model uses the ~31,000 figure throughout.
https://www.astrazeneca-us.com/media/press-releases/2026/imfinzi-durvalumab-approved-in-the-us-in-only-immunotherapy-combination-for-patients-with-bcg-naive-high-risk-non-muscle-invasive-bladder.html

58 **Medicare Part B buy-and-bill reimbursement mechanics**
Physician-administered drugs under Medicare Part B are reimbursed at the volume-weighted average sales price plus 6%, reduced to approximately ASP plus 4.3% by the 2% budget sequestration. ASP is reported quarterly by manufacturers and applied by CMS with a two-quarter lag, so a price change takes roughly six months to propagate into the reimbursement rate. Because the add-on is a fixed percentage, the absolute dollar margin to the administering practice scales with price. On the empirical question of whether that margin influences drug selection, see Jacobson M, et al. "Does reimbursement influence chemotherapy treatment for cancer patients?" Health Aff. 2006;25(2):437–443, and "How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment." Health Aff. 2010;29(7):1391–1399; also MedPAC, Report to the Congress, June 2016, Chapter 5. **The literature is mixed on magnitude — Hornbrook (2014) and Parsons (2016) find reimbursement effects small relative to clinical factors, and MedPAC notes few studies exist. The direction is robust; the size for a no-substitute drug is uncertain.**
https://www.medpac.gov/.../chapter-5-medicare-part-b-drug-and-oncology-payment-policy-issues-june-2016-report-.pdf

59 **The insulin list-price precedent, and why it cuts against the volume thesis**
Eli Lilly announced a 70% cut to Humalog and Humulin on March 1, 2023; Novo Nordisk cut NovoLog 75% and Novolin/Levemir 65% on March 14, 2023; Sanofi cut Lantus 78% and Apidra 70% on March 16, 2023 — all effective January 1, 2024. Analysis cited by CNN (Veda Partners) attributed the moves substantially to Medicaid rebate-cap mechanics rather than to a volume bet: Lilly avoided roughly $430m in added rebates, Novo roughly $350m. Net prices were largely unchanged, and lower list prices meant smaller rebates to pharmacy benefit managers, reducing their incentive to formulary the products; Novo Nordisk cited a decline of approximately 60% in Levemir patient access and discontinued the product. **Retail/Part D precedent, not Part B buy-and-bill — only partially analogous. No clean case exists of a manufacturer voluntarily cutting a Part B oncology biologic's list price to grow volume.**
https://investor.lilly.com/news-releases/news-release-details/lilly-cuts-insulin-prices-70-and-caps-patient-insulin-out-pocket

60 **Most-Favored-Nation drug pricing policy**
Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," signed May 12, 2025 (90 Fed. Reg. 20749), directs HHS to target the lowest price available in an OECD country with GDP per capita of at least 60% of the US level. CMS has proposed the GLOBE model for Part B and GUARD for Part D, with a proposed effective date of October 1, 2026; by January 2026 sixteen manufacturers had entered confidential MFN agreements. Saudi Arabia applies external reference pricing against a defined basket with centralized NUPCO tender procurement; the UAE applies international reference pricing through the MOHAP Drug Pricing Committee. **GLOBE and GUARD are proposed, not finalized; manufacturer agreement terms are confidential. The spillover mechanism for a small-cap oncology biologic is not settled.**
https://www.govinfo.gov/content/pkg/FR-2025-05-15/html/2025-08876.htm

61 **Product revenue is US-only**
Form 10-Q for the quarter ended June 30, 2026, filed August 4, 2026. Revenue recognition note: product revenue "was generated from U.S. sales of ANKTIVA." The geographic table shows a Europe line of $518k for the quarter and $542k for the half, reconciling into other revenue rather than product sales, and unexplained in the filing.
https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000079/ibrx-20260630.htm

62 **Composition-of-matter patent, N-803**
US 8,507,222 B2, “Multimeric IL-15 soluble fusion molecules and methods of making and using same.” Priority September 21, 2010; granted August 13, 2013; inventor Hing C. Wong et al.; original assignee Altor BioScience Corporation, now held through the ImmunityBio group. Nominal twenty-year term from priority gives an anticipated expiry of September 21, 2031, absent any term extension.
https://patents.google.com/patent/US8507222B2/en

63 **ANKTIVA-plus-BCG patent family**
ImmunityBio announcement, May 18, 2026, of US patents covering the combination of ANKTIVA with BCG with terms through 2035: US 11,173,191; 11,679,144; 11,890,323; 12,268,731; 12,318,432. Claims cover the intravesical regimen, the two-vial kit, and methods in non-muscle-invasive bladder cancer including BCG-naive disease. **COMPANY ANNOUNCEMENT** — individual claim scope and any terminal disclaimers were not independently verified against the USPTO file wrappers.
https://www.businesswire.com/news/home/20260518605297/en/

64 **Purple Book entry, ANKTIVA**
FDA Purple Book, BLA 761336, nogapendekin alfa inbakicept-pmln, applicant Altor BioScience LLC, original approval April 22, 2024, licensed under section 351(a). **DATE OF FIRST LICENSURE AND REFERENCE PRODUCT EXCLUSIVITY EXPIRY ARE NOT POPULATED**, and no orphan exclusivity is listed. FDA states that the absence of such a date does not mean a product is ineligible for exclusivity.
https://purplebooksearch.fda.gov/

65 **Sotio discontinues nanrilkefusp alfa**
Nanrilkefusp alfa (SOT101) is a subcutaneous fusion of the IL-15 receptor-α sushi+ domain to IL-15. In 51 patients in AURELIO-03 it raised circulating CD8+ T and NK cell proportions with a favorable safety profile and without expanding regulatory T cells. Sotio halted enrolment across AURELIO-03, -04 and -05 in October 2023, citing insufficient efficacy and no major safety issues. Grell et al., Cell Reports Medicine, February 2025; NCT04234113.
https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(25)00040-0

66 Inhaled IL-15 in dogs with spontaneous lung metastases
Phase 1 of nebulized recombinant human IL-15, twice daily for fourteen days, in dogs with pulmonary metastases from osteosarcoma or melanoma. The authors report promising clinical activity from monotherapy over that period and conclude the results have implications for humans with refractory lung metastases. Baseline lymphopenia correlated with clinical benefit. A Phase 2 in canine appendicular osteosarcoma followed.
https://pubmed.ncbi.nlm.nih.gov/35680383/

67 ImmunityBio lung program is systemic throughout
QUILT-2.023 (first-line NSCLC), QUILT-3.055 (checkpoint-experienced), ResQ201A (randomised second-line confirmatory) and the Lung-MAP substudy with pembrolizumab all administer N-803 systemically. No inhaled or nebulized presentation appears in the company pipeline as of August 2026.
https://immunitybio.com/pipeline/

68 Scaffold patents beyond IL-15
ImmunityBio holds granted US patents applying the IL-15 receptor-α sushi and Fc architecture to fusions with other cytokines, including IL-12 and IL-18 — for example US 11,872,272 and US 11,975,059. These are composition and preclinical claims; no program built on the scaffold beyond IL-15 has entered clinical trials.
https://patents.google.com/patent/US11872272B2/en

69 SHR-1501, the architectural competitor
Hengrui's SHR-1501 is an IL-15 and IL-15 receptor-α sushi domain IgG1 Fc fusion under study by intravesical administration in non-muscle-invasive bladder cancer — the same construct architecture and the same route as ANKTIVA, in the same indication. **TRIAL REGISTRY AND LITERATURE**; no claim-construction opinion exists in the public record on whether the ANKTIVA-plus-BCG claims would exclude it.
https://clinicaltrials.gov/

70 No validity challenge found
Searched August 2026 across USPTO Patent Trial and Appeal Board proceedings, EPO opposition records, and litigation and trade reporting, for challenges touching the ANKTIVA composition and combination patents. **ABSENCE OF EVIDENCE** — a search returning nothing is weaker than an affirmative record, and proceedings can be filed at any time.
https://ptacts.uspto.gov/ptacts/ui/search/public

71 Commercial spending stepped up without moving the adds
ImmunityBio quarterly selling, general and administrative expense: $32.7m, $42.3m, $36.3m and $38.7m through 2025; $45.8m in Q1 2026 and $51.8m in Q2 2026. Full-year 2025 SG&A fell to $150m from $168.8m, which management attributed to insourcing commercial consulting functions. The 2026 increases are attributed to professional services, personnel and commercial costs. SG&A is reported as a single line; selling and marketing is not disclosed separately, and no field headcount, territory count or ordering-account count is disclosed in any filing or call.
https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001326110&type=10-Q

72 Ownership and controlled-company status
ImmunityBio definitive proxy statement, April 2026. Soon-Shiong and affiliates held approximately 62.5% of outstanding common stock as of the April 13, 2026 record date. The company states it is a controlled company under Nasdaq rules and may elect not to comply with the requirements that a majority of the board be independent and that it maintain a nominating and corporate governance committee; it satisfies both voluntarily. Six of nine directors determined independent. Single class of common stock, one vote per share, no cumulative voting.
https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000049/ibrx-20260429.htm

73 Executive compensation, fiscal 2025
Summary compensation table, 2026 proxy. Richard Adcock, chief executive: $12,716,953 total, including $8,353,406 in option awards and $2,787,828 in stock awards. Patrick Soon-Shiong, executive chairman: $12,293,255 total on the same equity grants. Say-on-pay at the most recent advisory vote passed with approximately 99% support; the vote is held every three years and next falls in 2027.
https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000049/ibrx-20260429.htm

74 Related-party arrangements

Form 10-Q for the quarter ended March 31, 2026, related-party note. A facility license from a NantWorks entity in Culver City at approximately $0.9m a quarter; leases with Soon-Shiong-controlled entities carrying right-of-use assets near $12.5m; a shared-services agreement with NantWorks effective August 2015; and payments to the Immuno-Oncology Clinic, owned by a company officer, of approximately $1.2m in the quarter. A related-party transaction committee reviews these under a written policy.
https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000059/ibrx-20260331.htm

75 Going-concern language, verbatim

Form 10-K filed February 23, 2026 and Form 10-Q filed August 4, 2026. Substantial doubt exists regarding the ability to continue as a going concern without additional funding, alleviated "based primarily upon our Founder, Executive Chairman and Global Chief Scientific and Medical Officer's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required." **NO BINDING COMMITMENT, COMMITTED AMOUNT OR STATED LIMIT ACCOMPANIES THIS LANGUAGE.**
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000030/ibrx-20251231.htm

76 FDA warning letter on promotion

FDA Office of Prescription Drug Promotion warning letter, March 13, 2026, MARCS-CMS 725468, addressed to the chief executive. Cited a television advertisement and a January 19, 2026 podcast in which the founder stated the company had "the therapy to prevent cancer if you were exposed to radiation." FDA responded that it was not aware of data supporting claims that ANKTIVA can cure cancer, and found the communications misbranded the product. Untitled letters of September 9, 2025 and January 7, 2026 preceded it.
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters

77 Securities class action

Douglas v. ImmunityBio, Inc., No. 2:26-cv-03261, US District Court for the Central District of California, filed April 2026. Class period January 19 to March 24, 2026. Defendants include the company and Soon-Shiong. Shares closed down approximately 21% at $7.42 on March 24, 2026 when the warning letter was published. **EARLY STAGE** — lead-plaintiff and consolidation phase, no ruling on the merits.
https://www.globenewswire.com/news-release/2026/04/25/3281151/0/en/

78 Prior exits

Fresenius agreed to acquire American Pharmaceutical Partners in July 2008 at $23.00 a share, valuing fully diluted equity at approximately $3.7bn, or $4.6bn if the contingent value right were fully realized; the transaction closed in September 2008. Celgene agreed to acquire Abraxis BioScience in June 2010 for approximately $2.9bn in cash and stock plus contingent milestones of up to $650m.
https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&company=abraxis&type=425

79 What other revenue consists of

Form 10-Q for the quarter ended March 31, 2026, management's discussion: other revenues increased "primarily due to increased bioreactor related consumable product sales, and increased license royalty income." Both lines predate ANKTIVA — pre-merger NantKwest filings describe revenue from "non-exclusive license agreements related to our cell lines, the sale of our bioreactors and related consumables and grant programs." **THE FILING DISCLOSES WHAT OTHER REVENUE IS, BUT NOT THE GEOGRAPHIC SPLIT WITHIN IT**, so which component the European figure represents is not stated.
https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000059/ibrx-20260331.htm

80 Radiation-induced lymphopenia, meta-analysis

Systematic review and meta-analysis of severe radiation-induced lymphopenia across fifty-six studies and 13,223 patients in eleven tumor types: 37.25% incidence, pooled overall-survival hazard ratio 1.70 (95% CI 1.55–1.86). Tumor-specific figures include brain 1.63, lung 1.52 and pancreatic 1.92. Venkatesulu et al. and related pooled analyses.
https://pubmed.ncbi.nlm.nih.gov/?term=radiation-induced+lymphopenia+meta-analysis

81 Severe and persistent lymphopenia after chemoradiation

Grossman et al., Journal of the National Comprehensive Cancer Network 2015;13(10):1225–1231, n=297. Two months after starting chemoradiation, 43% of patients had developed severe and persistent lymphopenia, with a pooled death hazard ratio of 2.1 (95% CI 1.54–2.78, P<.0001). By cohort: gliomas 1.8, resected pancreas 2.2, unresected pancreas 2.9, lung 1.7.
https://pubmed.ncbi.nlm.nih.gov/26483062/

82 Mediation analysis, esophageal chemoradiation

Proton beam therapy reduced grade 4 radiation-induced lymphopenia relative to IMRT (odds ratio 0.41), and a formal mediation analysis attributed approximately 14.5% of the overall-survival difference between the two modalities to the lymphocyte effect itself. **SINGLE TUMOR TYPE** — establishes mediation rather than demonstrating that pharmacological correction would reproduce the benefit.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11382310/

83 Why the compendia route does not reach lymphopenia

Social Security Act §1861(t)(2)(B) requires Medicare to cover off-label uses of drugs "used in an anticancer chemotherapeutic regimen" that are supported by a recognized compendium; CMS Medicare Benefit Policy Manual Pub. 100-02 Ch. 15 §50.4.5 defines the regimen as a combination of anti-cancer agents. Raising a lymphocyte count is supportive care, not tumor-directed treatment. Precedent is consistent: filgrastim (1991), pegfilgrastim (2002), epoetin and darbepoetin (2002) each obtained their own FDA supportive-care indication. **NO CMS ADJUDICATION SQUARELY DECIDES A SUPPORTIVE-ONLY AGENT UNDER §50.4.5**, so this is statutory text plus precedent rather than a settled ruling.

https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

84 Customer concentration and revenue recognition

Form 10-Q. Revenue is recognized on shipment to specialty distributors rather than on administration. Four customers accounted for 41%, 20%, 18% and 17% of total revenue in the quarter ended September 30, 2025; an earlier quarter reported approximately 99% of gross revenue from the top four with the largest two at 31% each. Accounts receivable are mainly from specialty distributors. **CHANNEL INVENTORY AND SELL-THROUGH ARE NOT DISCLOSED**, so the filings do not separate end-demand from distributor stocking.

https://ir.immunitybio.com/static-files/cc3f8c08-b4ec-4c88-a39a-11d8c6800953

85 Short interest

Reported short interest in ImmunityBio has run from roughly 14% of shares outstanding to above a third of the float on some measures during 2026, against a peer-group average nearer 15%. A rally in January 2026 forced short covering. **POINT-IN-TIME AND BASIS-DEPENDENT** — figures differ materially between shares-outstanding and float denominators and between reporting dates.

https://www.nasdaq.com/market-activity/stocks/ibrx/short-interest

86 Why IL-2 and IL-15 have different toxicity ceilings

High-dose IL-2 is limited by vascular leak syndrome, in which increased vascular permeability produces interstitial edema, hypotension and pulmonary edema; the mechanism is attributed in part to IL-2 receptor-α expression on endothelium and direct binding of IL-2 to lung endothelial cells. IL-15 signals through the shared βγ complex but its private receptor-α is expressed on antigen-presenting cells and works by trans-presentation, not on endothelium in the same way. IL-15 carries its own systemic ceiling — cytokine release syndrome and neurotoxicity at higher subcutaneous doses — so this is a difference in mechanism rather than an absence of toxicity.

https://pmc.ncbi.nlm.nih.gov/articles/PMC7248178/

87 N-803 given subcutaneously

The Phase 1 study of ALT-803 in solid tumors reported subcutaneous dosing as well tolerated with minimal cytokine toxicities, and intravenous dosing was abandoned because high peak concentrations produced fever, rigors and hypotension. QUILT-3.055 administered N-803 subcutaneously with checkpoint inhibitors in checkpoint-experienced patients. The SFDA approved the 1.2 mg subcutaneous presentation for metastatic NSCLC in January 2026 and the Emirates Drug Establishment in July 2026 — the first subcutaneous approvals for the molecule. **SINGLE-ARM** — tolerability is established, randomized efficacy by this route is not.

https://pubmed.ncbi.nlm.nih.gov/30150104/

88 The two control arms, benchmarked

Nivolumab monotherapy in first-line advanced melanoma produced an objective response rate of approximately 44% in CheckMate 067, with a five-year overall survival rate of 44% and median overall survival near 37 months. Docetaxel monotherapy in second-line non-small cell lung cancer produces response rates of roughly 3–12% and median overall survival of roughly 5.7–9.5 months across randomized trials; the docetaxel arm of REVEL reached 9.1 months. The statistical task differs accordingly.

https://pubmed.ncbi.nlm.nih.gov/31562797/

89 No approved therapy for lymphopenia

Searched August 2026 across the FDA approved-drug database, the EMA medicines register and the WHO essential medicines list for any product approved to treat lymphopenia or restore absolute lymphocyte count as an indication. None was found. Supportive-care precedent in oncology runs to neutropenia (filgrastim, pegfilgrastim) and anemia (epoetin, darbepoetin); the lymphocyte compartment has no equivalent. **ABSENCE OF EVIDENCE** — a search returning nothing is weaker than an affirmative register entry, and off-label and investigational use is not captured.

https://www.accessdata.fda.gov/scripts/cder/daf/

90 The rBCG expanded-access program

FDA authorized expanded access for recombinant BCG (VPM1002BC, Serum Institute of India) in February 2025; first US dosing March 2025; ClinicalTrials.gov NCT06800963, administered through Anova Enterprises. Expanded access under 21 CFR 312 subpart I permits patients to receive an investigational drug outside a clinical trial where no comparable alternative exists. Participation requires site enrolment, institutional review board approval, written informed consent, adverse-event reporting and cold-chain handling of a live biologic.

https://clinicaltrials.gov/study/NCT06800963

91 Why the program cannot be promoted

21 CFR 312.7(a): a sponsor may not represent in a promotional context that an investigational drug is safe or effective for the use under investigation, or otherwise promote it. Charging for an investigational drug under 21 CFR 312.8 recovers direct costs and does not convert the product into a commercial one or lift the restriction. The sponsor may make the program's existence, protocol and logistics known; it may not market the product's benefits. **REGULATORY CEILING** — the constraint on rBCG uptake is structural rather than a failure of marketing effort.

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312

92 Shelf life and inventory reserves

Form 10-Q for the quarter ended June 30, 2026. Finished drug product carries a shelf life of two years from manufacture, extended to three years in September 2024; work-in-progress comprising bulk drug substance and drug product carries a multi-year shelf life. Inventory of $18.4m gross splits $16.7m work-in-progress and $1.7m finished goods. The allowance for inventory reserve was $0.2m at both June 30, 2026 and December 31, 2025, and no write-downs have been recorded since approval. Product manufactured before approval was expensed to research and development and carries no book value; $0.6m of such product remained on hand. Stated policy is to sell finished goods at least twelve months before expiry.

https://www.sec.gov/Archives/edgar/data/0001326110/000132611026000079/ibrx-20260630.htm

93 What the QUILT-2.005 interim does not disclose

The interim reported 6-month maintained complete response of 85% against 57% (p=0.0536) and 9-month of 84% against 52% (p=0.0455) in the first 43 efficacy-evaluable patients, presented at AUA 2024. With roughly twenty patients an arm, a two-proportion comparison at these values sits within one or two patients of the 0.05 threshold in either direction. **NOT DISCLOSED** — exact numerators and denominators, confidence intervals around each proportion, the randomization ratio, whether the timepoints were pre-specified, and whether any multiplicity adjustment was applied across the two looks. The company describes the interim as requested by the FDA to establish whether the study was trending favorably, which suggests an administrative rather than an alpha-spending analysis.

https://clinicaltrials.gov/study/NCT03022825

94 What the inhaled IL-15 study actually used

Rebhun, Canter et al., Journal for ImmunoTherapy of Cancer 2022;10(6):e004493. First-in-dog Phase 1 of nebulized *recombinant human IL-15* — the native cytokine, not a superagonist and not N-803 — twice daily for fourteen days in 21 dogs with spontaneous pulmonary metastases from osteosarcoma or melanoma. Among 18 evaluable dogs, one complete response beyond a year, one partial response and five stable disease. Baseline lymphopenia correlated with benefit. A recommended Phase 2 dose of 50 μg twice daily was established, and follow-on academic work added doxorubicin preconditioning. **NO HUMAN INHALED IL-15 OR IL-15 SUPERAGONIST TRIAL IS REGISTERED OR PLANNED BY ANY SPONSOR**, so the read-across is to the route rather than to the molecule.

https://pubmed.ncbi.nlm.nih.gov/35688557/

95 ResQ201A dosing and duration
ClinicalTrials.gov NCT06745908 and the WCLC 2025 abstract. Nogapendekin alfa inbakicept 1.2 mg subcutaneously with tislelizumab 200 mg intravenously on three-week cycles, alongside docetaxel 75 mg/m² for the first two cycles only; the registry states that N-803 and tislelizumab continue from cycle three onward until end of study, with no maximum cycle count or duration cap. For comparison, the pembrolizumab and nivolumab non-small cell lung labels cap treatment at twenty-four months or thirty-five cycles. The Phase 2 dose was 15 μg/kg, which for a 70–80 kg patient is roughly 1.05–1.2 mg, so the Phase 3 dose is equal to or slightly above it rather than reduced.
https://clinicaltrials.gov/study/NCT06745908

96 Targeted IL-15 constructs at other companies
Sotio's SOT201 is described by the company as a PD-1-targeted, cis-acting attenuated IL-15 agonist intended to activate PD-1-positive CD8 T cells preferentially; the VICTORIA-01 Phase 1 (NCT06163391) dosed its first patient in May 2024. Xencor's XmAb24306, an IL-15 and IL-15 receptor-α Fc construct, was licensed to Genentech. Both represent the tumor-targeting approach to widening the therapeutic window for systemic IL-15. ImmunityBio has disclosed no equivalent program; its systemic route remains untargeted subcutaneous administration.
https://clinicaltrials.gov/study/NCT06163391

97 Lymphopenia prevalence in the general population
Zidar et al., JAMA Network Open 2019;2(12):e1916526, National Health and Nutrition Examination Survey, n=31,178. 20.1% of US adults carry an absolute lymphocyte count at or below 1,500 cells per microliter and 3.0% at or below 1,000. Age and sex adjusted mortality hazard ratios of 1.3 and 1.8 respectively. **PREVALENCE OF A RISK MARKER** — this describes how many people carry the finding, not how many would be treated.
https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2757214

98 Radiotherapy volume and lymphopenia incidence
More than half a million US patients receive radiotherapy annually. Radiation-induced immunosuppression occurs in up to 70% of patients receiving conventional radiotherapy; a meta-analysis of 93 studies and 11,565 patients found severe grade 3 or higher radiation-induced lymphopenia averaging 26.7%, range 18.6–88.0%, with a pooled overall-survival hazard ratio of 1.72 (95% CI 1.33–1.87).
https://pubmed.ncbi.nlm.nih.gov/?term=radiation-induced+lymphopenia+meta-analysis

99 How comparable deficiencies won their labels
Filgrastim (1991) is indicated to decrease the incidence of infection as manifested by febrile neutropenia; the pivotal endpoint was febrile-neutropenia incidence, 1% against 17% on placebo. Immunoglobulin replacement for primary humoral immunodeficiency rests on a serious bacterial infection rate below 1.0 per patient per year under FDA's 2005 guidance. Interferon gamma-1b (1990) for chronic granulomatous disease rested on time to serious infection, a 67% relative risk reduction, p=0.0006, n=128. Romiplostim (August 2008) was approved on a durable platelet response, but for chronic immune thrombocytopenia — a defined autoimmune disease rather than a low count. In every case the label attaches to a clinical event or a disease with a known cause.
https://www.accessdata.fda.gov/scripts/cder/daf/

100 Idiopathic CD4 lymphocytopenia, thirty years without a therapy
A recognized entity defined as CD4 below 300 cells per microliter absent HIV or another cause, coded under ICD-10 D72.810 and studied in a 108-patient NIH natural-history cohort published in the New England Journal of Medicine in 2022. No therapy has ever been approved. Interleukin-7 raised circulating and tissue CD4 and CD8 counts in the ICICLE trial (NCT00839436) without advancing to a label. The current NIH interleukin-7 study in this population (NCT05600920) carries safety as its primary endpoint and CD4 elevation only as exploratory.
https://clinicaltrials.gov/study/NCT05600920

101 Interleukin-7: the count rises, the label does not follow
NeoImmuneTech's long-acting interleukin-7 met its lymphocyte endpoint in a Phase 2 in high-grade glioma with treatment-related lymphopenia (NCT03687957): median absolute lymphocyte count change at four weeks of +148% against +16.7% on placebo, p=0.007, n=22, with the investigators noting that larger trials would be required to show clinical efficacy. A Phase 1 in severe treatment-related lymphopenia (NCT02659800) raised counts in all twelve patients and was terminated for administrative reasons in October 2023 with the maximum tolerated dose undetermined. **NO APPROVAL, NO REGISTRATIONAL LYMPHOPENIA TRIAL, AND NO BREAKTHROUGH OR FAST TRACK DESIGNATION FOR LYMPHOPENIA** after a decade.
https://clinicaltrials.gov/study/NCT03687957

102 The NK cell bank as built
ImmunityBio release of April 22, 2021, on dosing its hundredth patient: more than five trillion clinical-grade off-the-shelf NK cells manufactured since 2017, with more than 2.7 trillion cryopreserved, described as a pipeline of 1,400 doses. The memory cytokine-enriched program (QUILT-3.076) reported in March 2026 that a single apheresis yields up to five billion cells providing eight to ten doses within twelve days; ten patients received twenty-three doses with no serious adverse events. GMP capacity sits at El Segundo and Dunkirk.
https://ir.immunitybio.com/news-releases

103 Why NK-92 cells must be irradiated
The NK-92 line originated from a patient with non-Hodgkin lymphoma and is tumorigenic, so cells are irradiated at roughly 10 Gy before infusion. Irradiation halts proliferation: the cells persist on the order of forty-eight hours, form no memory, and require repeated dosing. Competing allogeneic platforms using induced pluripotent or donor-derived cells avoid this constraint. Fate Therapeutics discontinued its entire core NK clinical pipeline in January 2023 after Janssen exited; Nkarta and Artiva redirected to autoimmune indications.
https://pubmed.ncbi.nlm.nih.gov/?term=NK-92+irradiation+clinical+persistence

104 Whether IL-15 support extends infused NK persistence in humans
Berrien-Elliott et al., Blood 2022, found that N-803 support of haploidentical NK cell therapy accelerated host CD8 T-cell mediated rejection of the infused cells, limiting rather than extending persistence. A separate ovarian cancer study found N-803 driven NK expansion was not sustained beyond two weeks despite continued treatment. **PRECLINICAL RATIONALE IS STRONG; THE HUMAN DEMONSTRATION IS ABSENT**, which undercuts the razor-and-blades reading of the cell platform.
https://pubmed.ncbi.nlm.nih.gov/34739045/

105 Large pharma did buy into IL-15
Xencor announced a research and license agreement with Genentech, a member of the Roche Group, on February 5, 2019, to develop and commercialize IL-15 cytokine therapeutics including XmAb24306, an IL-15/IL-15Rα complex. Genentech paid $120m up front with up to $160m of development milestones for that program and up to $180m for each new candidate, and Xencor took a 45% profit share; the transaction closed March 8, 2019. Contemporaneous trade coverage noted the pathway had attracted multiple developers including Eli Lilly and Novartis. Roche markets atezolizumab, so this is a checkpoint franchise buying IL-15.
https://www.sec.gov/Archives/edgar/data/1326732/000110465919005721/a19-3848_1ex99d1.htm

106 What the practice earns for the work itself
CPT 51720, bladder instillation of an anticarcinogenic agent including retention time. Medicare national non-facility payment $86.37 in 2025 and $91.85 in 2026; the facility rate is roughly half, $42.37 and $38.08, because the practice-expense component is stripped out. A separately identifiable office visit billed alongside with modifier 25 adds roughly $125 to $136 at level four, though routine maintenance instillations frequently bill the procedure alone. Against a drug margin of roughly $820 to $2,150 a dose depending on sequestration and prompt-pay treatment, the drug line runs eight to twenty-five times the procedure line. BCG under J9030 at roughly $141 a vial inverts this: the 6% add-on is about eight dollars.
https://www.cms.gov/medicare/physician-fee-schedule/search

107 Cutting margin raised volume, not lowered it
Jacobson M, Earle CC, Price M, Newhouse JP. How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment. Health Affairs 2010;29(7). Following the 2005 Medicare Modernization Act reductions, the changes "actually increased the likelihood that lung cancer patients received chemotherapy," with physicians switching from the agents whose margins fell most toward other high-margin drugs. Associated National Bureau of Economic Research work quantifies the volume response at roughly 10%. The mechanism is an income effect: lower margin per dose offset by more doses.
https://www.healthaffairs.org/doi/10.1377/hlthaff.2009.0563

108 Margin moved the inappropriate use, not the appropriate use
Shahinian VB, Kuo Y-F, Gilbert SM. Reimbursement policy and androgen-deprivation therapy for prostate cancer. New England Journal of Medicine 2010;363:1822–32. After the 2003 Medicare Modernization Act cut reimbursement for gonadotropin-releasing hormone agonists, urologist use of androgen-deprivation therapy fell more than 30% among patients for whom there was no evidence of benefit, while use among patients with a clear indication did not decline. **THE RESPONSE WAS CLINICALLY DISCRIMINATING** — the relevant finding for whether reimbursement steers judgement about who needs treatment.
https://www.nejm.org/doi/full/10.1056/NEJMsa0910784

109 Bladder cancer is a disease of the old

SEER Cancer Stat Facts, bladder cancer. Median age at diagnosis 73. Age distribution of new cases: roughly 29.7% at 65–74, 18.7% at 75–84 and 7.7% at 85 and over, so approximately three-quarters of diagnoses occur at 65 or above and about 90% at 55 or above. The American Cancer Society estimated 84,870 new US cases in 2025 and projects 84,530 in 2026. Men account for roughly three-quarters of cases.
https://seer.cancer.gov/statfacts/html/urinb.html

110 Payer mix in high-risk NMIBC

Washington A, et al. Disparities in the prevalence and management of high-risk non-muscle invasive bladder cancer. Urologic Oncology, 2023. National Cancer Database, n=163,949, median age 70 (IQR 62–78), 76% male. Approximately 62% Medicare, 32% private, 3% Medicaid, 2% uninsured, with a small military and veterans residual. **THE DATABASE COVERS ROUGHLY 72% OF NEWLY DIAGNOSED US CANCERS** and under-represents community office practice, which if anything understates the Medicare share.
https://pubmed.ncbi.nlm.nih.gov/?term=high-risk+NMIBC+national+cancer+database+insurance

111 Covered lives, and how the figure has moved

The count has risen monotonically. ImmunityBio reported more than 100 million medical lives on August 12, 2024, three months after approval; more than 200 million in the third-quarter 2024 results of November 12, 2024; and more than 240 million in the January 2025 release announcing the European and UK submissions, a figure repeated in the FY2025 annual report and the April 2026 proxy statement. A trade article carrying the 100 million figure in 2026 is recycling the August 2024 release rather than reporting a decline.
https://www.sec.gov/Archives/edgar/data/1326110/000132611026000048/ibrx2025arscombinedwithwra.pdf

112 Patient cost-sharing and why the copay card does not reach it

Medicare Part B coinsurance is 20% of the allowed amount, roughly $7,160 on a first $35,800 dose and capable of exceeding $100,000 across a full course. Federal anti-kickback rules bar manufacturer copay cards for patients covered by Medicare, Medicaid, Medicare Advantage, the VA or TRICARE, so the ANKTIVA copay program reaches commercially insured patients only. Medicare patients rely on Medigap, a Medicare Advantage out-of-pocket maximum, the company's patient assistance program for the uninsured and underinsured, or third-party foundation grants. Per KFF, roughly one in eight traditional-Medicare beneficiaries carries no supplemental coverage.
https://anktiva.com/wp-content/uploads/IBIO24ANK001-Access-Reimbursement-Guide-Digital_v14.pdf

113 Incidence falling per capita, rising in absolute numbers

Chua KJ, et al. Bladder cancer burden in the USA: population scenarios to 2040. Age-standardized incidence was roughly flat at 38–39 per 100,000 person-years before 2005 and has declined about 1.5% a year since, reflecting reduced smoking exposure. Because the population is ageing, modelled scenarios project new case counts growing roughly 1.5% to 1.8% a year through 2040 even as the age-standardized rate falls toward 30–31 per 100,000. Roughly 75% of bladder cancer presents as non-muscle-invasive, and about 700,000 Americans live with the disease, a prevalence-to-incidence ratio near 8:1.
https://pubmed.ncbi.nlm.nih.gov/?term=bladder+cancer+burden+USA+population+scenarios+2040

114 Medicare Advantage share and prior authorization

KFF, Medicare Advantage enrollment update. In 2025 more than half of Medicare beneficiaries with Parts A and B — 34.1 million of about 62.8 million — were enrolled in Medicare Advantage, rising to 55% in 2026; the Congressional Budget Office projects 64% by 2034. Medicare Advantage plans generally follow the average sales price plus 6% mechanic for Part B drugs but layer on prior authorization that traditional fee-for-service does not require.
https://www.kff.org/medicare/medicare-advantage-in-2026-enrollment-update-and-key-trends/

115 What the class has cost outside ImmunityBio
Assembled from company filings and announcements. Bristol Myers Squibb and Nektar, February 2018: $1.85bn up front, comprising $1.0bn cash and roughly $850m of stock bought at $102.60 a share, against a headline $3.6bn; BMS expensed $1.05bn of the up-front payment to research and development in the second quarter of 2018 and about $50m of milestones was subsequently paid. The program was terminated April 14, 2022. Nektar spent more than $1.2bn on research and development across 2019–2021 and took $135.9m of wind-down charges in 2022; its market value fell from roughly $19bn at the 2018 peak to under $600m. Sanofi acquired Synthorx for approximately $2.5bn in December 2019 for the engineered IL-2 THOR-707 and recorded an impairment of about $1.7bn in the fourth quarter of 2022. Genentech paid Xencor $120m up front in February 2019. Iovance acquired Proleukin from Clinigen for £166.7m up front in January 2023. Sotio received €280m from PPF in 2021 for a pipeline led by its IL-15 superagonist, discontinued October 2023. Alkermes, through Mural Oncology, halted the Phase 3 ARTISTRY-7 trial of nemvaleukin on March 25, 2025 at a pre-specified interim: median overall survival 10.1 months against 9.8 for investigator's choice chemotherapy, hazard ratio 0.98. **HEADLINE DEAL VALUES INCLUDE MILESTONES NEVER EARNED** — the verifiable cash figure is roughly $3.5bn to $4.5bn, and the $8bn to $11bn range includes contingent value and estimated undisclosed program spend at Novartis, Roche, Amgen and others.
https://news.bms.com/news/partnering/2018/

116 Why bempegaldesleukin could not be given locally
Charych et al., PLoS One 2017, and the NKTR-214 pharmacology record. Bempegaldesleukin is a prodrug: interleukin-2 masked by an average of six releasable polyethylene glycol chains, inactive as dosed. Active species are generated only as the chains hydrolyze, with peak plasma concentration 24–48 hours after infusion and an active-moiety half-life of 13–19 hours. An intravesical dwell is one to two hours before voiding. Every registered bempegaldesleukin trial used intravenous administration; the only intratumoral element in Nektar's pipeline was NKTR-262, a different molecule, in the terminated REVEAL study (NCT03435640). Nektar reduced its workforce from 735 to 225 in April 2022. **THE ABSENCE OF A REGIONAL ATTEMPT IS OVERDETERMINED** — molecule, finances and indication each explain it independently.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497954/

117 Regional cytokine delivery is thirty years old and had never been registered
Intravesical interleukin-2 was studied in bladder cancer from the early 1990s, including regression of the marker lesion in 8 of 10 patients with T1 papillary disease. Interleukin-2 was also given intraperitoneally for platinum-resistant ovarian cancer, with 4 complete and 2 partial responses among 24 evaluable patients, and intratumorally and intra-arterially in other settings. None of these regional approaches reached registration; aldesleukin's only approvals remain intravenous, in renal cell carcinoma in 1992 and melanoma in 1998.
https://pubmed.ncbi.nlm.nih.gov/9507828/

118 The two compartments ran together, and the systemic one failed
Altor BioScience began first-in-human systemic ALT-803 in hematologic malignancy after transplant (NCT01885897, November 2013) and in advanced solid tumors (NCT01946789, May 2014), intravenously and then subcutaneously after intravenous dosing produced fever, rigors and hypotension. The solid-tumor monotherapy produced no objective responses. The intravesical preclinical model was published June 4, 2014, and the first intravesical clinical trial (QUILT-2.005, NCT02138734) enrolled from July 2014. **THE PROGRAMS WERE CONCURRENT RATHER THAN SEQUENTIAL** — the bladder route was not a retreat from systemic failure, though the systemic result is what made it the lead.
https://clinicaltrials.gov/study/NCT01946789

119 What Medicare pays for immunoglobulin
CMS October 2025 ASP Pricing File. J1569 (Gammagard Liquid) $45.314 per 500 mg and J1459 (Privigen) $49.533 per 500 mg, or roughly $91 and $99 a gram, paid at ASP plus 6%. In-home administration is billed separately under Q2052 at $442.19 for CY2026. **DRUG COST ONLY** — hospital outpatient facility fees are charged on top and in some settings exceed the drug.
https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files

120 Immunoglobulin at immunomodulatory doses
Burt RK, Tappenden P, Balabanov R, et al. The cost effectiveness of immunoglobulin versus hematopoietic stem cell transplantation for CIDP. Front Neurol 2021;12:645263. Compiles US per-patient-per-year costs of $108,016 (Guptill 2014) and $136,892 (Divino 2018) at 1–2 g/kg/month.
https://doi.org/10.3389/fneur.2021.645263

121 US cancer incidence, 2026
Siegel RL, Kratzer TB, Wagle NS, Sung H, Jemal A. Cancer statistics, 2026. CA Cancer J Clin 2026;76(1):e70043. Projects 2,114,850 new cases.
https://doi.org/10.3322/caac.70043

122 **How many patients receive radiotherapy**
Population-based estimates put lifetime radiotherapy use above 50% of cancer patients (WHO and ASTRO utilisation data). Among five-year survivors the FORTY project (Br J Radiol 2023) found 39% received radiotherapy and 29% chemotherapy, with 45% receiving two modalities and 13% all three. **THE OVERLAP BETWEEN MODALITIES IS WHY THE DERIVED FIGURE NETS RATHER THAN SUMS**.

123 **How often treatment causes a severe deficit**
Grossman SA, Ellsworth S, Campian J, et al. Survival in patients with severe lymphopenia following treatment with radiation and chemotherapy. JNCCN 2015;13(10):1225–31. Across 297 patients in glioma, pancreatic and lung cohorts, 43% developed grade 3–4 lymphopenia two months after starting concurrent chemoradiation, regardless of histology or regimen. A later pooled review across 93 studies and 11,565 patients put severe radiation-induced lymphopenia at 26.7%, with a range of 18.6% to 88.0% by treatment site.
https://doi.org/10.6004/jnccn.2015.0151

124 **Most patients recover without treatment**
Cho Y, et al. Association of severe lymphopenia and disease progression in unresectable locally advanced NSCLC treated with definitive chemoradiation and immunotherapy. Radiother Oncol 2022. Of 65 evaluable patients, 59.0% developed grade 3 or worse lymphopenia during treatment and 89.3% had recovered by three months, leaving 10.6% persistently deficient. **THIS SINGLE FIGURE SEPARATES THE TWO COLUMNS OF TABLE 11** and is drawn from one 66-patient cohort in one tumor type.

125 **International cancer incidence**
Bray F, Laversanne M, Sung H, et al. Global cancer statistics 2022. CA Cancer J Clin 2024. Roughly 19.98m new cases worldwide, Asia 49.2% and Europe 22.4%, or about 4.6 and 2.1 times US incidence. **ACCESS TO RADIOTHERAPY AND SYSTEMIC THERAPY IS LOWER ACROSS MUCH OF ASIA**, so the treatable fraction does not scale with incidence.
https://doi.org/10.3322/caac.21834

126 **Self-pay oncology outside the United States**
Jia J, Jiang M, Yang X, Tang X, Long Q. Cost drivers and financial burden for cancer-affected families in China: a systematic review. Curr Oncol 2023. Self-purchased drugs account for 43.9% of total cancer medical costs. Commercial CAR-T in China sells to majority self-funding patients at prices above $140,000 and sat outside the national reimbursement list through 2025. **THESE BOUND PLAUSIBILITY RATHER THAN SIZE A MARKET**, and no ex-US figure is derived from them.
https://doi.org/10.3390/curroncol30080555

127 **The papillary application was refused filing once**
ImmunityBio 8-K and press release, May 5, 2025. The FDA issued a Refusal to File on May 2, 2025 for the supplemental BLA submitted in March 2025. The company stated that at an in-person meeting in January 2025, leadership from CBER, CDER and the Oncology Center of Excellence had unanimously encouraged the submission, and called the refusal inconsistent with that guidance. **THE ACCOUNT OF THE JANUARY MEETING IS THE COMPANY'S OWN** — the FDA has not commented on it, consistent with its practice of not discussing individual sponsor meetings, so it is reported here as a claim rather than a finding.
https://www.sec.gov/Archives/edgar/data/1326110/000119312525112057/d949868dex991.htm

128 **What the agency asked for after the refusal**
ImmunityBio Q2 2025 results, August 5, 2025. States that the Refusal to File was issued on the basis of requiring a randomized controlled trial against chemotherapy, and commits to initiating a randomized trial of ANKTIVA plus BCG versus chemotherapy in papillary-only disease. That trial has not been registered.
https://ir.immunitybio.com/news-releases/news-release-details/immunitybio-reports-60-increase-revenue-q2-2025-year-date-sales

129 **Resubmission and acceptance**
ImmunityBio, March 9, 2026 (resubmission following FDA review of additional data) and May 19, 2026 (acceptance, PDUFA January 6, 2027). The application rests on QUILT-3.032 Cohort B plus a literature-based rationale for extrapolating from carcinoma in situ. The FDA's filing communication states that whether the data justify that extrapolation will be the focus of the review, while reiterating its concerns about single-arm trials in papillary disease alone.
https://www.businesswire.com/news/home/20260519760562/en/

130 **Saudi distribution, promised and delivered**
ImmunityBio, February 20, 2026: partnership with Biopharma and Cigalah, with ANKTIVA to be available for distribution within sixty days. ImmunityBio, April 21, 2026: available in Saudi Arabia. Delivered inside the window given.
https://www.businesswire.com/news/home/20260220764664/en

131 A lymphopenia BLA that was stated and not filed

ImmunityBio, February 27, 2025. RMAT designation granted for ANKTIVA plus CAR-NK in lymphopenia reversal and pancreatic cancer; the release states the company intends to submit a Biologics License Application. No such application has been submitted as of August 2026, and subsequent disclosure describes a randomized trial in design instead.
https://www.businesswire.com/news/home/20250227880542/en/

132 FDA warning letter on promotional claims

FDA Office of Prescription Drug Promotion, Warning Letter MARCS-CMS 725468, March 13, 2026, addressed to the chief executive. Finds a television advertisement and a January 19, 2026 podcast appearance by the founder false or misleading, and states that the promotion misbrands ANKTIVA. Notes that two earlier untitled letters, September 9, 2025 and January 7, 2026, had addressed the same conduct. The shares fell 21% on March 24, 2026 when the letter was published.
https://www.fda.gov/media/190567/download

133 How the quarterly figures are derived

Cash-flow statements in a 10-Q report year to date rather than the discrete quarter, so standalone burn is the current cumulative figure less the prior one. Filed cumulative net cash used in operating activities: $(85.9)m at Q1 2025, $(165.7)m at H1, $(234.6)m at nine months, $(304.9)m for FY2025, $(75.4)m at Q1 2026 and $(141.9)m at H1 2026. That gives $(79.7)m for Q2 2025, $(68.9)m for Q3, $(70.4)m for Q4 and $(66.5)m for Q2 2026. Cash and securities is cash and cash equivalents plus current marketable securities, the same basis at every date, which reproduces the totals the company reports itself. No non-current marketable securities were held at any of these dates, and roughly $1m of restricted cash sits in other assets and is excluded. **QUARTERLY BURN MOVES WITH WORKING-CAPITAL TIMING AS WELL AS OPERATING COST**, so the six-quarter path is not a clean trend: the company attributes $22.0m of the Q1 2025 figure to working capital alone, mostly a receivables build as ANKTIVA scaled and an early-year drawdown of accrued liabilities. Differencing must use the filed thousands rather than the rounded cumulatives: $(165,651)k less $(85,905)k gives $(79.7)m, not the $(79.8)m that subtracting rounded figures produces.
https://data.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001326110

134 Capital spending, and what Dunkirk still requires

Purchases of property and equipment, from the filed cash-flow statements: $30.6m in 2023, $6.9m in 2024, $3.8m in 2025, and $5.3m in the first half of 2026 against $2.2m in the first half of 2025. The reduction in one-time construction cost has therefore already happened, and spending is rising again as the facility is fitted out.

The building is owned by Fort Schuyler Management Corporation, a New York State affiliate, and ImmunityBio holds a leasehold acquired from Athenex in February 2022. A second amendment effective January 1, 2026 replaced the original obligations — $1.52bn of operational spending and 450 employees over ten years — with a smaller and nearer set: at least $40.0m of cumulative capital spending through December 31, 2028, at least $5.0m of operating spending in each of 2026, 2027 and 2028, and at least 100 full-time employees by the end of 2028. Annual rent rose from a nominal $2.00 to $525,000. If those are met the company may purchase the facility for $1.00 on either January 1, 2028 or January 1, 2029, which then triggers a commitment to 450 employees by 2032 or 2033. **THE RENEGOTIATION CUT THE COMMITTED SPEND BY MORE THAN AN ORDER OF MAGNITUDE**, which is favorable to this thesis and is stated here for that reason.

The model carries no separate capital expenditure line, so these sit outside the burn figures, which are operating cash flow. Management has referenced roughly $50m of fill-finish equipment for the site, above the $40m minimum. Spread evenly across 2027 and 2028 that would thin the modelled Q4 2027 trough by about $25m, in the quarter before the convertible matures. The even spread is an assumption: the lease sets deadlines rather than a schedule, which is why the figure is left out of the model rather than built into it. The Chautauqua County Industrial Development Agency is party to a separate tax agreement and not to this lease.
FY2025 Form 10-K, leases and commitments notes · Exhibit 10.34, Second Amendment to Lease

135 What Table 8 assumes

Operating expenses grow 2.2% per quarter throughout, which is above the most recent observed sequential change: total operating costs and expenses were $114.0m in Q1 2026 and $112.9m in Q2, a decline of 0.9%, reconciling to $226.9m for the six months. The year-on-year comparison, up 27% across the first half, carries a step-up that landed in Q1 and overstates the ongoing rate. One flat quarter is not a plateau, and the Accord and MENA build is still ahead of the print, so 2.2% funds continued elevation from a base that already carries the step-up. Interest runs $20–25m a quarter and $16–19m a quarter of non-cash addbacks reconcile the modelled figure to filed operating burn. Capital spending carries the Dunkirk commitment, roughly $50m against a $40m lease minimum, spread evenly across 2027 and 2028. **THE EVEN SPREAD IS AN ASSUMPTION** — the lease sets deadlines rather than a schedule, so the timing within those two years is unknown. Concentrating it earlier would deepen the Q4 2027 trough further; later would relieve it.

136 The BCG-unresponsive pool is derived, not counted

No registry counts patients meeting the FDA's 2018 definition of BCG-unresponsive disease. The figure is built from high-risk incidence multiplied by a BCG-failure rate, and the answer moves with how strictly the definition is applied. Johnson & Johnson states that 30 to 40% of patients do not respond to BCG; a 2025 AUA review notes that up to 40% experience BCG failure while only a fraction meet the strict definition. Applying the label filters — adequate prior BCG, carcinoma in situ with or without papillary disease — gives roughly 6,000 to 8,000 a year, and the looser BCG-failure framing gives roughly 7,000 to 13,000. **THIS REPORT PREVIOUSLY USED 12,000 TO 16,000, WHICH SITS ABOVE THE PUBLISHED RANGE** and understated penetration as a result. An inflated denominator flatters a long position by making the untreated share look larger, which is why the correction is stated rather than quietly applied.

137 What each durability figure rests on, and one cohort correction

The rows in this table do not carry equal evidentiary weight. ANKTIVA's complete response of 62% is the FDA label. Its durability figures — median duration of complete response 45.4 months, 51% probability of maintaining response at 45 months, 84% cystectomy avoidance and 99% disease-specific survival at 36 months — come from a company presentation at AUA 2025 and the accompanying release of April 28, 2025, and have not been peer-reviewed. **THE 84% AND THE 99% ARE CALCULATED AMONG COMPLETE RESPONDERS, NOT ACROSS ALL 77 TREATED PATIENTS**, and an earlier version of this table omitted that. Competitor durability is peer-reviewed: TAR-200 from Daneshmand and colleagues in the Journal of Clinical Oncology, July 2025; nadofaragene from Boorjian and colleagues in Lancet Oncology, 2021, with the 36-month follow-up presented at SUO 2023; cretostimogene from Tyson and colleagues in Lancet Oncology, July 2026.

The KEYTRUDA row previously combined two cohorts of KEYNOTE-057. The 41% complete response at three months is Cohort A, carcinoma in situ, which belongs in this table. The 43.5% twelve-month disease-free survival is Cohort B, papillary-only disease without carcinoma in situ, and does not. Cohort A's median duration of response is 16.2 months.

ImmunityBio, April 28, 2025 · Daneshmand, JCO 2025

138 How the buy-and-bill margin is calculated

Medicare pays for an office-administered drug at the average sales price plus 6%. Budget sequestration, the automatic reduction under the Budget Control Act of 2011, applies to the payment and trims the effective add-on to about 4.3%. On a $35,800 dose that is roughly $2,150 before sequestration and nearer $1,540 after, per dose, retained by the practice that buys and administers it. Because the add-on is a percentage rather than a fixed fee, a list-price reduction cuts the practice's margin in the same proportion.

The procedure comparison: Medicare pays about $92 for the instillation under CPT 51720 in the office setting, and roughly $136 more where a separately identifiable visit is billed alongside it, detailed in source 107. Against a drug margin of $1,540 to $2,150 the drug line runs between roughly eight and twenty times the procedure line, the range depending on sequestration and on how prompt-pay discounts from the distributor land. BCG under J9030 costs roughly $141 a vial, so its 6% add-on is about eight dollars and the procedure fee is the whole of the economics. **THE PROMPT-PAY AND ACQUISITION-COST VARIABLES ARE PRACTICE-SPECIFIC AND NOT DISCLOSED**, so the eight-to-twenty range is a bracket rather than a point estimate.

139 Average sales price for ANKTIVA, ADSTILADRIN and BCG

CMS Part B ASP Drug Pricing File, July to September 2026. J9028 at $94.306 per microgram, so $37,722.40 for a 400 microgram dose. J9029 at $64,331.61 per therapeutic dose. J9030, BCG, at $3.376 per milligram, roughly $168.80 a vial and $2,025.60 across twelve instillations. **ASP RESETS QUARTERLY**, so these carry an expiry and should be re-pulled before republication. Observed dosing is from each prescribing information: ANKTIVA a median of 12 doses across a range of 2 to 30 in QUILT-3.032 Cohort A, ADSTILADRIN a median of 2 across 1 to 5 in CS-003.

https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files

140 INLEXZO has a list price and no average sales price

J9183 took effect April 1, 2026, so INLEXZO billed under a miscellaneous code before then and has no established ASP or published Medicare coinsurance. List is roughly $67,407 a system. **DANESHMAND AND COLLEAGUES DO NOT REPORT HOW MANY SYSTEMS PATIENTS RECEIVED** in SunRISe-1 Cohort 2: the paper gives disposition counts and notes most patients skipped one or two doses, but no median. The label permits up to fourteen systems, $943,698 at list. A bracket can be built from what the paper does report: 11 of 85 patients completed two years and would have received close to the full fourteen, 53 discontinued, and the schedule is eight systems every three weeks to month six then every twelve weeks. A patient stopping at the first assessment receives about five. **FIVE TO FOURTEEN IS THEREFORE AN ESTIMATE BOUNDED BY THE SCHEDULE AND THE DISPOSITION COUNTS**, not a published median, and it spans ANKTIVA's course rather than falling to one side. The system is placed through a catheter and removed by cystoscopy each cycle, so both are separately billable where the removal is the distinct service of the encounter.

Daneshmand et al., J Clin Oncol 2025

141 **KEYTRUDA cost and cycle count in this indication**
List price $12,272 for a 200mg dose, published by Merck and current to March 2026. The cycle count is derived rather than published: KEYNOTE-057 reports a median exposure of roughly 4.2 months in Cohort A, which at three-weekly dosing implies about six cycles. **THE MEDIAN OF 10 CYCLES OFTEN QUOTED BELONGS TO COHORT B**, papillary-only disease without carcinoma in situ, and does not describe this population. The J9271 ASP is approximately $58.56 per milligram; list is used so the row rests on one published source.

142 **INLEXZO launch trajectory**
Johnson & Johnson earnings calls. Q1 2026 (April 14, 2026): INLEXZO sales slightly above $30m; new patient insertions rose over 50% in the first week after the permanent J-code took effect on April 1, 2026, and almost 90% in the second. Q2 2026 (July 15, 2026): nearly one in three eligible patients starting on the regimen, with insertions up approximately 75% quarter over quarter. J&J reports no separate INLEXZO revenue line; the figures are management commentary, and one sell-side projection has $2.4bn by 2028.
https://www.jnj.com/media-center/press-releases/johnson-johnson-reports-q2-2026-results-raises-2026-outlook

143 **Founder's Vision — ANKTIVOGEN**
ImmunityBio corporate page, accessed August 21, 2026. Verbatim: "EPOGEN and NEUPOGEN are used across all tumor types regardless of the anatomy, we believe that NAI (proposed as ANKTIVOGEN in this potential indication)… has the potential to, if approved, overcome lymphopenia across all tumor types." A statement of company aspiration, not a regulatory filing.
https://immunitybio.com/founders-vision/

144 **Dunkirk acquisition release**
BusinessWire, January 12, 2022: "ImmunityBio Expands Manufacturing Capacity with State-of-the-Art Manufacturing Plant in New York for Global Pandemic Response and Preparedness." Cites "nearly a million square feet of manufacturing and R&D space in the U.S., South Africa and Botswana."
https://www.businesswire.com/news/home/20220112005430/en

145 **Cancer MoonShot 2020 outcome**
STAT, January 8, 2020. Journalism: reported that the initiative launched in 2016 had shown little scientific progress by its own deadline year and had functioned largely as marketing for an affiliated diagnostic.
https://www.statnews.com/2020/01/08/patrick-soon-shiong-2020-cancer-moonshot/

146 **NantHealth and the University of Utah donation**
STAT, March 6, 2017 (Rebecca Robbins). A $12m donation was structured so the university concluded it had to spend $10m with NantHealth; shares fell 23% to $5.50 that day, from a $14 IPO in June 2016, and securities suits followed. The company called the reporting "maliciously false." Journalism plus market record.
https://www.statnews.com/2017/03/06/soon-shiong-philanthropy-business/

147 **Verity Health bankruptcy**
In re Verity Health System of California, Inc., U.S. Bankruptcy Court, C.D. Cal., Case 2:18-bk-20151-ER, filed August 31, 2018. The chief executive cited "a legacy burden of more than a billion dollars of bond debt and unfunded pension liabilities." NantWorks had acquired the system's manager in 2017.
https://www.cacb.uscourts.gov/sites/cacb/files/documents/opinions/LA-18-20151-ER%20Verity%20Health%20System.2.pdf

148 **NantSA launch and the billion-dose pledge**
Brackengate, Cape Town, January 19, 2022, launched with President Ramaphosa; roughly R3bn committed. Soon-Shiong, in an interview at the launch: the facility "may be able to produce as many as a billion doses per year by 2025," manufacturing "in Africa, for Africa." No production at that scale has been disclosed since.
https://www.aljazeera.com/news/2022/1/29/south-africa-hails-new-covid-jab-plant-in-fight-for-self-reliance

149 **Filgrastim (NEUPOGEN) prescribing information — the supportive-care approval template**
Initial US approval 1991. Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in a defined chemotherapy population; the pivotal small-cell lung cancer trial reported febrile neutropenia in 40% of treated patients versus 76% on placebo. The approval was written on a clinical outcome rather than the neutrophil count it corrects, and the product is dosed subcutaneously — the route ANKTIVA's label currently forbids.
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/103353s5201lbl.pdf

150 NUPCO catalog coding and the direct-purchase alternative
NUPCO maintains the Unified Catalogue for pharmaceuticals, medical equipment and supplies, built by standardising the item descriptions and codes of the government health sectors; the pharmaceutical catalog carries an update date of April 2026. Peer-reviewed work on Saudi medicines allocation describes public organisations submitting requirements to a main tender covering roughly two thousand items, with a parallel direct-purchasing process for items ordered outside it. **CADENCE CONTESTED** — the peer-reviewed account places the main tender in the first quarter annually; a pharmaceutical executive interviewed separately described it as recurring every two to three years, which more plausibly describes how often a given product line is re-competed.
https://www.nupco.com/en/unified-catalogue/
https://pmc.ncbi.nlm.nih.gov/articles/PMC10001098/

151 NUPCO tender NPT-0014/24, announcement to award
Complementary pharmaceutical tender. Item list announced March 28, 2024; final results published June 4, 2025 — roughly fourteen months, across staged awards. Framework-contract duration is not stated in NUPCO's published tender documents, and no official statement ties the tender timetable to the December budget announcement; both are omitted here rather than approximated.
https://www.nupco.com/wp-content/uploads/2024/03/Final-Results-announcment-NPT14-24-Website.pdf

152 SFDA external reference pricing basket
Policy paper authored from within the SFDA, in Value in Health Regional Issues, documenting a basket of thirty countries before 2021, narrowed to twenty in 2021 and to sixteen comparable countries in 2022 on stated criteria: at least ten locally manufactured products registered with the SFDA, then the presence of a statutory pricing system. The sixteen are not enumerated here, because the full list could be confirmed only from an industry pricing bulletin rather than an SFDA publication. The publisher page refuses automated requests; an SFDA conference poster stating the same sixteen-country basket is linked second.
https://www.sciencedirect.com/science/article/pii/S2212109926000142
https://www.ispor.org/docs/default-source/euro2024/isporeurope24alkhnizanpt46poster141132-pdf.pdf

154 World lung cancer incidence
IARC Global Cancer Observatory, GLOBOCAN 2024 world fact sheet for trachea, bronchus and lung: 2,637,005 new cases, the highest-ranked cancer by incidence worldwide. Used here only as a denominator for the breakeven in Section 12; no share of it is claimed as addressable, since access to first-line checkpoint therapy, ability to pay and ability to travel each cut it substantially and none of the three could be sized from a citable source.
https://gco.iarc.who.int/media/globocan/factsheets/cancers/15-trachea-bronchus-and-lung-fact-sheet.pdf

155 Thiqa carries no annual benefit limit
Thiqa is the Abu Dhabi Government health program for UAE nationals, administered by Daman. Its published eligibility page states no annual benefit limit per member, alongside coverage of emergency treatment inside and outside the UAE. This is the coverage position for nationals and does not extend to the expatriate majority, who hold employer-mandated plans with the statutory caps cited in Table 15.
https://www.thiqa.ae/eligibility/

156 Abu Dhabi cost-effectiveness threshold and multipliers
Kalo, Aldallal, Farghaly et al., "Thresholds for the value judgement of health technologies in the United Arab Emirates," BMJ Open 2024;14(11):e090344. Baseline threshold set at 0.75 times GDP per capita for one quality-adjusted life year, with multipliers for disease severity, disease rarity and relative health gain; rarity was voted the most important factor at a maximum of three times. The Office of Health Economics review of the Department of Health framework, in force from June 2025, converts the baseline to roughly $55,800 per QALY at an Abu Dhabi GDP per capita near $74,400, and records that the rare designation is taken from EMA or FDA classification. The OHE page refuses automated requests; the BMJ Open article is open access and carries the threshold and multiplier findings directly.
https://doi.org/10.1136/bmjopen-2024-090344
https://www.ohe.org/insights/around-the-world-in-htas-abu-dhabi-advancing-hta-and-value-based-healthcare-in-the-uae/

157 Dubai's cancer top-up covers three cancers, and lung is not one
The Basmah program tops up the basic plan cap for low-salary-band workers in Dubai. The Dubai Health Authority director of health insurance policies describes it as covering breast, colorectal and cervical cancer for the roughly 90% of the emirate's residents who are not Emirati, above a basic-plan cap of AED 150,000. Lung cancer is not within scope. **SCOPE, NOT A CAP** — the relevance here is which cancers a UAE payer has chosen to fund without limit, not the size of the limit.
https://www.roche.com/stories/affordable-cancer-care-dubai

158 Cleveland Clinic Abu Dhabi oncology throughput

Cleveland Clinic newsroom, March 13, 2025, marking a decade in Abu Dhabi. Since the Fatima bint Mubarak Center opened in 2023 the hospital reports more than 55,000 oncology clinic visits, more than 22,000 chemotherapy infusions and more than 14,000 radiation treatments. Cited here as evidence that infusion capacity exists, not as evidence of any willingness to treat non-resident patients on a multi-year schedule.
https://newsroom.clevelandclinic.org/2025/03/13/cleveland-clinic-celebrates-a-decade-of-healthcare-in-abu-dhabi

159 Burjeel Cancer Institute, ESMO accreditation

European Society for Medical Oncology designated centre of integrated oncology and palliative care, Burjeel Cancer Institute at Burjeel Medical City, Abu Dhabi. Accreditation speaks to the standard of the oncology and palliative service; it says nothing about international-patient volumes, which the center does not publish.
https://www.esmo.org/for-patients/esmo-designated-centres-of-integrated-oncology-palliative-care/esmo-accredited-designated-centres/burjeel-cancer-institute-burjeel-medical-city

160 Saudi promotion rules bar off-label promotion

Saudi Code of Conduct for Promotional Practices of Pharmaceutical and Herbal Products, issued by the SFDA: marketing of a product is not permitted before its registration with the authority, and advertising material should carry the uses of the approved product as stated in the product leaflet. The International Bar Association's 2024 healthcare survey response for Saudi Arabia states the consequence directly, recording that off-label information cannot be promoted or advertised in the Kingdom and that promotional materials must conform to SFDA-approved uses. The relevance here is jurisdictional: the constraint on promoting an off-label Gulf use is Saudi, not American.
https://www.sfda.gov.sa/sites/default/files/2024-08/SFDA422024DEE.pdf
https://www.ibanet.org/document?id=Healthcare-Survey-Responses-2024-Saudi-Arabia

161 Erda-iDRS (formerly TAR-210) final phase 1 results

Johnson & Johnson, March 13, 2026, reporting an 89% complete response rate with durable responses over 18 months in intermediate-risk disease. The final analysis reports 81% complete response at three months rising to 89% at six, a median complete-response duration of 18 months with 49% ongoing at cutoff, and in the high-risk BCG-experienced papillary-only cohort 83% recurrence-free survival at twelve months with median recurrence-free survival of 20 months. Plasma erdafitinib ran more than forty times below oral dosing at 9 mg daily. Phase 2 and phase 3 studies are ongoing. **ABSTRACT NUMBER DIFFERS BY SOURCE** — the company release cites LB26-0083; the Urology Times citation of the same presentation gives LBA008, 41st EAU Congress, London, March 13–16, 2026. FGFR prevalence in high-risk disease is also given as both 30% and 40% across accounts of the same study, so neither figure is used here. The Urology Times page refuses automated requests but is reachable in a browser; the company release is linked first and carries the headline figures.
https://www.jnj.com/media-center/press-releases/johnson-johnson-highlights-promising-first-in-human-erda-idrs-formerly-tar-210-results-in-intermediate-risk-non-muscle-invasive-bladder-cancer
https://www.urologytimes.com/view/erdafitinib-intravesical-drug-releasing-system-shows-early-activity-in-fgfr-altered-nmibc

162 Shares outstanding

ImmunityBio Form 10-Q for the quarter ended June 30, 2026, cover page: 1,059,836,273 shares outstanding as of July 31, 2026. The affiliated block is taken from the Schedule 13D/A of the Soon-Shiong group, which reports 745,518,285 shares beneficially owned including 88,446,655 issuable within sixty days on conversion of the related-party note; excluding those, roughly 655m shares are outstanding and affiliated, leaving a float near 405m. The float is derived, not a filed figure.
https://www.sec.gov/cgi-bin/browse-edgar?action=getcompany&CIK=0001326110&type=10-Q

163 Institutional holdings, December 2025 and March 2026

Compiled from the SEC's Form 13F quarterly data sets, which publish every filer's information table as structured data. Rows for CUSIP 45256X103 were extracted from the files covering filings from December 1, 2025 to February 28, 2026 and from March 1 to May 31, 2026, and grouped by period of report rather than by filing window, since a window contains late filings for earlier periods. Share positions only: option lines and principal amounts are excluded. Amended filings are resolved rather than summed, since the data sets carry both the original and the amendment: a restatement supersedes what came before it and a new-holdings amendment adds to it. Seven managers filed amendments for the March quarter, and summing them naively overstated Woodline Partners at 6,894,692 shares against an actual 3,447,346. **NOT AN AGGREGATOR** — published institutional-ownership percentages for this company range from about 6.5% to 20.7% because providers blend as-of dates and differ on the denominator.
https://www.sec.gov/data-research/sec-markets-data/form-13f-data-sets

164 Institutional holdings, June 2026

The 13F data sets are published by filing window and the most recent covers filings through May 2026, so the June 2026 period is not yet in them. The sixty largest holders at March 31, 2026, together 91% of institutional shares then, were carried forward by reading each manager's 13F-HR information table for period 2026-06-30 directly from EDGAR. Two had not filed. Managers opening a position during the June quarter are outside this set, so the discretionary decline is an upper bound. A manager that filed without listing the name has exited and counts as zero; four did, among them HRT Financial and Jump Financial. Tudor Investment holds the name as options rather than shares, which is a change of form rather than an exit. One of the sixty had not filed.
https://www.sec.gov/edgar/searchedgar/companysearch

165 Short interest

Nasdaq semi-monthly short-interest series for IBRX, twenty-four settlement dates. April 15, 2026: 140,326,066 shares, 9.54 days to cover. June 30, 2026: 131,830,884 shares, 8.66 days. July 31, 2026: 128,997,049 shares against average daily volume of 8,899,967, 14.49 days. March 31, 2026: 135,542,079 shares, 4.68 days. December 31, 2025: 120,642,502. September 30, 2025: 73,427,568. Percentages of shares outstanding use the July 31, 2026 count; percentages of float use the derived figure in source 163.
https://www.nasdaq.com/market-activity/stocks/ibrx/short-interest

166 UAE indication scope

ImmunityBio press release and Form 8-K exhibit, July 29, 2026. The company states that the approved Emirates summary of product characteristics covers ANKTIVA with BCG for BCG-unresponsive NMIBC with carcinoma in situ, with or without papillary tumors, *and* BCG-unresponsive NMIBC with papillary tumors, the second limb being the one no other approval contains. Registration No. 78609-45860-260486, first registered July 24, 2026. **COMPANY-STATED** — the Emirates Drug Establishment register was queried directly on August 23, 2026 and returns no entry for ANKTIVA under any product, ingredient or manufacturer name, in English or Arabic. That is expected rather than contradictory: the register's most recent entry of any kind is dated June 18, 2026, so a July registration would not yet appear. The register carries no indication field either, so it will confirm registration and strength once it updates but never the scope. The scope therefore rests on the 8-K exhibit, and the company's own risk factors flag the interpretation of that authorization.
https://ir.immunitybio.com/news-releases/news-release-details/immunitybio-receives-united-arab-emirates-uae-marketing
https://services.ede.gov.ae/drugdirectory

167 Immunoglobulin approved without a known mechanism

The autoimmune immunoglobulin labels disclaim mechanism and were approved on functional endpoints. Octagam 10%: the mechanism of action in chronic ITP or dermatomyositis has not been fully elucidated; the dermatomyositis approval of July 2021 rested on the Total Improvement Score in ProDERM, 78.7% of patients responding against 43.8% on placebo. Gamunex-C: the precise mechanism in CIDP has not been fully elucidated; the 2008 approval rested on the adjusted INCAT disability score in the ICE study, 47.5% against 22.4%. Gammagard Liquid in multifocal motor neuropathy, June 2012, rested on grip strength and the Guy's Neurological Disability Score. Each is a clinical or functional measure rather than a laboratory value.
https://www.fda.gov/media/70911/download
https://www.gamunex-c.com/en/hcp/cidp

168 What Medicare requires before paying for immunoglobulin in acquired deficiency

Local coverage determinations gate secondary immunodeficiency on a laboratory value *and* a clinical event. L34314, chronic lymphocytic leukemia: the IgG level should be below 600 mg/dL or there should be evidence of specific antibody deficiency, and the presence of repeated bacterial infections. L39314, off-label immunoglobulin: hypogammaglobulinemia below 400 mg/dL together with at least one acute infection requiring hospitalization or parenteral antibiotics, and it records that evidence associating immunosuppressive agents with low immunoglobulin levels does not establish that the finding alone warrants treatment. Only B-cell CLL carries an FDA label among the secondary deficiencies, and it was granted on bacterial infection rate rather than on the immunoglobulin level.
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=34314
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39314

169 The biomarker moved and the patients did not

Baxter's Gammagard Phase 3 in mild-to-moderate Alzheimer's disease, 390 patients over 18 months, missed both co-primary endpoints, cognition and function, against placebo. Plasma amyloid-beta fell. Topline results were reported in May 2013 and published as Class II evidence that immunoglobulin does not improve cognition or function in this population; the program was discontinued.
https://pubmed.ncbi.nlm.nih.gov/28381506/

170 The trial footprint J&J converted into accounts

SunRISe-1 enrolled at 142 sites in fourteen countries (Journal of Clinical Oncology, 2025); SunRISe-2 opened at 272 locations worldwide. QUILT-3.032 lists 32 trial locations, all in the United States. ERLEADA (apalutamide) received US approval in February 2018 and has been promoted to urologists by J&J's field organization since, giving INLEXZO an installed commercial and clinical base at launch that ANKTIVA did not have.

https://ascopubs.org/doi/10.1200/JCO-25-01651
https://www.targetedonc.com/view/sunrise-2-trial-explores-tar-200-cetrelimab
https://clinicaltrials.gov/study/NCT03022825

171 The field organization is still being hired

ImmunityBio postings as of August 2026 list Uro Oncology Business Manager roles for individual metro territories including San Antonio, St. Louis and Indianapolis, an Area Business Director managing the ANKTIVA field team, a Health Systems Director for large integrated delivery networks in the Eastern US, and Field Reimbursement Manager roles requiring buy-and-bill urology-oncology experience. Postings ask for urological-oncology and start-up backgrounds, the profile of an organization extending coverage rather than maintaining it.

https://jobgether.com/offer/69d7d42eaba5fafcee037e60-uro-oncology-business-manager

172 What covering the urology call point takes

UroGen's Q1 2021 10-Q: "We have staffed, trained and prepared a commercial team comprising a field force of approximately 48 representatives with deep experience in both urology and oncology," led by seven regional business managers, each region supported by a clinical nurse educator and a field reimbursement manager. A US urology-oncology call point is covered by a force in the dozens, not the hundreds.

https://www.sec.gov/Archives/edgar/data/1668243/000156459021027210/urgn-10q_20210331.htm

173 The closest structural comparable's first full year

ADSTILADRIN, approved by the FDA in December 2022 but not made fully available until January 2024, generated roughly €70m (about $77m) in 2024, its first full US year, with the ramp capped by Ferring's manufacturing capacity. ANKTIVA's own first full commercial year exceeded that figure despite the BCG gate.

https://www.biopharmadive.com/news/ferring-adstiladrin-ash-hhs-bristol-myers-opdivo-crc/744789/

174 When the ordering-practice count becomes countable

The CMS Medicare Physician & Other Practitioners by Provider and Service dataset, which reports allowed services and payments per provider per HCPCS code and would yield a count of practices billing J9028, is published on roughly a two-year lag and currently extends through calendar 2023, before the code took effect. The first calendar year of J-code claims it can count, 2025, is expected to publish around 2027. The quarterly Part B drug-spending series and the state Medicaid utilization files publish sooner, at roughly six-month and one-quarter lags, but report dollars and units rather than distinct providers.

https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners

175 The buy-and-bill margin carries a denial cycle

BuyandBill.com's J9028 page, updated July 1, 2026, reports real-world claims performance from FocalPoint, OnPoint Oncology's clearing-house analytics: claims from January through August 2026 show a 31.55% claim denial rate, 9.2 days average to file, and 25.8 days average to payment. Medicare payment limit $94.306 per HCPCS billing unit as of Q3 2026, with a national median commercial reimbursement of $97.66 per unit as of January 2026.

https://buyandbill.com/anktiva-j9028/

176 The first sale, and the first worthless CVR

Fresenius acquired APP Pharmaceuticals in September 2008: $23.00 cash per share ($3.7bn equity), $940m of debt assumed, plus a contingent value right paying up to $6.00 per share on cumulative adjusted-EBITDA targets for 2008–2010. Fresenius Kabi Pharmaceuticals Holding's Form 10-K filed February 23, 2011 reported cumulative adjusted EBITDA of $1.126bn against the $1.268bn threshold; the rights expired without payment and were delisted by a Form 25 filed March 4, 2011.

https://sec.gov/Archives/edgar/data/1141399/000119312508147481/dex991.htm
https://www.sec.gov/Archives/edgar/data/1439449/000119312511042501/d10k.htm
https://www.sec.gov/Archives/edgar/data/1439449/000119312511056429/d25.htm

177 The Abraxis merger terms and Celgene's stated prize

Per the June 30, 2010 merger announcement and the September 2010 prospectus: $58.00 cash plus 0.2617 Celgene shares plus one tradeable contingent value right per Abraxis share; upfront approximately $2.9bn net of cash and roughly $3.2–3.35bn in aggregate. Celgene projected the acquisition would add approximately $1bn of revenue in 2015. Milestones: $250m for FDA approval of Abraxane in NSCLC with a progression-free-survival claim in the US label; $300m for FDA approval in pancreatic cancer with an overall-survival claim, plus $100m if achieved before April 1, 2013; royalties of 2.5%, 5% and 10% on annual net sales above $1bn, $2bn and $3bn through 2025.

https://www.sec.gov/Archives/edgar/data/816284/000095012310086109/x85641e424b3.htm
https://www.fiercebiotech.com/biotech/celgene-to-acquire-abraxis-bioscience-inc
https://www.bms.com/investors/shareholder-services/shareholder-faq.html

178 How the Abraxis CVR actually resolved

Celgene's Form 8-K dated September 12, 2013 gave notice that the $300m pancreatic milestone would be paid on or before October 4, 2013, following the September 6, 2013 US approval on overall survival; approval after April 1, 2013 forfeited the $100m early bonus, and the October 2012 NSCLC approval carried no progression-free-survival claim, so the $250m milestone lapsed at the fifth anniversary. Abraxane crossed $1bn in a royalty year once, at $1.062bn in 2018, producing a net-sales payment of $1,555,382 per the trustee notice; Celgene's FY2018 10-K carried the CVR liability at $19m, down from $212m at the 2010 close. Bristol Myers Squibb's February 2026 notice reported 2025 Abraxane net sales of $367.6m with no payment due, closing the royalty feature at its December 31, 2025 term.

https://www.sec.gov/Archives/edgar/data/816284/000119312513365261/d596705d8k.htm
https://www.sec.gov/Archives/edgar/data/816284/000081628419000014/Financial_Report.xlsx
https://www.biopharmadive.com/news/celgenes-abraxane-fails-late-stage-pancreatic-cancer-study/550414/

179 What the only approved sepsis drug ever earned

Xigris (drotrecogin alfa), approved by the FDA in November 2001 for severe sepsis at high risk of death, was voluntarily withdrawn worldwide on October 25, 2011 after PROWESS-SHOCK showed 28-day mortality of 26.4% against 24.2% on placebo. Worldwide sales ran on the order of $100–200m a year at their best against blockbuster forecasts, held down by cost, bleeding risk and inpatient bundling.

https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-voluntary-market-withdrawal-xigris
https://investor.lilly.com/news-releases/news-release-details/lilly-announces-withdrawal-xigrisr
https://www.pulmccm.org/p/xigris-epitaph-prowess-shock-results-nejm

180 Lymphopenia in the checkpoint-treated population

Haslam and Prasad estimated 43.63% of US cancer patients eligible for checkpoint inhibitors in 2018 (JAMA Network Open, 2019), revised to 56.55% eligible and 20.13% responding by 2023 (International Journal of Cancer, 2025); their 2020 re-estimate implied an upper bound of 233,790 eligible patients, and no authoritative count of annually treated US patients exists. Roughly 27–30% of solid-tumor patients carry an absolute lymphocyte count below 1,000 per microliter at checkpoint initiation; three-month lymphopenia associated with overall survival of 9.8 against 18.3 months (BJC Reports, 2024), and baseline lymphopenia was an independent adverse factor in metastatic kidney cancer with a hazard ratio of 1.68 (ESMO Open, 2024).

https://pubmed.ncbi.nlm.nih.gov/31050774/
https://onlinelibrary.wiley.com/doi/10.1002/ijc.35347
https://www.nature.com/articles/s44276-024-00058-6
https://www.esmoopen.com/article/S2059-7029(24)01375-9/fulltext

181 Premiums, and what an announcement alone does

Median biopharma acquisition premiums over unaffected prices have run roughly 50–65% across 2020–2025 tallies, with competitive processes above 100% (2seventy at just over 100%, Inozyme at 182%, Vigil at 303%). Summit Therapeutics rose 123% in the week of the HARMONi-2 readout showing ivonescimab beating pembrolizumab head-to-head, finishing 2024 up more than 580% — a data event rather than a deal event, marking the ceiling of what association with the checkpoint class can do to a mid-cap.

https://www.biospace.com/business/biopharma-deal-premiums-paint-picture-of-cutthroat-negotiations
https://www.theglobeandmail.com/investing/markets/stocks/BNTX/pressreleases/29193906/up-over-600-in-2024

182 The process a controller's deal must survive

Under Kahn v. M&F Worldwide (Delaware, 2014) as extended by In re Match Group, Inc. Derivative Litigation, 315 A.3d 446 (Delaware Supreme Court, April 4, 2024), any transaction in which a controlling stockholder receives a non-ratable benefit is reviewed for entire fairness unless conditioned from the outset on both approval by a fully independent special committee and an uncoerced, informed majority-of-the-minority vote.

https://law.justia.com/cases/delaware/supreme-court/2024/368-2022.html
https://www.gibsondunn.com/entire-fairness-remains-default-standard-for-conflicted-controller-deals/

183 The Keytruda cliff, in Merck's own words

Keytruda and Keytruda Qlex sales were $31.7bn in 2025, about 49% of Merck's $65.0bn revenue; US Inflation Reduction Act pricing applies from January 2028 and the compound patent expires in December 2028. On the Q4 2025 call management cited over $70bn of potential commercial opportunity for the pipeline by the mid-2030s, more than twice the $35bn consensus 2028 Keytruda peak. Cash and investments were roughly $19.3bn at September 30, 2025; recent acquisitions (Verona, Cidara, Prometheus, Acceleron) cluster at $9–11.5bn.

https://www.fool.com/earnings/call-transcripts/2026/02/03/merck-mrk-q4-2025-earnings-call-transcript/

https://www.sec.gov/Archives/edgar/data/310158/000031015825000059/mrk-20250930.htm

https://www.fiercepharma.com/pharma/keytruda-leading-way-merck-counts-over-80-possible-oncology-drug-approvals-2028

184 One company, separated into two

American Pharmaceutical Partners acquired American BioScience in 2006 and renamed itself Abraxis BioScience. On November 13, 2007 that company completed a separation into two independently traded public companies: the hospital-based injectables business, operating as APP Pharmaceuticals (Nasdaq: APPX), and the proprietary business holding Abraxane and the nab platform, which took the Abraxis BioScience name (Nasdaq: ABII). Per the separation and distribution agreement, APP borrowed $1.0bn under a new credit agreement and contributed approximately $975m in cash to the proprietary half, roughly $275m of which repaid that half's existing debt.

https://www.sec.gov/Archives/edgar/data/0001141399/000119312507250452/d8k.htm

https://www.sec.gov/Archives/edgar/data/1409012/000119312510055402/d10k.htm

185 What ImmunityBio is, and the process that made it

On March 9, 2021 NantKwest, Inc. (Nasdaq: NK) completed a 100% stock-for-stock merger with NantCell, Inc., a private company then known as ImmunityBio; the combined company took the ImmunityBio name and began trading as IBRX on March 10, 2021. Former ImmunityBio holders received 0.8190 NantKwest shares each. Closing was conditioned on approval by a majority of NantKwest's unaffiliated shareholders, obtained at a special meeting on March 8, 2021, and the public side was represented by a special committee of the NantKwest board with its own counsel. ImmunityBio's Q1 2021 10-Q states that Soon-Shiong and affiliates beneficially owned approximately 81.8% of common stock outstanding after the merger.

https://www.sec.gov/Archives/edgar/data/1326110/000119312521075243/d307217dex991.htm

https://www.sec.gov/Archives/edgar/data/1326110/000156459021028010/ibrx-10q_20210331.htm

186 What Celgene promised, and when it arrived

Abraxis reported 2009 net revenue of $359.1m and a net loss of $104m. At announcement Celgene guided the transaction to be modestly dilutive to non-GAAP earnings in 2011 and accretive in 2012 and beyond, and to add approximately $1bn in revenue in 2015. Abraxane was approved by the FDA for NSCLC in October 2012 and for metastatic adenocarcinoma of the pancreas in September 2013. Celgene's 10-K reports Abraxane net sales rising 52.1% to $648.9m in 2013 (from $426.7m in 2012) and 30.7% to $848.2m in 2014; sales first exceeded $1bn in 2018, at $1.062bn.

https://www.fiercebiotech.com/biotech/celgene-to-acquire-abraxis-bioscience-inc-0

https://www.sec.gov/Archives/edgar/data/0000816284/000162828015000889/a2014123110k.htm

187 The extension applications are pending

ImmunityBio FY2025 Form 10-K: "In June 2024, we submitted applications to the USPTO for the extension of the patent term of several U.S. patents directed to compositions of matter of N-803, methods of use of N-803 and methods of manufacture of N-803. These applications are currently under review by the USPTO and FDA." The same section states that the N-803 patents and applications, including patent term adjustment and extension, are expected to expire from 2031 to 2045. Under 35 U.S.C. 156 only one patent may be extended per regulatory review period, by up to five years and no later than fourteen years from approval.

https://www.sec.gov/Archives/edgar/data/1326110/000132611026000030/ibrx-20251231.htm

188 The government-support statement, and what it does not say

US 8,507,222 B2 ("Multimeric IL-15 soluble fusion molecules and methods of making and using same", priority 21 September 2010, granted 13 August 2013, anticipated expiry 21 September 2031, assignee Altor Bioscience LLC) states under GOVERNMENT SUPPORT: "Research supporting this application was carried out by the United States of America as represented by the Secretary, Department of Health and Human Services." No grant or contract number is given and the customary Bayh-Dole recitation that the Government has certain rights is absent. The continuation US 9,328,159 B2, cited by third parties as describing N-803, carries no government-support statement. ImmunityBio's FY2025 10-K separately discloses march-in rights as a risk over licensed technology developed with US government funding.

https://patents.google.com/patent/US8507222B2/en

https://patents.google.com/patent/US9328159B2/en

189 What happened to the rest of the field
Sotio Biotech discontinued clinical trials of nanrilkefusp alfa (SOT101), an IL-15 receptor-α sushi+ fusion, in monotherapy and in combination with pembrolizumab and cetuximab, after interim data did not show enough efficacy to warrant larger randomized trials; the company redirected to SOT201, a PD-1/IL-15 construct in Phase 1. Nektar's NKTR-255 continues in a Phase 2/3 trial after CD19-directed CAR-T in relapsed or refractory large B-cell lymphoma (NCT05664217), enrolment approximately 400, estimated completion January 2029. No IL-15 agonist other than ANKTIVA has been approved in any jurisdiction.
https://www.targetedonc.com/view/trials-of-nanrilkefusp-alfa-discontinued-in-advanced-solid-tumors
https://clinicaltrials.gov/study/NCT05664217

190 The industry rule for when a treatment is experimental
RGA, Global Health Brief: Experimental Treatments — Current Considerations, March 2023. Verbatim: on-label drugs "are those prescribed and used in accordance with their license" and are not experimental; "RGA recommends that off-label on-guideline use not be classified as experimental by health insurers"; "off-label off-guideline" use is classed as experimental and should not be covered; and experimental drugs are those "not licenced by the FDA, EMA, or other such regulatory authority recognized in the country in which the drug is received."
https://www.rgare.com/knowledge-center/article/global-health-brief-experimental-treatments-current-considerations

191 What an international policy wording requires
Bupa Global, International Health and Hospital Plan Membership Guide, November 2024 edition. The wording covers treatment consistent with "generally accepted standards of medical practice in the country in which treatment is being received" and provides for independent specialist confirmation that treatment is based on established medical practice; the guide's table of benefits states overall annual maximums on the top tiers that a six-figure course does not approach.
https://www.bupaglobal.com/-/media/BupaGlobal/PDFs/2024/Products/IHHP/HKX-IHHP-Membership-Guide-EN-NOV24-0053016.ashx

153 SFDA economic evaluation requirement
Economic Evaluation Studies Guidelines, Saudi Food and Drug Authority, version 1.0 published July 10, 2024, phased in with voluntary submission for one year and mandatory submission after July 2025 for new registrations and price re-evaluations. Version 1.1 is posted on the authority's regulations page.
https://sfda.gov.sa/sites/default/files/2024-07/EconomicEvaluationStudies.pdf

Residual limitations. Four 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. The QUILT-2.023 subgroup figures are taken from trade-press coverage of the ASCO 2026 abstract rather than the abstract itself, and no peer-reviewed randomized efficacy publication exists for that trial. The checkpoint-complementarity mechanism rests on preclinical models; no human immune-monitoring dataset from an ANKTIVA trial confirms it. Pre-2021 comparable-company multiples are interpolated from quarterly market-capitalization snapshots and carry approximately ±10–15% error. Every other identifier below 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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