

Imugene Limited (ASX: IMU)

Key Statistics

52 Week Range	A\$0.09 - A\$0.54
Avg. Volume (3 months)	2.28MM
Shares Outstanding	424.7MM
Market Capitalization	A\$40.77M
EV/Revenue	N/A
Cash Balance*	A\$5.96M
Analyst Coverage	3

*Cash Balance as of March 2026

Revenue (in A\$m)

June – FY	2025A	2026E	2027E
H1	0.00	0.00	0.00
H2	0.00	0.00	0.00
FY	0.00	0.00	0.00

EPS (in A\$)

June – FY	2025A	2026E	2027E
H1	(0.22)	(0.13)	(0.05)
H2	(0.10)	(0.03)	(0.04)
FY	(0.32)	(0.16)	(0.09)

Stock Price Chart (in A\$)



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Imugene Limited: Recent Encouraging Clinical Data, Expanded FDA Fast Track Designations, and Ongoing BTKi Combination Development Further Strengthen Azer-cel Positioning

Share Price

A\$0.096

Valuation

A\$0.43

Investment Highlights

FDA Fast Track Designation Strengthens Regulatory Positioning of Azer-cel in CLL/SLL and MZL:

Imugene announced that the U.S. FDA granted Fast Track Designation to azer-cel for two hematologic malignancy indications: relapsed or refractory Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL) and relapsed or refractory Marginal Zone Lymphoma (MZL). The designation is intended to facilitate expedited development and regulatory review for therapies addressing serious diseases with unmet medical need and may support more frequent FDA interaction, rolling submission review, and potential eligibility for Accelerated Approval and Priority Review. The designation was supported by encouraging Phase 1b clinical data demonstrating meaningful activity in both indications. In the CAR-T-naïve CLL/SLL cohort, azer-cel achieved a 100% overall response rate (ORR) among evaluable patients who had received a median of three or more prior lines of therapy. In MZL, updated post-ASCO data demonstrated an 83% ORR, including four complete responses among six evaluable patients. We note that the Fast Track designation further validates the growing clinical evidence supporting azer-cel's off-the-shelf allogeneic approach, particularly in patient populations with limited remaining treatment options following failure of standard therapies, and may support the expansion of potential registrational opportunities across additional B-cell malignancies as clinical data continues to mature.

ASCO 2026 Presentation Demonstrates Broad Clinical Activity and Manageable Safety Profile for Azer-cel in CAR-T Naïve B-Cell Malignancies:

Imugene announced that updated Phase 1b data for azer-cel was presented as an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, one of the most prominent global oncology conferences. Notably, the abstract was selected for oral presentation from more than 8,500 submissions, reflecting the perceived scientific significance and clinical relevance of the data by ASCO's peer-reviewed Scientific Program Committee. The presentation highlighted data from 25 CAR-T naïve patients with relapsed or refractory CD19-positive B-cell malignancies treated with azer-cel in combination with low-dose IL-2. Among the 24 efficacy-evaluable patients, responses were observed across all six cancer subtypes assessed, including a 67% response rate in DLBCL, 83% in marginal zone lymphoma (MZL), and 100% response rates in chronic lymphocytic leukemia (CLL), follicular lymphoma (FL), and Waldenström macroglobulinemia (WM). Additional ASCO data demonstrated encouraging durability trends and broad activity across indolent lymphomas, with overall response rates reaching 93% among 14 patients with indolent disease subtypes. The safety profile remained manageable, with no Grade ≥3 cytokine release syndrome (CRS) events reported, while ICANS events were largely concentrated in DLBCL patients and remained broadly consistent with autologous CAR-T experience. The data also further supports Imugene's ongoing expansion strategy for azer-cel, with enrollment continuing across CAR-T naïve, CAR-T relapsed, and BTKi combination cohorts in both the U.S. and Australia. The company additionally announced dosing of the first patient in the concurrent BTKi cohort, which is intended to evaluate whether BTK inhibition can further enhance CAR-T expansion, persistence, and efficacy.

Company Description

Imugene Limited is a clinical-stage biotechnology company developing immuno-oncology therapies with its pipeline centered around azer-cel, an allogeneic CD19 CAR-T therapy. azer-cel is designed to enable scalable, off-the-shelf treatment for B-cell malignancies with improved access, reduced vein-to-vein times, and simplified manufacturing complexity.

Imugene Expands Azer-cel Clinical Development with Initiation of BTKi Combination Cohort: Imugene announced the dosing of the first patient in the Bruton Tyrosine Kinase inhibitor (BTKi) combination cohort of its ongoing Phase 1b azer-cel study, marking an important expansion of the program into combination-based treatment strategies. The first patient, enrolled at Baylor University in Texas, is a mantle cell lymphoma (MCL) patient who had previously failed BTKi therapy. The new cohort is designed to evaluate the safety and preliminary efficacy of concurrent treatment with azer-cel and BTKi therapy in patients with relapsed or refractory B-cell malignancies. The rationale behind the approach is based on growing evidence suggesting that BTKi agents may enhance CAR T-cell expansion, persistence, and anti-tumor activity, particularly in heavily pre-treated patients. The expansion of the study into BTKi-relapsed populations also broadens the potential commercial and clinical scope of the azer-cel program, particularly given the approximately US\$11.6 billion [global BTKi market](#) and the significant unmet need among patients who eventually develop resistance or intolerance to currently approved BTKi therapies. We also note that the combination cohort may support future partnering and collaboration opportunities while helping prioritize indications where azer-cel demonstrates the strongest clinical activity and commercial potential. The Phase 1b study remains active across 10 U.S. and 5 Australian sites, evaluating azer-cel in both CAR T-relapsed and CAR T-naïve patient populations.

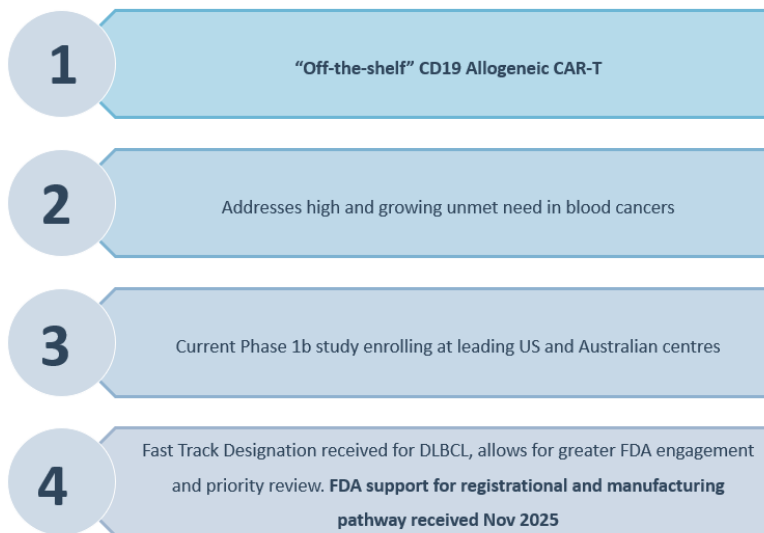
Valuation: Imugene remains a pre-revenue, clinical-stage biotechnology company, with its investment profile primarily driven by the clinical progression, regulatory advancement, and potential commercialization of azer-cel. Following recent capital raising initiatives, operating cost reductions, and pipeline prioritization efforts, the company has increasingly concentrated resources toward advancing its lead allogeneic CAR-T program through ongoing Phase 1b expansion cohorts and potential registrational pathways. We note that recent financing activity is expected to extend the company's operational runway into late CY2026, while management has also materially reduced operating intensity and non-core program expenditure. For valuing Imugene, we adopt a probability-adjusted discounted cash flow (DCF) framework, with azer-cel representing the primary contributor to future cash flows. Our model incorporates key assumptions around pricing of approximately \$350,000 in the U.S. and \$262,500 in ex-U.S. markets, peak market penetration of 25% in the U.S. and 20% internationally, and a probability of success of 30%, reflecting its Phase 1b stage and encouraging early clinical signals. We apply a discount rate of 12.0% and assume no terminal value, given the finite visibility of pipeline cash flows, while assigning a 90% weighting to DCF and 10% to comparable company analysis. Based on this blended methodology, we derive an illustrative valuation of A\$0.43 per share, contingent upon successful execution by the company.

Company Overview

Imugene Limited (ASX: IMU) is an Australia-based clinical-stage biotechnology company that has increasingly centered itself around the development of azer-cel (azercabtagene zapreleucel), an allogeneic, CAR-T cell therapy targeting CD-19 expressing hematological malignancies. The company acquired global rights to azer-cel from Precision BioSciences, gaining access to an advanced clinical dataset, established manufacturing infrastructure, and prior regulatory engagement, which collectively accelerated development timelines. The transaction is structured with up to \$227 million in milestone payments and double-digit royalties, creating a back-ended economic framework with commercialization success. Development is currently focused primarily on relapsed or refractory diffuse large B-cell lymphoma (DLBCL), with potential expansion into other CD19-expressing malignancies over time. Designed as an off-the-shelf therapy, azer-cel utilizes a scalable manufacturing approach, enabling rapid treatment initiation compared to autologous CAR T therapies. The product is manufactured using the proprietary ARCUS gene-editing platform, which inserts the CAR construct into the TRAC locus, eliminating the native T-cell receptor and supporting a more controlled and consistent product profile.

Introducing azer-cel

Imugene's potential first-in-class, off-the-shelf Allogeneic CAR-T Cell Therapy



Allo CAR T Cell Therapy IMUGENE

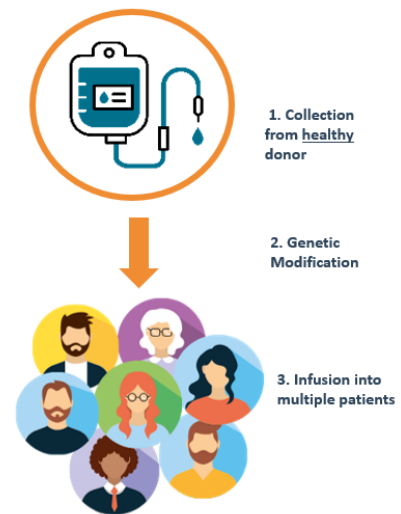


Exhibit 1: Imugene Clinical Pipeline. Source: Company Presentation

Azer-cel is currently being evaluated in a global Phase 1/1b study across both CAR T-relapsed and CAR T-naïve patient populations. Dose escalation has been completed, establishing a recommended Phase 2 dose of 500 million cells alongside an optimized lymphodepletion regimen, with the FDA subsequently endorsing this dosing regimen for registrational development. Early clinical data demonstrate encouraging response rates in heavily pre-treated populations, with durability signals and a manageable safety profile, including no evidence of graft-versus-host disease or high-grade cytokine release syndrome observed to date. The program has also progressed on the regulatory front, with a successful FDA Type C meeting completed in November 2025. This interaction resulted in alignment on a registrational pathway in third-line or later DLBCL, including support for a single randomized Phase 3 trial with dual endpoints designed to enable both accelerated and

full approval. In addition to monotherapy development, Imugene is exploring combination approaches, particularly with Bruton's tyrosine kinase inhibitors (BTKi), a well-established class of therapies with more than \$10 billion in annual global sales.¹ These combinations are intended to enhance CAR T-cell expansion, persistence, and overall efficacy, while potentially broadening the addressable patient population across multiple B-cell malignancies.

Imugene's current profile is defined by a concentrated strategic focus on azer-cel, reflecting a transition toward a more streamlined, asset-centric operating model. The company has combined an advanced clinical dataset with internalized manufacturing capabilities and ongoing regulatory engagement to establish a structured development pathway for the program. This approach positions Imugene within a select group of companies advancing allogeneic CD-19-directed CAR-T therapies, where progress is increasingly shaped by execution, trial design, and alignment with evolving treatment paradigms. At the same time, the company's concentrated reliance on a single core asset amplifies both upside potential and execution risk, making the timely delivery of clinical milestones, regulatory advancement, and eventual commercialization strategy central to long-term value creation.

Imugene is a clinical-stage immune-oncology company primarily focused on advancing azer-cel, which integrates clinical validation, scalable manufacturing, and regulatory alignment to target r/r DLBCL.

Azer-cel - Scalable Off-the-Shelf Allogeneic CAR-T Targeting CD19

The company's acquisition of Precision BioSciences' allogeneic CAR-T cell therapy program in 2023 represents a strategically significant step toward expanding its capabilities in scalable, cell-based immunotherapy. The transaction provides access to azer-cel (azercabtagene zapreleucel), a clinically advancing CD19-targeted CAR-T candidate, along with associated manufacturing infrastructure and enabling technologies required to advance the program. Importantly, azer-cel's standardized manufacturing process is designed to support batch production, improve product consistency, and potentially lower the cost of goods, thereby addressing key structural constraints that have historically limited the scalability of CAR-T therapies. By integrating this platform, the company can utilize donor-derived, pre-manufactured T cells, enabling an off-the-shelf treatment approach that eliminates patient-specific manufacturing and materially reduces vein-to-vein time (approximately 3-5 days vs. 2-4 weeks for autologous CAR-T therapies)². This reduction in turnaround time is particularly important in aggressive hematologic malignancies such as relapsed or refractory diffuse large B-cell lymphoma, where delays in treatment can directly impact eligibility and outcomes. This effect has been observed in autologous CAR-T therapies, where shorter vein-to-vein times are associated with higher complete response rates and improved survival outcomes. Consistent with this, real-world data indicate that patients receiving autologous CAR-T therapies such as Yescarta, where vein-to-vein times are typically ≤ 30 days, achieve higher complete response rates (50-55%) compared to therapies with longer timelines (>30-40 days), such as

Azer-cel represents Imugene's core value driver, offering a scalable, off-the-shelf CAR-T approach that addresses key limitations of autologous therapies, with early clinical validation and a clear path to commercialization

¹ Pharmsources.com

² ajmc.com

Kymriah, where CR rates decline to 30–35%.³ Taken together, this highlights the clinical importance of rapid treatment deployment and strengthens the strategic rationale for advancing an off-the-shelf CAR-T approach.

The current commercial landscape for CAR-T therapies reflects a key disconnect between strong clinical efficacy and limited real-world scalability. While approved autologous therapies have established a multi-billion-dollar market, their penetration remains restricted to a subset of eligible patients. In this context, azer-cel is strongly positioned for the next phase of CAR-T evolution, shifting from individualized treatment models to much broader accessibility.

Company	Drug	Targeted Disease	Line of Treatment	Annual Revenue
Gilead Sciences/Kite Pharma	Yescarta® (axi-cel)	R/R DLBCL, FL	2L and 3L+	\$1.5 billion
Novartis	Kymriah® (tisa-cel)	R/R DLBCL, ALL	3L+	\$0.38 billion
Bristol Myers Squibb	Breyanzi® (liso-cel)	R.R DLBCL	2L and 3L+	\$1.35 billion
Bristol Myers Squibb	Abecma® (ide-cel)	Multiple Myeloma	4L+	\$0.43 billion
Jhonsen & Jhonsen / Legend Biotech	Carvykti® (cilta-cel)	Multiple Myeloma	2L-4L+	\$1.9 billion

Exhibit 2: Key Autologous CAR-T Therapies by Indication and their 2025 Annual Revenue. Source: Company Website

Azer-cel’s Mechanism of Action, Clinical Positioning, and Target Indications

Azer-cel is an allogeneic CAR-T cell therapy engineered to target CD-19, a surface antigen broadly expressed across B-cell malignancies. Following lymphodepletion, donor-derived T-cells expressing a chimeric antigen receptor are infused into the patient, enabling direct recognition of CD-19-positive malignant cells. Upon binding to the target antigen, CAR-T cells undergo activation and proliferation, releasing cytotoxic granules and pro-inflammatory cytokines that induce tumor cell apoptosis and amplify the immune response. While this mechanism is consistent with established CAR-T biology, the key differentiation lies in the allogeneic design, which allows pre-manufacturing from healthy donors and immediate availability at the point of care.

ARCUS Enables Precise Insertion of a CD19 CAR Into the TRAC Locus

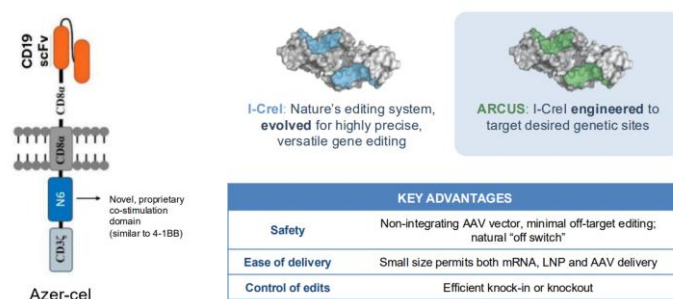


Exhibit 3: ARCUS Gene Editing Enables Precise CAR Insertion and TCR Disruption in azer-cel. Source: Company Presentation.

³ Locke FL et al., Blood Adv, 2025

A critical challenge historically associated with allogeneic CAR-T therapies has been the risk of graft versus host disease (GvHD) and host immune rejection, which can limit both safety and persistence of the infused cells. In this context, Precision’s ARCUS® gene-editing platform enables precise insertion of the CD19 CAR into the TRAC region of the T-cell, effectively switching off the cell’s natural receptor that could perceive the patient’s cells as foreign and attack them. This modification allows azer-cel to address the limitations through gene editing strategies that disrupt natural T-cell receptor (TCR) signaling, thereby reducing the ability of donor-derived T-cells to recognize and attack host tissues, which is the primary driver of GvHD.

Additionally, the use of adjunctive low-dose interleukin-2 (IL-2) is intended to enhance in vivo expansion and persistence of CAR-T cells. The ARCUS platform also enables improved compatibility and persistence in the host environment, including modifications aimed at reducing immune-mediated clearance of the infused cells. This approach is consistent with broader industry efforts to develop “universal” CAR-T products, where gene editing has been shown to significantly mitigate alloreactivity while preserving anti-tumor function.

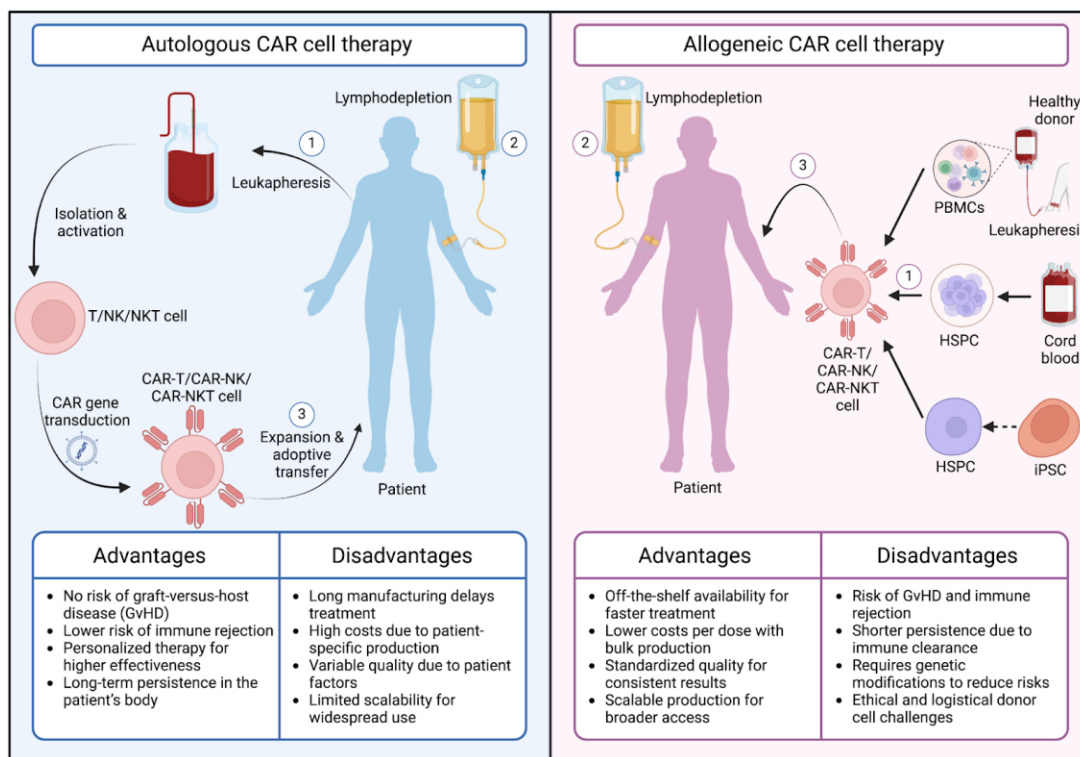


Exhibit 4: Autologous and Allogeneic CAR Therapy. Source: Yan-Ruide Li et al.

Clinically, azer-cel is being developed for relapsed or refractory B-cell malignancies, particularly diffuse large B-cell lymphoma, where CD-19-directed therapies have demonstrated strong efficacy and established CAR-T as a standard of care in later-line settings.⁴ Azer-cel is being evaluated across both CAR-T naive and relapsed patient populations, with potential expansion into additional CD-19 positive indications such as follicular lymphoma, chronic lymphocytic leukemia, and mantle cell lymphoma. If supported by continued clinical validation, the therapy may be positioned not only as an alternative in later-line settings but also as a platform capable of enabling earlier intervention and broader adoption across the treatment paradigm.

⁴ Ghilardi G., The Emerging Role of CAR-T Cell Immunotherapy in Early Treatment of Large B-Cell Lymphoma

Clinical Evidence Showcasing Early Efficacy Signals and Positive Safety Profile

Azer-cel is being evaluated under a Phase 1/1b clinical study structure, beginning with a dose-escalation phase and progressing into a focused cohort-expansion phase. The initial dose-escalation is shown having treated 84 patients, comprising 23 patients with B-ALL and 61 patients with NHL. This phase was primarily used to assess safety, dose levels, lymphodepletion strategies and early clinical activity. This process supported selection of the go-forward regimen, including a 500 million-cell dose of azer-cel and an optimized lymphodepletion regimen (Aug/Cy – Flu 30mg/m² x 3 days, Cy 750mg/m² x 3 days)

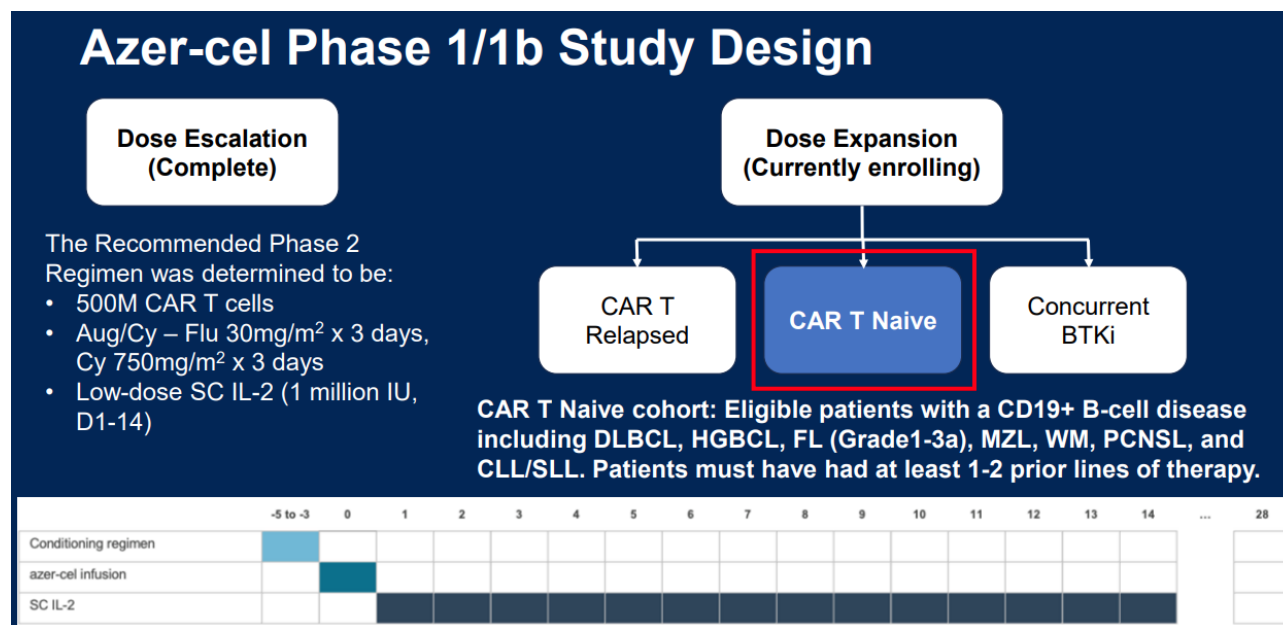


Exhibit 5: Azer-cel Phase 1/1b Study design. Source: 2026 ASCO Annual Meeting Presentation

Following completion of dose escalation, the program moved into Phase 1b expansion, where the focus shifted from broad dose/regimen optimization to testing the selected regimen in more clinically defined patient cohorts. The most advanced expansion group is Cohort 1, which evaluates azer-cel in heavily pretreated 3L+ relapsed/refractory DLBCL patients who failed prior autologous CD19 CAR-T therapy. This is particularly difficult treatment setting because patients have already failed one of the most active approved treatment modalities, and many have also received multiple prior lines of therapy, including bispecific antibodies. The primary endpoint is overall response rate by Lugano criteria, while secondary endpoints include complete response rate, duration of response, progression-free survival, overall survival, time to next treatment, and adverse events.

Early Phase 1/1b data for azer-cel demonstrate compelling efficacy and manageable safety, particularly among high-risk post-CAR-T DLBCL patients, supporting its potential as a differentiated allogeneic CAR-T therapy.

Cohort 1 of the study enrolled patients (n=18) with relapsed or refractory DLBCL who had received multiple prior lines of therapy (median prior lines of therapy, n=4), including autologous CAR-T, and in many cases, bispecific antibodies.⁵ This is a particularly challenging population, as outcomes following CAR-T failure are

⁵ Company Conference Presentation

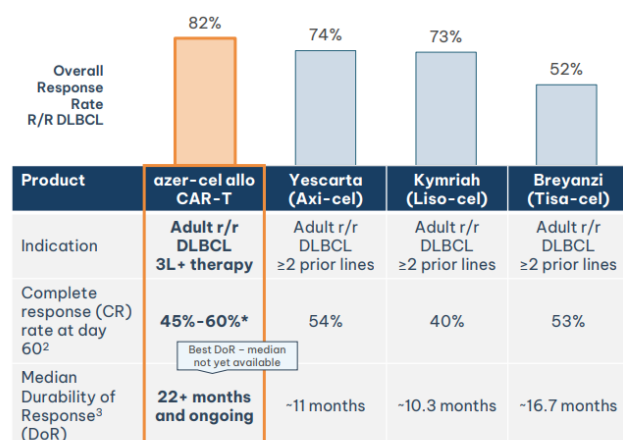
typically poor, with limited effective treatment options and short progression-free survival. The ongoing Cohort 2 expands this by enrolling a broader group of CAR-T-naïve patients across various indications, including DLBCL, FL, CLL/SLL, MZL, WM, and PCNSL, with 9 patients enrolled, and recruitment remains ongoing, thereby enabling evaluation across a more heterogeneous patient population.⁶ Across both cohorts, the study applies the optimized regimen of 500 million cells in combination with Aug Cy lymphodepletion, along with adjunctive low-dose interleukin-2 (IL-2) to support in vivo expansion and persistence of the infused CAR-T cells. This standardized approach enables more consistent assessment of efficacy and safety while supporting dose selection for potential registrational development.

Azer-cel compared to existing Approved Auto CAR-T Therapies



Initial azer-cel Ph 1b R/R DLBCL data is compelling when compared to approved Auto CAR-T treatments

Azer-cel is comparable to approved Auto CAR-Ts for treatment of DLBCL 2L+ of therapy¹



Despite all patients failing prior Autologous CD19 CART products and approximately 50% failing bispecific therapies, azer-cel demonstrates Response Rates similar to CD19 CART-naïve patients.

¹Company announcements and FDA.gov
²Initial response at D28 of PR, which improved to CR at later date. For approved, autologous CD19 CART products, the average time to best response is 2-3 months. Outcomes of CD19-Directed Chimeric Antigen Receptor T Cell Therapy for Transformed Nonfollicular Lymphoma. Dong, Ning et al. Transplantation and Cellular Therapy, Official Publication of the American Society for Transplantation and Cellular Therapy, Volume 29, Issue 6, 349.e1 - 349.e8
³Azer-cel Complete Response rate and median DoR can not yet be accurately determined as trial and patients are ongoing

*CR % may vary with ongoing enrolment and time to best response

Exhibit 6: Azer-cel compared to existing approved auto CAR-T therapies. Source: Company Presentation

Interim results from the Phase 1b study demonstrate encouraging efficacy and a favorable safety profile, beginning with Cohort 1, which enrolled heavily pre-treated patients who had progressed following prior autologous CAR-T Therapy. Azer-cel achieved an overall response rate of 82% (14/17 evaluable patients), including 7 complete responses and 7 partial responses, demonstrating consistent anti-tumor activity.⁷ Notably, durability signals are particularly strong with the best duration of response extending to approximately 24 months and ongoing, indicating the potential for sustained disease control.⁸ Additionally, clinical responses are supported by strong in vivo CAR-T expansion and persistence. From a safety perspective, the regimen was well tolerated with no evidence of GvHD, no Grade ≥3 CRS, and infrequent ICANS, although Grade 3 ICANS events were reported and resolved. These data support continued evaluation in a heavily pre-treated post-autologous CAR-T relapsed populations.

Azer-cel's clinical activity is further demonstrated in Cohort 2, which evaluates CAR-T naïve patients across rare and niche CD19-positive B-cell malignancies, expanding the scope of clinical validation beyond DLBCL.

⁶ Company Press Release

⁷ Company Press Release

⁸ Company Presentation

In this context, the therapy achieved a 100% ORR (4/4) in CLL/SLL and 80% ORR (4/5) in MZL patients who had received multiple prior lines of therapy.⁹ Early data also suggest favorable durability trends, with responses ongoing and comparing positively to existing treatment options, including BTK inhibitors and autologous CAR-T therapies. Collectively, Cohort 2 extends azer-cel's clinical relevance beyond the post-CAR-T DLBCL setting, highlighting its potential applicability across a broader range of CD19-positive malignancies and supporting a multi-indication development strategy.

Cohort 3 Demonstrates Potential Synergy with BTK Inhibitor Combination

Cohort 3 represents a strategically important extension of the azer-cel program, as it moves beyond demonstrating activity as a standalone allogeneic CAR-T and begins to explore whether combination therapy can improve the two areas critical for long-term success: depth of response and durability. While CAR-T therapies have demonstrated high initial response rates, long-term outcomes are often limited by T-cell exhaustion, suboptimal persistence, and an immunosuppressive tumor microenvironment. BTK Inhibitors offer a mechanistically compelling strategy to address these limitations by directly modulating both tumor biology and immune function.

BTK inhibitors target Bruton's Tyrosine Kinase, a critical signaling node within the B-cell receptor (BCR) pathway that regulates proliferation, survival, and trafficking of malignant B-cells. Inhibition of BTK disrupts downstream signaling cascades, including NF- κ B, PI3K-AKT, and MAPK, thereby reducing tumor cell viability and mobilizing malignant cells from protective lymphoid niches. Beyond direct tumor suppression and modulation of the tumor microenvironment (TME), BTK inhibitors also exert immunomodulatory effects. They have been shown to attenuate T-cell exhaustion markers and alter cytokine profiles, thereby enhancing T-cell functionality and creating a more favorable immune milieu for antitumor activity. This mechanism has been clinically validated across multiple B-cell malignancies, with BTK inhibitors now established as standard-of-care therapies in indications such as CLL, MCL, WM, and MZL, supporting their broad utility and durable clinical benefit across diverse disease settings.

The integration of BTK inhibitors with CAR-T therapies represents a mechanistically synergistic approach to enhance T-cell expansion, persistence, and depth of response by modulating both tumor biology and the immune environment

The evolution of BTK inhibitors across multiple generations, with improvements in selectivity, safety, and activity in resistant disease, has expanded their role beyond monotherapy and positioned them as an attractive combination therapy in B-cell malignancies. In particular, their integration with CD19-directed CAR-T therapies has gained increasing clinical interest, given the complementary mechanisms of action.¹⁰ While CAR-T therapies provide direct cytotoxic targeting of malignant B-cells, BTK inhibitors modulate both tumor biology and the immune microenvironment, creating conditions that may enhance CAR-T cell expansion, persistence, and overall therapeutic efficacy. This combination approach is therefore aimed not only at improving initial response rates but more importantly at deepening responses and extending durability, which remain key challenges in the CAR-T treatment paradigm.

⁹ Company Press Release

¹⁰ Luo et al., Blood 2024

Drug	Company	Key Indications	Generation	Annual Sales
Imbruvica® (Ibrutinib)	AbbVie/Johnson & Johnson	CLL, MCL, WM, MZL	1 st Generation	\$2.87 billion
Calquence® (Acalabrutinib)	AstraZeneca	CLL, MCL	2 nd Generation	\$3.51 billion
Brukina® (Zanubrutinib)	BeOne	CLL, MCL, WM	2 ND Generation	\$3.9 billion
Jaypirca® (Pirobrutinib)	Eli Lilly	CLL, MCL	3 rd Generation	\$0.51 billion

Exhibit 7: Key BTK Inhibitors and Annual Revenue (2025). Source: Diamond Equity Research, Company Sources.

Clinical evidence supports a synergistic interaction between BTK inhibitors and CD-19-directed CAR-T therapies across multiple B-cell malignancies. Combination studies have demonstrated consistently high overall and complete response rates, alongside improved minimal residual disease (MRD) negativity and extended progression-free survival. Ibrutinib in combination with tisagenlecleucel in patients with R/R mantle cell lymphoma has shown an ORR of 85% and CR rates approaching 80%, with high MRD negativity rates, while combinations with lisocabtagene maraleucel in patients with R/R CLL/SLL have demonstrated an ORR of 86% with durable responses and median progression-free survival extending beyond 30 months.¹¹ In a pilot cohort from a Phase I/II open-label study of CD19 CAR-T therapy in relapsed/refractory CLL (n=19) patients treated with concurrent ibrutinib, reported an ORR of 83% at 4 weeks compared to 56% in the non-ibrutinib cohort, alongside a more favorable safety profile.¹¹ Notably, any grade CRS was reduced (74% vs 95%), with no Grade ≥3 CRS observed in the ibrutinib cohort (vs 11%), and lower rates of neurotoxicity overall. Across these studies, enhanced CAR-T cell expansion and persistence have been observed, supporting the hypothesis that BTK inhibition improves the functional quality of infused T-cells.

Cohort 3 positions azer-cel for broader adoption, as a combination with BTK inhibitors could address key limitations of allogeneic CAR-T therapies while enabling expansion into earlier lines and BTKi-established indications

Additional datasets involving second-and third-generation BTK inhibitors further support the robustness of this combination strategy. Regimens incorporating acalabrutinib, zanubrutinib, and pirobrutinib have demonstrated high response rates across r/r DLBCL, MCL, and other CD19-positive malignancies, with complete response rates frequently exceeding 70% and durable remissions observed beyond 18-24 months. Notably, these combinations have generally maintained a favorable safety profile, with a low incidence of high-grade CRS and ICANS. In the context of azer-cel, the incorporation of BTK inhibitors is particularly compelling given the allogeneic platform, where immune-mediated clearance and limited persistence remain key challenges. By modulating both intrinsic T-cell functionality and the tumor microenvironment, BTK inhibition may enhance CAR-T expansion, prolong persistence, and improve durability of response, thereby addressing one of the primary historical limitations of allogeneic CAR-T therapies. From a clinical development perspective, this strategy also enables expansion into indications where BTK inhibitors are

¹¹ BTK Inhibitors with CAR T-cell therapy, Pharmacy Times

already embedded within the treatment paradigm, including CLL/SLL, MCL, and MZL, potentially facilitating earlier-line use and broader adoption.

Overall, Cohort 3 reflects a mechanistically grounded approach to improving CAR-T performance through combination therapy. If validated in clinical studies, the integration of BTK inhibitors with azer-cel could enhance depth and durability of response while expanding the addressable market, positioning the therapy within a more durable and scalable treatment framework across CD-19 positive malignancies.

Broad Pipeline and Narrow Leadership, as CD19 Allogeneic CAR-T Field Consolidates Around a Few Viable Players

The CD19-directed allogeneic CAR-T landscape represents an emerging but still evolving segment within the broader cell therapy market, aimed at addressing key limitations of autologous CAR-T therapies, including manufacturing complexity, vein-to-vein time, and scalability constraints. Multiple companies are pursuing off-the-shelf CD19 CAR-T approaches, with leading clinical programs including cema-cel (Allogene Therapeutics), CTX110 (CRISPR Therapeutics), UCART19 (Cellestis), and FT819 (Fate Therapeutics), to name a select few. Despite this apparent breadth, the competitive field remains uneven, with only a couple of programs demonstrating sufficient clinical activity and development progression to support a credible path toward registrational studies.

Company	Program	Development Stage	Target Setting	Key Takeaway
Allogene Therapeutics	Cema-cel (ALLO-501A)	Pivotal Phase 2 (ALPHA3)	1L consolidation (MRD+) + prior r/r LBCL	Most advanced and de-risked program
Imugene	Azer-cel	Phase 1b	r/r LBCL	Higher upside, but early-stage risk
CRISPR Therapeutics	Zugo-Cel (CTX112™)	Phase 1/2	r/r B-cell malignancies and Autoimmune Diseases	Early but promising CD19 allogeneic program
Cellestis	UCART19	Early Phase 1	ALL/NHL	Limited recent progress
Fate Therapeutics	FT819	Phase 1	r/r B-cell malignancies	Conceptually strong, clinically early

Exhibit 8: CD19 CAR-T Cell Therapy Landscape. Source: Diamond Equity Research, Company Sources.

Among these cema-cel has emerged as the most clinically advanced program. In the pooled Phase 1 ALPHA trial and ALPHA2 trial dataset, which included 33 evaluable r/r LBCL patients, cema-cel delivered a 58% overall response rate and 42% complete response rate, with a median duration of response of 23.1 months among complete responders. In the preferred FCA90 regimen subgroup, efficacy improved further to 67% ORR and 58% CR, while safety remained notable for the absence of GvHD, ICANS, or grade ≥ 3 CRS.¹² More recently, cema-cel has progressed into a randomized pivotal Phase 2 ALPHA3 trial in a first-line MRD-positive consolidation LBCL, which is expected to enroll approximately 220 patients. An interim futility analysis conducted after the first 24 patients (12 per arm) reached assessment demonstrated MRD negativity in 58.3% of treated patients versus 16.7% in the control arm, although the primary endpoint of event-free survival

¹² Locke et al., J Clin Oncol, 2025

remains blinded.¹³ Azer-cel, on the other hand, represents an earlier-stage but more broadly explored program. The Phase 1/1b dose escalation component included 84 treated patients across relapsed/refractory NHL and B-ALL, comprising 61 NHL and 23-B-ALL patients, and provided an optimized dose level, lymphodepletion strategy. The ongoing Phase 1b study, structured as a multi-cohort expansion across both post CAR-T and CAR-T naive patients, has reported an 82% ORR (14/17 evaluable patients - cohort 1) in heavily pre-treated r/r DLBCL, and a favorable safety profile.

We believe both cema-cel and azer-cel stand out as the most clinically relevant and strategically positioned programs, albeit at different stages of development. Cema-cel currently represents the more de-risked and advanced asset, supported by a more homogeneous, indication-specific dataset and progression into a randomized pivotal study in an earlier-line setting, which enhances visibility on a registrational pathway. In contrast, azer-cel reflects a broader but more exploratory clinical approach, with encouraging efficacy signals across heterogeneous populations, particularly in the post-autologous CAR-T relapse setting. Recent interactions with the FDA suggest alignment on pursuing this later-line population as an initial regulatory entry point, while ongoing trial expansion preserves the option to move into earlier lines of therapy over time. This divergence is also reflected in the current market capitalization contrast, with Allogene at approximately \$822 million versus Imugene at \$38 million. While this gap partly reflects differences in clinical maturity and financing capacity, and breadth of Allogene's pipeline (most of them are in very early stages), we believe the current market valuation may not fully capture the strength of azer-cel's emerging clinical signal in a high unmet need setting. Accordingly, while cema-cel offers greater near-term certainty, azer-cel presents a significant asymmetric opportunity, with potential for meaningful re-rating as its clinical data mature and its development pathway becomes more clearly defined.

DLBCL Landscape: Disease Overview, Market Opportunity, Treatment Paradigm, and CAR-T M&A Trends

The selection of diffuse large B-cell lymphoma (DLBCL) as the lead indication for azer-cel reflects both its clinical urgency and commercial attractiveness, as evidenced by azer-cel's U.S. FDA Fast Track designation for relapsed/refractory (R/R) DLBCL. Strategically, Imugene's focus on DLBCL is well aligned with the evolving treatment landscape, where rapid disease progression, high relapse rates, and logistical constraints associated with autologous CAR-T therapies create a clear opportunity for off-the-shelf allogeneic approaches such as azer-cel. Epidemiologically, DLBCL represents the largest and most commercially relevant subtype of non-Hodgkin lymphoma (NHL), accounting for approximately 30-40% of all NHL cases globally.¹⁴ This translates into an estimated 150,000 new cases worldwide each year, including approximately 20,000-30,000 in the United States.¹⁵ Incidence rate is estimated at 5.6 per 100,000 population in the U.S., with global variation between 2.3 and 13.8 per 100,000, reflecting geographic and demographic differences. Despite curative intent in frontline therapy, outcomes remain suboptimal for a meaningful proportion of patients. Standard first-line chemoimmunotherapy achieves durable remission in approximately 60% of patients, leaving up to 50% of patients who either relapse or become refractory to treatment.¹⁴ This relapsed/refractory population (second and further lines) represents the primary target for advanced therapies, including CAR-T and bispecific antibodies. Within this group, real-world analyses suggest that up

¹³ Allogene Press Release

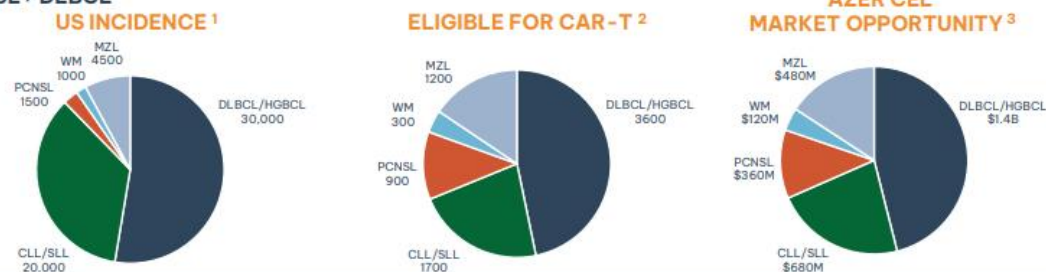
¹⁴ Sineshaw HM et al., Cancer Med, 2024 – Real-world DLBCL treatment patterns by line of therapy

¹⁵ Laurie H. Sehn & Gilles Salles, N Engl J Med, 2021 – DLBCL review

to 60-65% of patients may be clinically eligible for CAR-T therapy, based on disease status and fitness criteria; however, approximately 25% eligible patients ultimately receive CAR-T therapy.¹⁶⁻¹⁷ This highlights a significant treatment gap, with the majority of eligible patients unable to access therapy due to factors such as rapid disease progression, manufacturing timelines, referral delays, and logistical constraints associated with autologous cell therapy. This implies that out of approximately 10,000 - 12,000 DLBCL patients entering the relapsed/refractory setting (second line and further), 6,000 - 7,000 patients may be eligible for CAR-T, implying an estimated total addressable market (TAM) of \$2.4 - \$2.8 billion based on an assumed per-patient treatment cost of \$400,000.

Azer-cel Commercialization Opportunity

\$3bn+ p.a. US potential market opportunity in rare & niche indications and 3L+ DLBCL



Azer-cel: Commercial Opportunity may leverage a De-risked Regulatory Roadmap

- **Azer-cel Targets High-Need Indications for Single-Arm Registrational/Pivotal Trial:** Ideal for pursuing accelerated approval without comparators.
- **Prioritizing Fast-to-Market Opportunities:** azer-cel is positioned to leverage other high-need, less comparator-intensive indications for faster-to-market entry, using DLBCL to support broader development.
- **Promising Niche Indications with Strong Commercial and Regulatory Potential**
- **A \$2B+ Market Built on Strategically Chosen, Comparator-Free Indications:** azer-cel's commercial roadmap is to prioritize rapid regulatory path with capital-efficient development for fast to market entry.

1. SEER 2020 Estimate: numbers of potential patients
 2. NCCN guidelines, ASH, Peer-reviewed literature & CAR-T clinical trials; Assumes 3L+ for DLBCL and 2L+3L for all other cancers
 3. TAM: total addressable market is total number of treatable patients x price (assumes \$400,000/dose) at 100% market share. TAM is a potential market only and depends upon regulatory approval, successful commercialization, market share and timing

PCNSL = Primary Central Nervous System Lymphoma (≥1 prior line of therapy containing high-dose MTX)
 CLL/SLL = Chronic or Small Lymphocytic Leukemia (Prior BTKi and BCL2i or only prior BTKi and high-risk features)
 DLBCL = Diffuse Large B-cell Lymphoma (≥1 prior line of therapy, including anti-CD20 + anthracycline)
 MZL = Marginal Zone Lymphoma (≥2L of prior therapy, including anti-CD20 chemoimmunotherapy)
 WM = Waldenström's Macroglobulinemia (≥2L of prior therapy, including anti-CD20 chemoimmunotherapy)

Exhibit 9: Imugene's Estimation of the U.S. Market Opportunity for Multiple Hematological Malignancies at 3L+.
Source: Company Presentation

The treatment gap in relapsed/refractory DLBCL, combined with the high economic value of advanced therapies, has driven increasing strategic interest across the CAR-T landscape. As competition intensifies and the limitations of first-generation autologous CAR-T therapies become more apparent, large pharmaceutical and biotechnology companies have actively pursued mergers, acquisitions, and partnerships to strengthen their presence in cell therapy. These transactions reflect a broader shift toward the acquisition of next-generation platforms, including allogeneic CAR-T, gene editing technologies, in vivo approaches, and scalable manufacturing capabilities, which are expected to define the next phase of growth in the CAR-T market.

The following table highlights selected recent strategic transactions across the CAR-T and broader cell therapy landscape, illustrating the accelerating consolidation and focus on next-generation platforms.

¹⁶ Puckrin R et al., Transplant Cell Ther, 2022 – Real-world eligibility for 2L CAR-T in LBCL

¹⁷ Cartvision.com

Year	Acquirer	Target	Deal Value	Strategic Focus
2026	Eli Lilly	Orna Therapeutics	Up to \$2.4 billion	RNA-based in vivo CAR-T platform, scalable non-viral engineering.
2026	Gilead Sciences	Arcellx	\$7.8 billion	Acquisition of anito-cel (BCMA CAR-T) to strengthen leadership in multiple myeloma with next-gen efficacy and safety profile.
2025	AbbVie	Capstan Therapeutics	Up to \$2.1 billion	mRNA/LNP-based in vivo CAR-T platform targeting autoimmune disease, enabling repeat dosing and expansion beyond oncology
2025	AstraZeneca	EsoBiotech	Up to \$1.0 billion	ENaBL viral delivery platform enabling rapid in vivo CAR-T generation, reducing manufacturing complexity and treatment time.
2025	Kite Pharma	Interius BioTherapeutics	\$350 million	DNA-based in vivo CAR-T delivery approaches to eliminate ex vivo manufacturing and improve scalability.
2025	Bristol Myers Squibb	2Seenty BIO	\$286 million	Full control of Abecma economics and pipeline; consolidates cell therapy franchise and improves margin capture
2025	Bristol Myers Squibb	Orbital	\$1.5 billion	RNA-based delivery platform applicable to next-gen cell therapies, including in vivo CAR-T, expands modality toolkit beyond viral vectors.
2024	Roche	Poseida Therapeutics	Up to \$1.5 billion	Allogenic CAR-T platform using piggyBac transposon system, enabling off-the-shelf therapies with lower cost and scalable manufacturing.
2024	AstraZeneca	Gracell Biotechnology	\$1.2 billion	Next-gen CAR-T pipeline including dual-target constructs (BCMA/CD19) to address antigen escape and improve durability.

Exhibit 10: Recent M&A Activity in the CAR-T and Cell Therapy Landscape. Source: Diamond Equity Research.

Azer-cel, as an allogenic CAR-T therapy, occupies a strategically important middle ground between first-generation autologous CAR-T treatments and emerging in vivo approaches, and this positioning shapes both its opportunity and risk profile. Autologous CAR-T therapies, developed by companies such as Gilead/Kite and Bristol Myers Squibb, have demonstrated strong clinical efficacy but are inherently constrained by complex, patient-specific manufacturing, long vein-to-vein timelines, high cost of goods, and limited scalability. At the other end of the spectrum, the current wave of M&A is increasingly focused on in vivo CAR-T platforms, which aim to engineer immune cells directly within the patient, thereby eliminating manufacturing bottlenecks and potentially enabling significantly lower costs, faster treatment, and broader access, albeit with significantly higher clinical and regulatory uncertainty at this stage. Azer-cel sits between these two paradigms by addressing key limitations of autologous therapies while still relying on ex vivo processes. Importantly, this positioning supports a more attractive risk-adjusted value proposition, as azer-cel benefits from established biological validation of the CAR-T mechanism and manufacturing processes, in contrast to in vivo platforms where clinical outcomes remain largely unproven. While allogeneic approaches introduce their own challenges, such as GvHD and persistence, these risks are better characterized and are actively being

addressed through evolving engineering strategies. As a result, azer-cel offers a compelling balance between innovation and de-risking, providing meaningful operational and economic advantages over autologous CAR-T without assuming the same level of clinical uncertainty embedded in next-generation in vivo modalities. Recent M&A transactions indicate that large pharmaceutical companies are pursuing a dual-track strategy, consolidating best-in-class CAR-T assets while investing in disruptive delivery technologies. In this context, azer-cel could represent an attractive “bridge asset” with both near-term commercial relevance and strategic optionality, and given the ongoing release of strong trial data, it is likely to attract acquisition interest from players seeking to strengthen their cell therapy portfolios as they transition toward next-generation platforms.

Appendix

Year-end 30 TH June (in A\$)	2024A	2025A	2026E	2027E	2028E
INCOME STATEMENT					
Revenue	-	-	-	-	-
Cost of Sales (Depletion)	-	-	-	-	-
Gross Profit	-	-	-	-	-
Operating expenses					
General and administrative exp.	(59,906,919)	(27,769,555)	(18,050,211)	(14,440,169)	(15,162,177)
Research and Development	(86,885,484)	(46,691,367)	(45,757,540)	(32,030,278)	(33,631,792)
Total Operating Expenses	(146,792,403)	(74,460,922)	(63,807,751)	(46,470,446)	(48,793,969)
Income From Operations	(146,792,403)	(74,460,922)	(63,807,751)	(46,470,446)	(48,793,969)
Interest and Other Inc. / Exp.	(2,888,136)	5,439,310	3,583,441	2,310,479	669,686
Profit Before Tax (PBT)	(149,680,539)	(69,021,612)	(60,224,310)	(44,159,967)	(48,124,283)
Profit After Tax (PAT)	(149,680,539)	(69,021,612)	(60,224,310)	(44,159,967)	(48,124,283)
Basic Shares Outstanding	208,494,300	218,703,200	371,795,440	483,334,072	555,834,183
EPS - basic	(0.72)	(0.32)	(0.16)	(0.09)	(0.09)

BALANCE SHEET					
Cash and cash equivalents	93,107,5380	21,935,432	14,114,129	2,065,232	10,464,619
Other current assets	19,926,273	19,809,194	19,809,194	19,809,194	19,809,194
Total current assets	113,033,811	41,744,626	33,923,323	21,874,426	30,273,813
Non-current assets	38,364,006	41,843,051	39,082,698	36,247,344	33,336,991
Total Assets	151,397,817	83,587,677	73,006,021	58,121,770	63,610,804
Short-term borrowing	-	6,666,667	6,666,667	6,666,667	6,666,667
Other current liabilities	29,298,575	15,483,803	19,711,393	15,377,068	15,957,948
Total current liabilities	29,298,575	22,150,470	26,378,060	22,043,734	22,624,615
Long-term borrowing	-	2,582,333	2,582,333	2,582,333	2,582,333
Other non-current liabilities	3,844,835	13,822,541	16,404,874	16,404,874	16,404,874
Total liabilities	33,143,410	38,555,344	42,782,935	38,448,609	39,029,489
Total Equity	118,254,407	45,032,333	30,223,086	19,673,162	24,581,315
Total Liabilities & Equity	151,397,817	83,587,677	73,006,021	58,121,770	63,610,804

CASH FLOW STATEMENT					
Cash Flow from Operating	(101,726,143)	(75,568,516)	(48,616,866)	(42,257,863)	(40,761,345)
Cash Flow from Investing	(7,250,386)	(12,698,635)	1,145,157	558,559	(489,674)
Cash Flow from Financing	49,428,222	17,371,435	40,000,000	30,000,000	50,000,000
Increase (decrease) in cash	(59,548,307)	(70,895,716)	(7,821,303)	(12,048,897)	8,399,387
Cash at the end of period	93,107,538	21,935,432	14,114,129	2,065,232	14,464,619

Exhibit 11: Financial Statement Snapshot.
Source: Diamond Equity Research

Risk Profile

Clinical and Translational Risk: The investment case is heavily dependent on the successful clinical progression of azer-cel. While early-stage data are encouraging, they are derived from small, uncontrolled cohorts. There is a material risk that efficacy, durability, or safety outcomes may not be replicated in larger, randomized trials, particularly as the program advances toward registrational studies.

Regulatory Pathway Risk: Despite FDA alignment on a potential registrational pathway, including a single Phase 3 study design, regulatory outcomes remain uncertain. Failure to meet agreed endpoints, changes in regulatory expectations, or delays in trial execution could materially impact timelines and approval probability.

Execution and Trial Expansion Risk: The expansion of azer-cel across multiple cohorts (CAR T-relapsed, CAR T-naïve, and combination arms) increases operational complexity. Delays in patient recruitment, site activation, or protocol amendments could extend development timelines and increase capital requirements.

Manufacturing and Scalability Risk: Although the allogeneic model offers scalability advantages, commercial manufacturing of cell therapies remains technically complex. The company must demonstrate consistent, regulatory-compliant production at scale. Any issues related to process validation, comparability, or supply chain could delay commercialization.

Competitive and Modality Risk: The CD19 treatment landscape is highly competitive, with approved autologous CAR T therapies and emerging alternatives such as bispecific antibodies. Additionally, other allogeneic CAR T programs are in development. Superior efficacy, safety, or logistical advantages will be required to achieve meaningful market penetration.

Combination Strategy Risk: The BTKi combination strategy introduces incremental scientific and regulatory risk. While the mechanistic rationale is strong, clinical validation is limited, and failure to demonstrate an additive benefit could constrain expansion into broader indications.

Pipeline Concentration Risk: Near- to medium-term value is primarily driven by azer-cel. Any adverse clinical or regulatory developments related to this program would have a disproportionate impact on the company's valuation.

Financing and Dilution Risk: As a clinical-stage company, Imugene is expected to require additional capital to fund ongoing trials and manufacturing scale-up. Future equity raises may result in dilution, particularly if conducted prior to key value inflection points.

Early-Stage Pipeline Risk: Other programs, including CF33 oncolytic viruses and B-cell vaccines, remain in early stages of development and carry higher scientific and commercial uncertainty, though they are not currently primary valuation drivers.

This list of risk factors is not comprehensive. For a full list risk factors, please read Imugene's latest prospectus and/or annual filings

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