EVOLUTION CAPITAL

ATX | UPDATE REPORT | HEALTHCARE

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5 CRs, 11.1-Month mOS: ACCENT Delivers

Amplia Therapeutics Ltd

Amplia has released an ASX update reporting mature data from the ACCENT trial, anchored by two landmark developments: (i) an independent, centralised analysis using RECIST 1.1 criteria has confirmed five complete responses (CRs), a 7.8% rate that is unprecedented in first-line metastatic PDAC; and (ii) the trial has delivered a median Overall Survival (mOS) of 11.1 months, representing an approximate 2-month improvement over gemcitabine/Abraxane alone with no additional toxicity burden. The updated ORR is 35.9% (23/64). The company has been selected to present at the AACR annual meeting in April 2026. We place our fair valuation under review pending model updates, maintain our Speculative Buy recommendation, and expect to revise our probability of success assumptions upward.

Five Confirmed CRs: An Unprecedented Signal

The headline finding is the reclassification of response data by an independent, expert central-read laboratory. This analysis has identified four additional confirmed CRs beyond the one previously reported. The total CR count now stands at 5 out of 64 evaluable patients receiving the 400mg dose across both stages of the 1b/2a trial, yielding a CR rate of 7.8%. This does not include the pathological complete response (pCR) announced in June 2025. In the benchmark MPACT study (n=431), gem/Abraxane produced just one confirmed CR; a rate of 0.2%. NAPOLI 3 (the pivotal trial of NALIRIFOX – a first-line chemotherapy regimen approved in 2024) similarly recorded CR rates of 0.3% in both the gem/Abraxane and NALIRIFOX arms.

The independent validation of these CRs is also a meaningful de-risking event. Prior response data had been assessed by investigators at each trial site. The central read removes any potential site-level bias and applies a rigorous, standardised framework. This suggests that the drug's efficacy may have been underreported to date. Additionally, a further confirmed partial response was identified, lifting the ORR to 35.9% (23/64). Four patients remain on study as of 15 March 2026, with one patient approaching 24 months on trial.

mOS of 11.1 Months: Matching NALIRIFOX Without Additional Toxicity

The median overall survival of 11.1 months represents a ~2-month (31%) improvement over the 8.5-month benchmark from the MPACT study of gem/Abraxane alone. Importantly, this figure is identical to the 11.1-month mOS achieved by NALIRIFOX in its pivotal NAPOLI 3 trial, a regimen that was subsequently approved by the FDA.

However, the comparison is not straightforward and warrants careful interpretation. ACCENT is a single-arm Phase 1b/2a trial with 64 patients, whereas NAPOLI 3 was a 770-patient randomised Phase 3 study. Cross-trial comparisons carry inherent limitations due to differences in patient populations, geographies, and trial design. Nevertheless, the fact that narmafotinib combined with a simple two-drug chemotherapy backbone achieves a survival figure equivalent to an aggressive four-drug regimen (NALIRIFOX) is noteworthy, particularly given narmafotinib's consistently favourable tolerability profile. The combination of narmafotinib with gem/Abraxane continues to show an adverse event profile similar to chemotherapy alone.

Recommendation	**Spec Buy**
Previous Close	**$0.11**
Fair Valuation	**UR; Prev. $0.47**
TSR	**327%**

Company Profile (on Prev Close)

Market Cap	$79.5M
Enterprise Value	$48.4M
SOI (undiluted)	513.1M
Free Float	89.2%
ADV (3-month)	$297k
52-Week Range	$0.049 - $0.425

Price Performance

Company Overview

Amplia Therapeutics (ASX: ATX) is a clinical-stage biotechnology company developing targeted therapies for aggressive, treatment-resistant cancers. Its lead asset, narmafotinib (AMP945), is a highly potent and selective FAK inhibitor designed to enhance the efficacy of chemotherapy by dismantling the tumour's fibrotic and immunosuppressive defences. With FDA Fast Track and Orphan Drug designations secured, a second trial (AMPLICITY) underway in the US, and an AACR presentation forthcoming, Amplia is positioned at a key value inflection point ahead of anticipated partnership discussions.

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Coverage:

Initiation	*9 Jul 2025*
Update	*7 Augt 2025*
Update	*10 Oct 2025*

Comparative Efficacy: ACCENT in Context

Figure 1: Table comparing compares the updated ACCENT trial data against key historical benchmarks and the recently approved NALIRIFOX regimen. *Sources: company data; MPACT (NEJM 2013); NAPOLI 3 (Lancet 2023).*

Efficacy Metric	ACCENT (Narma + Gem/Abr) n = 64	MPACT (Gem/Abr) n = 431	NAPOLI 3 (Gem/Abr arm) n = 387	NAPOLI 3 (NALIRIFOX) n = 383
Confirmed CR	7.8% (5/64)	0.2% (1/431)	0.3%	0.3%
ORR	35.9%	23%	36.2%	41.8%
Median OS (mths)	11.1	8.5	9.2	11.1
Median PFS (mths)	7.6	5.5	5.6	7.4

Note: mPFS number last reported in August 2025 interim data.

The standout metric is the CR rate. While ORR and mOS figures are broadly comparable to NALIRIFOX, the depth of response signal is qualitatively different. As outlined in our initiation report, these CRs represent not merely disease control but complete tumour eradication; a result historically associated with durable long-term remission in other cancer types. The cluster of 5 CRs in a 64-patient all-comer population strongly suggests the existence of a responder subgroup, reinforcing the case for biomarker discovery work which the company has indicated is underway.

Comparative Safety: No Additional Toxicity Burden

Figure 2: Table comparing Grade 3 or higher adverse events across the ACCENT trial and key benchmarks. NR = not reported at the Grade ≥ 3 threshold in that study. *Sources: company data; MPACT (NEJM 2013); NAPOLI 3 (Lancet 2023).*

Adverse Event (Grade ≥ 3)	ACCENT (Narma + Gem/Abr) n = 55	MPACT (Gem/Abr) n = 421	NAPOLI 3 (Gem/Abr arm) n = 379	NAPOLI 3 (NALIRIFOX) n = 370
Neutropenia	38.2%	38%	24.5%	14.1%
Anemia	9.1%	13%	17.4%	10.5%
Thrombocytopenia	NR	13%	NR	NR
Diarrhea	5.5%	6%	4.5%	20.3%
Peripheral Neuropathy	3.6%	17%	5.8%	3.5%
Fatigue	NR	17%	NR	NR
Nausea	3.6%	NR	2.6%	11.9%
Febrile Neutropenia	5.5%	3%	NR	NR
Vomiting	3.6%	NR	NR	NR
Hypokalemia	NR	NR	4.0%	15.1%

Note: ACCENT safety data from August 2025 topline readout. Figures to change pending market update.

The safety data reinforces a critical pillar of the narmafotinib investment thesis: that FAK inhibition can be layered on top of standard chemotherapy without compounding the toxicity burden. Across the major haematological toxicities (neutropenia, anemia, thrombocytopenia), ACCENT's rates are broadly comparable to or better than the MPACT benchmark. The most striking finding remains peripheral neuropathy at just 3.6% versus 17% in MPACT. This is clinically meaningful: peripheral neuropathy is a debilitating, often irreversible side effect of chemotherapy that frequently forces dose reductions or treatment discontinuation. A regimen that can deliver superior efficacy while dramatically reducing this toxicity has a clear quality-of-life advantage and may allow for longer treatment duration.

While NALIRIFOX achieves an identical 11.1-month mOS, it carries substantially higher rates of gastrointestinal toxicity – Grade 3+ diarrhoea of 20.3% and nausea of 11.9%, alongside 15.1% hypokalemia. By contrast, the narmafotinib combination shows diarrhoea of 5.5% and nausea of 3.6%. This tolerability differential could be a meaningful commercial differentiator, particularly for the large population of older or less fit patients who may not tolerate the more aggressive NALIRIFOX regimen. Narmafotinib's superior selectivity profile, as detailed in our initiation report, is the likely contributor to this clean safety signal.

Implications for the Investment Case

This data materially strengthens the investment thesis on several fronts. First, the independent validation of the CRs eliminates a key bear-case concern: that the response data may have been subject to site-level assessment bias. Second, the 11.1-month mOS, while not the paradigm-shifting leap that the bull case envisaged (our initiation noted that a mOS in the 11.5-12.5-month range would still carve a significant niche), is commercially viable. Recall that NALIRIFOX was approved with this exact mOS figure.

The differentiating feature of narmafotinib's data package is the unprecedented CR rate, not the mOS. This creates a dual narrative for the drug: it offers comparable population-level survival to NALIRIFOX in a more tolerable regimen, while simultaneously delivering complete tumour eradication in a meaningful subset of patients. If a predictive biomarker can be identified for this subset, narmafotinib's commercial positioning would shift from a broad combination agent to a precision medicine with a "long-tail" value proposition: some patients stand a chance at durable remission rather than merely extended survival.

Additionally, the AACR presentation in April provides a near-term catalyst for market awareness. AACR is a premier oncology conference, and the presentation of independently validated data to a global audience of oncologists and potential pharmaceutical partners is a significant value-creation opportunity.

Valuation & Outlook

We place our previous fair valuation of $0.47 per share under review while we update our model to reflect the new data. The key model change will be an upward revision to our probability of success (PoS) assumption, which currently sits at 10% for Phase II to Approval. The independently validated CR signal, the commercially viable mOS figure, and the continued favourable safety profile collectively justify a meaningful increase in this input. We expect to publish an updated valuation shortly.

We note the following near-term catalysts: the AACR presentation (April 17-22, 2026); anticipated ACCENT trial completion in Q3 2026; ongoing AMPLICITY trial updates (narmafotinib + FOLFIRINOX, daily dosing); and potential partnership discussions which, in our view, are likely to intensify following these data.

Income Statement *A$Ms*	FY25a	FY26	FY27	FY28	FY29
Revenue	-	-	50.00	-	100.00
Other Income	4.06	5.66	4.35	3.05	3.05
Total Revenue	**4.06**	**5.66**	**54.35**	**3.05**	**103.05**
Operating expenses	-10.49	-15.75	-13.01	-10.30	-10.03
EBITDA	**-6.43**	**-10.10**	**41.34**	**-7.25**	**93.01**
D&A	-0.09	-0.00	-0.00	-0.00	-0.00
EBIT	**-6.52**	**-10.10**	**41.34**	**-7.25**	**93.01**
Net Interest	-0.06	0.21	0.48	1.37	1.17
NPBT	**-6.57**	**-9.89**	**41.82**	**-5.88**	**94.18**
Tax expense	-	-	-	-	-
Discontinued ops	-	-	-	-	-
NPAT	**-6.57**	**-9.89**	**41.82**	**-5.88**	**94.18**

Balance Sheet *A$Ms*	FY25a	FY26	FY27	FY28	FY29
Cash	10.86	25.22	70.80	65.09	160.34
Receivables	-	-	-	-	-
Inventory	-	-	-	-	-
R&D Incentive Receivable	3.77	5.66	4.35	3.05	3.05
Other	0.29	0.51	0.39	0.27	0.27
Current assets	**14.93**	**31.38**	**75.54**	**68.41**	**163.66**
Intangibles	7.94	7.94	7.94	7.94	7.94
PPE	0.00	0.00	0.00	0.00	0.00
Other	0.07	0.07	0.07	0.07	0.07
Non-current assets	8.01	8.01	8.01	8.00	8.00
Total Assets	**22.94**	**39.39**	**83.54**	**76.42**	**171.66**
Accrued Liabilities	1.80	2.72	2.25	1.78	1.73
Borrowings	-	-	-	-	-
Lease Liabilities	0.01	-	-	-	-
Other	0.07	0.36	0.06	-	-
Current liabilities	**1.89**	**3.08**	**2.31**	**1.78**	**1.73**
Borrowings	-	-	-	-	-
Other liability	0.02	0.03	0.03	0.04	0.04
Non current liabilities	**0.02**	**0.03**	**0.03**	**0.04**	**0.04**
Total Liabilities	**1.91**	**3.10**	**2.34**	**1.81**	**1.77**
Net Assets	**21.02**	**36.29**	**81.21**	**74.60**	**169.89**
Contributed Equity	167.39	188.57	194.08	194.89	194.89
Retained earnings	-145.54	-155.43	-113.60	-119.49	-25.31
Reserves/Other	-0.83	3.14	0.73	-0.80	0.28
Total Equity	**21.02**	**36.28**	**81.21**	**74.61**	**169.87**

Statement of Cashflows *A$Ms*	FY25a	FY26e	FY27e	FY28e	FY29e
Net profit for period	-6.57	-9.89	41.82	-5.88	94.18
D&A	0.09	0.00	0.00	0.00	0.00
ΔNWC	-0.82	3.28	-2.19	-1.95	-0.05
Other	-	-	-	-	-
Operating cash flow	**-7.30**	**-6.60**	**39.63**	**-7.83**	**94.13**
Payments for PPE	-0.00	-	-	-	-
Other payments	-	-	-	-	-
Asset sale	-	-	-	-	-
Investing cash flow	**-0.00**	**-**	**-**	**-**	**-**
Equity raised	17.28	20.00	-	-	-
Transaction costs	-1.33	-1.20	-	-	-
Exercise of options	-	2.38	5.51	0.81	-
Net borrowings	-1.47	-	-	-	-
Finance costs	-0.08	-0.05	-0.05	-0.05	-0.05
Other	-0.08	0.21	0.48	1.37	1.17
Financing cash flow	**14.40**	**21.34**	**5.95**	**2.13**	**1.12**
Free cash flow	**-7.31**	**-6.60**	**39.63**	**-7.83**	**94.13**
Net cash flow	**7.10**	**14.74**	**45.58**	**-5.71**	**95.25**
Effects of exchange rate	-	-	-	-	-
Cash year end	10.48	25.22	70.80	65.09	160.34

Investment Fundamentals	FY25a	FY26	FY27	FY28	FY29
Liquidity					
Current Ratio	7.9	10.2	32.8	38.5	94.5
Quick Ratio	2.2	2.0	2.1	1.9	1.9
Solvency					
Debt to Equity	0.0	0.0	0.0	0.0	0.0
Debt to Assets	0.0	0.0	0.0	0.0	0.0
LT Debt to Assets	0.0	0.0	0.0	0.0	0.0
Profitability					
Net Margin	n/a	n/a	77%	n/a	91%
ROA	-29%	-25%	50%	-8%	55%
ROE	-31%	-27%	51%	-8%	55%
Valuation					
P/E	n/a	n/a	5.8	n/a	2.6
P/B	8.7	6.2	2.9	3.2	1.4
EV/EBITDA	n/a	n/a	4.1	n/a	0.9
EV/Sales	n/a	n/a	3.4	n/a	0.8

Key Risks

Clinical development and regulatory risks

While the independently validated ACCENT data is encouraging, the trial remains a single-arm Phase 1b/2a study with 64 patients. The primary risk is that these results may not be replicated in a larger, randomised, placebo-controlled pivotal Phase 3 trial. Historically, many promising Phase 2 oncology assets have failed to demonstrate a statistically significant benefit in Phase 3 due to inherent differences in patient selection, trial design, and statistical powering. Metastatic pancreatic ductal adenocarcinoma (mPDAC) remains a notoriously difficult indication with a high rate of clinical trial failure, and the broader class of FAK inhibitors has a mixed clinical track record. The 11.1-month mOS, while commercially viable, does not yet demonstrate a statistically significant separation from the NALIRIFOX benchmark – a larger trial will be needed to confirm superiority or non-inferiority with a differentiated safety and response profile. Furthermore, like other ATP-competitive kinase inhibitors, narmafotinib only blocks FAK's enzymatic function, leaving the protein's kinase-independent scaffolding role intact, which may mediate adaptive resistance over time.

Competition and market risk

The mPDAC treatment landscape is intensely competitive and rapidly evolving. NALIRIFOX has established an 11.1-month mOS benchmark as the new standard of care, meaning narmafotinib's survival data alone – while matching this figure – does not yet demonstrate clear superiority. Direct competition from Verastem Oncology's defactinib, which is already FDA-approved for another indication and is being aggressively developed in combination for PDAC in the RAMP 205 trial, presents a potential first-mover advantage that could narrow narmafotinib's market opportunity if its combination is approved first. Additionally, several other companies with different mechanisms of action (including Arcus Biosciences' quemliclustat in Phase 3, and Cantargia's nadunolimab) have reported strong survival signals in mid-to-late-stage trials. The success of any of these competitors could further raise the efficacy bar for clinical adoption.

Commercialisation risk

Amplia's corporate strategy is predicated on securing a licensing partnership with a major pharmaceutical company to fund the substantial costs of Phase 3 development and global commercialisation. The company's ability to negotiate favourable deal terms is contingent on the totality of its clinical data package, including the ACCENT final readout and early data from the AMPLICITY trial (narmafotinib + FOLFIRINOX). While the independently validated CR signal and mOS data strengthen Amplia's negotiating position, failure to secure a partner would place the full financial burden of pivotal trials directly on the company, likely necessitating substantial and highly dilutive capital raises. The timing and terms of any partnership remain uncertain and represent a key source of binary risk.

Funding and financial risks

Following the A$25M capital raise in July 2025, Amplia has a cash runway extending into 2027, sufficient to fund the ongoing ACCENT and AMPLICITY trials. However, this funding is not sufficient to support Phase 3 development, which we estimate would require in excess of A$40M. As a pre-revenue biotechnology company, Amplia will require substantial additional capital or partnership funding to initiate and execute global pivotal studies. Future financing, if required outside of a partnership, will likely be dilutive to existing shareholders and dependent on prevailing market conditions and clinical progress.

Asset concentration risk

Amplia's valuation and near-term prospects are almost entirely dependent on the clinical and commercial success of a single lead asset, narmafotinib. This lack of diversification significantly magnifies the impact of any potential setbacks. Any clinical failures, safety issues, regulatory delays, or manufacturing problems related to narmafotinib would have a material and disproportionately adverse impact on the company's valuation.

Intellectual property risk

The long-term commercial viability of narmafotinib relies on Amplia's ability to successfully obtain, maintain, and defend its intellectual property portfolio. While the company has a multi-layered IP strategy with protection extending into the 2040s, competitors may challenge existing patents or pending applications. There is no guarantee that Amplia's current IP strategy will provide sufficient protection to prevent the entry of competing products.

Evolution Capital Ratings System

Recommendation Structure	• **Buy:** The stock is expected to generate a total return of >10% over a 12-month horizon. For stocks classified as 'Speculative', a total return of >30% is expected. • **Hold:** The stock is expected to generate a total return between -10% and +10% over a 12-month horizon. • **Sell:** The stock is expected to generate a total return of <-10% over a 12-month horizon.
Risk Qualifier	• **Speculative ('Spec'):** This qualifier is applied to stocks that bear significantly above-average risk. These can be pre-cash flow companies with nil or prospective operations, companies with only forecast cash flows, and/or those with a stressed balance sheet. Investments in these stocks may carry a high level of capital risk and the potential for material loss.
Other Ratings:	• **Under Review (UR):** The rating and price target have been temporarily suppressed due to market events or other short-term reasons to allow the analyst to more fully consider their view. • **Suspended (S):** Coverage of the stock has been suspended due to market events or other reasons that make coverage impracticable. The previous rating and price target should no longer be relied upon. • **Not Covered (NC):** Evolution Capital does not cover this company and provides no investment view.

Expected total return represents the upside or downside differential between the current share price and the price target, plus the expected next 12-month dividend yield for the company. Price targets are based on a 12-month time frame.

Disclaimer & Disclosures

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