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Azitra, Inc. (AZTR: NYSE)

AZTR: ATR-01 Data Presented

Azitra's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates for commercialization of ATR-12 in Netherton syndrome. We apply a success probability of 20% to the program. The model includes contributions from the United States and the developed world.

Current Price (11/17/2025)	$0.34
Valuation	**$3.40**

OUTLOOK

Azitra is developing genetically engineered bacteria for therapeutic use in dermatology. The company possesses a microbial library of 1,500 unique bacterial strains that are candidates for a variety of indications. Azitra's lead candidate is ATR-12 for the rare disease Netherton syndrome (NS). A second candidate is ATR-04 targeting EGFRi-associated rash and a third, ATR-01, ichthyosis vulgaris. Each one is topically formulated.

Preclinical work has shown effective and safe use of ATR-12 as a potentially disease-modifying therapy able to colonize the skin and replace the missing LEKTI protein. An IND has been cleared and Azitra has started a Ph1 for NS. ATR-04 began to enroll its first patients in 3Q:25.

ATR-12 provides the missing active protein segment for NS and, if successful, will be a disease modifying therapy. The therapy is not a cure and patients will require ongoing treatment.

We expect clinical trials for NS will follow an expedited pathway as NS is a rare disease that affects children. Our forecasts call for Ph2 and pivotal trials leading to a Biologics License Application (BLA) submission in 2028 and approval the following year. ATR-12 may also qualify for a rare pediatric disease priority review voucher.

SUMMARY DATA

52-Week High	**4.33**
52-Week Low	**0.32**
One-Year Return (%)	**-88.8**
Beta	**-1.7**
Average Daily Volume (sh)	**4,949,058**
Shares Outstanding (mil)	**10.2**
Market Capitalization ($mil)	**3.4**
Short Interest Ratio (days)	**0.2**
Institutional Ownership (%)	**0.4**
Insider Ownership (%)	**0.2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**N/A**
P/E using 2026 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	$0.0 A	$0.8 A	$0.0 A	$0.0 A	$0.8 A
2025	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024					-$15.78 A
2025	-$1.55 A	-$1.18 A	-$0.67 A	-$0.37 E	-$2.67 E
2026					-$0.88 E
2027					-$0.64 E

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WHAT'S NEW

Azitra, Inc. (NYSE: AZTR) reported third quarter 2025 results in a November 12th press release and provided a business update. Since our previous quarterly update in August, Azitra has announced that its first patient has been dosed in the ATR-04 trial and it has presented preclinical data for its ATR-01 program. The ATR-12 study in Netherton Syndrome continues to evaluate patients. Management has participated in several conferences updating investors and other stakeholders on recent performance. In the financial sphere, the company raised additional funds with Alumni Capital. Looking ahead, Azitra expects to share topline efficacy results for the Netherton and ATR-04 trials in 1Q:26 and mid-year 2026 respectively.

Operational and Financial Results

Azitra reported 3Q:25 results in a press release and Form 10-Q filing with the SEC on November 12th. For the quarter ending September 30th, 2025 and versus the prior year's comparable period, no revenues were reported. Net loss for the three-month period totaled ($2.8) million or ($0.67) per share.[1] Operational expenses fell 5% as decreases in general and administrative (G&A) expenses were only partially offset by higher research and development (R&D) expenses. Below, we detail financial results for 3Q:25, compared to the same prior year period:

- Research and development expenses increased by 16% to $1.2 million from $1.0 million stemming from greater clinical trial costs for the ATR-04 and ATR-01 programs, increased payroll costs due to raises and a new hire along with more lab supplies partially offset by lower clinical consultant expenditures;
- General & Administrative expenses totaled $1.6 million, down 17% from $1.9 million due to reduced legal fees, public company compliance initiatives, stock options expense, hiring costs and other expenses. This was partially offset by a rise in costs related to obtaining the company's equity line of credit with Avenue, greater use of business consultants higher public relations, accounting, and auditing expense and a lift in software, equipment and insurance costs;
- Net interest income was $4,000 compared to $44,000 with the prior year dominated by interest income related to a higher cash balance;
- Other expense was negligible compared with $1.9 million largely related to positive change in fair value of warrants which occurred in the prior year;
- Net loss was ($2.8) million or ($0.67) per share vs. ($1.0) million or ($1.14) per share;[2]

As of September 30th, 2025, cash totaled $1.4 million. This amount compares to the $4.6 million balance in cash held at the end of 2024. No debt was held on the balance sheet. Cash burn for the first nine months of 2025 was ($8.4) million, slightly greater in magnitude than the ($7.9) million consumed in the same prior year period. Cash from financing was $5.3 million representing proceeds from public offerings and the equity line of credit with Alumni Capital partially offset by principal payments on finance leases. We expect that Azitra will regularly access the equity line to continue funding the pipeline activities. Post quarter end, Azitra raised $2.4 million with the equity line of credit.

ATR-12 Clinical Trials

Azitra received investigational new drug (IND) clearance for its Netherton syndrome candidate, ATR-12, in January 2023. The company has since launched a Phase Ib clinical trial under the identifier NCT06137157 and expects to enroll 12 patients. Primary endpoints will examine safety and tolerability while secondary and exploratory endpoints will assess efficacy signals and biomarkers. ATR-12 will be topically administered twice daily. Clinical sites at Yale University and Stanford University have been established.

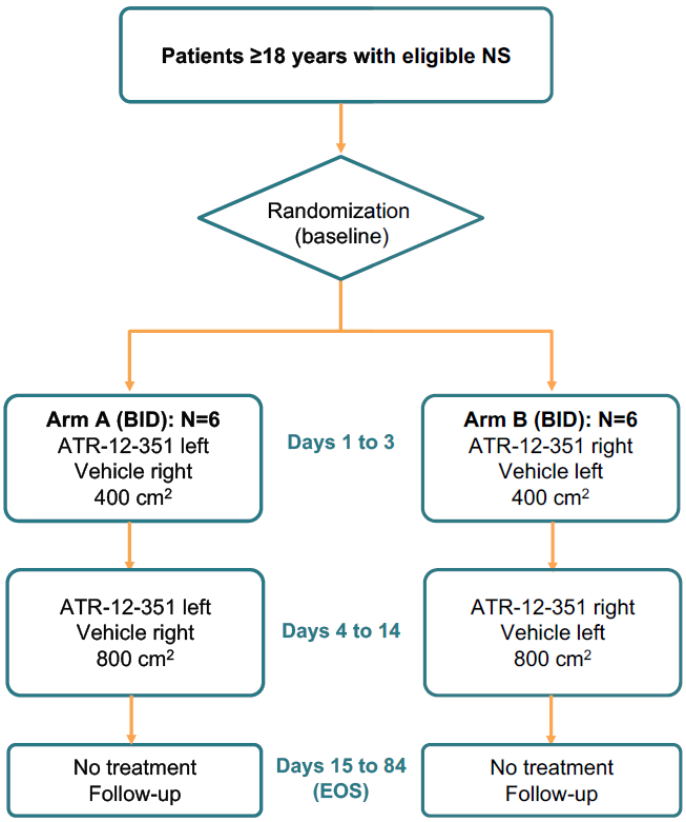
June 2025 Interim Update
In an interim update, the Phase Ib trial reported safety data in a June 17th press release. There have been no reports of severe or serious adverse events. Application site reactions have been transient and self-resolving and included mild to moderate localized itch, redness, and a burning sensation with application. Such reactions have been observed bilaterally, suggesting this is not a drug effect. The trial remains blinded, and data regarding the effect of the drug is not yet available.

[1] We update per share amounts in this report to reflect the 15:100 reverse stock split that took place on August 21st, 2025.
[2] We use financial statement data as originally reported and apply a 1:6.66 reverse stock split ratio for periods prior to August 21st, 2025. Prior year numbers in our reporting may not match Azitra's current period comparisons.

ATR-12 Trial Details
The study will apply ATR-12 to lesions on one side of a subject's body and apply the vehicle to the other. Application of ATR-12 and the vehicle will be performed twice daily for two weeks. Patients will be randomized to receive ATR-12 on either the right or left side. Initially, the FDA required that patients be dosed one at a time and sequentially to provide an initial safety profile before allowing parallel enrollment. Azitra has since crossed this hurdle and had enrolled six patients as of mid-June 2025, achieving 50% of target enrollment. Two sites are active. One at Yale University and the other at Stanford in Northern California. The study requires that the young patients stay at the location for two weeks for treatment.

The primary endpoint is adverse events at 84 days as well as quantifying and qualifying incidence, severity, seriousness and relatedness of adverse events. Secondary endpoints include investigators' and patients' global assessment of severity, concentration of recombinant human lymphoepithelial Kazal-type related inhibitor (rhLEKTI) in the plasma and on the skin following topical application. Biomarkers will be evaluated including KLK5, KLK7, IL-36, TARC/CCL17, trypsin-like activity and chymotrypsin-like activity.

Exhibit I – ATR-12 Trial Design



Source: Azitra SID Poster, May 2024

ATR-04

Epidermal growth factor receptor inhibitors (EGFRi) are targeted cancer therapies that have been effective in breast, colon, lung and pancreatic cancer. EGFR is a protein found on the surface of cells, and it plays a role in cell growth and division. In some cancers, such as certain types of lung cancer and colorectal cancer, the EGFR gene is mutated or overexpressed, leading to uncontrolled cell growth. EGFR inhibitors work by blocking the activity of this protein, thereby slowing or stopping cancer cell growth.

In the skin, EGFR regulates multiple keratinocyte functions including proliferation, adhesion and migration, survival, and differentiation. Consequently, inhibition of EGFR in the skin results in adverse skin reactions, which make it difficult for patients to continue therapy. Two of the leading EGFR inhibitors, erlotinib and gefitinib, carry FDA labels that warn of rash and skin reactions in over 20% of patients. In many cases it is severe enough for the individual to stop EGFRi therapy. The skin reaction, which is referred to as an acneiform or papulopustular rash, can vary in intensity. Mild rash is treated with topical medications and oral antibiotics; however, in severe cases a doctor may stop treatment.

The side effect is an unmet need that may be addressed using ATR-04, which is a genetically modified strain of *S. epidermidis*. The strain demonstrated properties of inhibiting IL-36γ, *S. aureus* and related biofilms. ATR-04 has been modified to be auxotrophic for D-alanine. The product is formulated as a topical application and may also help reduce the use of antibiotics, allow for better compliance with EGFRi regimens and improve patient quality of life.

Preclinical work for ATR-04 was completed and assembled with other required data into an investigational new drug (IND) application submitted last year to the FDA. In September 2024, the FDA granted Fast Track Designation to ATR-04 for Azitra's indication. In an August 22nd, 2024 press release, Azitra announced that the IND had been cleared which allows the company to begin its Phase I/II study of ATR-04 for moderate to severe EGFRi associated dermal toxicity. On August 27th, 2025 a press release reported that the first patient had been dosed.

Trial Design
ATR-04 or its vehicle will be applied to the face as well as affected areas on the neck, chest, back and areas around nailbeds in a 3:1 randomization. The key objectives of the study will be to assess the safety and tolerability of topical ATR-04 and to evaluate efficacy signals including severity of disease, pruritus, and pain. The bioavailability of the candidate and pharmacodynamic parameters will also be studied. This clinical study will establish the basis for continued clinical development of ATR-04.

ATR-04 will enroll eight patients in a single ascending dose Phase I study over 28 days. The Phase II portion will target 24 patients for this segment of the study. A contract research organization (CRO) is in place and four sites across the US are being identified for use. Azitra anticipates a rapid enrollment as these are high volume cancer centers with many potential candidates receiving EGFRi treatment.

Rash Incidence Literature Review
We conducted a brief literature review on the incidence of rash in EGFRi patients and of side effects experienced by patients. References are included in the footnotes.[3,4,5,6] EGFRi treatment side effects are frequent with skin rash being the most common.

EGFR inhibitors belong to the kinase inhibitor or tyrosine kinase inhibitor (TKI) class and include such agents as Erbitux (cetuximab), Tarceva (erlotinib) and Iressa (gefitinib). EGFR is expressed in many tissues including epithelial tissue, skin, hair follicles and the gastrointestinal tract. Many of these sites are some of the most affected with EGFRi treatment. The condition is so severe that it may lead to the discontinuation of the therapy. The most common of the side effects is a dose-dependent rash or pustular lesions that appear on the face, scalp, chest and upper back. Researchers have noted a positive correlation between the appearance of rash and the clinical benefit of EGFRis.

Treatment for the dermatological toxicities include the use of emollient ointments and moisturizers, sun and irritant avoidance, and short showers. However, even with these approaches, many patients discontinue treatment preempting the benefits of the underlying drug. The relationship between toxicity and discontinuation is even more distinct when placed in the context of numerous studies that show a positive association between skin toxicity and efficacy. With this as background, it is clear that treating the rash will not only improve the quality of life in patients on EGFRi therapy but also improve outcomes for those who are able to avoid discontinuation.

Exhibit II – Incidence of Rash in EGFRi Patients

Drug Type	Examples	Incidence of Rash / Acneiform Eruption
EGFR TKIs	Erlotinib, Gefitinib, Afatinib, Osimertinib, Dacomitinib	60–90%
EGFR mAbs	Cetuximab, Panitumumab	75–90%
Severe Rash (Grade 3–4)	All agents	10–20%

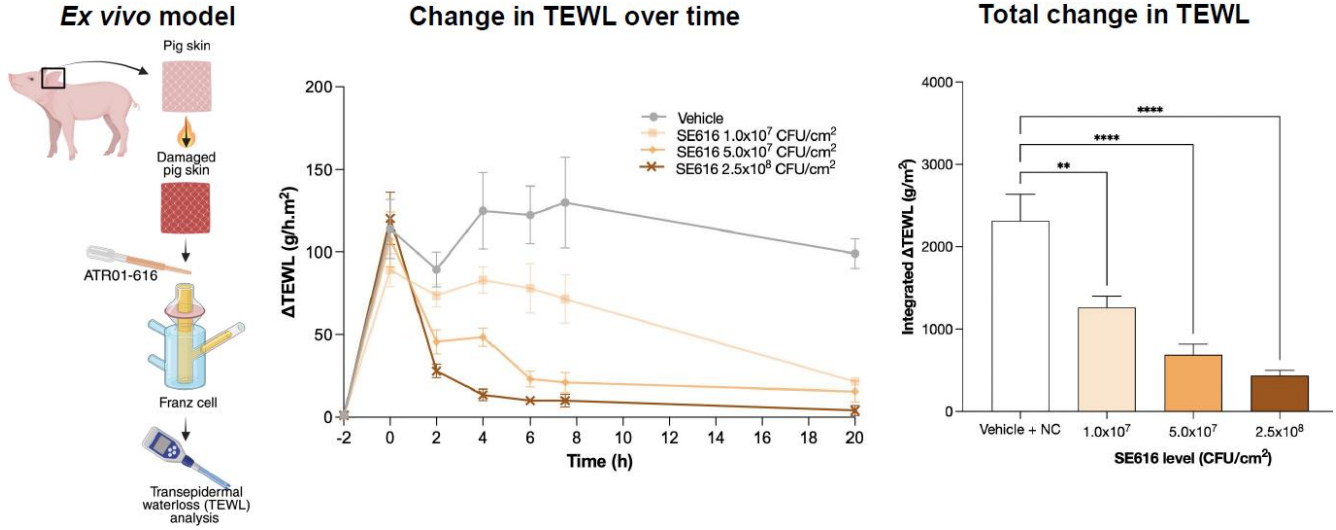
Source: Compiled by Zacks Analyst

[3] Fabbrocini, G., *et al*. Acneiform Rash Induced by EGFR Inhibitors: Review of the Literature and New Insights. Skin Appendage Disorders. February 2015.
[4] Pérez-Soler, R., Cutsem, E.V. Clinical Research of EGFR Inhibitors and Related Dermatologic Toxicities. Oncology. October 2007.
[5] Lacouture, M.E., *et al*. Dermatologic Toxicity Occurring During Anti-EGFR Monoclonal Inhibitor Therapy in Patients With Metastatic Colorectal Cancer: A Systematic Review. Clinical Colorectal Cancer. June 2018.
[6] Murphy-Rodríguez, E., *et al*. Cutaneous Toxicity Associated With Cetuximab Treatment in Metastatic Colorectal Cancer. Farmacia Hospitalaria. May 2011.

ATR-01 Preclinical Data

On October 20th, Azitra announced that it presented ATR-01 data at the BIO-Europe conference. ATR-01 is a filaggrin-secreting strain of S. epidermidis for ichthyosis vulgaris. Ichthyosis[7] vulgaris is an inherited skin disorder that is characterized by dry, scaly skin that is similar in appearance to fish scales. The presentation emphasized that ATR-01 offers a positive pharmacology profile across multiple preclinical models. In *in vitro* models, ATR-01 secreted functional filaggrin, as measured by keratin binding assays. Furthermore, in *ex vivo* human skin, it was found to deliver filaggrin through the stratum corneum, as was measured with fluorescence immunohistochemistry. In this model, ATR-01 delivered filaggrin below the skin barrier ($p < 0.05$). Finally, in an *ex vivo* damaged pig skin model, ATR-01 was shown to significantly reduce transepidermal water loss compared to vehicle control ($p < 0.002$). Together, these data demonstrate positive pharmacological activity and biodistribution. Azitra plans to conduct additional investigational new drug (IND)-enabling studies and submit an IND in 2026.

Exhibit III – ATR-01 Decreases Transepidermal Water Loss on *Ex Vivo* Damaged Skin

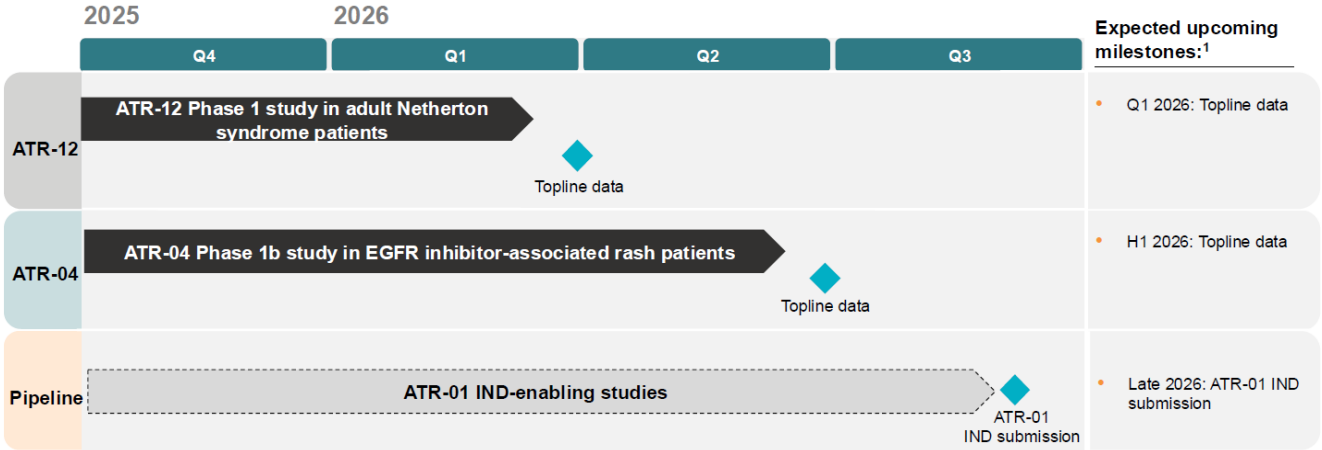


Source: Azitra November 2025 Corporate Presentation

Alumni Capital Share Purchase Agreement

In April, Azitra announced a share purchase agreement with Alumni Capital for up to $20 million to fund the clinical pipeline. Azitra controls the timing of the common stock sales and can put up to $750,000 of shares to Alumni at its own discretion and up to $4 million with Alumni's consent. Shares are sold at a discount to the lowest daily volume weighted price in the five days preceding the transaction. Warrants equal to 10% of the shares issued will also be granted to Alumni with an exercise price of 130% of the price paid for the common stock shares. To date, Azitra has drawn $6 million from the arrangement and $14 million remains.

Exhibit IV – Timeline for Azitra Programs



Source: November 2025 Corporate Presentation

[7] The root of the word Ichthys is Greek for fish (ἰχθύς).

Milestones

- Presentations at BIO CEO – 1Q:25
- Presentation at Microbiome Times Partnering Forum – March 2025
- Share purchase agreement with Alumni Capital – April 2025
- Presentation of ATR-04 data and clinical plan at ASCO – May 30 to June 3, 2025
- Initial safety data from Phase Ib ATR-12 – June 2025
- BIO International attendance – June 2025
- First patient dosed with ATR-04 for EGFRi rash (Phase I/II) – August 2025
- Participation in HC Wainwright Global Investment Conference – September 2025
- NYSE American issues deficiency letter for equity below $4 million – October 2025
- Participation in Dermatologic Rare Disease Panel at Maxim Growth Summit – October 2025
- Azitra notifies stakeholders of false report of securities sale – November 2025
- Topline report for Phase Ib ATR-12 trial – 1Q:26
- ATR-04 topline announcement – Mid-year 2026
- ATR-01 IND submission to FDA - 2026

Exhibit V – Azitra Pipeline



Source: 3Q:25 10-Q Corporate Presentation

Summary

Azitra reported third quarter 2025 results and highlighted the dosing of its first patient in the ATR-04 program, the presentation of ATR-01 preclinical data at BIO-Europe and a capital raise with Alumni. As 2025 comes to a close, we look ahead to several anticipated milestones. The ATR-12 program is expected to report topline results in 1Q:26 and the ATR-04 program will report its topline mid-year 2026. The preclinical ATR-01 program will continue to conduct IND-enabling work and is targeting an IND submission in 2026. We update our price target to reflect existing and anticipated shares outstanding over the next year. The result of this calculation generates a target price of $3.40 per share.

PROJECTED FINANCIALS

Azitra, Inc. - Income Statement

Azitra, Inc.	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
Revenues	**$8**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
General & Administrative	$6,269	$1,850	$1,470	$1,588	$1,450	$6,358	$5,500	$5,750
Research & Development	$4,723	$1,250	$1,402	$1,180	$2,350	$6,182	$9,100	$10,200
Operating Income	($10,985)	($3,100)	($2,871)	($2,768)	($3,800)	($12,540)	($14,600)	($15,950)
Operating Margin								
Interest Income, net	$110	$36	$15	$4	$0	$55	$0	$0
Other Income (Loss)	$1,916	($4)	($33)	($0)	$0	($37)	$0	$0
Loss Before Income Taxes	($8,958)	($3,068)	($2,889)	($2,765)	($3,800)	($12,522)	($14,600)	($15,950)
Income Tax	($9)	$0	$0	$0	$0	$0	$0	$0
Net Loss	**($8,967)**	**($3,068)**	**($2,889)**	**($2,765)**	**($3,800)**	**($12,522)**	**($14,600)**	**($15,950)**
Preferred Stock Dividends	$0	$0	$0	$0	$0	$0	$0	$0
Net Loss Per Share	**($15.78)**	**($1.55)**	**($1.18)**	**($0.67)**	**($0.37)**	**($2.67)**	**($0.88)**	**($0.64)**
Weighted Average Shares	568	1,978	2,444	4,118	10,200	4,685	16,500	25,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Azitra, Inc. – Share Price Chart



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