

Issuer Free Writing Prospectus  
Filed Pursuant to Rule 433  
Registration No. 333-276598  
January 19, 2024



**CORPORATE PRESENTATION**  
January 2024

**Precision dermatology powered by synthetic biology.**

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements concerning Azitra, Inc. ("Azitra", the "Company," "we," "us," and "our"). The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- our future financial and operating results;
- our intentions, expectations and beliefs regarding anticipated growth, market penetration and trends in our business;
- the timing and success of our plan of commercialization;
- our ability to successfully develop and clinically test our product candidates; and the
- adequacy of the net proceeds of this offering.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including (i) we are an early-stage clinical biopharmaceutical company with limited operating history, (ii) there are no drug products to date that incorporate our microbial library and genetic engineering platform and the clinical and commercial utility of our microbial library and genetic engineering platform is uncertain and may never be realized; (iii) we have only recently commenced Phase 1 clinical studies of our initial product candidates and our product candidates will require extensive additional preclinical and clinical testing; (iv) we expect we will need additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all; and (v) those other risk described in "Risk Factors" section of the prospectus ("Prospectus") dated January 19, 2024 filed by Azitra with the Securities and Exchange Commission on January 19, 2024.

In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Azitra does not undertake and specifically disclaims any obligation to update or revise our forward-looking statements to reflect new circumstances or unanticipated events as they occur, except as required by law.

This document contains only basic information concerning Azitra. Because it is a summary it does not contain all of the information you should consider with regard to Azitra. You should read the Prospectus for more complete information about Azitra.

## Free Writing Prospectus

This presentation highlights basic information about us and the proposed offering. Because it is a summary, it does not contain all of the information that you should consider before investing. We have filed a registration statement (including a prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering.

You may access these documents for free by visiting EDGAR on the SEC Web site at <http://www.sec.gov>. Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact ThinkEquity, Prospectus Department, 17 State Street, 41st Floor, New York, New York 10004, telephone: (877) 436-3673.

This presentation shall not constitute an offer to sell, or the solicitation of an offer to buy, nor will there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such state or jurisdiction. The offering will only be made by means of a prospectus pursuant to a registration statement that is filed with the SEC after such registration statement becomes effective.

## Offering summary

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**Issuer:**

Azitra, Inc.

**Symbol:**

NYSE American: AZTR

**Expected Offering Size:**

\$6,150,000 (15% Over-allotment Option)

**Securities Offered:**

Shares of Common Stock  
(or for purchasers who cannot beneficially own more than 4.99% of the outstanding shares of common stock, one pre-funded warrant in lieu thereof)

**Use of Proceeds:**

- Clinical trials and product development
- Research and development
- Clinical manufacturing
- Working capital and other general corporate purposes

**Sole Book-Runner:**

ThinkEquity

# Azitra is led by world-class management team



**Francisco Salva, MSc.**  
President and CEO

- Prior Co-Founder and VP of Operations at Acerta Pharma – Sold for \$6.3 billion
- Formerly Senior Director –Corporate Development at Pharmacyclics
- 25+ years experience in life science venture capital, investment banking and operating roles



**Travis Whitfill, M.P.H.**  
Co-Founder and COO

- Partner at Bios Partners
- Assistant Professor Adjunct in the Department of Pediatrics at Yale University
- Named one of Forbes' 30 Under 30 in healthcare in 2018



**Norman Staskey, CPA**  
CFO

- Currently Acting CFO via Danforth Advisors
- Previously, Managing Director E&Y
- 20+ years accounting experience, including multiple IPO, SPAC and M&A transactions



**Roger Leger, Ph.D.**  
Vice President – Chemistry and Formulation

- Prior Senior Director Chemistry and CMC at Thrasos (Kidney Diseases)
- Former VP Research Indel Therapeutics Inc (Antimicrobials)
- Former VP Chemistry and Co-Founder Ulysses Pharmaceuticals Inc (Bacterial Infections)



**Leonard Milstone, M.D.**  
Professor Emeritus of Dermatology  
Yale School of Medicine  
Azitra Scientific Advisory Board

- Led the group that first demonstrated gene editing in the epidermis
- Discovered the unique proteoglycan Epican as well as keratins 4 and 13
- Former Chair, Medical and Scientific Advisory Board, Foundation for Ichthyosis and Related Skin Types







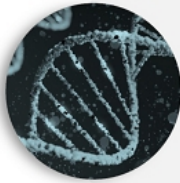
## Bacterial Cell Library

- Proprietary, robust library of ~1,500 microbial strains
- Engineered and non-engineered bacterial chassis
- Over 60 species in house, mostly *Staphylococcus epidermidis*



## Collaboration for Artificial Intelligence / Machine Learning Discovery

- Predictive algorithms for **novel microbial-derived proteins, peptides & small molecules**
  - Exclusive agreement covering specific strains with team from Carnegie Mellon
  - Based on genetic sequences and biosynthetic gene clusters
  - Includes post-assembly modifications & non-natural structures

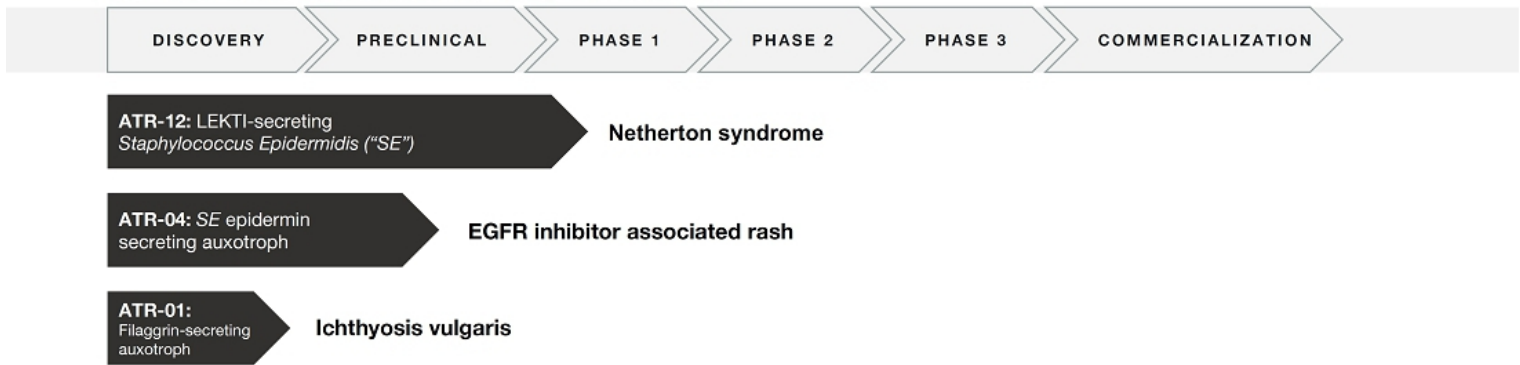


## Microbial Genetic Engineering Platform

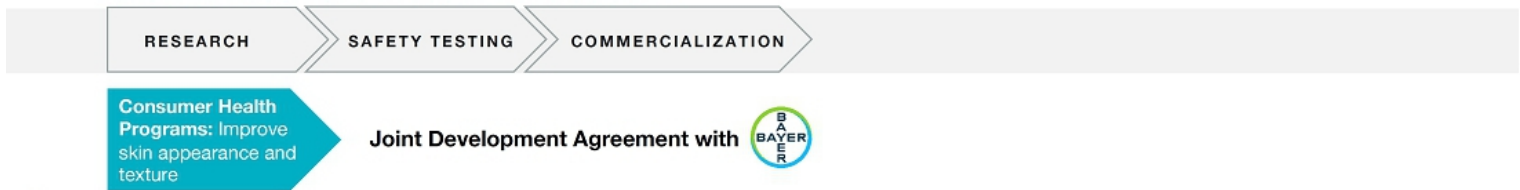
- Demonstrated ability to make **novel transformations**
  - Exclusive worldwide license with Fred Hutchinson Cancer Center
  - Overcome restriction modification systems
- Successfully transformed gram positive microbes to overcome challenge of thick cell walls


# Azitra's pipeline creates near-term value

## FDA-regulated candidates for drug development



## Consumer/Cosmetic Product Development





ATR-12 Program

# Netherton Syndrome

 azitra

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# ATR-12: LEKTI-Secreting *Staphylococcus epidermidis* for Netherton syndrome

## ATR-12 Summary

- **Netherton syndrome** is a rare, orphan autosomal recessive disease with no current FDA-approved treatment option
- Characterized by severe inflammation, pruritus, scaling, red, and dehydrated skin
  - Caused by mutations in the *SPINK5* gene, which encodes the serine protease inhibitor, **LEKTI** (lympho-epithelial Kazal-type related inhibitor)
  - Results in overactive proteases causing desquamation, skin barrier defects, and activation of inflammation
  - ~10% mortality rate in infants
- **Mechanism of action:** Auxotrophic ATR-12 inhibits the overactive proteases through LEKTI fragment secretion
- **Pediatric Rare Disease Designation** received from FDA

## ATR-12 Key Facts



**Primary Mechanism:**  
Kallikrein Inhibition



**Clinical Status:**  
Phase 1b



**Global Prevalence:**  
~20K+ Patients



**Peak Sales Opportunity:**  
~\$250M

## Two Netherton syndrome phenotypes are driven by *SPINK5* mutations

### Ichthyosis Linearis Circumflexa (ILC)

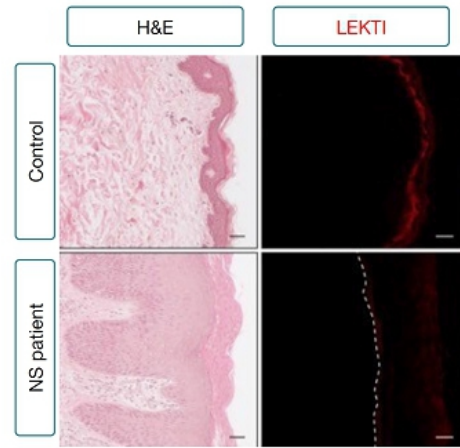
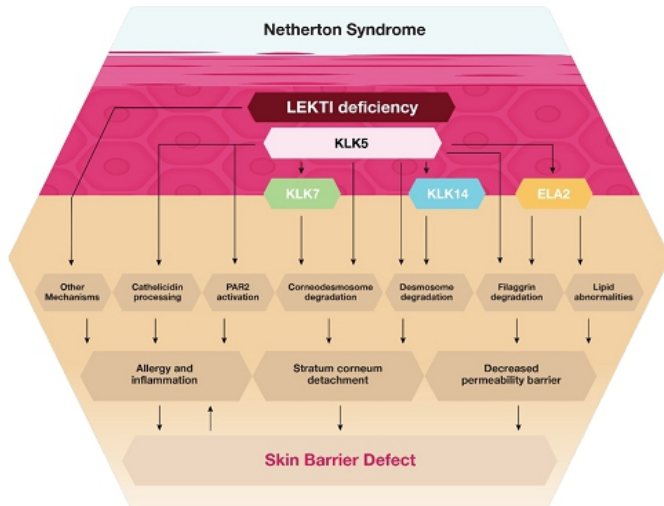


### Scaly Erythema (SE)



Barbieux et al, J Allergy Clin Immunol 2021

# Rationale to target KLK5 in Netherton syndrome via LEKTI delivery



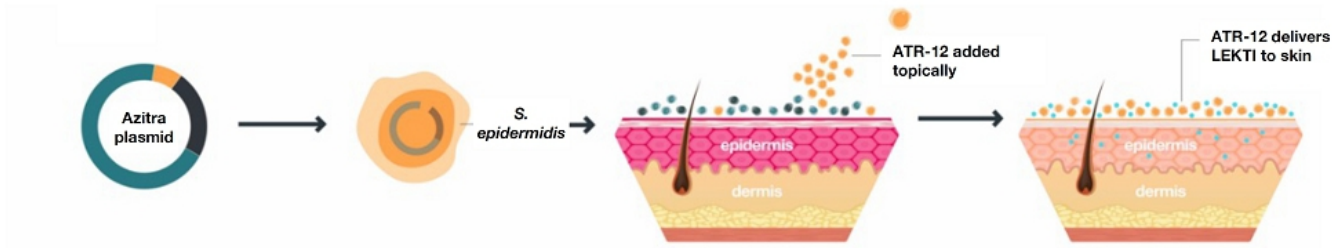
Mintoff, Fischer, *Mol Genet Genomic Med.*, 2021, 9, e1611

- LEKTI fragments inhibit KLK5, KLK7 and KLK14 and controls desquamation
- In NS patients, overactive KLKs lead to disease

- Netherton syndrome patients have undetectable levels of LEKTI in skin

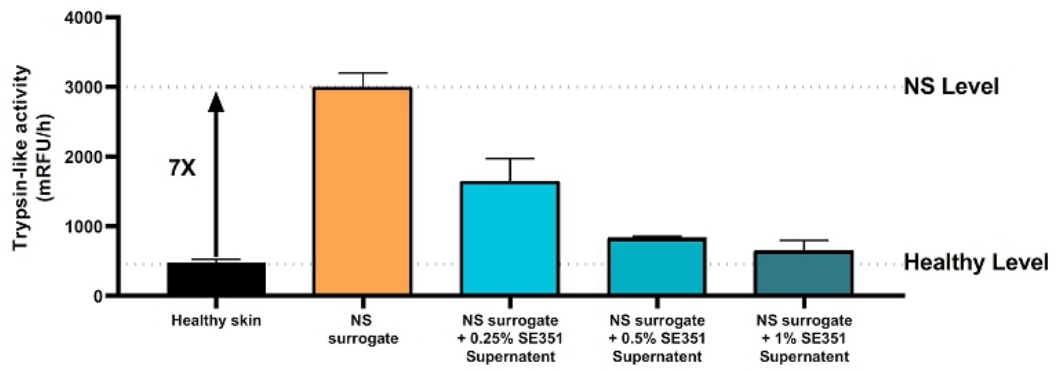
# Engineering *S. epidermidis* into ATR-12 for Netherton syndrome

- 1 Insert *SPINK5* gene fragment that encodes LEKTI
- 2 Insert gene into chromosome of *S. epidermidis*
- 3 Colonize Netherton syndrome skin with ATR-12
- 4 Secrete LEKTI to inhibit kallikreins for therapeutic treatment



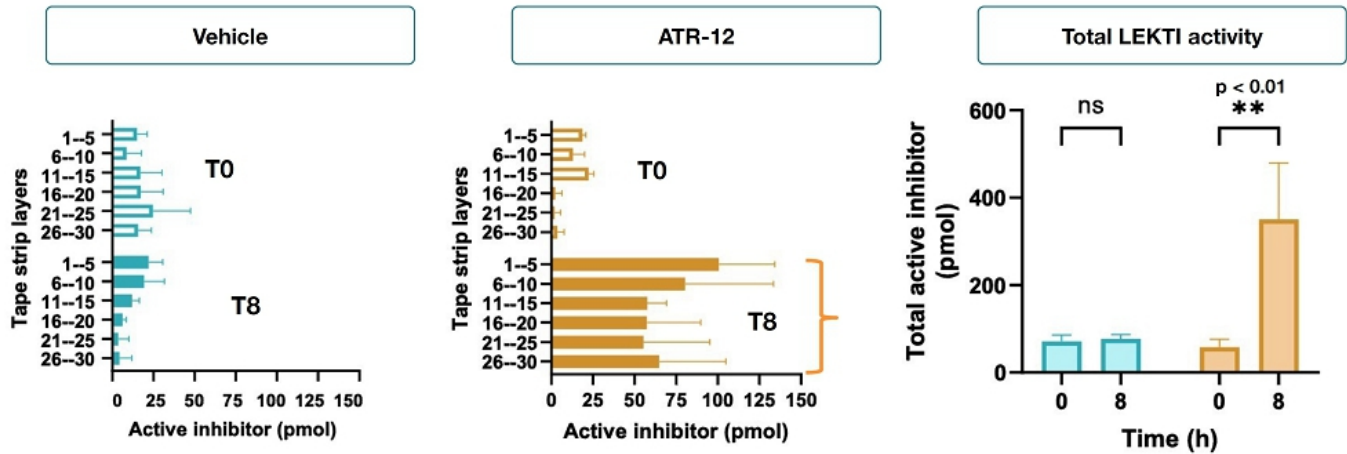
## Ex vivo activity of ATR-12 shows decreased trypsin-like activity

*S. epidermidis* strain SE351 (LEKTI-secreting) spent broth (SB) inhibition of human skin tape stripped extracts



- ✓ Trypsin-like activity (key measure of protease activity in NS patients) decreased after addition of spent broth from LEKTI-secreting strain SE351 in ATR-12
- ✓ Dose-dependent response seen across concentrations of supernatant

## Penetration of LEKTI-like activity into *ex vivo* human skin



- ✓ LEKTI activity is significantly higher after 8 hours compared to T0 in all layers following ATR-12 application
- ✓ The LEKTI activity penetrates to at least 30 layers deep in substantial amounts

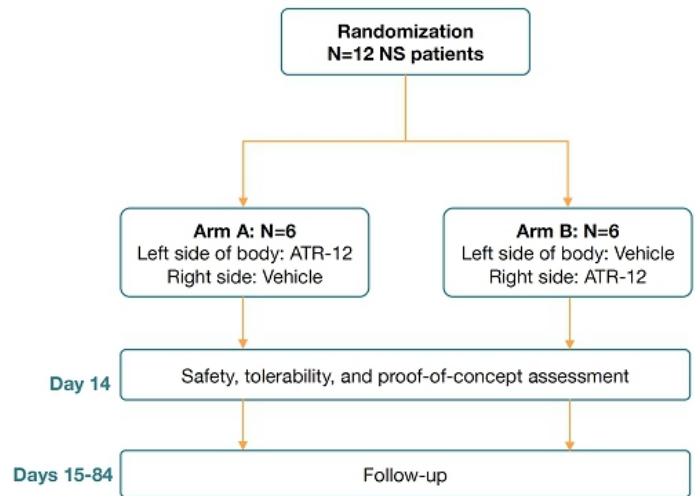


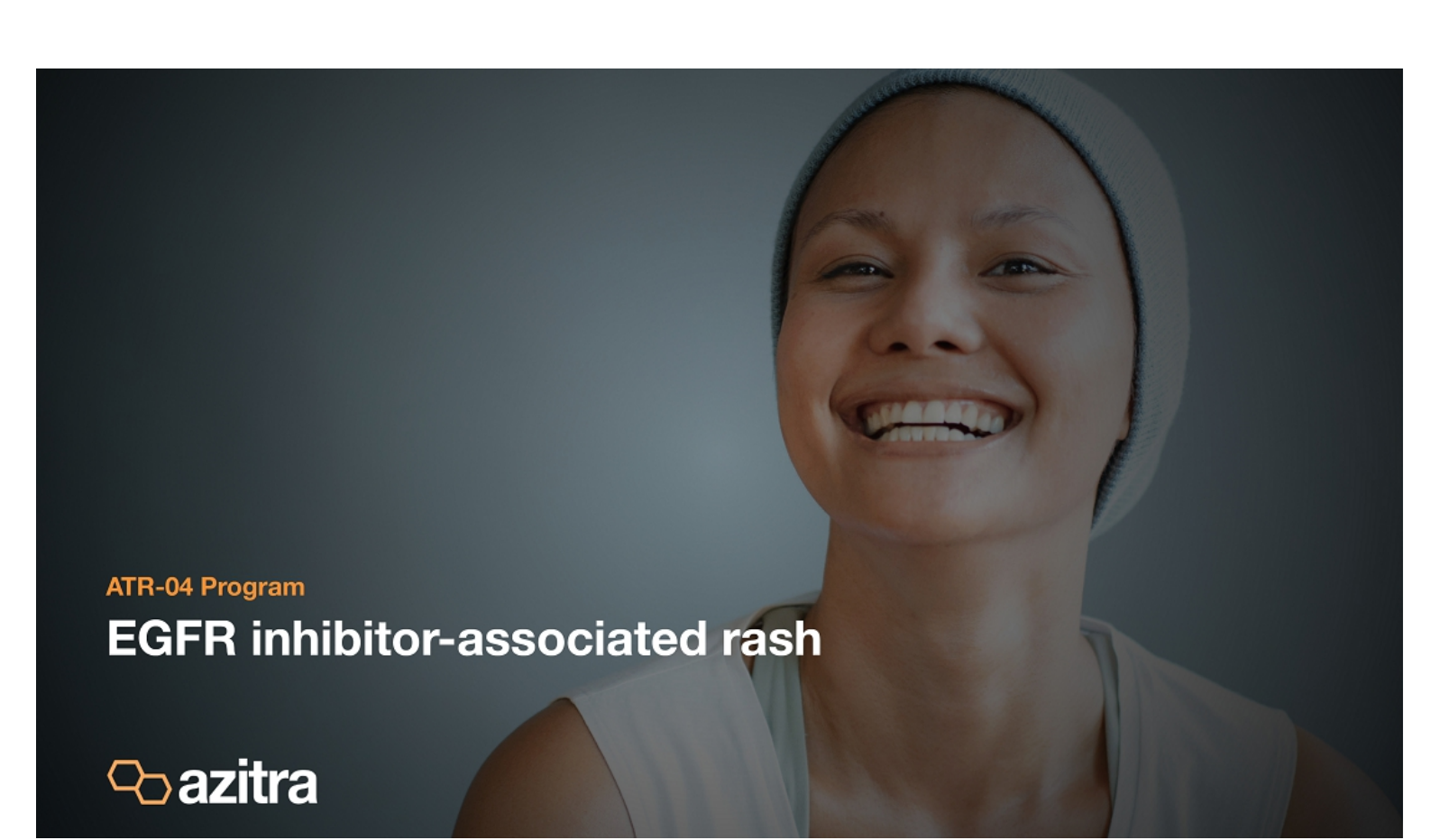
# Phase 1 clinical trial design

## Study overview

- Multicenter, randomized, double-blind, vehicle-controlled Phase 1 study in adult Netherton syndrome patients
- Dose level:  $10^9$  CFU / g ATR-12
- N=12 patients dosed twice daily over 14 days
- Primary endpoint: safety and tolerability
- Secondary endpoints:
  - Efficacy endpoints
  - Pharmacokinetics
- Exploratory endpoints:
  - Biomarkers: KLK5, KLK7, IL-36, TARC/CCL17, trypsin-like activity, and chymotrypsin-like activity

## Design





ATR-04 Program

# EGFR inhibitor-associated rash

 azitra

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## ATR-04: auxotrophic *S. epidermidis* for EGFR inhibitor-associated rash

### ATR-04 Summary

- Chemotherapy agents such as EGFR inhibitors and immunotherapies such as early BTK inhibitors lead to an aggressive and debilitating rash on most patients
- Severity of the rash is linked to IL-36g signaling as well as correlations to *S. aureus* increases
- EGFR inhibitors produce the most prevalent and most predictable affliction
- **ATR-04** is topically administered and inhibits IL-36g and *S. aureus*

### ATR-04 Key Facts

**Primary Mechanism:**

IL36g Inhibition, *S. aureus* control

**Clinical Status:**

IND filing expected mid-2024

**US Prevalence:**

~150,000 patients

**Peak Sales Opportunity:**

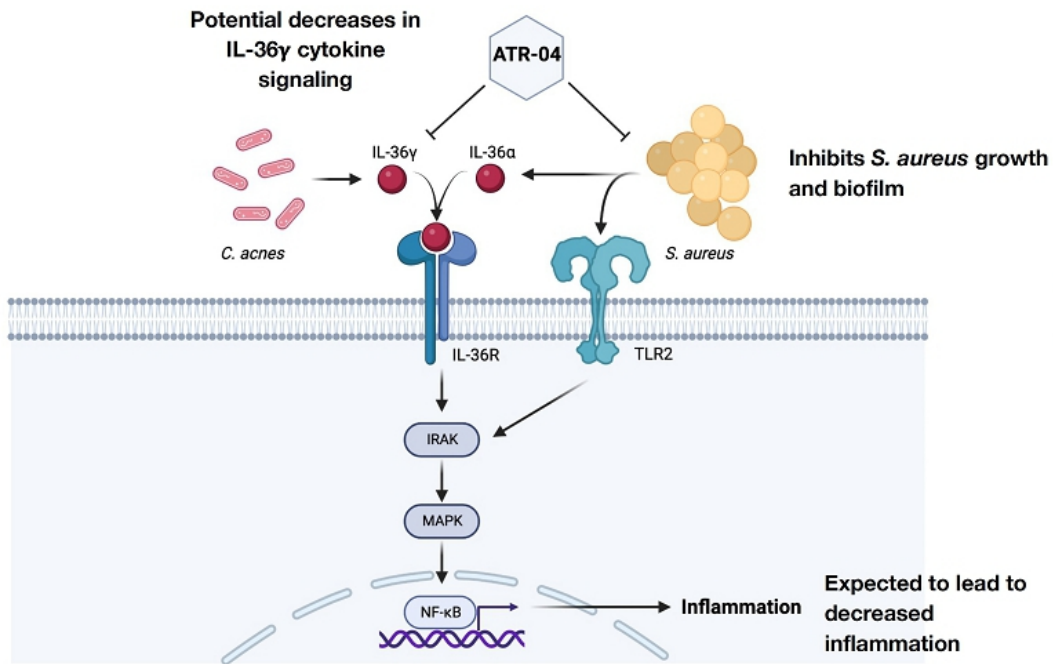
>\$1B

## EGFRi-driven rash is highly prevalent with significant clinical impact



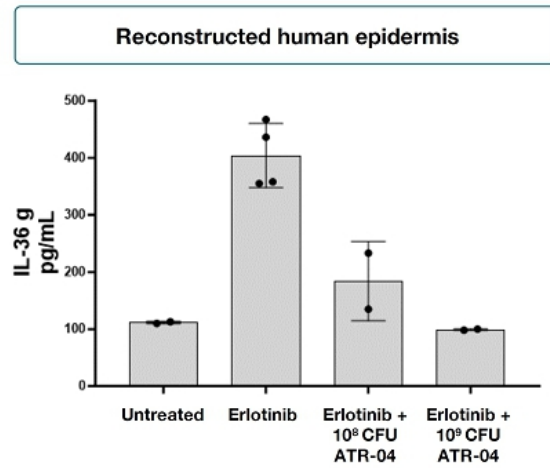
- Rash severity often linked to cancer drug dosing and correlates with *S. aureus* levels on the skin
- Rash can lead to significant changes in course of therapy and QOL
- **As many as 15-20% discontinue EGFRi therapy due to skin rash**

# Proposed mechanism of action of ATR-04



Collectively, ATR-04 addresses rash severity driven by EGFR inhibition

## In vitro data show ATR-04 reduces erlotinib-induced IL-36g

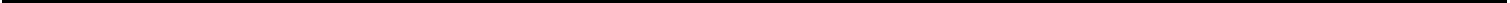
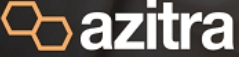


- ✓ IL-36g is elevated in reconstructed human epidermis following erlotinib exposure
- ✓ ATR-04 reduces IL-36g induced by erlotinib
- ✓ Dose-dependent effect observed





# Collaborations and Future Directions



## Bayer consumer health product joint development partnership

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- ✓ Long-established expertise in dermatology and consumer skin health
  - ✓ Global brand recognition
- ✓ Formulation, marketing and regulatory expertise



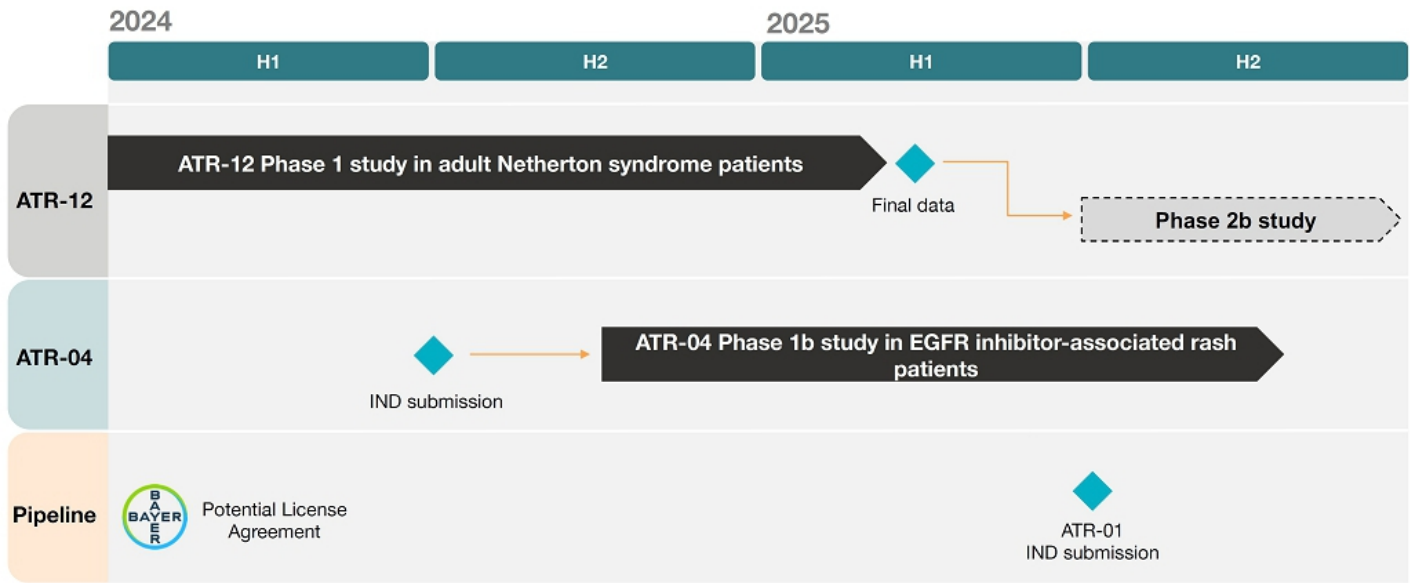
- ✓ Deep expertise, broadly applicable platform, and 1,500+ proprietary *S. epidermidis* strains
- ✓ Translational leader in dermatology and *S. epidermidis* biology
  - ✓ Key academic and clinical collaborator network

### Build a leading, world-class consumer care product line













#### Joint Development Agreement overview:

- ✓ Joint development on *S. epidermidis* strains and products for eczema-prone skin
- ✓ Azitra is responsible for early research, and Bayer is responsible for clinical development and commercialization

# ATR-12 and ATR-04 bring value-creating milestones in 2024-2025



## Robust intellectual property with key patents issued

 <p><b>2038</b> *Treating skin disease with recombinant organisms <i>*Issued</i></p>	 <p><b>2038</b> Treatment of skin disease with recombinant commensal skin microorganisms</p>	 <p><b>2038</b> *Auxotrophic strains of Staphylococcus bacteria <i>*Issued</i></p>	 <p><b>2038</b> Filaggrin subunits for treatment of eczema and ichthyosis vulgaris</p>
 <p><b>2039</b> LEKTI for Pruritis, Pain, Inflammation</p>	 <p>Formulations for stabilizing microbiome products</p>	 <p><b>2034</b> *Treating atopic dermatitis with recombinant organisms <i>*Issued</i></p>	 <p><b>2038</b> Treating inflammatory skin disease with recombinant organisms</p>
 <p><b>2038</b> Commensal bacteria to treat cancer associated rash</p>	 <p><b>2038</b> Cosmetic compositions with engineered bacteria</p>	 <p><b>2038</b> Treatment of Netherton syndrome with LEKTI expressing microbes</p>	 <p><b>2039</b> LEKTI for treating skin cancer</p>

## Balance sheet summary and pre-offering capitalization table

	September 30, 2023 <sup>1</sup>		Pre-Offering Cap Table
Cash and cash equivalents	\$4,400,327	Common Shares	12,097,643
Working capital	\$3,410,044	Warrants (WAEP: \$4.75)	323,736
Total assets	\$7,490,244	Options (WAEP: \$1.36)	1,288,255
Total stockholders' equity	\$5,332,087	Fully Diluted Shares Outstanding:	13,709,634

## Azitra well-positioned to take advantage of synthetic biology innovations



### Established platforms for precision dermatology

- ✓ Established manufacturing and formulation systems
- ✓ Orphan dermatology indications
- ✓ Multiple shots on goal for 2024-2025



### Strong business foundation

- ✓ \$~47 million invested to date, including Bayer
- ✓ Comprehensive intellectual property



### Partnerships to expand the pipeline

- ✓ Key collaboration with top-tier consumer health corporation, Bayer
- ✓ Partnerships with top-tier academic institutions



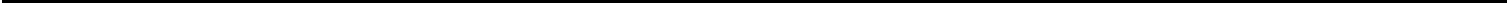
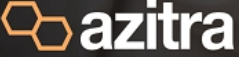


**THANK YOU**

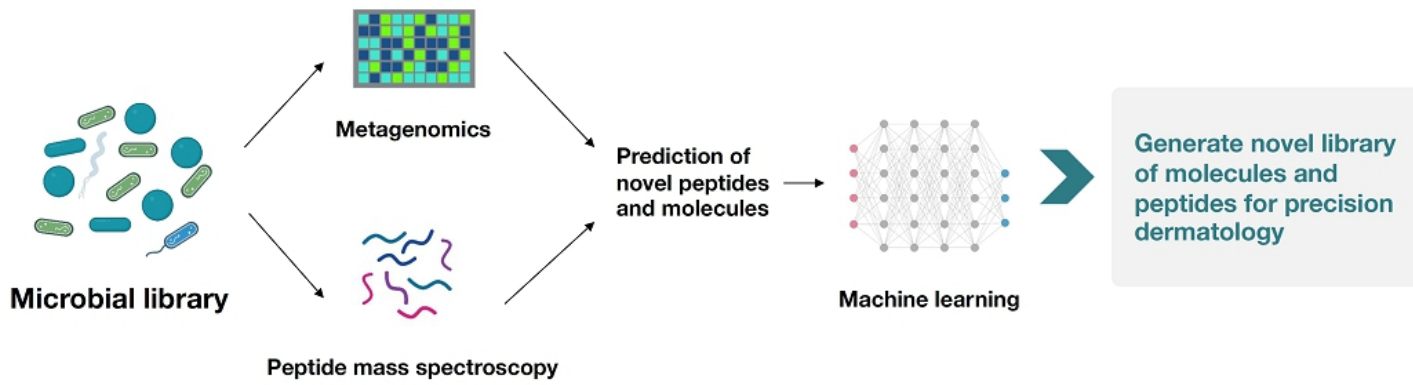
Precision dermatology powered by synthetic biology.



**APPENDIX**



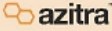




# Machine learning for novel drug discovery



## AI/ML-driven drug discovery benefits:

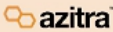





- ✓ Expand possible universe of possible drug candidates
- ✓ Expand knowledge of function of skin bacteria
- ✓ Combine with phenotypic screens for accelerated target discovery and validation
- ✓ Potential to cut 1-3 years off the discovery stage into clinical testing

## ATR-12 is a differentiated approach for Netherton syndrome

	Company	Asset	Description	Status	Topical treatment	Protein replacement	Disease Modifying
Kallikrein inhibitors	 azitra™	ATR-12	<i>S. epidermidis</i> strain engineered to express LEKTI; topical	Phase 1b	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	SIXERA PHARMA	SXR1096	KLK inhibitor; topical	Phase 1/2 (EU)	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Gene therapy	 MoST	BBP-561	KLK5/7 inhibitor; topical	IND-enabling	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
	 Krystal	KB104	Gene therapy; topical (admin at home)	IND-enabling	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Other	Investigator-initiated trial	Cosentyx <sup>1</sup>	IL-17A antibody; subcutaneous injection	Phase 2			
	 MatriSys	MSB-6005	Skin microbiome therapy; topical	Preclinical	<input checked="" type="checkbox"/>		
	 QUOIN	QRX-003	Protease inhibitor; topical	Phase 3	<input checked="" type="checkbox"/>		

<sup>1</sup> Under investigation for broader category of ichthyoses.

## ATR-04 is a differentiated approach for EGFRi-related skin toxicities

	Company	Asset	Description	Status	Topical treatment	Disease modifying	IL-36γ targeted	Notes
US-based	 azitra	ATR-04	Epidermin-secreting <i>S. epidermidis</i> auxotrophic strain; anti- <i>S. aureus</i> and anti-IL-36γ; topical	IND-enabling	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	IND submission planned by YE 2023
	 LUTRIS	LUT-014	B-Raf inhibitor; topical	Phase 2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Phase 1 showed effect but did not reach statistical significance
	 HOTH THERAPEUTICS	HT-001	Immune cell inhibitor; topical	Phase 2	<input checked="" type="checkbox"/>			505(b)(2) pathway. No previous clinical data
Ex-US	 twiB	AC-707	Antibiotic and anti-inflammatory; topical	Phase 2	<input checked="" type="checkbox"/>			No updated Phase 2 data since trial completion in 2021
	 DAEWOONG	DWP708	Human HGF spray; topical	Phase 2 (Korea)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		Korean IND cleared in 2022
	 GENOME & CO	GEN-501	Microbiome-based therapy	Preclinical	<input checked="" type="checkbox"/>			Little information available