UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 7, 2023

AZITRA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41705**	**46-4478536**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

21 Business Park Drive
Branford, CT 06405
(Address of principal executive offices)(Zip Code)

(203) 646-6446
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock: Par value $0.0001	AZTR	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

In connection with a proposed non-deal roadshow, we intend to provide participants a corporate presentation. The presentation materials are attached to this Current Report on Form 8-K as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit is furnished with this report:

Exhibit 99.1	Azitra Inc.'s July 2023 Corporate Presentation	Filed Electronically herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

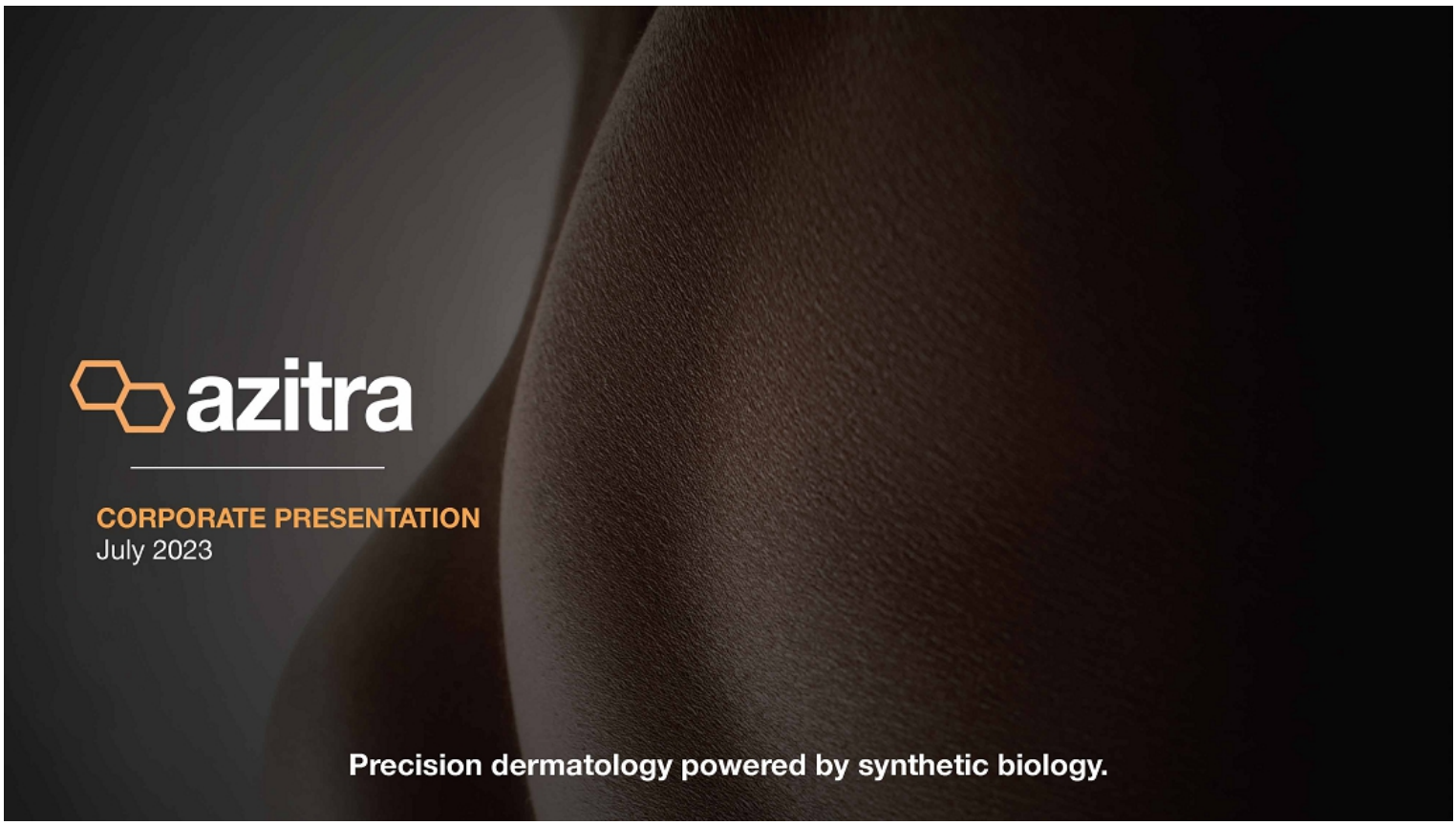
AZITRA, INC.

Dated: July 7, 2023

/s/ Francisco D. Salva

Francisco D. Salva
Chief Executive Officer

Exhibit 99.1


azitra
CORPORATE PRESENTATION
July 2023
Precision dermatology powered by synthetic biology.

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 June 15, 2023 filed by Azitra with the Securities and Exchange Commission on June 21, 2023.

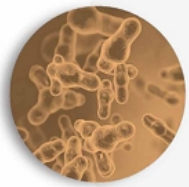
In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements. You should not rely upon forward-looking 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.

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	Acerta Pharma pharmacyclics
	**Travis Whitfill, M.P.H.** Co-Founder and Incoming 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	Bios | Partners Yale
	**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	EY
	**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)	THRASOS Indel Therapeutics
	**Leonard Milstone, M.D.** Professor Emeritus of Dermatology Yale Medical School 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	Yale FIRST

Precision dermatology powered by synthetic biology and the metagenome

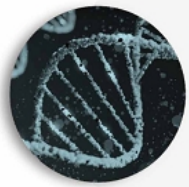


Bacterial Cell Library

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

Collaboration for Artificial Intelligence / Machine Learning Discovery

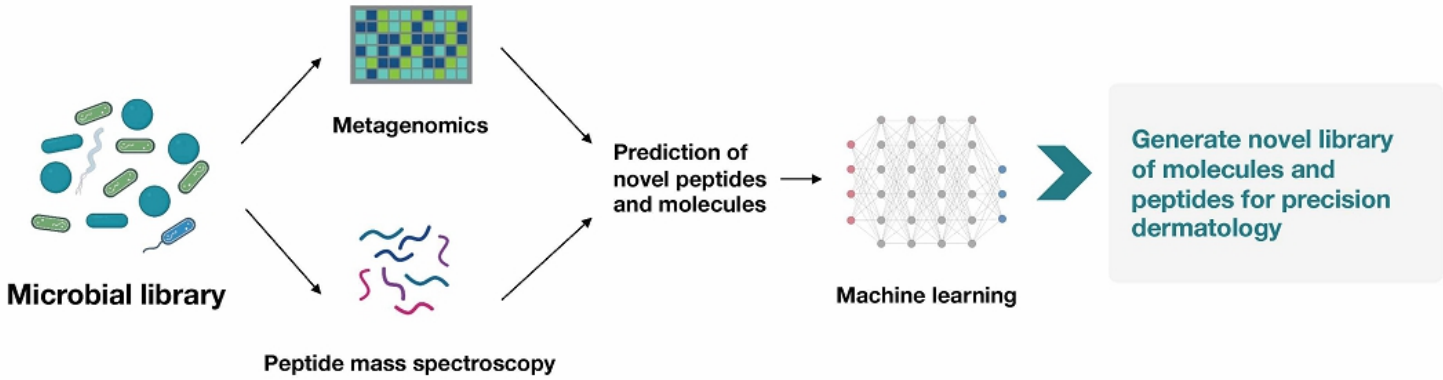
- Predictive algorithms for **novel microbial-derived proteins, peptides & small molecules**
  - Exclusive agreement covering specific strains with team from Carnegie Mellon
  - Based on genetic sequences and biosynthetic gene clusters
  - Includes post-assembly modifications & non-natural structures



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

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

Azitra's pipeline creates near-term value

FDA-regulated candidates for drug development

Consumer/Cosmetic Product Development

ATR-12 Program

Netherton Syndrome

azitra

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

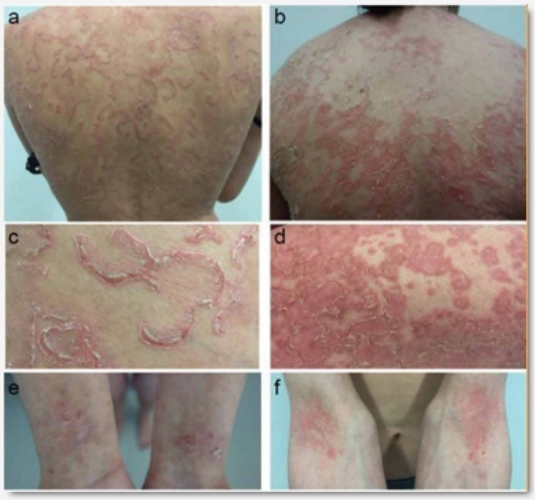
Clinical Status:
Phase 1b IND cleared in Jan. 2023

Global Prevalence:
~20K+ Patients

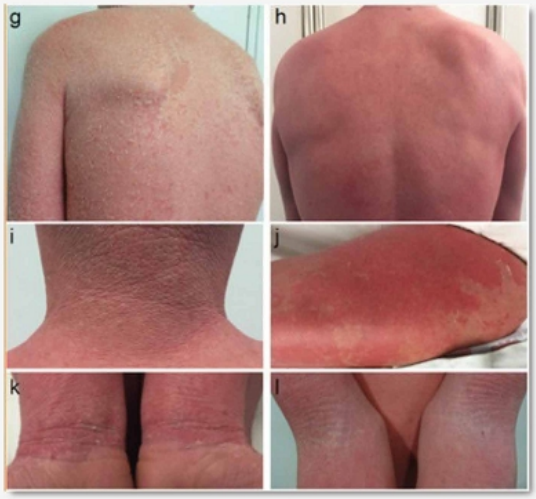
Peak Sales Opportunity:
~$250M

Two Netherton syndrome phenotypes are driven by *SPINK5* mutations

Ichthyosis Linearis Circumflexa (ILC)

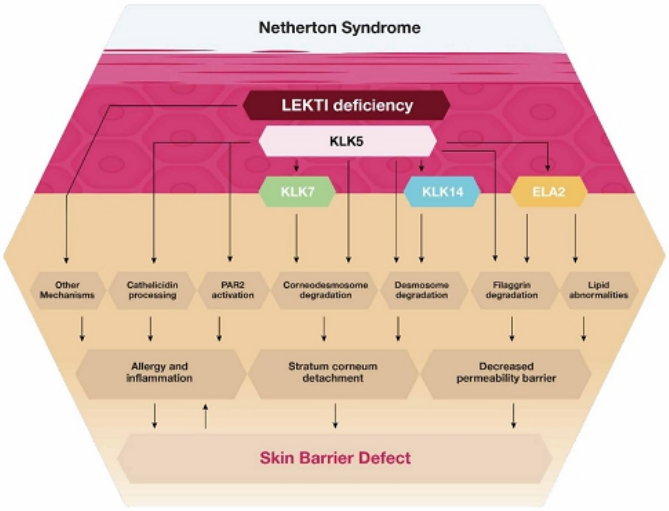


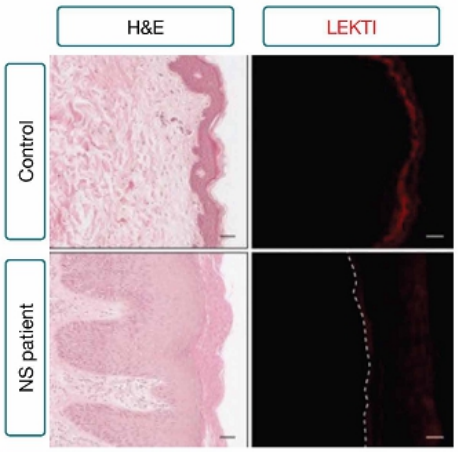
Scaly Erythema (SE)



Barbieux et al, J Allergy Clin Immunol 2021

Rationale to target KLK5 in Netherton syndrome via LEKTI delivery



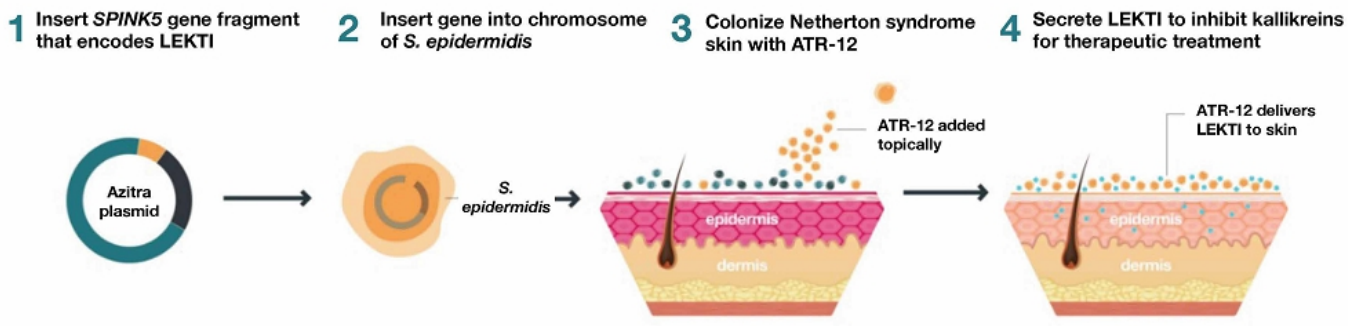


Mintoff, Fischer, *Mol Genet Genomic Med.*, **2021**, *9*, e1611

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

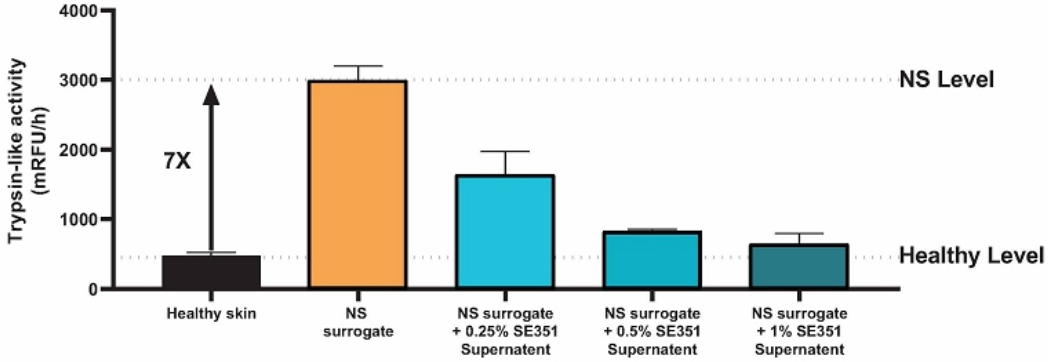
- Netherton syndrome patients have undetectable levels of LEKTI in skin

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



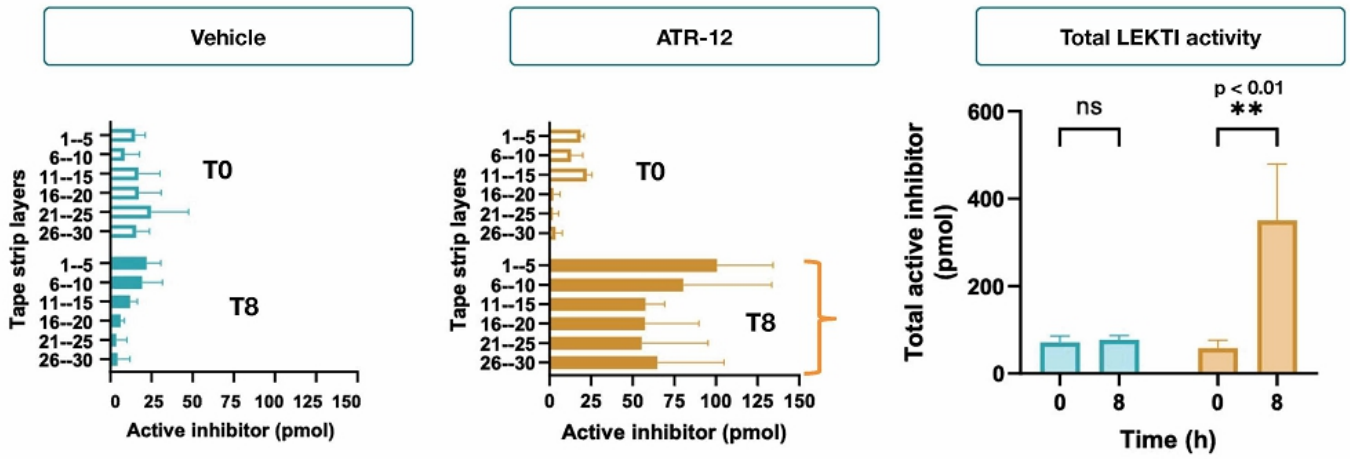
Ex vivo activity of ATR-12 shows decreased trypsin-like activity

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



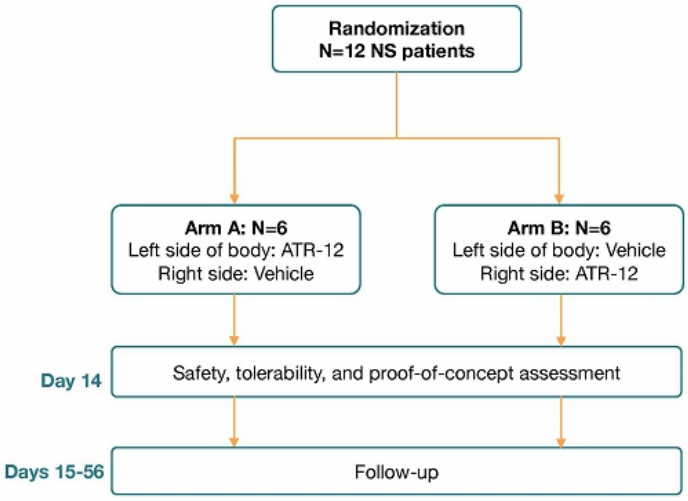
- ✓ LEKTI activity is significantly higher after 8 hours compared to T0 in all layers following ATR-12 application
- ✓ The LEKTI activity penetrates to at least 30 layers deep in substantial amounts

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

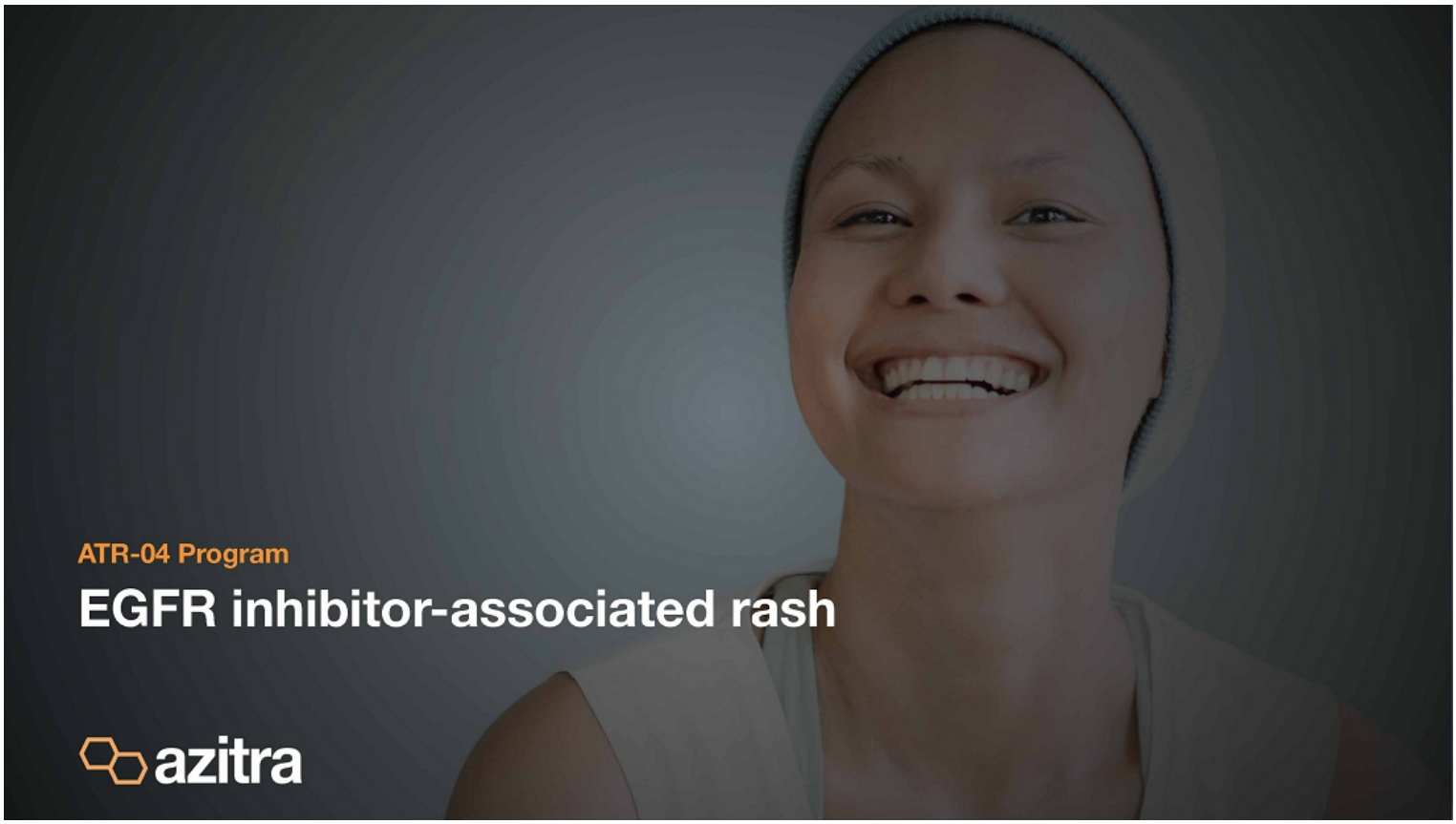
Design



ATR-12 is a differentiated approach for Netherton syndrome

	Company	Asset	Description	Status	Topical treatment	Protein replacement	Disease Modifying
Kallikrein inhibitors	azitra	ATR-12	*S. epidermidis* strain engineered to express LEKTI; topical	IND-enabling	☑	☑	☑
	SIXERA PHARMA	SXR1096	KLK inhibitor; topical	Phase 1 (EU)	☑		☑
Gene therapy	MoST	BBP-561	KLK5/7 inhibitor; topical	IND-enabling	☑		☑
	Krystal	KB104	Gene therapy; topical (admin at home)	IND-enabling	☑		☑
Other	Investigator-initiated trial	Cosentyx[1]	IL-17A antibody; subcutaneous injection	Phase 2			
	AnaptysBio	ANB019[1]	IL-36R antibody; injection	Phase 2			
	MatriSys	MSB-6005	Skin microbiome therapy; topical	Preclinical	☑		
	QUOIN	QRX-003	Protease inhibitor; topical	Phase 2	☑		

[1] Under investigation for broader category of ichthyoses.


ATR-04 Program
EGFR inhibitor-associated rash
azitra

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

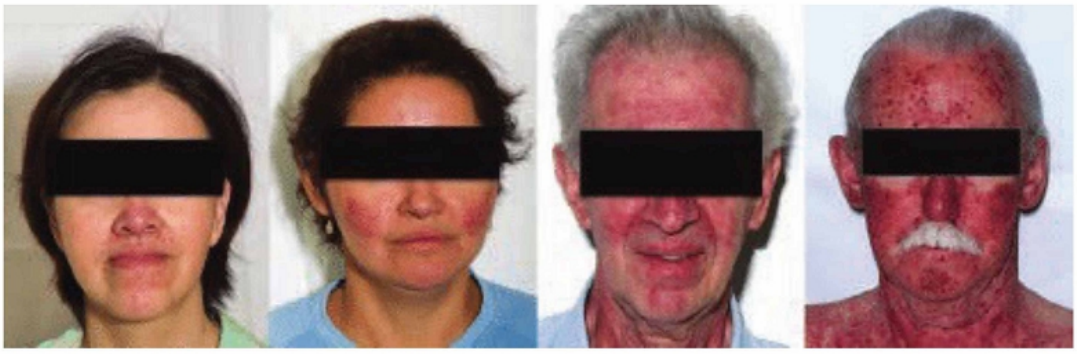
Primary Mechanism:
IL36g Inhibition, *S. aureus* control

Clinical Status:
IND filing expected 2H 2023

US Prevalence:
>200,000 patients

Peak Sales Opportunity:
>$1B

EGFRi-driven rash is highly prevalent with significant clinical impact



Grade 1	Grade 2	Grade 3	Grade 4

- 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**

Source: Melosky et al. (2015). Grade 1, gefitinib; grade 2, erlotinib; grade 3, erlotinib; grade 4, erlotinib


Collaborations and Future Directions
azitra

Bayer consumer health product joint development partnership

- ✓ 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

Broad spectrum of potential future applications

Medicines & Biopharmaceuticals

- Drug discovery
- Antibody production
- Vaccine innovation
- mRNA vaccines

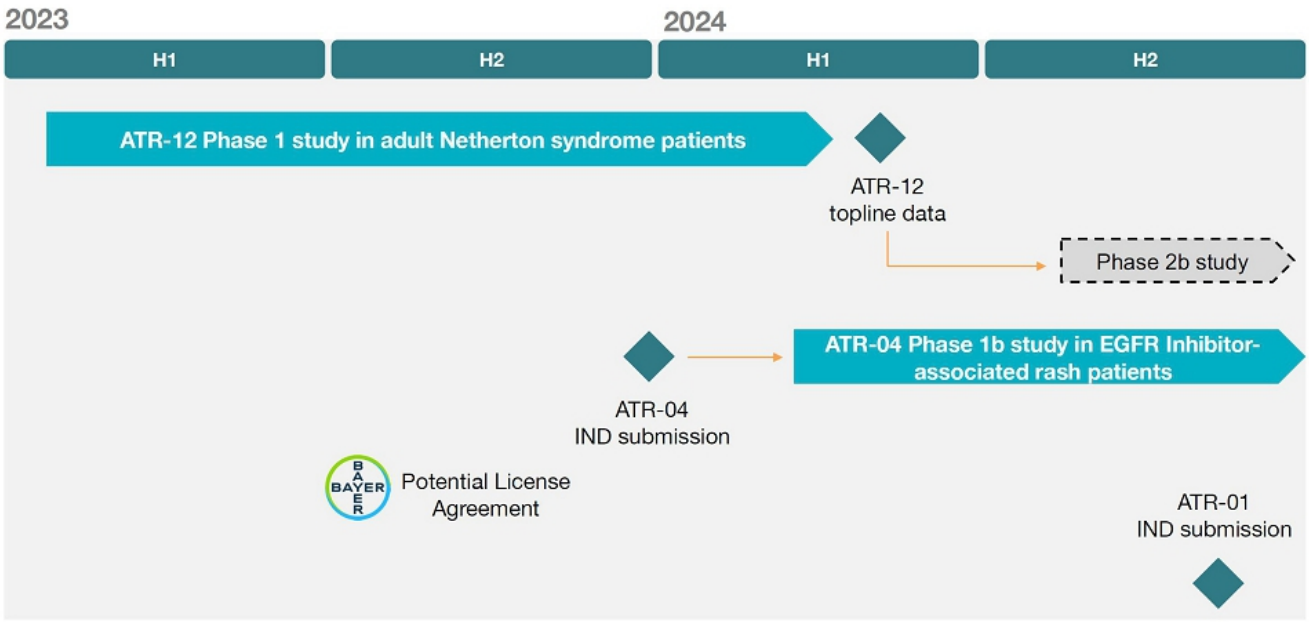
Biofuels and Sustainable Energies

- Fermentation processes
- Ethanol made by thermophilic organisms
- Biodiesel from yeast cultured on sugarcane

Environmental Bioremediation

- Biodegradation of methylphenols
- Biosensors alerting for toxic substances
- Microbes to clean up chemical waste

ATR-12 and ATR-04 bring value-creating milestones in 2023-2024



Robust intellectual property with key patents issued

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

Capitalization table

	Offering
Common Shares	12,097,643
Warrants (WAEP: $4.59)	335,199
Options (WAEP: $1.34)	1,260,681*
Fully Diluted Shares Outstanding:	13,693,523

*Does not include an overallotment option held by our IPO underwriter to purchase up to 225,000 shares of our common stock at $5.00 per share exercisable through July 30, 2023.

Investment Highlights

Azitra well-positioned to take advantage of synthetic biology innovations

Established platforms for precision dermatology

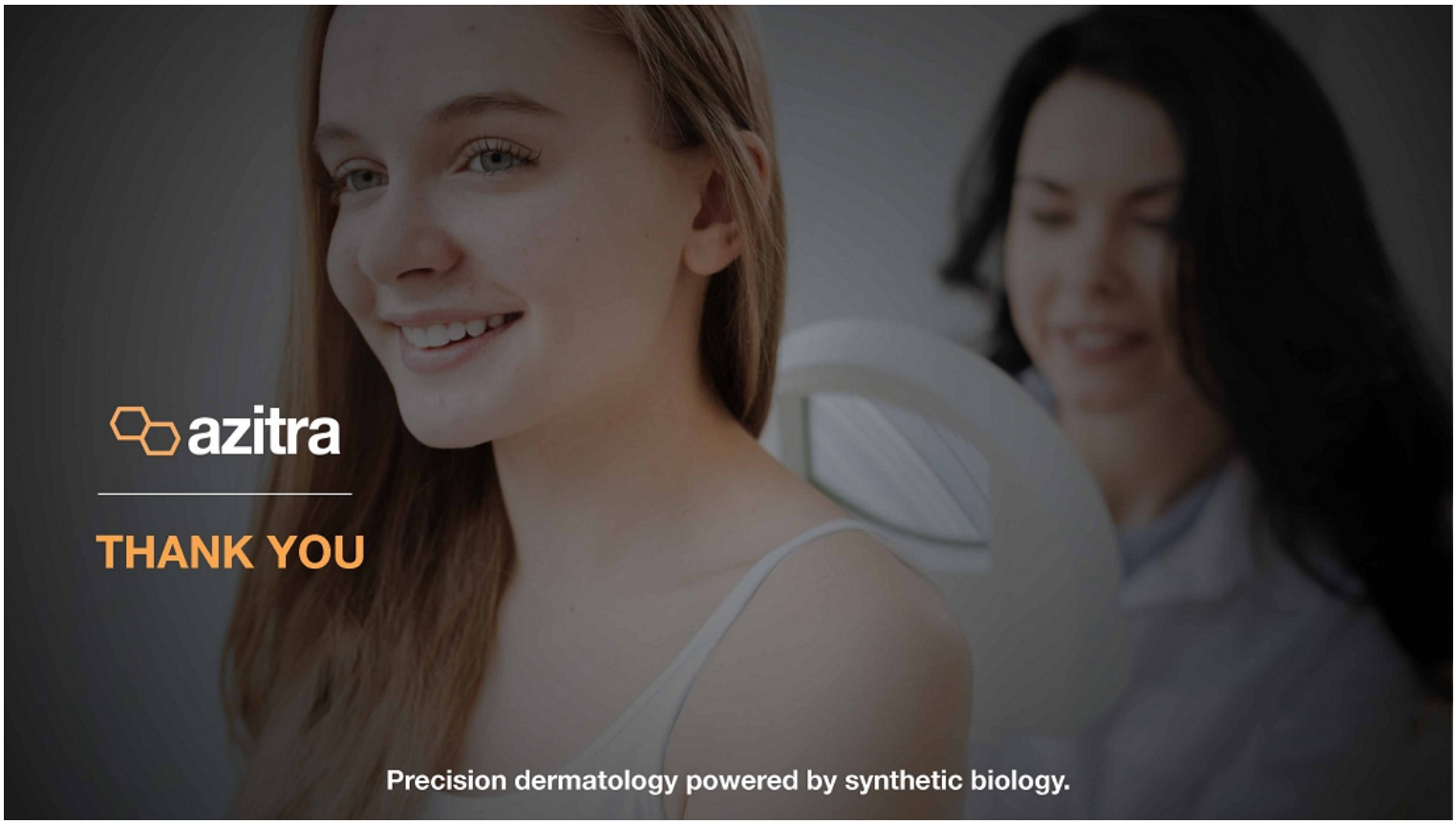
- ✓ Established manufacturing and formulation systems
- ✓ Orphan dermatology indications
- ✓ Multiple shots on goal for 2023-2024

Strong business foundation

- ✓ $~40 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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THANK YOU
Precision dermatology powered by synthetic biology.