



# Company Overview

Dr. Neal Walker  
President and CEO

July 2016



# Disclaimer

This presentation contains forward-looking statements, including statements regarding the treatment and market opportunity for SK, common warts, alopecia areata, androgenetic alopecia, vitiligo, and the future operations of Aclaris. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. For further information regarding these risks, uncertainties and other factors you should read Aclaris' Annual Report on Form 10-K for the year ended December 31, 2015 and Aclaris' other filings it makes with the Securities and Exchange Commission from time to time. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



# The Aclaris Opportunity

## MANAGEMENT TEAM EXPERTISE IN DERMATOLOGY

- Founded and sold several companies
- Directly relevant experience in Dermatology
- Board-certified dermatologists as CEO and CSO
- Developed and commercialized multiple products

## DRUG DEVELOPMENT PIPELINE

A-101: Proprietary formulation of high concentration  $H_2O_2$

- Seborrheic Keratosis
  - Phase 3 commenced in Jan 2016
- Common Warts
  - Phase 2 – commenced in Dec 2015

ATI-50001/ATI-50002: JAK 1/3 Inhibitors

- Alopecia Areata
  - Topical and Oral
  - PoC demonstrated with JAK inhibitors

## ATTRACTIVE DERMATOLOGY MARKETS

- Time and capital efficient
- Highly concentrated prescriber base
- Large unmet market segments with no FDA-approved drugs
- Growing market for cash pay aesthetic and medical dermatology products

Build a Fully Integrated Dermatology Company



# Our Drug Candidates

Exclusive, Worldwide Right to Commercialize A-101, A-102, ATI-50001 and ATI-50002

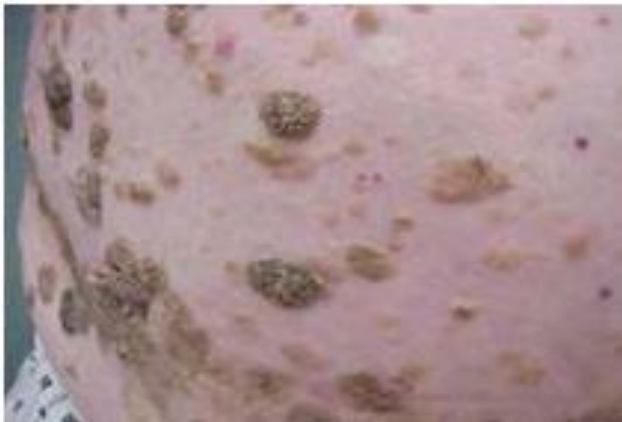
	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
A-101*					
Seborrheic Keratosis (topical)					**
Common Warts (topical)					***
ATI-50001					
Alopecia Areata (oral)					
ATI-50002					
Alopecia Areata (topical)					

\* Also developing A-102 topical gel as a lifecycle management opportunity for A-101

\*\* Commenced Phase 3 clinical trials

\*\*\* Commenced Phase 2 clinical trial

# Seborrheic Keratosis (SK) Background



**Untreated SK**



**Before  
Treatment**

**3 Months Post  
Cryosurgery**

- SK is one of most common diagnoses made by dermatologists
  - >83 million people with the disease in the U.S.
  - 18.5 million patient visits to dermatologists
  - 8.3 million procedures to remove SKs annually
  - \$1.2 billion - historic costs of treatments for SK
- Patients seek diagnosis and treatment
  - Fear of skin cancer
  - Concern about appearance
  - Discomfort from itching and inflammation
- Current options for SK removal: cryosurgery, curettage, electrodesiccation or excision
  - Limitations of current removal options:**
    - Dyspigmentation (hypo or hyper)
    - Scarring
    - Pain
    - Surgical - invasive
    - Treatment of numerous SK is impractical



# Potential to Be First FDA-approved Drug for SK

A-101 is appealing concept for SK treatment

- Topical, non-invasive
- Minimal discomfort; no need for anesthesia
- Reduced risk of pigmentary changes and scarring
- Ability to treat larger numbers of lesions
- Ability to hand off to ancillary staff

## Background

- Developed a proprietary formulation of 40.0%  $\text{H}_2\text{O}_2$
- Conducted formal dose-ranging studies
- MOA: drives apoptotic and necrotic cell death

UNTREATED

TREATED



**Inventor's Proof of Concept**  
*(with his initial formulation)*



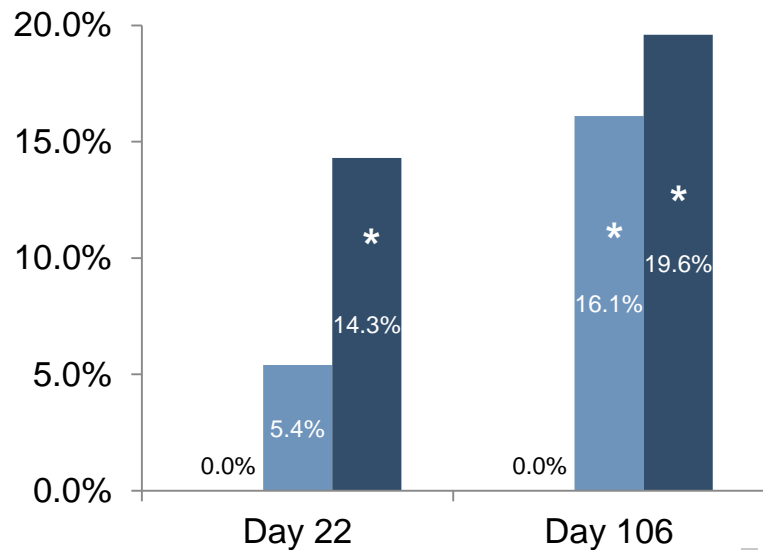
# Summary of Completed Phase 2 Trials for SK

Trial	SK Lesion Area	Date Completed	Trial Design	Trial Outcome
SEBK-201 (n=35) Phase 2	Trunk (Back)	June 2014	<ul style="list-style-type: none"> <li>• Single center, intra-subject</li> <li>• Four lesions treated</li> <li>• A-101 concentrations: 25.0%, 32.5%, 40.0%</li> <li>• 1 or 2 applications</li> <li>• Duration: 78 days</li> </ul>	<ul style="list-style-type: none"> <li>• Efficacy: 32.4% clear; 67.7% clear or near clear with 40% concentration</li> <li>• Favorable safety profile</li> </ul>
SEBK-202 (n=172) Phase 2	Trunk and Extremities	December 2014	<ul style="list-style-type: none"> <li>• Multicenter, parallel group</li> <li>• Four lesions treated</li> <li>• A-101 concentrations: 32.5%, 40.0%</li> <li>• 1 or 2 applications</li> <li>• Duration: 106 days</li> </ul>	<ul style="list-style-type: none"> <li>• Efficacy: Demonstrated statistically significant clearance of all 4 lesions in top dose group (Phase 3 primary end point)</li> <li>• Favorable safety profile</li> </ul>
SEBK-203 (n=119) Phase 2	Face	March 2015	<ul style="list-style-type: none"> <li>• Multicenter, parallel group</li> <li>• One lesion treated</li> <li>• A-101 concentrations: 32.5%, 40.0%</li> <li>• 1 or 2 applications</li> <li>• Duration: 106 days</li> </ul>	<ul style="list-style-type: none"> <li>• Efficacy: Statistically significant clearance</li> <li>• Favorable safety profile</li> </ul>



# A-101 Phase 2 Trunk/Extremities Study: PLA Responder Analysis

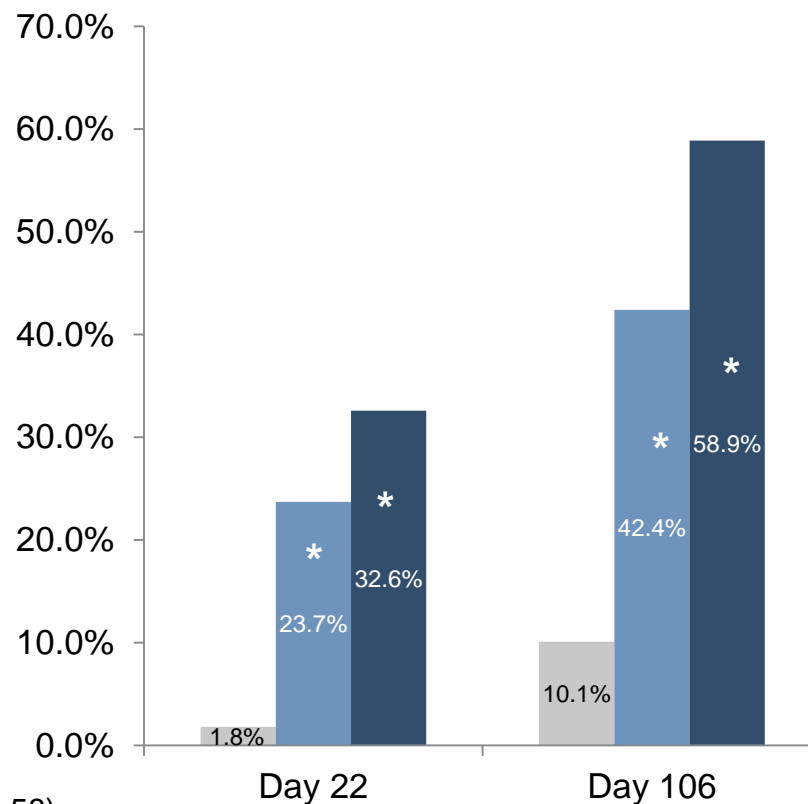
Percentage of Subjects Achieving  
Total Clearance



\* P-value<0.01

■ Vehicle (n=58)  
■ A-101 32.5% (n=57)  
■ A-101 40.0% (n=57)

Percentage of Subjects Achieving  
Total Clearance or Near Clearance



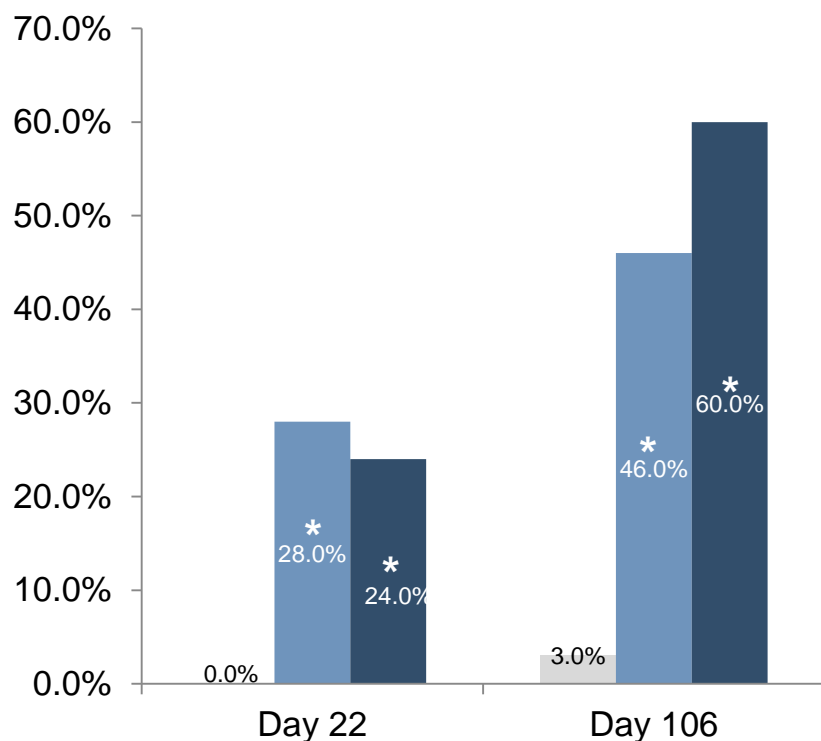
\* P-value<0.0001





# A-101 Phase 2 Face Study: PLA Responder Analysis

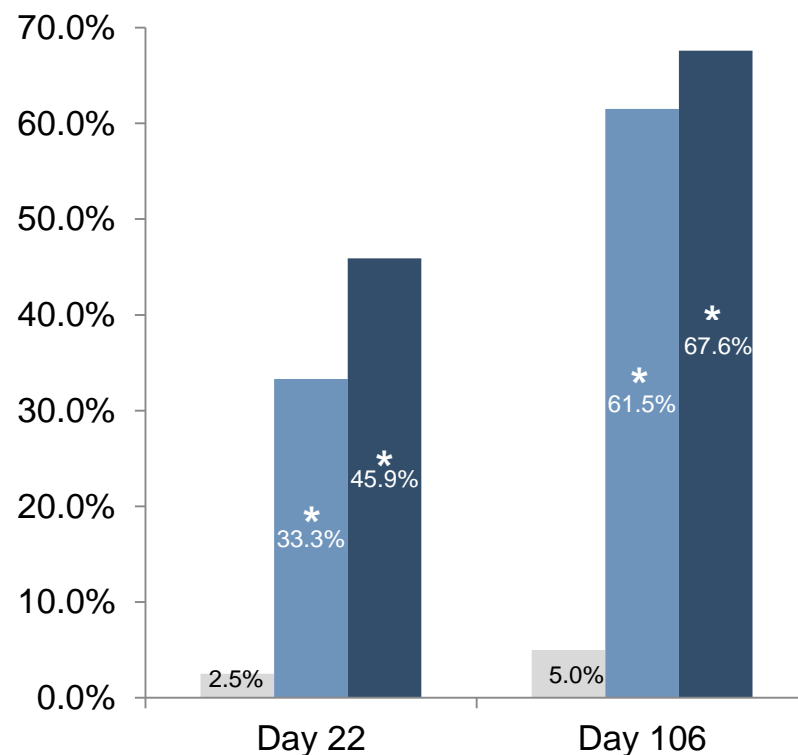
Percentage of Subjects With Target Lesion  
Clear



\* P-value<0.001

■ Vehicle (n=40)  
■ A-101 32.5% (n=39)  
■ A-101 40.0% (n=37)

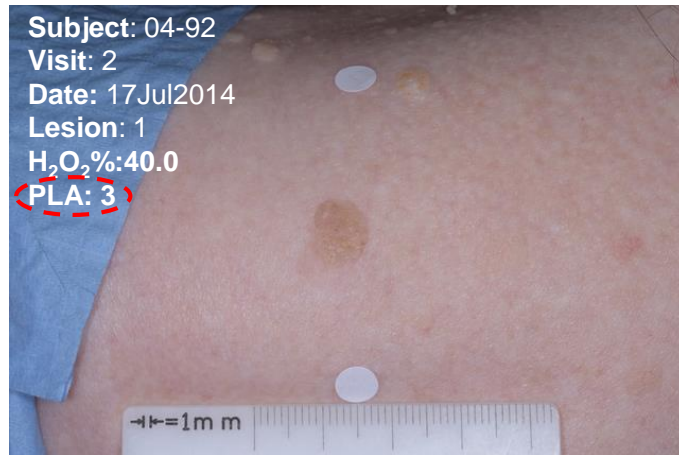
Percentage of Subjects With Target Lesion  
Clear or Near-Clear



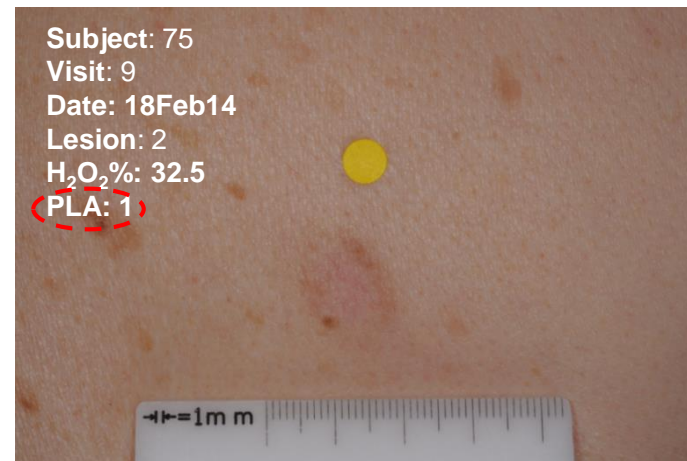
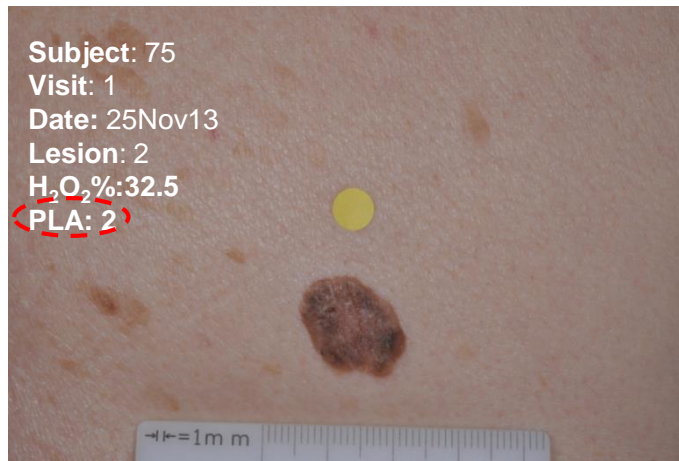
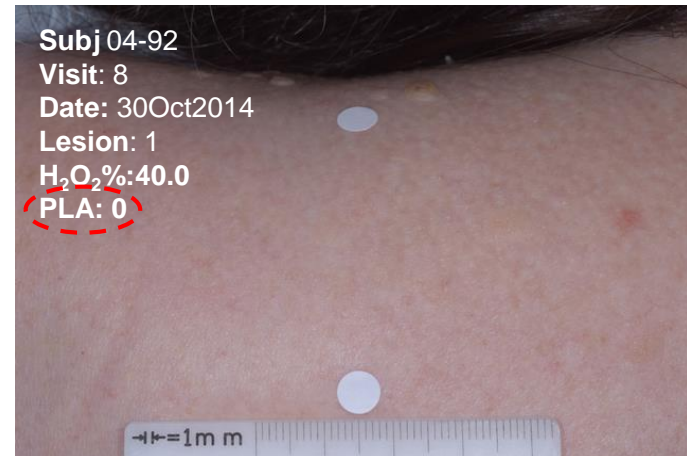
\* P-value<0.001

# Grading of SKs using PLA Scale in Clinical Trials

## Pre-Treatment with A-101



## Post-Treatment with A-101





# A-101 Next Steps: Phase 3 Overview

- A-101 40.0% is being used for Phase 3 clinical testing
- Initiated Phase 3 program – January 2016
  - Pivotal trials (SEBK-301/302): Two identical Phase 3 trials
    - 4 lesions treated in total with at least one on face and one on trunk or extremities
    - 400 subjects each
    - Primary endpoint: Proportion of subjects with clear on PLA scale
    - 3 month drug-free follow-up
  - Open-label (SEBK-303): 4 SK lesions
    - Up to four applications
    - 200 subjects
- Plan to submit NDA – 4Q 2016



# A-101 Commercialization Strategy

## Buy and Bill Model

- Cash pay, minimally invasive procedure
- Lower cost relative to other aesthetic treatments (Botox®, Fillers, Laser treatments)

## Concentrated Prescriber Base

- 5,000 dermatologists in US, accounting for over 70% of procedures performed
- Concentrated call point allows for high reach and frequency

## Disease Awareness

- Disease state awareness initiatives
- KOL engagement, conference presentations and publications

## Commercial Launch

- 50-60 person specialty sales team focused on high tier targets
- Comprehensive promotional campaign to include peer-influence programs

## Patient Engagement

- Campaigns focused on driving awareness and furthering interest in treatment options

ATI-50001/ATI-50002  
Candidates for  
Alopecia Areata



# Alopecia Areata (AA) Background



AA – Patchy



Alopecia  
Universalis

- AA is an autoimmune condition, characterized by patchy, non-scarring hair loss on the scalp and body
- Large unmet need: >6.6 million people in the U.S. have had or will develop AA at some point in their lives
  - 2/3 of affected individuals  $\leq 30$  years old at disease onset
  - 25-50% of patients have persistent patchy AA
  - 14%-25% of patients progress to totalis or universalis
- Current off label treatments include topical steroids, steroid injections, and minoxidil
- Recent translational research work by Dr. Angela Christiano
  - Furthered genetic understanding of disease
  - Identified JAK inhibitors as a potential treatment for AA

Potential to be First FDA-Approved Drug for AA





# ATI-50001/ATI-50002: JAK Inhibitors in Alopecia Areata

- Lead asset: Selective JAK 1/3 inhibitor from Rigel
  - Exclusive, worldwide license and development collaboration
  - Oral and topical rights
- Known mechanism of action and biological response in humans
- Promoted hair regrowth in mouse model of AA
- Drug Candidates:
  - ATI-50001 for oral administration in Alopecia Totalis and Alopecia Universalis
  - ATI-50002 for topical administration in Patchy Alopecia Areata
- Development Strategy
  - Planned submission of IND: 2H 2016
  - Initiation of clinical trial: 1H 2017



# Recent Business Development Transactions

- Vixen (Columbia University IP) and Key Organics/JAKPharm
  - Broadens our IP estate
    - Methods of use covering JAK inhibitors for the treatment of:
      - Alopecia Areata
      - Androgenetic alopecia (female and male pattern hair loss)
      - Additional hair loss disorders
  - Next generation JAK inhibitors
    - Covalently bound highly selective JAK3 inhibitors

# Indication expansion

- Androgenic alopecia (male and female pattern hair loss)
  - AGA is the most common cause of hair loss and is experienced by 70% of men and 40% of women at some point in their lives
  - In 2012, 35 million men and 21 million women suffered hair loss
  - Topical JAK inhibitor
- Vitiligo
  - Vitiligo impacts 1% to 2% of the overall global population irrespective of sex, race, or age
  - Disease onset occurs in about one-half of sufferers between the ages of 10 and 30
  - Oral and topical JAK inhibitor



Male with AGA



Female with AGA



# Near-Term Milestones

Milestone	2016				2017			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>A-101 SK</b>								
Phase 3 Trial Initiated								
Submit NDA								
<b>A-101 Common Warts</b>								
Phase 2 Trial Underway								
<b>ATI-50001/ATI-50002 Alopecia Areata</b>								
Submit IND								
Commence Clinical Trial								



THANK YOU

[www.aclaristx.com](http://www.aclaristx.com)