
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): May 27, 2016

Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37581
(Commission File Number)

46-0571712
(IRS Employer
Identification No.)

101 Lindenwood Drive, Suite 400
Malvern, PA 19355
(Address of principal executive offices, including zip code)

(484) 324-7933
(Registrant's telephone number, including area code)

N/A
(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 obligation 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))
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Item 7.01 Regulation FD Disclosure.

On May 27, 2016, Aclaris Therapeutics, Inc. (the “Company”) issued a press release announcing a contemplated private placement of 1,081,082 shares of its common stock at a purchase price of \$18.50 per share (the “Private Placement”), which press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Neither this Current Report on Form 8-K nor any exhibit attached hereto is an offer to sell or the solicitation of an offer to buy shares of common stock or other securities of the Company.

In accordance with general instruction B.2 of Form 8-K, the information in this Item 7.01, including the press release furnished as an exhibit to this Current Report on Form 8-K, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 8.01 Other Events.

In connection with the Private Placement, the Company presented a presentation to investors and potential investors. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference. The information contained in this Current Report on Form 8-K speaks only as the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Aclaris Therapeutics, Inc. dated May 27, 2016.
99.2	Aclaris Therapeutics, Inc. Investor Presentation dated May 2016.

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.

ACLARIS THERAPEUTICS, INC.

Date: May 27, 2016

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release of Aclaris Therapeutics, Inc. dated May 27, 2016.
99.2	Aclaris Therapeutics, Inc. Investor Presentation dated May 2016.



Aclaris Therapeutics Announces \$20.0 Million Private Placement

Malvern, PA – May 27, 2016 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage specialty pharmaceutical company, announced today that it has entered into a stock purchase agreement with a group of institutional accredited investors for the private placement of 1,081,082 shares of common stock at a purchase price of \$18.50 per share, yielding expected gross proceeds of \$20.0 million. The private placement is expected to close on or about June 2, 2016, subject to the satisfaction of customary closing conditions.

The private placement was led by Aisling Capital with participation by additional new and existing investors.

Net proceeds from this offering are expected to be used to fund research and development, including new JAK inhibitor programs for androgenetic alopecia (also known as male or female pattern baldness) and vitiligo, as well as ongoing business development.

The securities being issued and sold in the private placement have not been registered under the Securities Act of 1933, as amended. Accordingly, these securities may not be offered or sold in the United States, except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act. This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of the securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

William Blair acted as the lead placement agent for the offering. Guggenheim Securities served as the co-placement agent.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage specialty pharmaceutical company focused on identifying, developing, and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Aclaris Therapeutics, Inc. is based in Malvern, Pennsylvania.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe”, “expect”, “may”, “plan,” “potential,” “will,” and similar expressions, and are based on Aclaris’ current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of Aclaris’ A-101 drug candidate for the treatment of SK and for common warts and its JAK inhibitor drug candidates for the treatment of alopecia areata and other dermatological conditions. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris’ reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Risk Factors section of Aclaris’ Annual Report on Form 10-K for the year ended December 31, 2015, filed with the Securities and Exchange Commission (SEC) on March 23, 2016, and other filings Aclaris makes with the SEC from time to time. These documents are available under the “Financial Information” section of the Investors page of Aclaris’ website at <http://www.aclaristx.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to Aclaris as of the date of this release, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Corporate Presentation

May 2016

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Disclaimer

This presentation, the information contained herein and the materials accompanying it (collectively, this “presentation”) constitutes confidential information and is provided to you on the condition that you agree that you will hold it in strict confidence and not reproduce, disclose, forward or distribute it in whole or in part without the prior written consent of Aclaris Therapeutics, Inc. (“Aclaris”) and is intended for the recipient hereof only. The presentation is for information purposes only.

This presentation contains forward-looking statements, including statements regarding the treatment and market opportunity for SK, common warts and alopecia areata, 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 H₂O₂

- 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 All Current Candidates



- * 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% H₂O₂
- 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

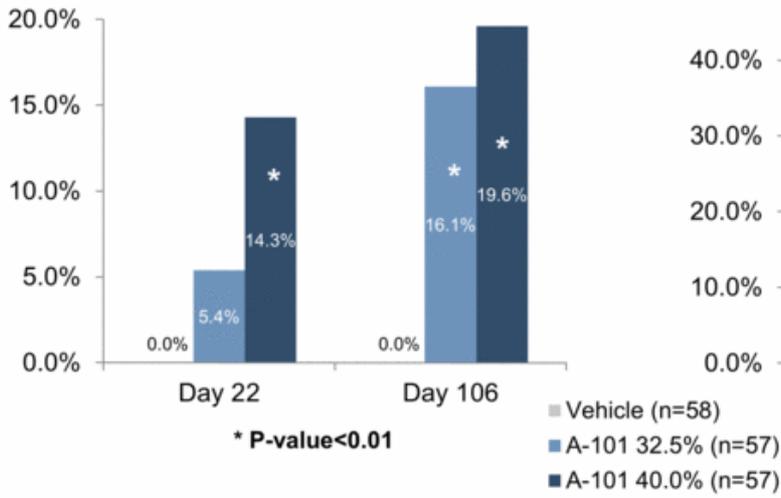
Trial	SK Lesion Area	Date Completed	Trial Design	Trial Outcome
SEBK-201 (n=35) Phase 2	Trunk (Back)	June 2014	<ul style="list-style-type: none">• Single center, intra-subject• Four lesions treated• A-101 concentrations: 25.0%, 32.5%, 40.0%• 1 or 2 applications• Duration: 78 days	<ul style="list-style-type: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



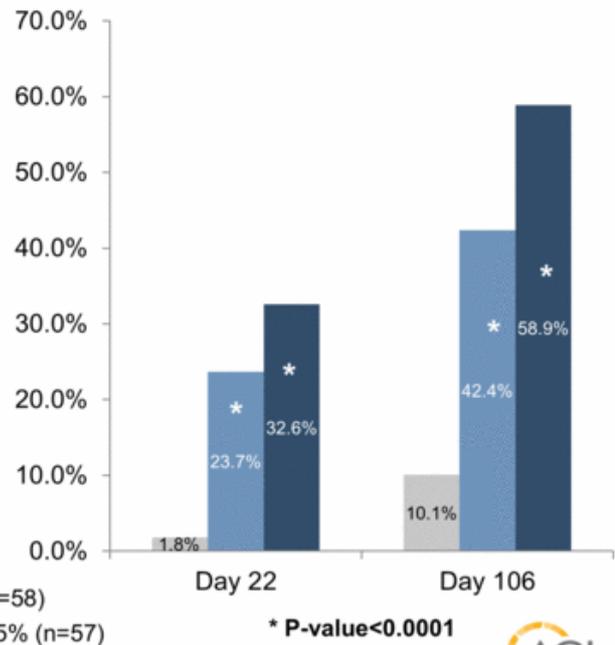


A-101 Phase 2 Trunk/Extremities Study: PLA Responder Analysis

Percentage of Subjects Achieving Total Clearance



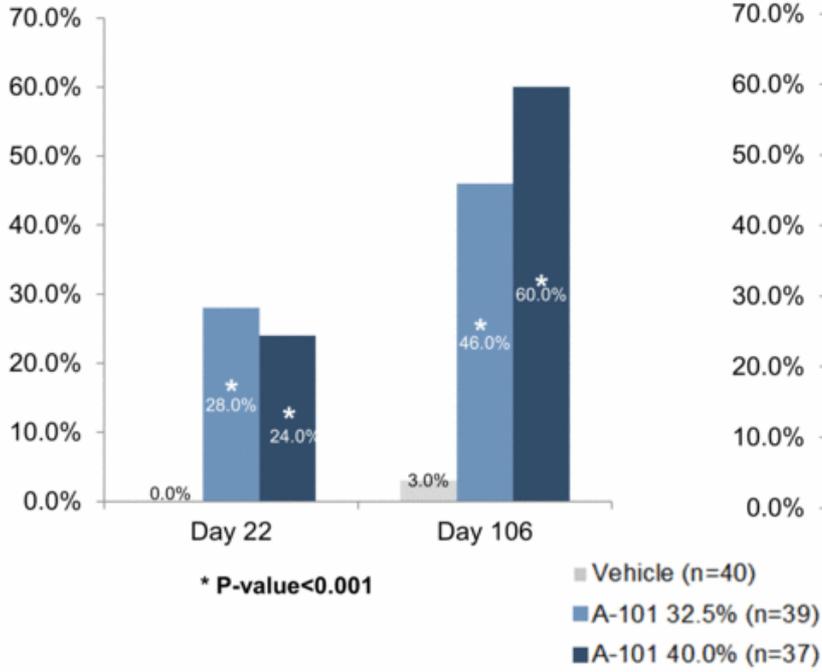
Percentage of Subjects Achieving Total Clearance or Near Clearance



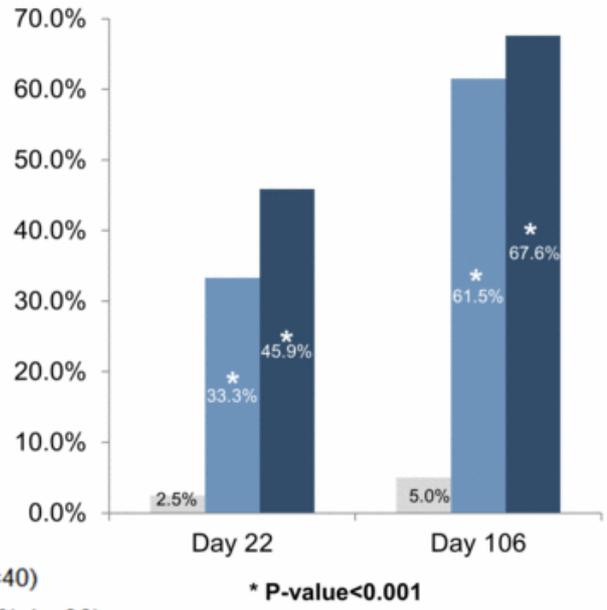


A-101 Phase 2 Face Study: PLA Responder Analysis

Percentage of Subjects With Target Lesion Clear



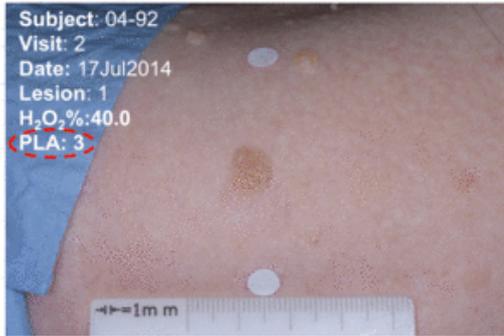
Percentage of Subjects With Target Lesion Clear or Near-Clear



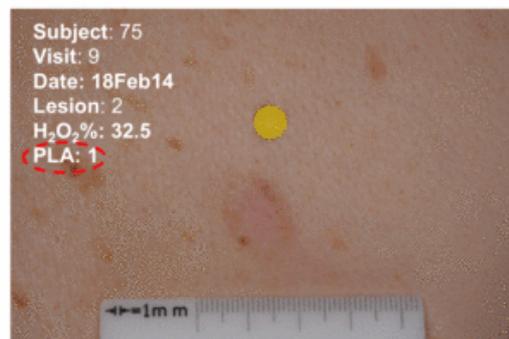
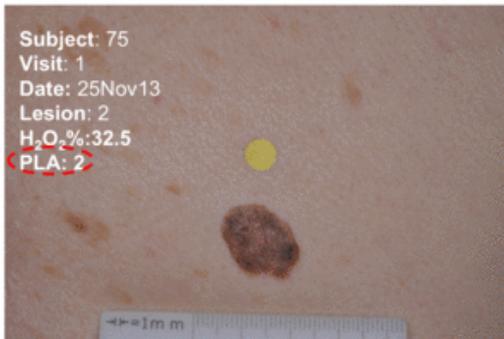
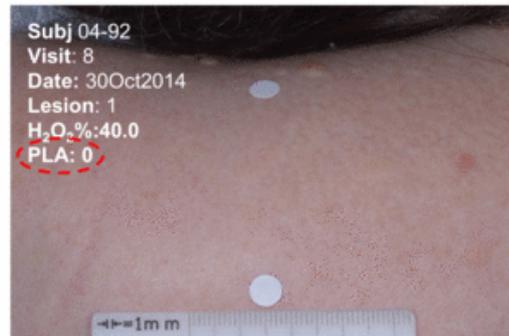


Grading of SKs using PLA Scale in Clinical Trials

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 ≤ 30 years old at disease onset
 - 25-50% of patients have persistent patchy AA
 - 14%-25% of patients progress to AA totalis or AA 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
- Opportunity to broaden our target indications

Indication Expansion



Androgenic Alopecia





Androgenic Alopecia (AGA): Growing Market with Many Unmet Needs

Market Opportunity

- An estimated 800,000 individuals are seeking some kind of treatment for hair loss worldwide ¹
- Women have been increasingly interested in solutions for AGA ²
- The Rx treatment market was roughly \$600M globally in 2013, and approximately \$1.9B was spent on hair restoration surgery in 2012 ³
- There are two drugs indicated for AGA: Propecia (finasteride) and Rogaine (minoxidil) – neither product has market exclusivity ³
 - Use of these products is limited by perceptions that they do not work
 - Propecia carries a large number of unwanted side-effects, and is contraindicated in women ^{3,4}

Epidemiology

- 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 ³
- In 2012, 35 million men and 21 million women suffered hair loss
- By the age of 35, about two-thirds of American men have some level of noticeable hair loss

Burden of Hair Loss

- A survey underscored the emotional distress caused by hair loss:
 - 47% reported that they would spend their life savings to regain a full head of hair
 - 60% responded that they would rather have more hair than more money and friends
 - 30% would give up sex if it meant they could get their hair back ³

¹Medgadget. Global Alopecia (Hair Loss) Treatment Market, 2016 – 2022. 04.11.2016.

²International Society of Hair Restoration Surgery. Female Hair Loss.

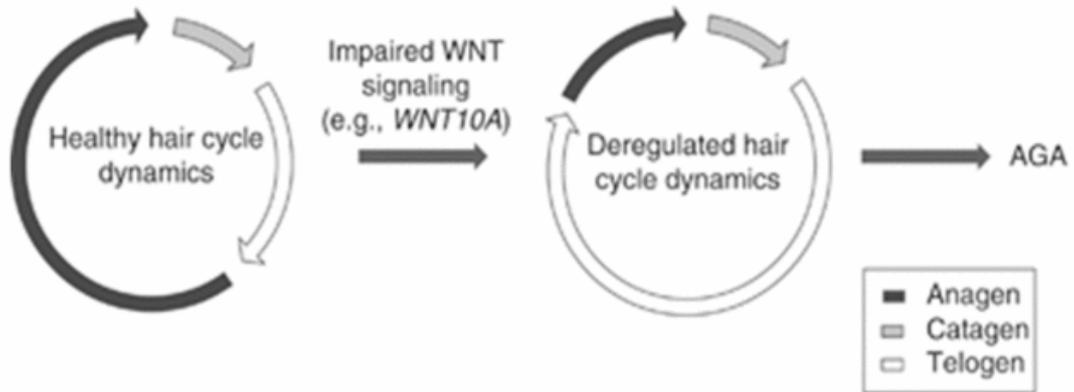
³Cassiopea. Androgenic Alopecia.

⁴Bergeson, L. The Truth About Hair Loss and Baldness Cures. 11.08.2014.





Background: Hair cycle dynamics in AGA

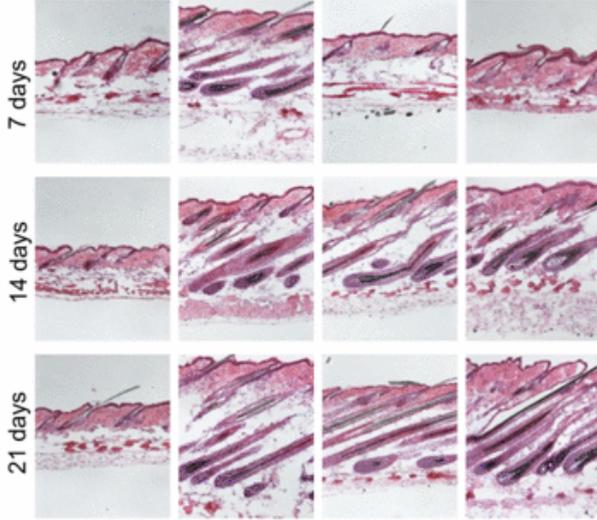
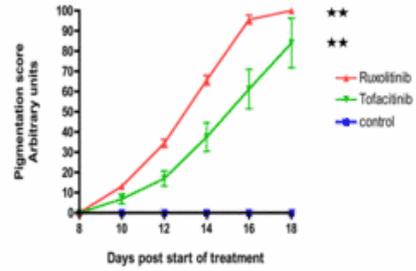
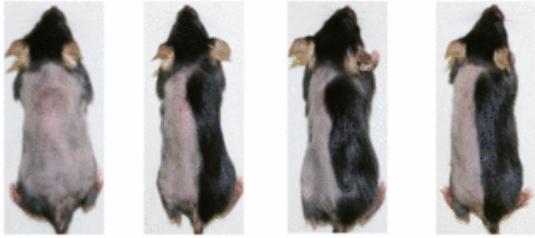


In AGA, telogen (rest) becomes longer and anagen (growth) becomes shorter
JAK-STAT signaling is elevated in telogen (resting) hairs
Hypothesis: Treatment with a JAK inhibitor can start anagen (growth)



Inhibition of JAK-STAT signaling initiates anagen in normal mice

Vehicle SAG Ruxolitinib Tofacitinib



Category	Differentially expressed in Ruxolitinib and Tofacitinib T0-T5, FC>1.5 or <0.5, P<0.05	P-value
Melanogenesis	Tyrp1, Syt4, Mlana, Pmel, Dct, Tyr, Sos1, Dbf4, Pax3, PIK3ca, Rps6kb1, Mlph, Stx17	0.003
Wnt pathway	Acvr2a, Sfrp4, Sox5, Cdh2, Fzd5, Wif1, Wnt2, Fzd8, Apc, Sox9, iLK	0.017
Hair development	Shh, Krt25, Dlx2, Prom1, S100a9, Vegfc, Ptgfr, Pdgfrl, Igfbp4, Gli2	0.001





Pathophysiology and Mechanism

- **Dynamics of hair cycle**

- In Androgenetic Alopecia (AGA), the duration of anagen decreases with each successive hair cycle, whereas the duration of telogen becomes prolonged.
- This leads to a reduction in the anagen-to-telogen ration and corresponds to periods of excessive hair shedding.
- Prolongation of telogen increases the proportion of vellus hairs on the scalp, further contributing to the AGA process.
- Most research and pharmaceutical development has focused on the role of androgens in AGA and hair follicle miniaturization, however, other factors such as stem cell quiescence may play a role in telogen arrest.

- **New discoveries in AGA**

- Inhibition of JAK-STAT signaling:
 - Initiates anagen hair growth in mice
 - Promotes hair elongation in humans and improves dermal papilla inductivity
 - Acts directly on activating hair follicle bulge stem cells, independent of androgens
 - Can induce anagen hair growth from telogen stage hairs, suggesting it may have efficacy in disorders of arrested telogen, such as AGA



Vitiligo





Background on Vitiligo: Market is Large, Has a Huge Social Impact and is Greatly Underserved

- Vitiligo is among the most common autoimmune diseases along with rheumatoid arthritis, celiac disease, lupus and psoriasis¹
- Vitiligo is considered the most frequently occurring depigmenting disorder²
- While the cause is not well understood, vitiligo is a condition in which the pigment producing cells of the skin (melanocytes) do not function or are absent. As a result, melanin (pigment) is absent and lighter patches of skin appear on various parts of the body.³

Market Opportunity

- The global market for vitiligo was estimated at \$1.4B in 2011 and is expected to reach \$2.7B by 2019⁴
- There are no approved treatments and the pipeline is considered to be weak. Most commonly used medications are generic, used off-label and considered average efficacy⁴
- Key unmet needs in medications include:
 - Novel mechanisms
 - Disease modifying characteristics
 - The ability to promote adequate levels of repigmentation
 - Improved safety⁴

Epidemiology

- 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
- A positive family history is reported in over 30% of sufferers⁶

Disease Burden

- The visual disfigurement of vitiligo leads to marked reduction in the physical functioning, psychological state, and social interactions among sufferers
- 75% of vitiligo sufferers believe that their appearance is moderately to severely intolerable
- Patients may feel embarrassment and experience fear of revealing the bodies, leading to a negative impact on their sexual relationships⁷

¹Roddick, J. Autoimmune Diseases. Healthline. 07.22.2015.

²Boniface K1, Taleb A, Seneschal J. New Insights Into Immune Mechanisms of Vitiligo. G Ital Dermatol Venereol. 2016 Feb;151(1):44-54. Epub 2015 Oct 29.

³Oakley, A. Vitiligo. DermnetNZ. 08.2015.

⁴ASDRReports. The Vitiligo Therapeutics Market is Expected to Show Moderate Growth up to 2019. 08.22.2012

⁵Picardo M., et al. Vitiligo. Nature Reviews Disease Primers 1. 08.04.2015.

⁶Fitzpatrick T., et al. Vitiligo Facts. American Vitiligo Research Foundation Inc.

⁷Basra M., et al. Burden of Skin Diseases. Expert Rev Pharmacoeconomics Outcomes Res. 2009;9(3):271-283.





Vitiligo: JAK Inhibitor proof-of concept case report

Tofacitinib Citrate for the Treatment of Vitiligo: A Pathogenesis-Directed Therapy

Brittany G. Craiglow, MD; Brett A. King, MD, PhD *JAMA Derm* 2015;151(10)1110-2



Baseline: numerous white macules & patches evident

A Before treatment



Post- 5 months of tx w/ Tofacitinib: repigmentation nearly complete.

B After treatment



Baseline: White macules and patches evident



Post tx :re-pigmentation

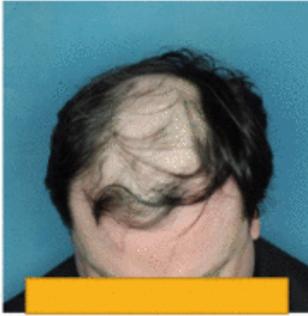




Patient with coexistent vitiligo and alopecia areata

Rapid skin repigmentation on oral ruxolitinib

Baseline



Week 4



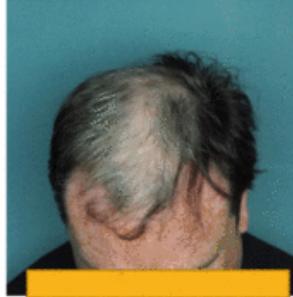
Week 8



Week 12



Week 16



Week 20



Harris et al, JAAD 2016





Near-Term Milestones

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





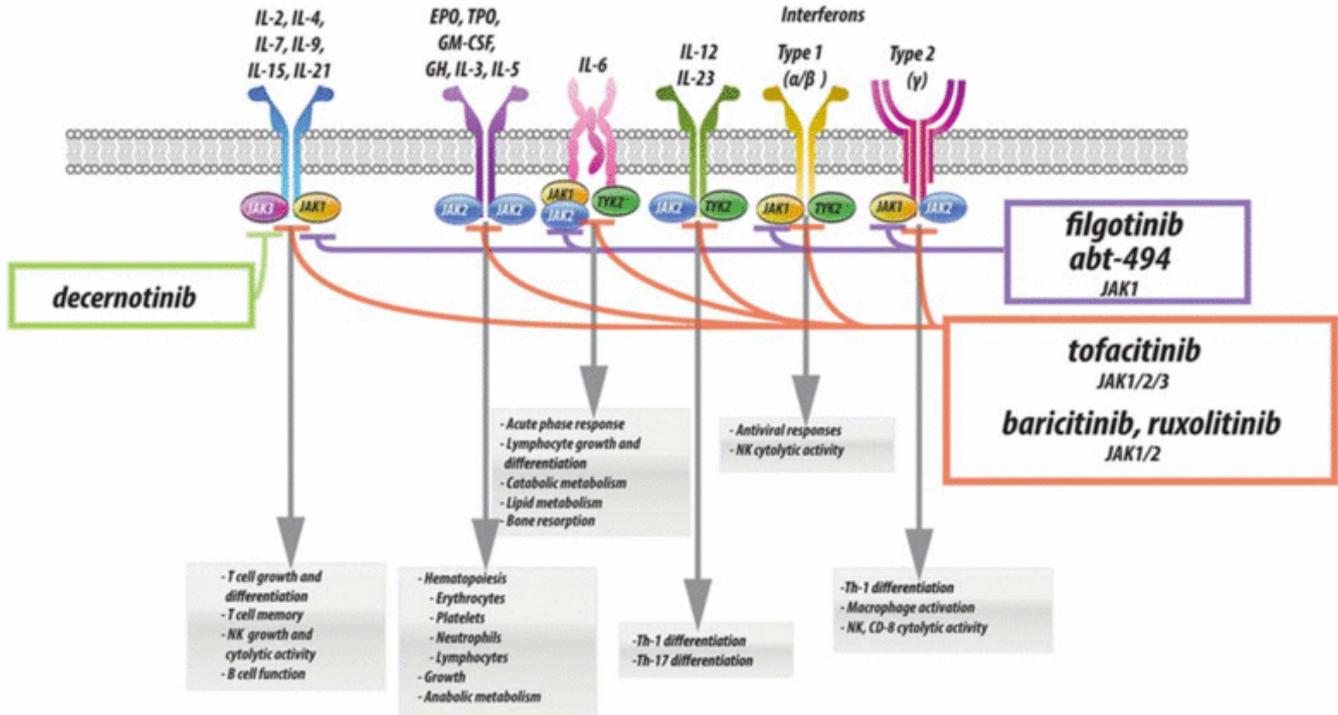
THANK YOU

www.aclaristx.com

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Mechanism of action of the JAK inhibitors

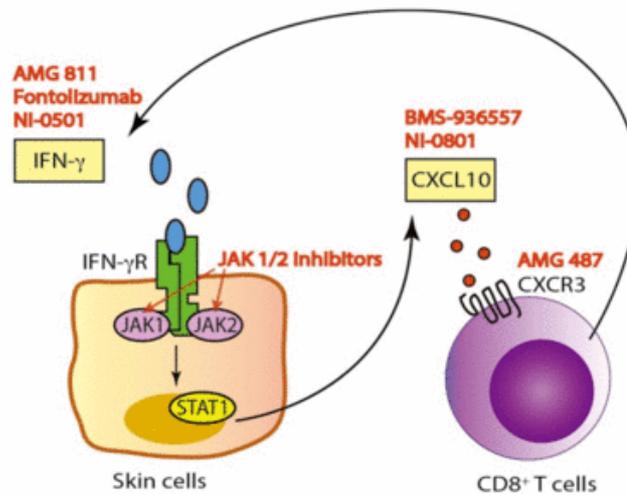


Adapted from Gadina, Arth & Rheum V68, no. 1 (2016) pp31-4





Interfering with the IFN- γ /CXCL10 pathway using JAK inhibitors to develop new targeted treatments for vitiligo



IFN- γ /CXCL10 signaling pathway in vitiligo. Binding of IFN- γ to its receptor (IFN- γ R) activates the JAK-STAT pathway and leads to CXCL10 secretion in the skin. CXCL10 promotes recruitment of additional autoreactive CD8⁺ T cells through its cognate receptor (CXCR3), which increases inflammation through a positive feedback loop. Compounds that have been developed to target each step are indicated in red.

From Rashighi and Harris, 2015



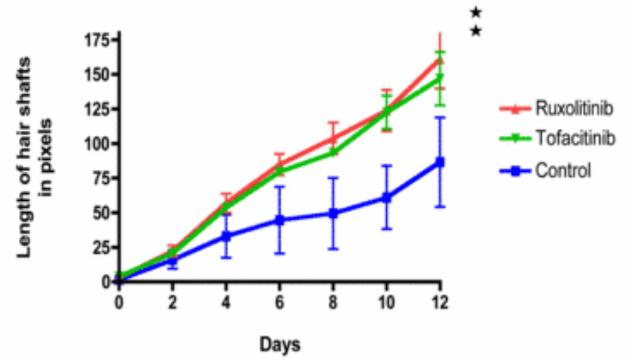
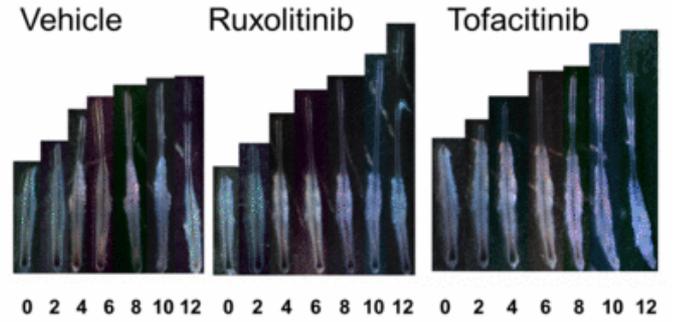
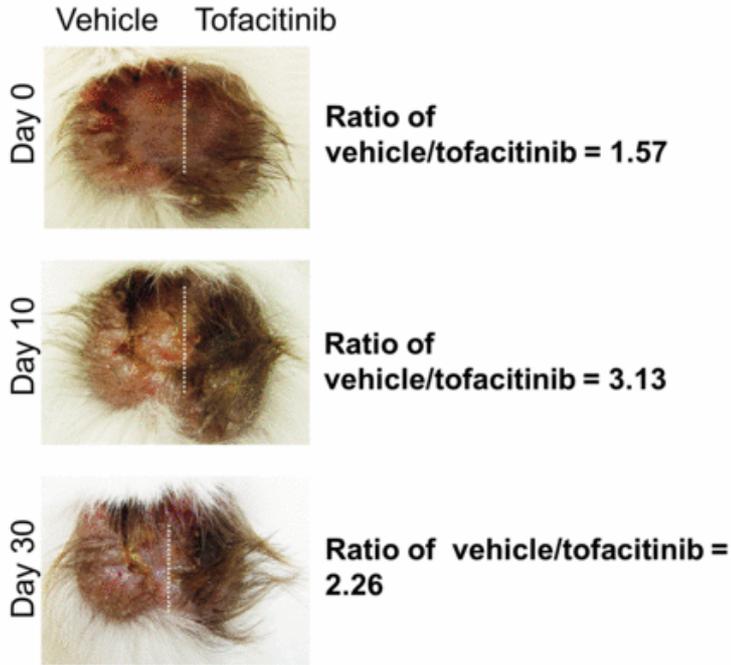


Androgenetic Alopecia scalp contains predominantly telogen hairs





Inhibition of JAK-STAT promotes human hair follicle growth





Inhibition of JAK-STAT promotes dermal papilla inductivity

