UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

May 10, 2021
Date of Report (Date of earliest event reported)

Forte Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38052**	**26-1243872**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1124 W Carson Street **MRL Building 3-320** **Torrance, California**	**90502**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (310) 618-6994

(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 $0.001 per share	**FBRX**	**The Nasdaq Stock Market LLC**

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 2.02. Financial Statements and Exhibits

On May 10, 2021, Forte Biosciences, Inc. (the "Company") issued a press release reporting its financial results for the first quarter ended March 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Current Report under Item 2.02 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

A copy of a slide presentation that the Company intends to present to investors is attached to this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein solely for purposes of this Item 7.01 disclosure.

The information furnished in this Current Report under Item 7.01 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 10, 2021
99.2	Investor Presentation
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.

Forte Biosciences, Inc.

Date: May 10, 2021

By: /s/ Paul Wagner
Paul Wagner
Chief Executive Officer

Exhibit 99.1

FORTE BIOSCIENCES, INC

FORTE BIOSCIENCES, INC. ANNOUNCES FIRST QUARTER 2021 RESULTS AND PROVIDES A GENERAL BUSINESS UPDATE

TORRANCE, CA – MAY 10, 2021 – Forte Biosciences, Inc. (www.fortebiorx.com) (NASDAQ: FBRX), a clinical-stage biopharmaceutical company announces first quarter 2021 results and provides a general business update on May 10, 2021.

"Forte has continued to make excellent progress in the fist quarter of 2021. As we have previously highlighted, our randomized clinical trial of FB-401 in atopic dermatitis patients 2 years of age and older, including adolescents and adults, completed enrollment. We expect to report the topline results from that trial in the third quarter of 2021. There is a significant unmet need for safe effective therapies, particularly for children suffering from atopic dermatitis and we are hopeful that FB-401 will address that need" said Paul Wagner, Ph.D., CEO of Forte Biosciences. "In addition to the operational progress, two more patents have now issued, bringing the total number of patents covering FB-401 and our process to eleven as we continue to expand the intellectual property protection."

First Quarter 2021 Results

First Quarter 2021 Business Highlights

In September 2020, Forte initiated a multi-center, placebo-controlled clinical trial of its lead product candidate, FB-401 which was expected to enroll approximately 124 pediatric, adolescent and adult atopic dermatitis subjects aged 2 years of age and older. Enrollment was completed in March 2021 with 154 subjects. Additional information about our Phase 2 trial can be found at ClinicalTrials.gov using the identifier NCT04504279.

Forte ended the first quarter of 2021 with approximately $54.8 million in cash and cash equivalents which Forte believes is sufficient to fund operations for at least the next 12 months. Cash utilization for the first quarter of 2021 was $4.0 million. Forte had approximately 13.5 million shares of common stock outstanding as of March 31, 2021.

First Quarter 2021 Operating Results

Research and development expenses were $3.3 million and $1.4 million for the three months ended March 31, 2021 and 2020, respectively. The increases in 2021 were primarily due to manufacturing, clinical, regulatory and other expenses, including non-cash stock-based compensation, as Forte continues to advance FB-401 through Phase 2 clinical trials.

General and administrative expenses were $1.4 million and $0.7 million for the three months ended March 31, 2021 and 2020, respectively. The increases in 2021 were primarily due to legal, professional, insurance and other expenses as a result of being a public company as well as increases in payroll and related expenses including non-cash stock-based compensation expense as we increased our headcount.

Losses per share were $0.36 and $0.97 for the three months ended March 31, 2021 and 2020, respectively.

Balance Sheets Data

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 54,762	$ 58,765
Prepaid expenses and other current assets	1,110	1,133
Total current assets	55,872	59,898
Property and equipment, net	83	97
Other assets	1,113	1,244
Total assets	$ 57,068	$ 61,239
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,206	$ 1,240
Accrued liabilities	1,164	1,019
Total current liabilities	2,370	2,259
Commitments and contingencies		
Series A Convertible Preferred Stock, $0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of March 31, 2021 (unaudited) and December 31, 2020; aggregate liquidation preference of $0 at March 31, 2021 (unaudited) and December 31, 2020	—	—
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 200,000,000 shares authorized as of March 31, 2021 (unaudited) and December 31, 2020; 13,511,716 and 12,830,598 shares issued and outstanding at March 31, 2021 (unaudited) and December 31, 2020, respectively	13	13
Additional paid-in capital	110,946	110,424
Accumulated deficit	(56,261)	(51,457)
Stockholders' equity:	54,698	58,980
Total liabilities, convertible preferred stock and stockholders' equity	$ 57,068	$ 61,239

Statements of Operations Data

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31, 2021	March 31, 2020
Operating expenses:		
Research and development	$ 3,322	$ 1,354
General and administrative	1,419	673
Total operating expenses	4,741	2,027
Loss from operations	(4,741)	(2,027)
Other expenses, net	(63)	(23)
Net loss	$ (4,804)	$ (2,050)
Per share information:		
Net loss per share - basic and diluted	$ (0.36)	$ (0.97)
Weighted average shares outstanding, basic and diluted	13,252,921	2,115,795

Additional detail on our financial results for the first quarter of 2021 can be found in Forte's Form 10-Q as filed with the SEC on May 10, 2021. You can also find more information in the investor relations section of our website at www.fortebiorx.com.

Conference Call and Webcast Information

Forte management will host a conference call and webcast on Wednesday, May 10th at 4.30 PM Eastern Time. Participants may access the call by dialing 877-705-6003 (Domestic) or 201-493-6725 (International). The conference ID number is: 13719507.

Participants may also access the webcast through the following link:
http://public.viavid.com/index.php?id=144805

A replay of the call will be available through May 17th from the investor relations section of Forte's website at https://www.fortebiorx.com/ or through the following link: http://public.viavid.com/index.php?id=144805

About Forte

Forte Biosciences, Inc. is a clinical-stage, biopharmaceutical company developing a live biotherapeutic, FB-401, for the treatment of inflammatory skin diseases. There is a significant unmet need for safe and effective therapies particularly for pediatric atopic dermatitis ("AD") patients. To date, a Phase 1/2a study has been completed with pediatric and adult patients 3 years of age and older, demonstrating compelling safety and activity in patients with mild, moderate and severe disease, across age groups including pediatrics and adults, and across key endpoints.

In September 2020, Forte initiated a multi-center, placebo-controlled clinical trial of FB-401 which has enrolled pediatric, adolescent and adult AD subjects aged 2 years of age and older. Additional information about our Phase 2 trial can be found at ClinicalTrials.gov using the identifier NCT04504279.

Forward Looking Statements

Forte cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negatives of these terms or other similar expressions. These statements are based on the Company's current beliefs and expectations. Forward looking statements include statements regarding Forte's beliefs, goals, intentions and expectations regarding the potential impact of Fast Track designation to accelerate development and approval of FB-401and achieve potential clinical development milestones in the future and the Phase 2 trial of FB-401. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Forte's ability to obtain sufficient additional capital to continue to advance Forte's product candidates and preclinical programs; uncertainties associated with the clinical development and regulatory approval of Forte's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the

course of developing and testing product candidates; risks associated with the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and risks related to the impact of the COVID-19 outbreak on Forte's operations, the biotechnology industry and the economy generally. Information on these and additional risks, uncertainties, and other information affecting Forte's business and operating results is contained in Forte's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 as filed with the Securities and Exchange Commission on May 10, 2021 and in its other filings with the Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Forte undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Contact:
Forte Biosciences, Inc.
Paul Wagner, CEO
investors@fortebiorx.com

LifeSci Advisors
Mike Moyer, Managing Director
617.308.4306
mmoyer@lifesciadvisors.com

Exhibit 99.2

FORTE BIOSCIENCES

TOPICAL LIVE BIOTHERAPEUTIC FOR THE TREATMENT OF INFLAMMATORY SKIN DISEASE

CORPORATE PRESENTATION

MAY 2021

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

- Certain statements contained in this presentation regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Act of 1995, known as the PSLRA. These include statements regarding management's intention, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Forte Biosciences, Inc. ("we", the "Company" or "Forte") undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as "anticipates," "believes," "plans," "expects," "projects," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.

- Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to the sufficiency of the Company's cash balance to fund the Company's activities, and the expectation with respect thereto; the business and prospects of the Company; Forte's plans to develop and potentially commercialize its product candidates, including FB-401; the timing of initiation of Forte's planned clinical trials; the timing of the availability of data from Forte's clinical trials; the timing of any planned investigational new drug application or new drug application; Forte's plans to research, develop and commercialize its current and future product candidates; Forte's ability to successfully enter into collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Forte's product candidates; Forte's commercialization, marketing and manufacturing capabilities and strategy; Forte's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Forte's competitors and its industry; the impact of government laws and regulations; Forte's ability to protect its intellectual property position; Forte's estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction; and the impact of COVID-19 on the Company, the Company's industry or the economy generally.

- The known risks and uncertainties are described in detail under the caption "Risk Factors" and elsewhere in the Company's Annual Report on Form 10-K for the year ending December 31, 2020 and subsequent filings with the Securities and Exchange Commision, Forward-looking statements included in this presentation are based on information available to Forte as of the date of this presentation. Accordingly, our actual results may materially differ from our current expectations, estimates and projections. Forte undertakes no obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation.

SUMMARY OF FORTE BIOSCIENCES:
FB-401 – *POTENTIAL FIRST-IN-CLASS TOPICAL LIVE BIOTHERAPEUTIC FOR THE TREATMENT OF INFLAMMATORY SKIN DISEASE*

LATE-STAGE CLINICAL ASSET	▪ Phase 2a trial in atopic dermatitis completed including pediatrics 3 years and older, FB-401 was well tolerated and demonstrated clinical improvement **Randomized** Phase 2 trial in adults and pediatrics 2 years and older with atopic dermatitis (AD) data readout expected in 3Q-2021
LARGE MARKET WITH UNMET NEED	▪ 10-20% of children in industrialized countries develop atopic dermatitis (AD) ▪ In the U.S., AD affects 17 million people (over 50% are children) ▪ Significant unmet need for safe and effective AD therapy for pediatrics
POTENTIAL FIRST-IN-CLASS TOPICAL LIVE BIOTHERAPEUTIC	▪ Clinical data demonstrates FB-401 was well-tolerated and active ▪ Phase 2a study, including pediatrics, demonstrates potential for acceptable safety profile and significant reduction in atopic dermatitis disease and pruritus, as well as control of S. aureus while tapering/eliminating steroid use
INTELLECTUAL PROPERTY	▪ Exclusive license to NIH-owned patent families as well as Forte owned IP. Coverage includes composition and method of use patents ▪ Patent coverage through at least 2037 (11 U.S. patents issued)
FINANCING / MANAGEMENT	▪ Experienced life science investor base ▪ Additional high-quality investors brought in with $46 m secondary offering in November 2020 ▪ Management team with significant drug development, innovation and corporate strategy experience

FORTE BIOSCIENCES: OVERVIEW OF FB-401

- **FB-401 drug product consists of 3 therapeutic bacterial strains of commensal Gram-negative *R. mucosa* specifically selected based on screening for impact on inflammatory skin disease parameters**

- **Topical application of the specifically selected therapeutic bacterial strains of *R. mucosa* drug product:**
  - Drives immune pathways that are defective
  - Suppresses Staphylococcus aureus growth
  - Improves skin barrier function

- **Clinical data demonstrates FB-401 live biotherapeutic therapy was well-tolerated and active in both adults and pediatric**
  - Phase 2a study, including pediatrics, well tolerated and demonstrated clinical improvement in atopic dermatitis disease and pruritus, as well as control of *S. aureus* while tapering/eliminating steroid use
  - Randomized Phase 2 trial readout in mid/3Q-2021

- **FDA granted Fast Track designation to FB-401 for the treatment of atopic dermatitis**

EXPERIENCED MANAGEMENT AND ADVISORY TEAMS

- Forte BioSciences team has extensive experience in microbial manufacturing, quality, regulatory and clinical development in dermatology

Paul Wagner, Ph.D. – CEO	CANbridge, PFEnex, Allianz Global Investors, PDL BioPharma, Lehman Brothers
Dan Burge, MD – Head of Clinical Development	Dermira, Trubion Pharmaceuticals, Amgen, Immunex
Tony Riley – Chief Financial Officer	Krystal, Aclara, Kosan
Hank Talbot, Ph.D. – Head of Process Development and Quality	Mycogen, Dow, PFEnex

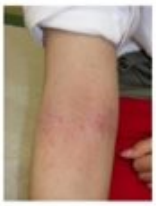
Scientific Advisory Board (SAB)

- Prof. Amy Paller, MD – Chair, Department of Dermatology Northwestern University Feinberg School of Medicine
- Prof. Lawrence Eichenfield, MD – Chief of Pediatric and Adolescent Dermatology at Rady Children's Hospital-San Diego, Editor in Chief of Pediatric Dermatology
- Prof. Eric Simpson, MD –Professor of Dermatology, Oregon Health & Science University, Portland
- Dr. Patricia Walker, MD, Ph.D. – Former CMO of Allergan Medical and Dermatology TA Head

ATOPIC DERMATITIS

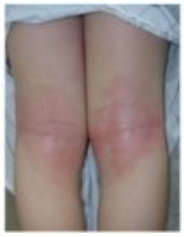
- Atopic dermatitis (AD) is characterized by itching, a scaly rash, dry skin, and cutaneous sensitization to allergens. The underlying pathology of AD consists of a triad of defective skin barrier function, susceptibility to *Staphylococcus aureus* skin infection, and immune imbalance (overactive adaptive immunity in lieu of innate immunity)
- 10-20% of children in industrialized countries develop atopic dermatitis with increasing incidence. 80% of children with severe disease continue to have lifelong exacerbations
- There is currently no cure for AD
- In the US, the prevalence of atopic dermatitis is approximately 17 million
  - More than half of that prevalence is pediatric (<17 years old)
  - Treatment options for pediatrics are very limited

Affects flexural areas of neck, elbows, knees, wrists, and ankles



Lichenified, erythematous plaques behind the knees

Erythematous, excoriated papules with overlying crust in the antecubital fossa



Erythematous ill-defined patches with overlying scale and erosions on her cheeks

FDA Pediatric Subcommittee October 29-30, 2003
American Academy of Dermatology

SKIN MICROBIOME

The skin is a complex barrier organ characterized by symbiotic relationship between microbial communities and host tissue via complex signals provided by the innate and the adaptive immune systems

Exposure to various endogenous and exogenous factors impact the system balance potentially leading to inflammatory skin conditions comprising infections, allergies or autoimmune diseases

Researchers in microbiology and dermatology identified and characterized the microorganisms present on the skin, to evaluate the bacterial diversity and their relative abundance and to understand how microbial diversity may contribute to skin health and dermatological conditions

Recent work has revealed that the skin microbiome is significantly different between healthy controls and patients with AD and that symptoms are associated with a loss of commensal diversity

Dreno et al, European Academy of Dermatology and Venerology 2016, 30, 2038-2047
Kong HH et al. *Genome research.* 2012;22(5):850-859

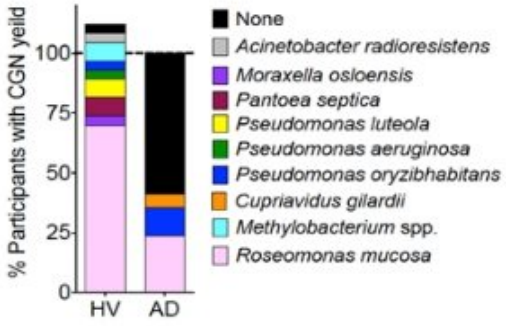
SKIN MICROBIOME DIFFERENCES IN ATOPIC DERMATITIS

Genetic-based microbiome identification revealed significant differences in the Gram-negative skin biome between atopic dermatitis (AD) patients and healthy controls (HV)

NIH (Myles et. al.) identified substantial differences in the gram-negative microbiome present on the skin of AD patients and healthy volunteers

The predominant species of skin commensal Gram-negative bacteria (CGN) in HV found to be *Roseomonas mucosa*

Over 50% of AD patients did not have any culturable Gram-negative flora, consistent with DNA-based analysis



Myles IA, Williams KW, Reckhow JD, et al. *JCI Insight*. 2016;1(10)
Kong HH et al. *Genome research*. 2012;22(5):850-859

MECHANISM OF FB-401

Extensive preclinical work by Forte in collaboration with NIH, investigating the activity of FB-401 has demonstrated:

1) FB-401 activates tissue repair and anti-inflammation pathways in keratinocytes, dendritic cells and fibroblasts
    1) Gene sequencing of the FB-401 strains and mRNAseq highlights the activation of TLR5, TNFR and CXCR2 (IL-8 signaling)

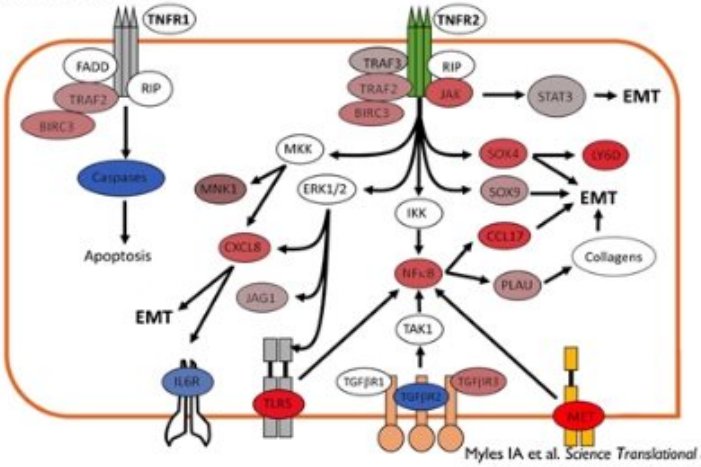
2) FB-401 inhibits *S. aureus* through metabolites produced by the 3 strains of *R. mucosa*
    1) The 3 strains of *R mucosa* were specifically selected based on their ability to suppress different strains of S aureus including methicillin resistant *S. aureus* (MRSA)
    2) Phosphatidylcholine and phosphatidylethanolamine metabolites produced by FB-401 suppress *S. aureus*

MULTIPLEX GENE PATHWAY ANALYSIS (RNASEQ): FB-401 ACTIVATES TISSUE REPAIR/ANTI-INFLAMMATION PATHWAYS

Gene	FB	ESC	KC	DC
GPR(IN3	2.76			
TLR5	2.30			
LY6D	1.99			
SOX9	0.46			
IL6R	-0.33			
CYP27b1	-0.78			3.22
CXCL8	-1.39		3.25	6.96
GSTM1	-1.29			
SP3B3		1.39		
MKNK2		1.38		-0.47
SOX4		1.24		0.61
UAP1		-0.91		
RAP1GDS1		-1.40		
WDR26		-1.41		
AC013271.3			2.88	
FIRRE			2.43	
GPCIML			2.29	
RP11-263C10.5			2.23	
GRAMD1B			1.97	
AC009336.24			1.66	
RP4-625F18.2			1.58	
BIRC3			0.83	4.06
DACT2			-1.56	
RTL1			-2.76	
CM89-7SA1.1			-2.99	
CCL15				8.40
CCL20				7.78
TNFAIP6				7.34
CXCL5				7.31
WNT5A				5.41
GJC2				2.30
PNPLA1				2.27
JAM2				2.23
NEURL2				2.01
CD200R1				-2.01
PRUNE2				-2.62
GCOM1				-3.09
RP4-594I4				-3.43

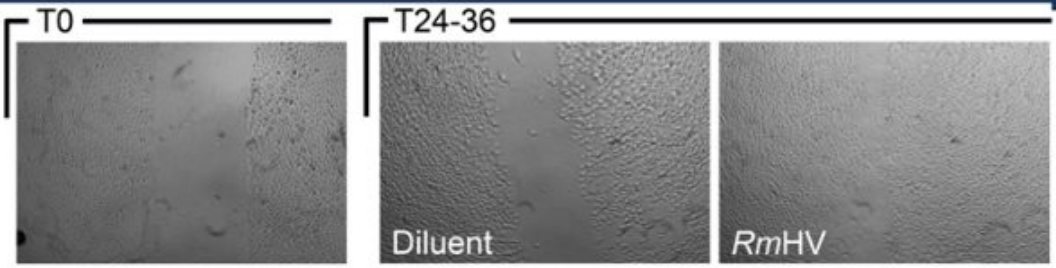
Skin Fibroblast (FB), keratinocyte (KC), Embryonic Stem cell (ESC) and Dendritic cell (DC)

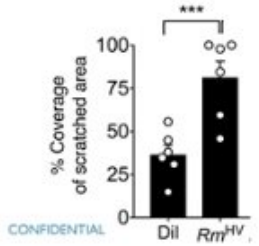
Fibroblast, keratinocyte, embryonic stem cell and dendritic cell demonstrate tissue repair pathway activation following exposure to FB-401 including TLR5, TNFR and CXCR2 driving epithelial to mesenchymal transition (EMT) tissue repair/anti-inflammation



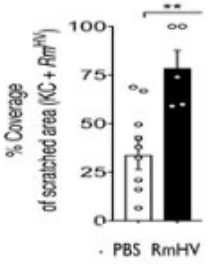
Myles IA et al. *Science Translational Medicine*. 2020; 12

FIBROBLAST AND KERATINOCYTE SCRATCH MODELS CONFIRM TISSUE REPAIR THROUGH TLR5 PATHWAY ACTIVATION BY FB-401



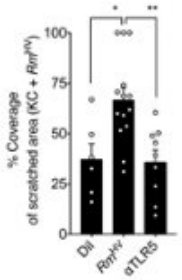


FB Coverage



KC Coverage

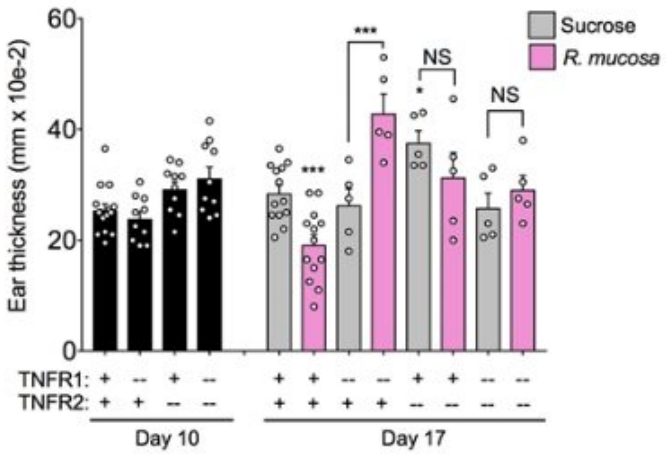
Scratch model for both keratinocytes and fibroblasts demonstrates tissue repair by FB-401



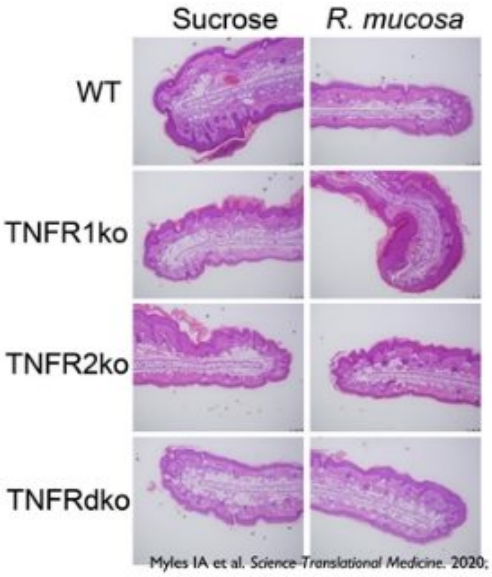
Blocking TLR5 (anti-TLR5 antibody) prevents tissue repair by FB-401

Myles IA et al. *Science Translational Medicine*. 2020; 12

TNFR KNOCK OUT MOUSE MODELS CONFIRMS RESPONSE TO FB-401 IS DEPENDENT ON TNFR SIGNALING

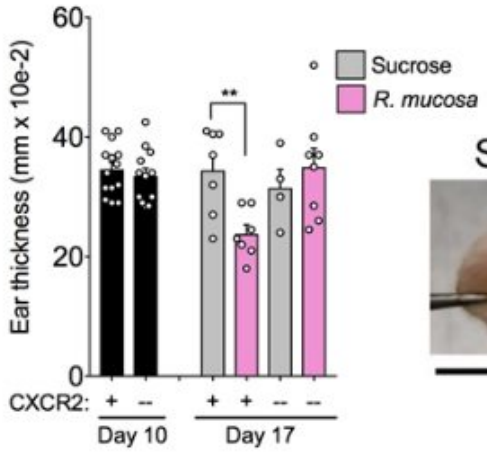


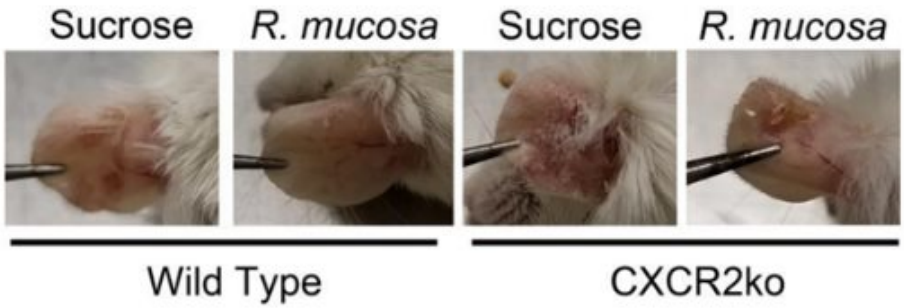
- TNFR wild type mice demonstrate atopic dermatitis activity of FB-401
- TNFR knockout inhibits FB-401 activity



Myles IA et al. *Science Translational Medicine*. 2020; 12

CXCR2 KNOCK OUT MOUSE MODEL DEMONSTRATES RESPONSE TO FB-401 IS DEPENDENT ON IL-8 SIGNALING





- CXCR2 wild type mice demonstrate atopic dermatitis activity of FB-401
- CXCR2 knockout inhibits FB-401 activity

PHASE 2A FIRST HUMAN STUDY OF FB-401 - CUTANEOUS LIVE BIOTHERAPEUTIC FOR THE TREATMENT OF ATOPIC DERMATITIS


• Your kit should have Two (2) items per treatment

Drug product: FB-401 (3 specifically selected therapeutic R. mucosa strains) lyophilized and reconstituted with sterile water in single-use, self-administered spray

Design: Phase 1/2a enrolled 2 cohorts:

- Initial cohort enrolled 10 adult atopic dermatitis patients 18 years and older
- Following positive safety assessment from cohort 1, the second cohort of 20 pediatric patients was enrolled

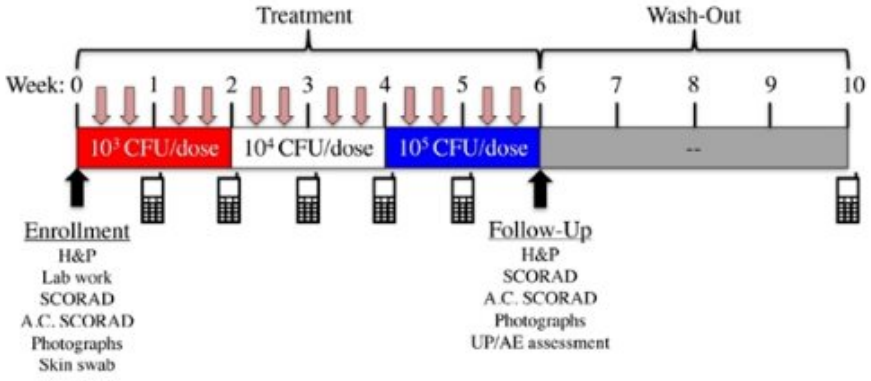
Primary Objective: To evaluate the safety and activity of *R mucosa* as a live biotherapeutic for treatment of AD

Secondary Objective: To evaluate the effect of *R mucosa* live biotherapy on quality of life of participants with AD

Exploratory Objectives

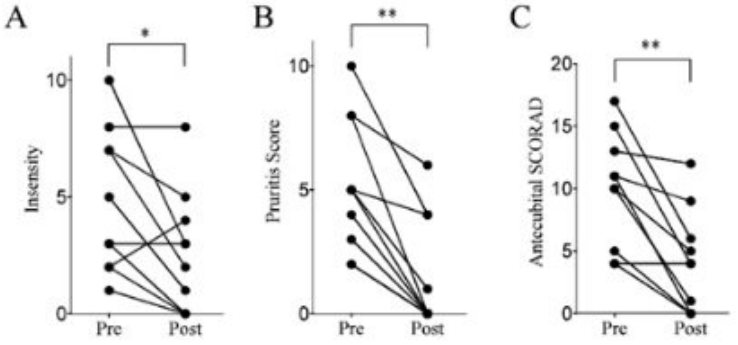
- Measure trans epidermal water loss (TEWL)
- Characterize changes to total and specific IgE
- Evaluate potential changes to pre-diagnosed asthma and/or food allergies
- Evaluate incidence of S aureus infections that require treatment
- Persistence of R mucosa colonization after treatment

COHORT 1 COMPLETED TREATMENT OF 10 ADULTS WITH AD



Ten adult AD patients ages 18 years and older were treated in 2-week intervals with 10^3, 10^4, and then 10^5 CFU of *R mucosa* twice per week (BIW) for a total of 6 weeks

STATISTICALLY SIGNIFICANT, DOSE-DEPENDENT IMPROVEMENTS OBSERVED IN ADULT COHORT OF PHASE 1/2a STUDY



(A) Intensity of AD disease was measured in a blinded manner using SCORAD measures of dryness, redness, lichenification, excoriation, crusting and edema (0-3 scale for each measure)

(B) Subjective pruritus reported by the patient on 0-10 scale

(C) Antecubital-specific SCORAD (blinded) assessed antecubital region by summing local intensity and pruritic scores

* $p<0.05$ ** $p<0.01$

Only treated areas responded. No AD lesions that were untreated resolved over the course of the study

Results from Cohort 1 indicate that six patients responded (60%) with mean improvement of 85%, one patient reported partial response with 44% improvement and three were non responders with 9% mean improvement

Myles et al, JCI Insight, 2018;3(9):e120608

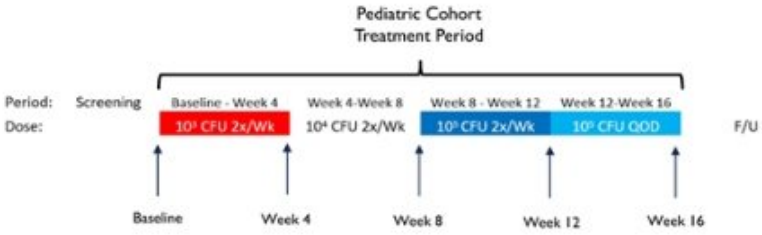
COHORT 2: FB-401 TREATMENT OF 20 CHILDREN WITH AD

20 pediatric/adolescent patients with active AD:

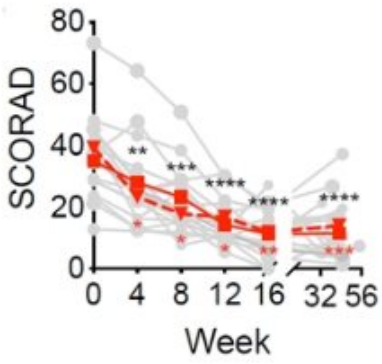
- First 5, ages 7-17
- Remainder, ages 3-17
- Baseline SCORAD >10

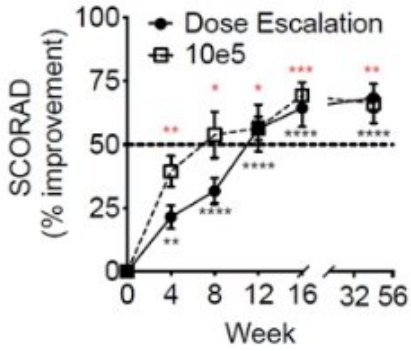
Design:

- Treat AD-involved skin with FB-401
  - 10^3 CFU BIW for 4 weeks
  - 10^4 CFU BIW for 4 weeks
  - 10^5 CFU BIW for 4 weeks
  - 10^5 CFU QOD for 4 weeks
- Efficacy assessments at baseline and Q4W
- SCORAD, pruritus, EASI (%, -50,-75,-90) TEWL, FDLQI, CDLQI
- Microbiome assessment
- Adverse events throughout and at F/U



PEDIATRIC PATIENT DATA SHOWS SIGNIFICANT ACTIVITY – TREATMENT THROUGH W16, FOLLOW UP 6 M AFTER TREATMENT COMPLETION





Dotted lines are data from patients that went direct to 10^5
Solid lines are dose escalation patients

* p<0.05
** P<0.01
*** p<0.001
**** p<0.0001

Average Response

	N	*Ave baseline SCORAD*	*Responder*	*%*	*All*	*Responders*
SCORAD (50% improvement)	20	36.1	17	85.0%	65.6%	73.2%

Myles IA et al. *Science Translational Medicine*. 2020; 12

PRURITIS (ITCH) SIGNIFICANTLY IMPROVED OVER COURSE OF THERAPY

Pruritus Measures	Part 2A N=15	Part 2B N=5	Total N=20
Mean baseline pruritus score	6.4	7.1	6.6
Mean Week 16 pruritus score	2.3	3.4	2.6
Mean % improvement	59.7%	51.0%	57.6%

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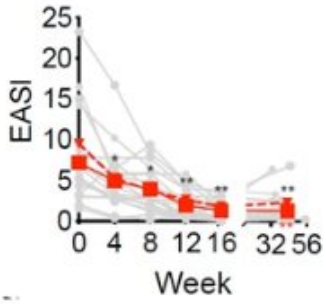
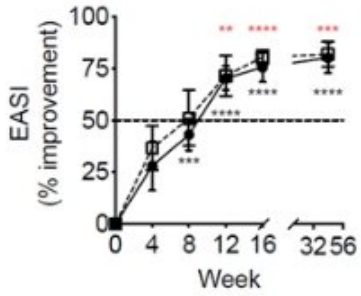
PEDIATRIC PATIENT EASI EFFICACY DATA SHOWS SIGNIFICANT ACTIVITY





- Dotted lines are data from patients that went direct to 10^5
- Solid lines are dose escalation patients

* p<0.05
** P<0.01
*** p<0.001
**** p<0.0001

EASI Severity
Mild<7
Moderate 7-21
Severe>21

	N	Ave baseline EASI	Responders	%	Average Response All	Average Response Responders
EASI-50	20	7.8	18	90.0%	76.8%	83.6%

	N	Ave baseline EASI	Responders	%
EASI-75	20	7.8	14	70.0%

	N	Ave baseline EASI	Responders	%
EASI-90	20	7.8	6	30.0%

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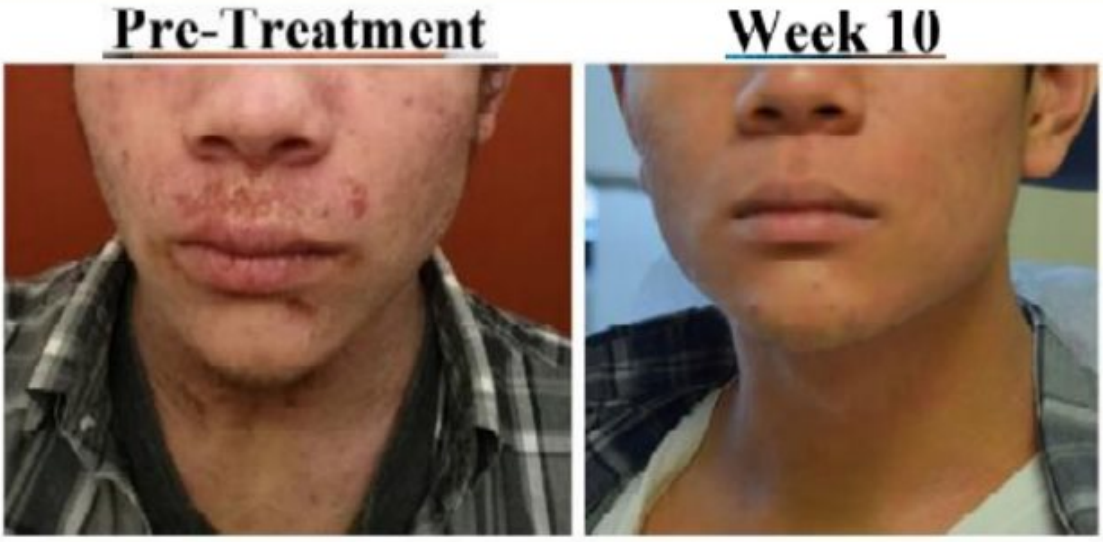
PEDIATRIC PATIENT EFFICACY DATA SHOWS SIGNIFICANT ACTIVITY ACROSS DISEASE SEVERITY

	Mild Disease EASI=<7 at baseline N=11	Moderate/Severe Disease EASI>=7 at baseline N=9	Trial Protocol EASI =>5 at baseline N=14	Total N=20
EASI 50	81.8% (9/11)	100% (9/9)	100% (14/14)	90% (18/20)
EASI 75	54.5% (6/11)	88.9% (8/9)	78.6% (11/14)	70% (14/20)
EASI 90	27.2% (3/11)	33.3% (3/9)	35.7% (5/14)	30.0% (6/20)

TREATMENT WITH FB-401 DEMONSTRATES SIGNIFICANT IMPROVEMENT



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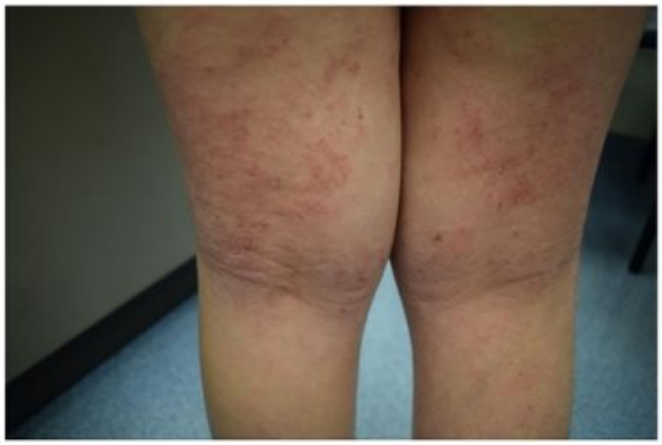
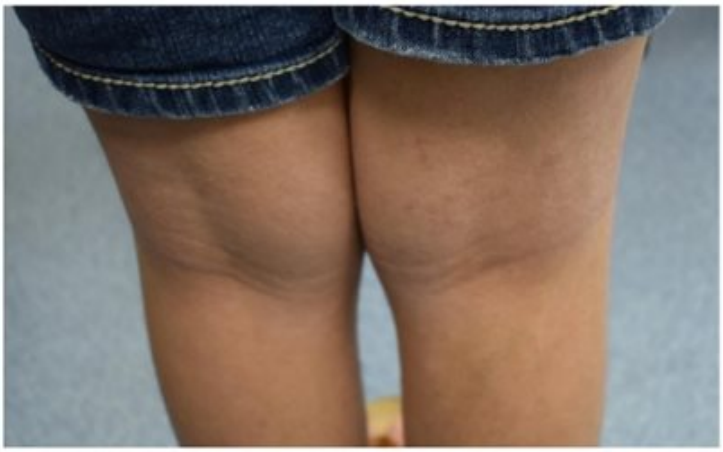
REPRESENTATIVE IMAGE OF IMPROVEMENT FOLLOWING THERAPY

Week 0



Week 16



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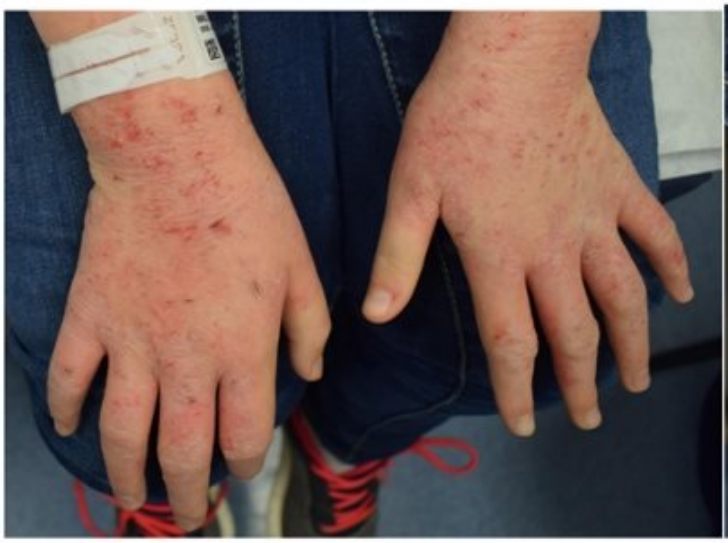
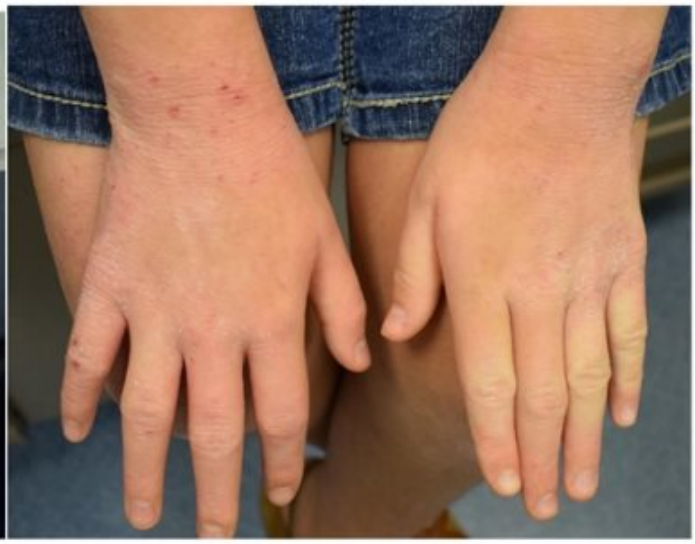
REPRESENTATIVE IMAGE OF IMPROVEMENT FOLLOWING THERAPY

Week 0

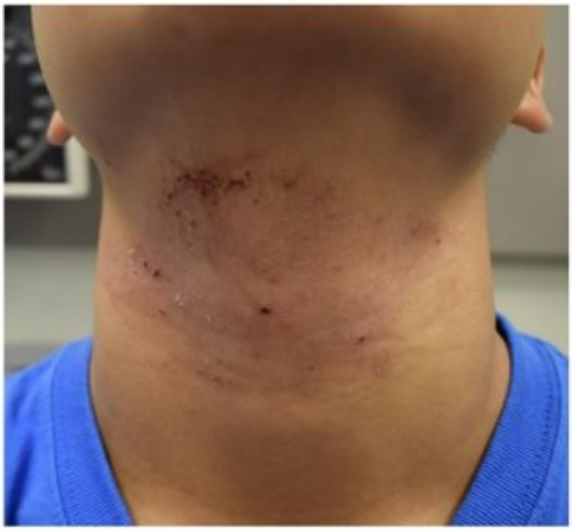


Week 16

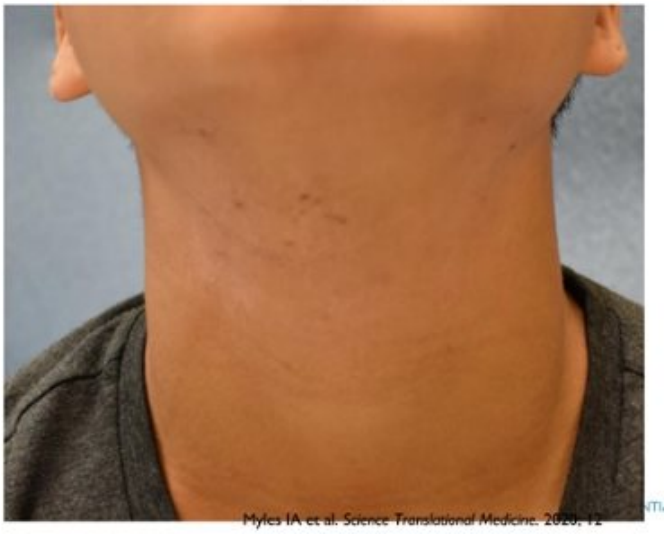


REPRESENTATIVE IMAGE OF IMPROVEMENT FOLLOWING THERAPY

Week 0



Week 16



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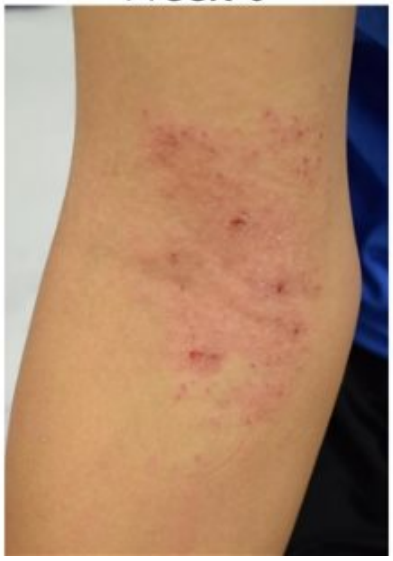
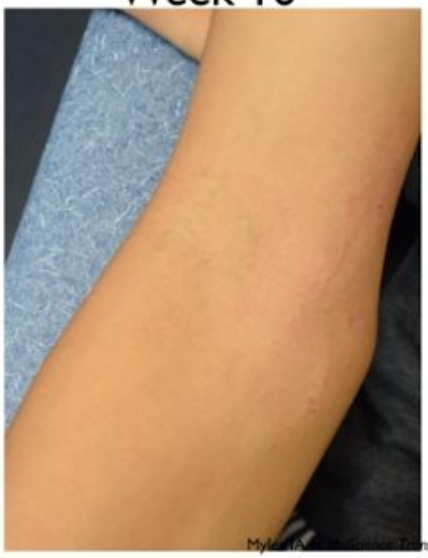
REPRESENTATIVE IMAGE OF IMPROVEMENT FOLLOWING THERAPY

Week 0



Week 16



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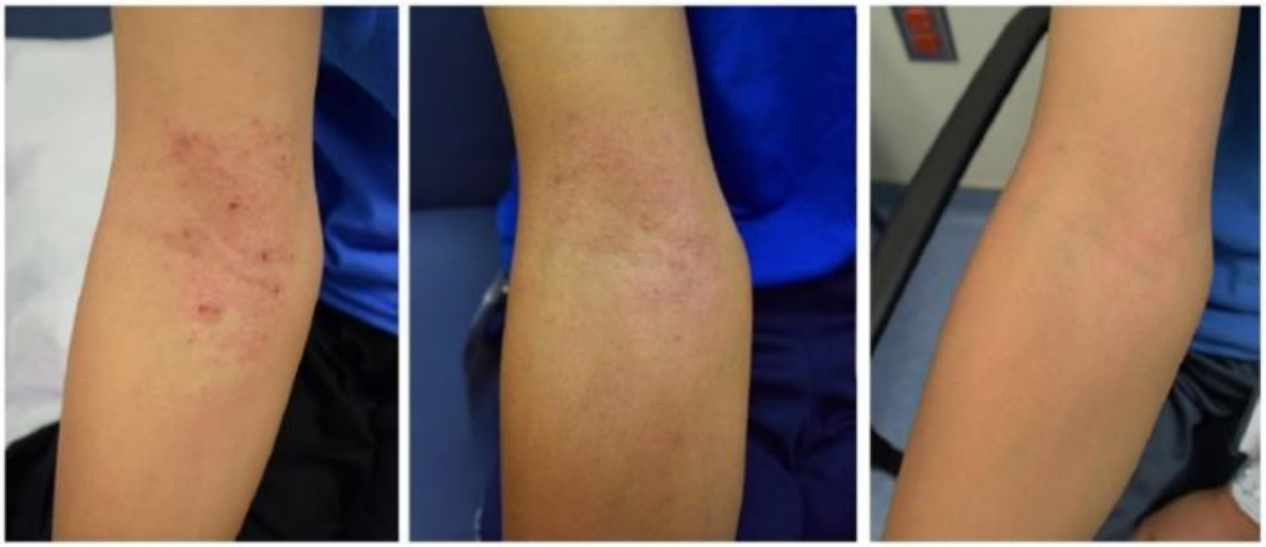
REPRESENTATIVE IMAGE OF IMPROVEMENT FOLLOWING THERAPY

Week 0 | Week 4 | Week 8



PLANNED FB-401 RANDOMIZED PHASE 2 STUDY

- Randomized, placebo-controlled, multi-center study
- Includes children (2 years and older), adolescents and adults with mild to moderate atopic dermatitis
- Subjects randomized 1:1 to receive FB-401 or placebo for 16 weeks
- Endpoints include Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), pruritus

INTELLECTUAL PROPERTY OVERVIEW – 11 ISSUED PATENTS TO DATE

- Exclusive license to NIH-owned patent family focused on treatment of AD with a consortia of Gram-negative bacteria from healthy donors
  - Patent coverage through at least 2037
  - 10 US patents issued
  - Entered in >15 Ex-US jurisdictions
- Company-owned IP directed to compositions for treatment of skin conditions associated with inflammation and skin barrier disruption
  - Broadly covers use of Gram-negative bacteria for treatment of atopic disorders
  - 1 US patent issued
  - Entered in 15 Ex-US jurisdictions

SUMMARY OF FORTE BIOSCIENCES:
FB-401 – *POTENTIAL FIRST-IN-CLASS TOPICAL LIVE BIOTHERAPEUTIC FOR THE TREATMENT OF INFLAMMATORY SKIN DISEASE*

LATE-STAGE CLINICAL ASSET	▪ Phase 2a trial in atopic dermatitis completed including pediatrics 3 years and older, FB-401 was well tolerated and demonstrated clinical improvement **Randomized** Phase 2 trial in adults and pediatrics 2 years and older with atopic dermatitis (AD) data readout expected 3Q-2021
LARGE MARKET WITH UNMET NEED	▪ 10-20% of children in industrialized countries develop atopic dermatitis (AD) ▪ In the U.S., AD affects 17 million people (over 50% are children) ▪ Significant unmet need for safe and effective AD therapy for pediatrics
POTENTIAL FIRST-IN-CLASS TOPICAL LIVE BIOTHERAPEUTIC	▪ Clinical data demonstrates FB-401 was well-tolerated and active ▪ Phase 2a study, including pediatrics, demonstrates potential for acceptable safety profile and significant reduction in atopic dermatitis disease and pruritus, as well as control of S. aureus while tapering/eliminating steroid use
INTELLECTUAL PROPERTY	▪ Exclusive license to NIH-owned patent families as well as Forte owned IP. Coverage includes composition and method of use patents ▪ Patent coverage through at least 2037 (11 U.S. patents issued)
FINANCING / MANAGEMENT	▪ Experienced life science investor base ▪ Additional high-quality investors brought in with $46 m secondary offering in November 2020 ▪ Management team with significant drug development, innovation and corporate strategy experience