

**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**

Date of Report (Date of earliest event reported): July 9, 2026

FORTE BIOSCIENCES, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38052
(Commission
File Number)

26-1243872
(IRS Employer
Identification No.)

3060 Pegasus Park Dr.
Building 6
Dallas, Texas
(Address of Principal Executive Offices)

75247
(Zip Code)

Registrant's Telephone Number, Including Area Code: (310) 618-6994

Not Applicable
(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 (see General Instruction A.2. below):

- 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, \$0.001 par value	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 7.01. Regulation FD Disclosure.

On July 9, 2026, Forte Biosciences, Inc. (the “Company”) issued a press release announcing positive results from the FB102 double-blind placebo-controlled Phase 1b study in vitiligo. As part of the press release, the Company announced that it would be hosting a conference call at 8:30 a.m. ET on July 9, 2026 to review the study results. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

All of the information furnished in this Item 7.01 (including Exhibit 99.1) 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

In connection with the conference call to review the Phase 1b study results, the Company will be reviewing the FB102 Phase 1B Vitiligo Data Presentation attached hereto as Exhibit 99.2, which is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release, dated July 9, 2026.
99.2	FB102 Phase 1B Vitiligo Data Presentation, July 2026.
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.

Date: July 9, 2026

FORTE BIOSCIENCES, INC.

By: /s/ Antony Riley
Antony Riley
Chief Financial Officer

FORTE BIOSCIENCES, INC

FB102 ACHIEVES STATISTICALLY SIGNIFICANT IMPROVEMENT IN VITILIGO AT WEEK 24 AFTER COMPLETION OF 12-WEEK TREATMENT PERIOD

Statistically Significant FB102 Benefit Observed By Day 64 and Continued through Week 24

FB102-Treated Subjects Continued Improving Through Week 24 After Completion of the 12-Week Treatment Period Supporting FB102 Mechanistic Modulation of Both IL-2- and IL-15-Dependent Pathogenic T-cell Biology while Preserving Regulatory T Cells

Forte will be Hosting a Conference Call to Discuss the Results at 8:30 am ET

DALLAS, TX –JULY 9, 2026 – Forte Biosciences, Inc. (www.fortebiorx.com) (NASDAQ: FBRX), a clinical-stage biopharmaceutical company focused on autoimmune and autoimmune-related diseases, today announced positive results from the FB102 double-blind placebo-controlled phase 1b study in vitiligo:

- FB102 achieved 29.6% mean FVASI improvement from baseline at week 24 (p-value = 0.020)
- Response to FB102 was observed early, with statistically significant improvements observed by the day 64 visit (p=0.023), continuing through week 24, after completion of the 12-week treatment period.
- FB102 achieved 43.2% mean FVASI improvement from baseline at week 24 (p-value = 0.006) in subjects with greater disease involvement having baseline FVASI ≥ 0.75 (approximately one-quarter of face depigmented), including:
 - FVASI50 = 58.8%
 - FVASI75 = 23.5%
- Responder endpoints in overall population achieved FVASI50 in 34.4% of FB102 treated subjects at week 24 with FVASI 75 achieved in 12.5% of FB102 treated subjects at week 24; this endpoint was impacted by one placebo FVASI75 responder, reinforcing the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.
- The majority of FB102 treated subjects continued to improve through week 24 after completion of the 12-week treatment period with an additional 8 percentage point FVASI improvement between week 12 and 24.
 - Among FB102-treated subjects with baseline FVASI ≥ 0.75 the mean FVASI improvement increased an additional 14 percentage points between week 12 and 24.
- 84% (27/32) of FB102 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subjects worsened during the 24 week period.
- FB102 continues to demonstrate a strong safety profile and compared favorably to placebo with only mild to moderate AEs.
- These independent centrally-reviewed, placebo-controlled data demonstrate statistically significant FB102 mean FVASI improvements from baseline, with progressive improvement and a strong responder profile through week 24 after completion of the 12-week treatment period.

Forte will be hosting a call at 8:30 am ET with Prof. David Rosmarin, MD, the Kampen-Norins scholar and Chair of the Department of Dermatology at Indiana University School of Medicine. The call can be accessed through the following link: <https://events.q4inc.com/attendee/542970326> and dial-in numbers: USA / International Toll +1 (646) 307-1963, USA - Toll-Free (800) 715-9871 and Conference ID: 2547706

The event and accompanying slides can also be accessed by visiting the investor relations section of the company's website at <https://www.fortebiorx.com/investor-relations/default.aspx>. An archived webcast will be available on the company's website following the event.

“With statistically significant placebo-controlled activity now demonstrated in vitiligo and the prior Phase 1b activity demonstrated in celiac disease, we look forward to the imminent readout from our ongoing Phase 2 celiac disease trial as the next important clinical catalyst for FB102,” said Paul Wagner, PhD, Chairman and CEO of Forte Biosciences. “Forte’s optimized FB102 blockade of CD122 was designed to modulate both IL-2– and IL-15–dependent pathogenic T-cell biology while preserving regulatory T cells, and clinical data to date support this profile. This may enable broader immune pathway modulation than IL-15 blockade alone and may avoid the regulatory T-cell modulation that can occur with overly potent CD122 inhibition. Data from this Phase 1b vitiligo study and from the previously reported Phase 1b trial in celiac disease reinforce the activity and broad potential for FB102.”

Summary of FB102 Phase 1b Vitiligo results

The FB102 double-blind placebo-controlled phase 1b vitiligo study enrolled 43 subjects 3:1 randomized with 11 on placebo and 32 on FB102. Forte enrolled 2 FB102 treatment cohorts in the trial including the 3 mg/kg maintenance cohort previously disclosed. There were 15 on FB102 in Cohort A and 17 in Cohort B. The primary endpoint of the study was mean percent FVASI improvement from baseline assessed by central-review.

The mean percent FVASI improvement from baseline in the ITT population was 29.6% for FB102 (n=32) compared to a mean deterioration of 16.2% for placebo (n=11), for a placebo-adjusted FB102 benefit of 45.8% (p=0.005). The group of 11 placebo subjects in the ITT population had one subject that was not part of the protocol-defined efficacy-evaluable population due to facial hair and that subject also experienced vitiligo progression during the study. The protocol defined efficacy-evaluable population excluded this one placebo subject (n=10) which also provides a more conservative assessment of the FB102 activity.

In the protocol-defined efficacy evaluable population (FB102: 32, PBO:10), FB102 achieved 29.6% mean FVASI improvement from baseline at week 24 vs 7.9% on placebo for a placebo-adjusted FB102 benefit of 21.7% (p-value = 0.020). Response to FB102 was observed early, with statistically significant improvement observed by the day 64 visit (p=0.023), continuing through week 24, after completion of the 12-week treatment period. In Cohort A, FB102 achieved a 28.8% mean FVASI improvement from baseline at week 24 compared to 7.9% for placebo for a placebo-adjusted FB102 benefit of 20.9% (p-value = 0.04) while in Cohort B, FB102 achieved a 30.4% mean FVASI improvement from baseline at week 24 compared to 7.9% for placebo for a placebo-adjusted FB102 benefit of 22.5% (p-value = 0.027).

In subjects with greater disease involvement having baseline FVASI ≥ 0.75 (approximately one-quarter of face depigmented), FB102 achieved 43.2% mean FVASI improvement from baseline at week 24 compared to 0.5% for placebo treated subjects for a placebo-adjusted FB102 benefit of 42.7% (p-value = 0.006) with 10 of 17 FB102 treated subjects achieving an FVASI50 (58.8%) and 4 of 17 achieving an FVASI75 (23.5%) compared to 0 of 4 achieving FVASI50 and FVASI 75 for placebo subjects (0%). In

the protocol-defined efficacy evaluable population 11 of 32 FB102 treated subjects achieved FVASI50 (34.4%) with 4 of 32 FB102 treated subjects achieving an FVASI 75 (12.5%) compared to 1 of 10 placebo subjects achieving FVASI50/75; the placebo FVASI75 responder reinforces the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.

FB102 treated subjects continued to improve through week 24 after completion of the 12-week treatment period with an additional 8 percentage point FVASI improvement between week 12 and 24. Among FB102-treated subjects with baseline FVASI ≥ 0.75 the mean FVASI improvement increased an additional 14 percentage points between week 12 and 24.

84% (27/32) FB102 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subject worsened during the 24 week period.

All AEs were mild/moderate with FB102 comparing favorably to placebo, and taken together with the phase 1b celiac study, FB102 continues to demonstrate a strong safety profile.

About Forte

Forte Biosciences, Inc. is a clinical-stage biopharmaceutical company that is advancing FB102, which is a proprietary anti-CD122 monoclonal antibody therapeutic candidate with potentially broad autoimmune and autoimmune-related indications.

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 the Company’s beliefs, goals, intentions and expectations regarding its product candidate, FB102 and the therapeutic and commercial market potential of FB102, expectations for patient enrollment and timing of clinical data readouts. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various 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 candidate, FB102; uncertainties associated with the clinical development and regulatory approval of Forte’s product candidate, FB102, including potential delays in the commencement, enrollment and completion of clinical trials, including the timing of the completion of the Company’s patient-based trials; the risk that results from preclinical and any interim result of our ongoing clinical trials may not be predictive of future results from clinical trials; the risk that, notwithstanding the positive data from the Phase 1b vitiligo study and from the previously reported Phase 1b trial in celiac disease, the ongoing Phase 2 celiac disease trial will not produce similar results; risks associated with the failure to realize any value from FB102 in light of inherent risks, expense and difficulties involved in successfully bringing product candidates to market; and additional risks, uncertainties, and other information affecting Forte’s business and operating results is contained in Forte’s Annual Report on Form 10-K for the year ended December 31, 2025 filed on March 31, 2026, Quarterly Report on Form 10-Q filed on May 11, 2026, 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.

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FORTE FBI02 PHASE I B VITILIGO DATA

JULY 9, 2026



CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

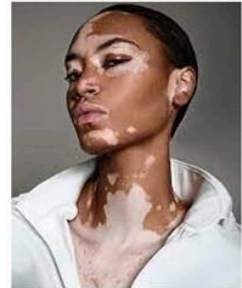
Certain statements contained in this presentation regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Act of 1995, known as the PSLRA. These include 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 business and prospects of the Company; Forte's plans to develop and potentially commercialize its product candidates, including FB102; the risk that results from preclinical studies and early-clinical trials, including any interim results of Forte's ongoing clinical trials, completed by Forte and third parties may not be predictive of results from later-stage clinical trials; the timing of initiation of Forte's planned clinical trials; expectations for patient enrollment and timing of clinical data readouts, any interim result of our ongoing 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 projections of the size of the market in certain indications for FB102; the clinical utility, potential benefits and market acceptance of Forte's product candidates; Forte's commercialization, marketing and manufacturing capabilities and strategy; 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; and the impact of global events on the Company, the Company's industry or the economy generally.

Forte has based these forward-looking statements largely on its current expectations and projections about future events and trends that it believes may affect its financial condition, results of operations, business strategy and financial needs, and these statements represent our views as of the date of this presentation. Forte may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Information regarding certain risks, uncertainties and assumptions may be found in Forte's filings with the Securities and Exchange Commission, including under the caption "Risk Factors" and elsewhere in Forte's Annual Report on Form 10-K for the year ending December 31, 2025, and other filings with the Securities and Exchange Commission. New risk factors emerge from time to time and it is not possible for Forte's management team to predict all risk factors or assess the impact of all factors on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. While Forte may elect to update these forward-looking statements at some point in the future, Forte specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this presentation.

LARGE UNMET NEED IN VITILIGO PRESENTS A SUBSTANTIAL MARKET OPPORTUNITY

- Vitiligo is an autoimmune disease of the skin driven by pathogenic T cells that kill melanocytes and create white spots
- Vitiligo results in sensitive skin (increasing likelihood of sun burns), eye abnormalities, emotional challenges, and leads to a predisposition of other autoimmune conditions.
- Market Opportunity
 - Prevalent in 0.76% of population – 2 Million in US
 - While JAK inhibitors have demonstrated efficacy in vitiligo, regulatory scrutiny of the JAK class including black box warnings has dampened enthusiasm for this class and as a result there remains a significant unmet need for safe and effective therapies for treating AA and vitiligo

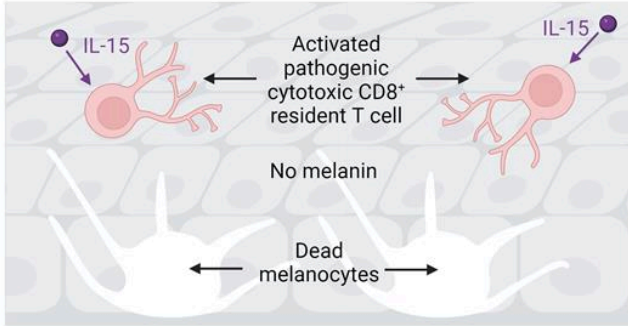


Amy Deanna / CoverGirl cosmetics

<https://my.clevelandclinic.org/health/diseases/12419-vitiligo>

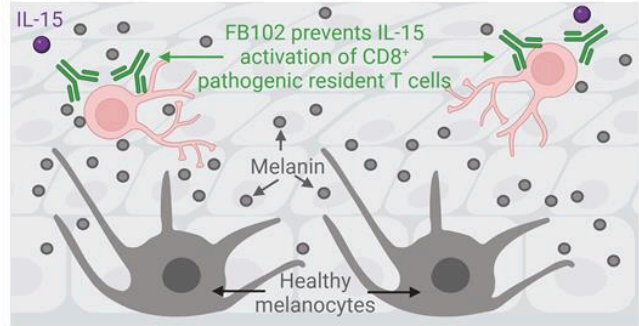
IL-15 ACTIVATION OF PATHOGENIC CD8+ T CELLS IN SKIN

Vitiligo patients have unpigmented skin due activated pathogenic T cells killing melanocytes



Tokura Front Immunol. 2021 PMID 33633737

FB102 blocks activation of pathogenic T cells, restoring melanocyte health and skin pigmentation



IL-2 THERAPY DRIVES VITILIGO

Enhanced Survival Associated with Vitiligo Expression during Maintenance Biotherapy for Metastatic Melanoma⁽¹⁾

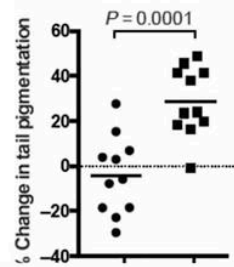
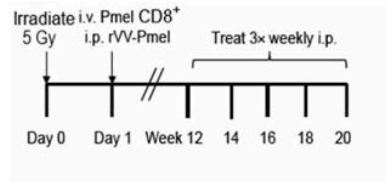
Peter D. Boasberg¹, Dave S.B. Hoon², Lawrence D. Piro¹, Maureen A. Martin¹, Akhide Fujimoto², Timothy S. Kristedja¹, Sandeep Bhachu¹, Xing Ye², Regina R. Deck¹ and Steven J. O'Day¹

In a large retrospective analysis of 374 metastatic melanoma patients treated with high-dose IL-2, a total of 84 patients (22%) developed treatment-related vitiligo, although in patients with objective clinical responses the incidence of vitiligo was nearly 50% ⁽²⁾

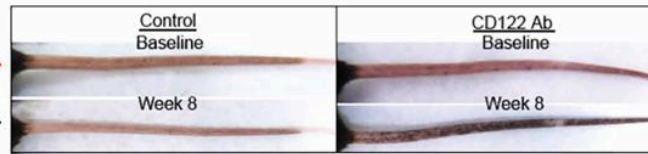
1) Journal of Investigative Derm. (2006) Vol 126
2) Journal of Clinical Oncology V19(15)

AN ANTI-CD122 ANTIBODY IS EFFECTIVE IN A MOUSE VITILIGO MODEL WITH ESTABLISHED DISEASE

Repigmentation study



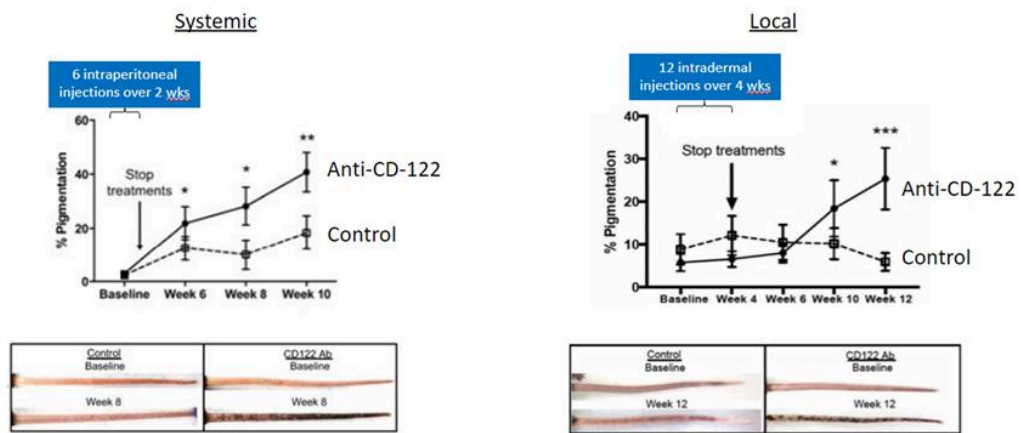
Melanin-reactive T cells eliminated pigment in tail →
Vehicle (control) treatment did not restore pigment →



← Melanin-reactive T cells eliminated pigment in tail
← Anti-CD122 treatment restored pigmentation

Richmond, 2012. Sci Transl Med. 2018 PMID 30021889

ANTI-CD122 IN A MOUSE MODEL OF VITILIGO: POTENTIAL OF DURABLE RESPONSE WITH INFREQUENT DOSING REGIMEN



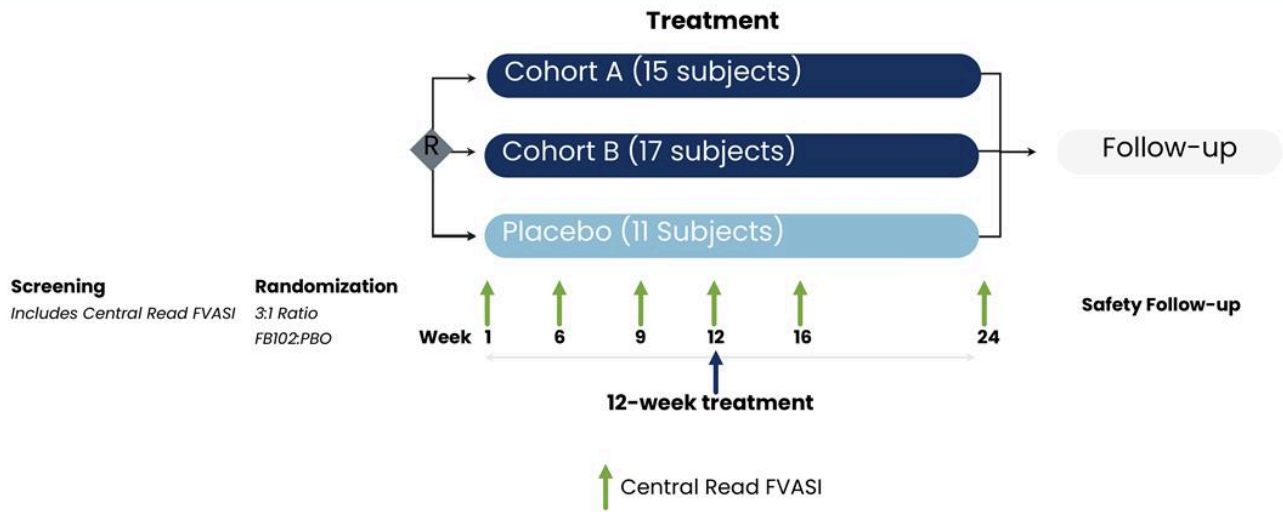
Note: anti-mouse CD122 (surrogate molecule) was used in these studies.



FBI02 PLACEBO CONTROLLED PHASE IB VITILIGO



FBI02-401 DOUBLE-BLIND PLACEBO-CONTROLLED PHASE 1B VITILIGO STUDY DESIGN



SUMMARY OF FBI02 PHASE I b VITILIGO STUDY

- The FBI02 phase I b double-blind placebo-controlled vitiligo study enrolled 43 subjects 3:1 randomized with 11 on placebo and 32 on FBI02.
 - The primary endpoint of the study was mean percent FVASI improvement from baseline at week 24 as assessed by central-review
 - 12-week treatment with FBI02 or Placebo then observed through Week 24
 - Forte enrolled 2 FBI02 treatment cohorts in the trial including the 3 mg/kg maintenance cohort previously disclosed : FBI02 Cohort A (N=15) and FBI02 Cohort B (N=17)
 - 11 placebo subjects were in the ITT population
 - The protocol defined efficacy-evaluable population excluded one placebo subject (n=10) due to facial hair and that subject also experienced significant vitiligo progression during the study.
 - As a result, the protocol defined efficacy-evaluable placebo population (N=10) provides a more conservative assessment of the FBI02 activity.

ITT: STATISTICALLY SIGNIFICANT PRIMARY ENDPOINT OF FVASI WEEK 24 PERCENT IMPROVEMENT FROM BASELINE: INTENT TO TREAT (ITT) POPULATION

Week 24 Mean % Improvement	FB102	PBO (ITT: N=11)	PBO Adjusted	p-value
Cohort A (N=15)	28.8%	-16.2%	+45.0 pts	0.013
Cohort B (N=17)	30.4%	-16.2%	+46.6pts	0.009
FB102 (N=32)	29.6%	-16.2%	+45.8 pts	0.005

Intent to Treat placebo population includes 1 placebo subject that was excluded from the efficacy evaluable population. (ITT PBO n=11). The protocol defined efficacy-evaluable (EE) population excluded this one placebo subject due to facial hair (EE PBO n=10). That placebo subject also had worsening vitiligo. As a result, the EE PBO group provides a more conservative assessment of the FB102 activity.

EE: STATISTICALLY SIGNIFICANT PRIMARY ENDPOINT OF FVASI WEEK 24 PERCENT IMPROVEMENT FROM BASELINE: PROTOCOL-DEFINED EFFICACY EVALUABLE (EE) POPULATION

Week 24 Mean % Improvement	FB102	PBO (EE: N=10)	PBO Adjusted	p-value
Cohort A (N=15)	28.8%	7.9%	+20.9 pts	0.040
Cohort B (N=17)	30.4%	7.9%	+22.5pts	0.027
FB102 (N=32)	29.6%	7.9%	+21.7 pts	0.020

The protocol defined efficacy-evaluable (EE) population excluded one placebo subject due to facial hair (EE PBO n=10). That placebo subject also had worsening vitiligo.

As a result, the EE PBO group provides a more conservative assessment of the FB102 activity.

STATISTICAL SIGNIFICANCE ACHIEVED BY DAY 64 AND CONTINUED THROUGH 24 WEEKS WITH 12-WEEK TREATMENT

	FVASI mean % improvement	FB102 (N=32)	PBO (N=10)	PBO-Adjusted	p-value
	Week 6	5.6%	0.3%	+5.3 pts	0.059
	Week 9 (Day 64)	14.4%	1.9%	+12.5 pts	0.023
End of treatment period →	Week 12	21.9%	5.4%	+16.5 pts	0.028
	Week 16	28.6%	8.2%	+20.4 pts	0.023
	Week 24	29.6%	7.9%	+21.7 pts	0.020

FB102 activity observed at day 64, with statistically significant 12.5 percentage point separation from placebo (p=0.023) and continued through week 24, after 12-week treatment period.

84% (27/32) FB102 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subject worsened during the 24-week period.

SUBJECTS WITH GREATER BASELINE VITILIGO INVOLVEMENT OUTPERFORMED ON FB102 (BASELINE FVASI ≥ 0.75)

	FVASI mean % improvement	FB102 (N=17)	PBO (N=4)	PBO-Adjusted	p-value
	Week 6	7.2%	0.5%	+6.7 pts	0.167
End of treatment period	Week 9 (Day 64)	19.4%	1.2%	+18.2 pts	0.058
→	Week 12	29.6%	1.7%	+27.9 pts	0.033
	Week 16	40.2%	1.5%	+38.7 pts	0.010
	Week 24	43.2%	0.5%	+42.7 pts	0.006

FB102 demonstrated significant responses in subjects with more extensive disease with a 43% mean percent improvement from baseline at week 24 (P=0.006), underscoring robust FB102 disease activity.

- 0.75 baseline FVASI corresponds to 20-25% facial depigmentation.

FVASI IMPROVEMENT AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI Percent Improvement at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	34.0%	14.4%
Upadacitinib 11 mg	35.6%	14.4%
Povorcitinib 75 mg	29.4%	5.1%
Povorcitinib 45 mg	36.4%	5.1%
Ritlecitinib 50 mg	18.5%	-2.1%
Ritlecitinib 100/50 mg	21.2%	-2.1%
Oral JAK Range	21-36%	2-14%
FB102 (n=32)	29.6% (p=0.020)	7.9%
FB102 Baseline FVASI ≥ 0.75 (n=17)	43.2% (p=0.006)	0.5%

[Passeron T, et al. eClinicalMedicine. 2024](#)
[Pandya AG, et al. J Am Acad Dermatol. 2025](#)
[Ezzedine K, et al. J Am Acad Dermatol. 2023](#)

WEEK 24 FVASI50 AND FVASI75 DATA

Population	FVASI50 FB102	FVASI50 PBO	FVASI75 FB102	FVASI75 PBO
Protocol Defined Efficacy-evaluable	11/32 (34.4%)	1/10 (10.0%)	4/32 (12.5%)	1/10 (10.0%)
Baseline FVASI ≥ 0.75	10/17 (58.8%)	0/4 (0.0%)	4/17 (23.5%)	0/4 (0.0%)

FB102 achieved FVASI50 of 58.8% in FVASI ≥ 0.75 subjects and 34.4% in overall FB102 treated subjects at week 24

FB102 achieved FVASI75 of 23.5% in FVASI ≥ 0.75 subjects and 12.5% of overall FB102 treated subjects at week 24

Responder endpoint was impacted by one placebo FVASI75 responder, reinforcing the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.

FVASI50 AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI50 at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	39.5%	10.9%
Upadacitinib 11 mg	38.3%	10.9%
Povorcitinib 75 mg	23.8%	7.0%
Povorcitinib 45 mg	34.9%	7.0%
Ritlecitinib 50 mg	Not Reported	Not Reported
Ritlecitinib 100/50 mg	Not Reported	Not Reported
Oral JAK Range	23.8-39.5%	7-10.9%
FB102 (n=32)	34.4%	10.0%
FB102 baseline FVASI \geq 0.75 (n=17)	58.8%	0.0%

[Passeron T, et al. eClinicalMedicine. 2024](#)
[Pandya AG, et al. J Am Acad Dermatol. 2025](#)
[Ezzedine K, et al. J Am Acad Dermatol. 2023](#)

FVASI75 AT WEEK 24 VS COMPETITORS (PHASE 2 DATA)

F-VASI75 at Week 24		
Medication	Treatment	Placebo
Upadacitinib 22 mg	14.0%	2.2%
Upadacitinib 11 mg	19.1%	2.2%
Povorcitinib 75 mg	11.9%	2.3%
Povorcitinib 45 mg	14.0%	2.3%
Ritlecitinib 50 mg	7.7%	0.0%
Ritlecitinib 100/50 mg	8.5%	0.0%
Oral JAK Range	7.7-19.1%	0-2.3%
FB102 (n=32)	12.5%	10.0%
FB102 Baseline FVASI \geq 0.75 (n=17)	23.5%	0.0%

[Passeron T, et al. eClinicalMedicine. 2024](#)
[Pandya AG, et al. J Am Acad Dermatol. 2025](#)
[Ezzedine K, et al. J Am Acad Dermatol. 2023](#)

FBI02 RE-PIGMENTATION



Baseline
FVASI = 0.75



Week 12
FVASI = 0.20
73% improvement



Week 24
FVASI = 0.10
87% improvement

FBI02-401 CONTINUES TO DEMONSTRATE STRONG SAFETY PROFILE

Safety	FBI02	Placebo
≥1 TEAE	25/32 (78.1%)	9/11 (81.8%)
Mild (Grade 1)	23/32 (71.9%)	9/11 (81.8%)
Moderate (Grade 2)	18/32 (56.3%)	6/11 (54.5%)
Severe (≥ Grade 3)	0	0

FBI02 continues to demonstrate a strong safety profile and compared favorably to placebo with only mild to moderate AEs.

SUMMARY

In double-blind placebo-controlled study, FB102 demonstrated robust activity, with statistically significant improvement in vitiligo from baseline to week 24, statistically significant responses occurring early (day 64), robust responder analysis, and continuing improvement through week 24 after 12-week treatment period and continuing strong safety profile:

- FB102 achieved 29.6% mean FVASI improvement from baseline at week 24 (p-value = 0.020)
- Response to FB102 was observed early, with statistically significant improvements observed by the day 64 visit (p=0.023), continuing through week 24, after completion of the 12-week treatment period.
- FB102 achieved 43.2% mean FVASI improvement from baseline at week 24 (p-value = 0.006) in subjects with greater disease involvement having baseline FVASI ≥ 0.75 (approximately one-quarter of face fully depigmented), including:
 - FVASI50 = 58.8%
 - FVASI75 = 23.5%
- Responder endpoints in overall population achieved FVASI50 in 34.4% of FB102 treated subjects at week 24 with FVASI 75 achieved in 12.5% of FB102 treated subjects at week 24
 - Placebo responder reinforces the importance of randomized controlled studies and baseline severity when interpreting vitiligo responder endpoints.
- The majority of FB102 treated subjects continued to improve through week 24 after completion of the 12-week treatment period with an additional 8-14 percentage point FVASI improvement between week 12 and 24.
- 84% (27/32) of FB102 treated subjects improved from baseline to week 24 following the 12-week treatment period and 0% (0/32) worsened. 27% (3/11) of placebo subjects worsened during the 24 week period.
- FB102 continues to demonstrate a strong safety profile and compared favorably to placebo with only mild to moderate AEs.