

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): October 23, 2026

60 DEGREES PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of Incorporation)

001-41719

(Commission File Number)

45-2406880

(IRS Employer
Identification Number)

**1025 Connecticut Avenue NW Suite 1000,
Washington, D.C.**

(Address of registrant's principal executive office)

20036

(Zip code)

(202) 327-5422

(Registrant's telephone number, including area code)

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, par value \$0.0001 per share	SXTP	The Nasdaq Stock Market LLC
Warrants, each warrant to purchase one share of Common Stock	SXTPW	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 October 23, 2026, the Company updated its investor presentation, which it intends to use from time to time in meetings with investors, analysts and other members of the investment community. A copy of the updated investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished pursuant to 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, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements involve risks and uncertainties that could cause the Company’s actual results and financial position to differ materially. These risks and uncertainties include uncertainties associated with market conditions and other risks described under the heading “Risk Factors” in the Company’s SEC Filings on Form 10-K and Form 10-Q. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date hereof.

Item 9.01 Financial Statements and Exhibits

(a) Exhibits

Number	Description
99.1	60 Degrees Pharmaceuticals, Inc. Investor Presentation, dated October 23, 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.

60 DEGREES PHARMACEUTICALS, INC.

Date: October 23, 2026

By: /s/ Geoffrey Dow

Name: Geoffrey Dow

Title: Chief Executive Officer and President



Tafenoquine for Babesiosis

Progress across acute, relapsing and chronic disease

Geoffrey S. Dow, PhD
Chief Executive Officer

2026 ILADS Annual Scientific Conference
October 22–25, 2026 | Herndon, Virginia

Reframing Complex Disease: Pathways to Treatment

2026 update

A marketed antimalarial platform now has converging evidence across three clinical settings.

CHRONIC DIAGNOSTICS

RELAPSING DISEASE

HOSPITAL READOUT

Regulatory objective

A potential sNDA in 2027 — and a request for national-priority review.

Disclaimer and Forward-Looking Statements

DISCLAIMER. The information contained herein has been prepared to assist prospective investors in making their own evaluation of 60 Degrees Pharmaceuticals, Inc. (the “Company”) and does not purport to be all-inclusive or to contain all of the information a prospective or existing investor may desire. In all cases, interested parties will be expected to have conducted their own due diligence investigation regarding these and all other matters pertinent to investment in the Company. The Company makes no representation or warranty as to the accuracy or completeness of this information and shall not have any liability for any representations (expressed or implied) regarding information contained in, or for any omissions from, this information or any other written or oral communications transmitted to the recipient in the course of its evaluation of the Company. This presentation and contents herein are the exclusive property of the Company and may not be copied without the express prior written consent of the Company.

FORWARD-LOOKING STATEMENTS. This communication includes forward-looking statements based on the Company’s current expectations and projections about future events. All statements contained in this communication other than statements of historical fact, including any statements regarding our future operations, are forward-looking statements. The words “believe”, “may”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, “could”, “would”, “project”, “plan”, “potentially”, “likely” and similar expressions are intended to identify forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995.

Important factors that could cause our actual results and financial conditions to differ materially from those indicated in the forward-looking statements include, among others, the following: there is substantial doubt as to our ability to continue on a going-concern basis; we might not be eligible for Australian government research and development tax rebates; if we are not able to successfully develop, obtain FDA approval for, and otherwise provide for the commercialization of non-malaria-prevention indications for tafenoquine (ARAKODA or another regimen) or other product candidates in a timely manner, we may not be able to expand our business operations; we cannot guarantee our ability to conduct successful clinical trials; and we have no manufacturing capacity, which poses the risk of lengthy and costly delays in bringing products to market. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company’s filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC’s website. As a result of these matters, changes in fact, assumptions not being realized or other circumstances, actual results may differ materially from expected results discussed in this presentation.

In light of these risks, uncertainties and assumptions, you should not place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. Although we believe our expectations are based on reasonable assumptions, we can give no assurance that our expectations will materialize. Unless required by law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Disclaimer, Off-Label Use Statement & CME Goals

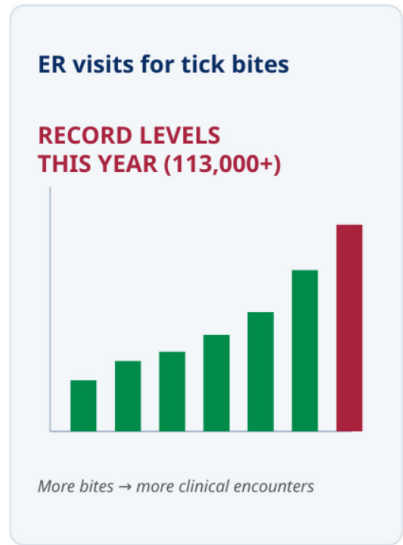
Speaker disclosure	I am an Officer, Director and Shareholder of 60 Degrees Pharmaceuticals, Inc. The Company has a commercial interest in tafenoquine for babesiosis.
Perspective	Opinions expressed are the speaker’s own and do not necessarily reflect those of 60 Degrees Pharmaceuticals or its stakeholders. I am not a health care provider.
Scope	This talk covers synthetic small-molecule therapeutics and molecular diagnostics.
Approved uses	Tafenoquine is FDA-approved for malaria prevention (ARAKODA) and single-dose radical cure of P. vivax malaria in combination with chloroquine (KRINTAFEL). Tafenoquine is not approved for any indication in Europe.
Safety information	The tafenoquine safety summary shown here is not complete. Clinicians should refer to the full ARAKODA Prescribing Information.

Tafenoquine has not been proven effective for treatment or prevention of babesiosis and is not approved by FDA or EMA for such indications.

Full ARAKODA Prescribing Information: www.arakoda.com

Ticks Transmit a Widening Set of Serious Diseases in the U.S.

Record tick-bite emergency room visits in 2026 underscore the rising need for targeted therapies.



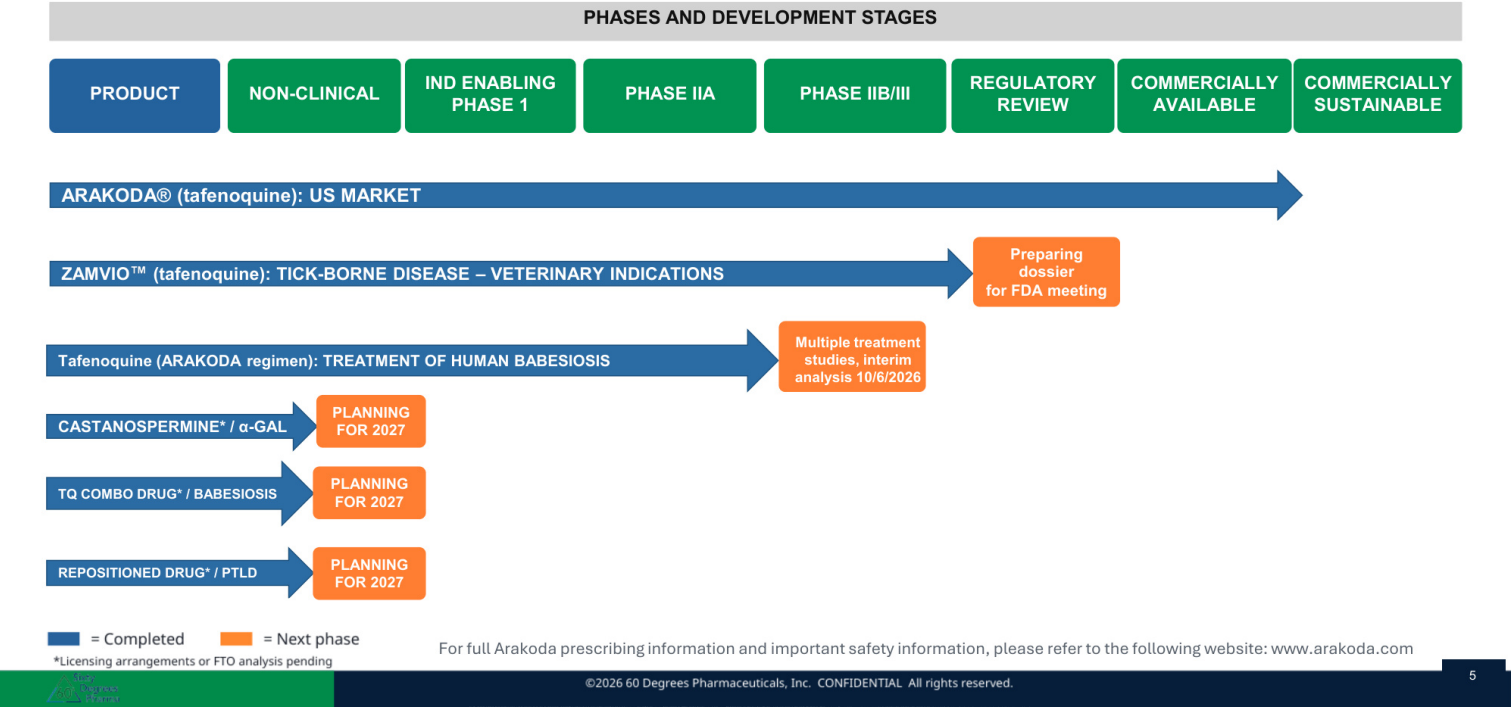
One bite can transmit multiple pathogens

Examples of diseases transmitted or associated with U.S. ticks

Lyme disease	Anaplasmosis
Relapsing fever	Ehrlichiosis
Rocky Mountain spotted fever	Babesiosis
Tularemia	Powassan virus
Alpha-gal syndrome	Bourbon / Heartland viruses
STARI	Colorado tick fever

- Bacterial
- Parasitic
- Viral
- Allergic syndrome

Portfolio October 2026



What Has Changed Since ILADS 2025?

Five developments now shape the tafenoquine program.

30**Hospital subjects
randomized**

Blinded follow-up completes in early January 2027; unblinding follows.

3**Expanded-access cures
confirmed**

The first three patients were NAT-negative after treatment; cases 4–5 are approaching disclosure.

45**Published cases
reconstructed**

A regimen-level analysis now tests duration, prior exposure and tafenoquine counterfactuals.

2/9**Genus-level molecular
screening signal**

Early chronic-study screening has not produced a species-specific *B. microti* signal.

SOI**CNPV request submitted**

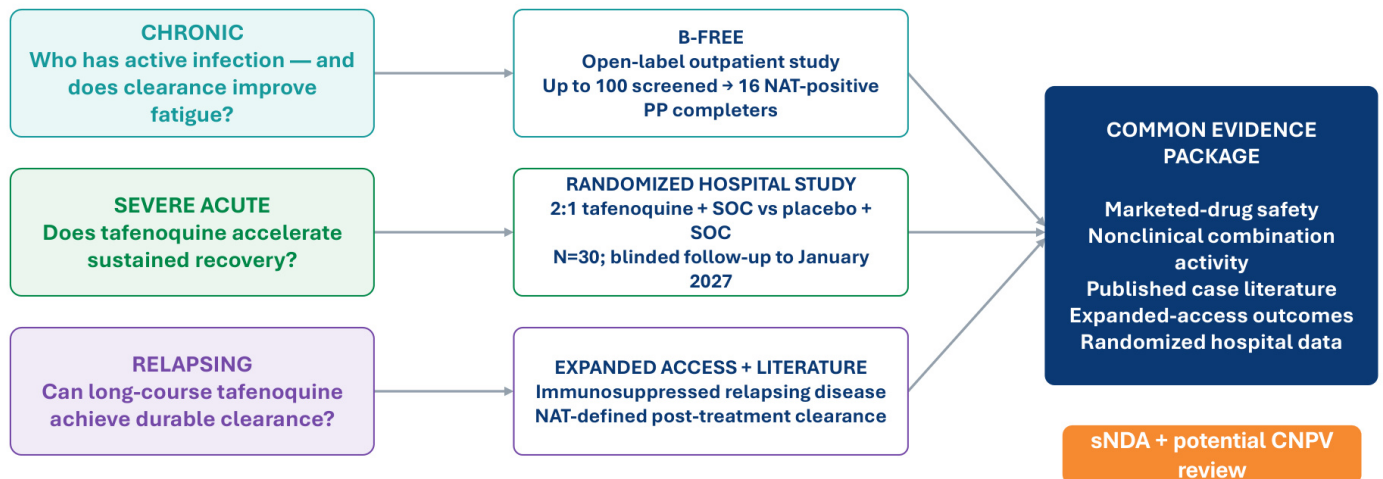
A September 2026 statement of interest asks FDA for national-priority review.

The program has moved from a single off-label clinical signal to an integrated clinical, statistical and regulatory package.

Today: orient to the development program → review safety → update chronic diagnostics → examine relapsing evidence → discuss the hospital readout and regulatory path.

ARAKODA® for Babesiosis: Clinical Development Map

Three clinical programs answer different questions — and feed one regulatory package.



The chronic program is hypothesis-generating; the severe and relapsing programs are the near-term regulatory engine.

One Tafenoquine Backbone — Three Clinical Settings

The sponsored studies use a four-day loading regimen followed by weekly dosing.

LOADING



WEEKLY MAINTENANCE



Weekly until study-specific stopping rule

Hospitalized acute disease	4-day load + 200 mg weekly for four weeks, added to standard of care
Chronic outpatient study	4-day load + 200 mg weekly through Day 89
Relapsing immunosuppressed	Continue weekly with an atovaquone-containing background regimen until two negative PCRs and symptom resolution; protocol allows up to one year

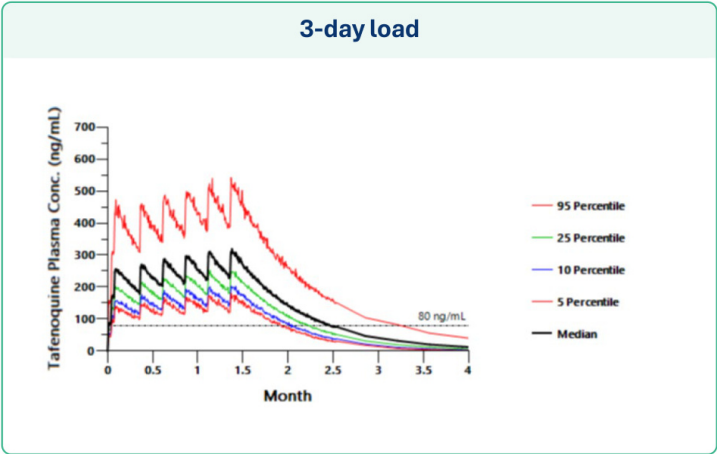
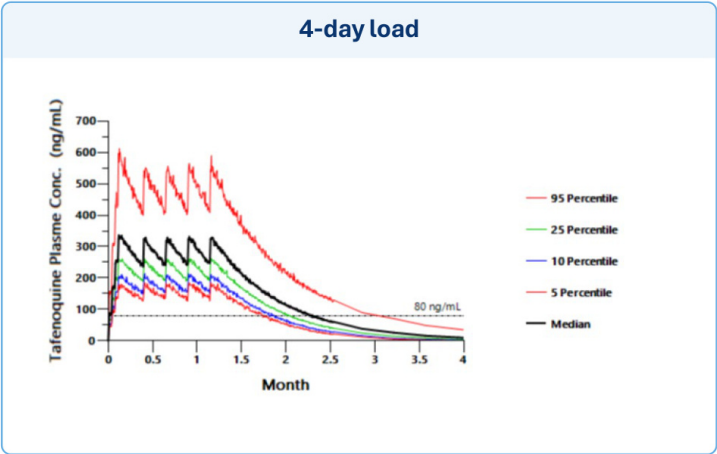
Important distinction

The sponsored babesiosis studies use a four-day loading regimen. The approved malaria-prophylaxis label uses a three-day loading regimen.

For full ARAKODA prescribing information and important safety information, see www.arakoda.com. ARAKODA is not approved for babesiosis.

Three-Day vs Four-Day Tafenoquine Loading Regimens

Illustrative plasma tafenoquine exposure with equal numbers of 200 mg doses



C_{max}

4-day loading produces a slightly earlier, modestly higher C_{max}.

≈

Steady-state concentrations are similar after weekly dosing.

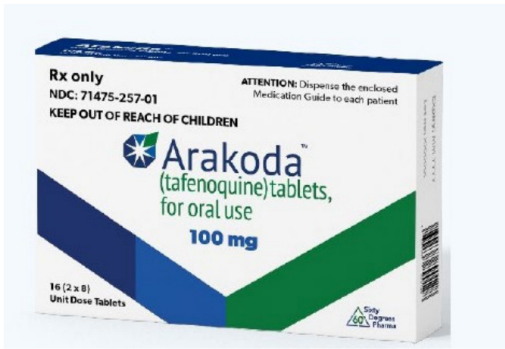
MIC

For the same number of 200 mg doses, time above the MIC is similar.

Illustrative plasma concentration profiles; MIC threshold shown at 80 ng/mL.

ARAKODA®: A Marketed Tafenoquine Safety Platform

Safety evidence from malaria prophylaxis informs — but does not establish — use in babesiosis.



FDA-approved malaria prophylaxis

Adults 18 years and older • weekly maintenance dosing • marketed since 2019

2018

U.S. approval

2019

Commercial launch

8

clinical studies

>1,100

participants

52 weeks
Controlled weekly-
dosing safety data

~16 days
Long terminal half-life
supports weekly dosing



Known dosing platform

A fixed 100 mg tablet and weekly maintenance regimen simplify repurposing.



Defined patient selection

G6PD testing and labeled contraindications are central to safe use.

Babesiosis safety update

The blinded hospital DSMB reported no safety signal that prevented continued use of tafenoquine as intended.

Safety data summarized from the ARAKODA prescribing information and Novitt-Moreno et al., 2022.

For Important Safety Information, please visit www.arakoda.com or view the full ARAKODA prescribing information

Weekly Tafenoquine Safety Was Comparable to Placebo

The main predictable difference was reversible cornea verticillata.

52-WEEK CONTROLLED STUDY

91.0%

Any adverse event
Tafenoquine

89.9%

Any adverse event
Placebo

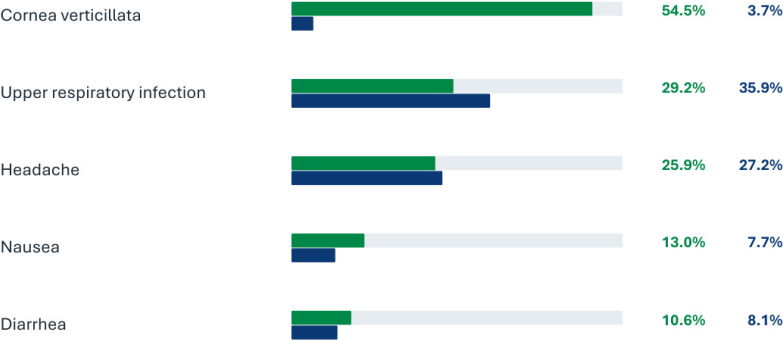
6.3%

Serious adverse event
Tafenoquine

5.0%

Serious adverse event
Placebo

Common events in the 52-week study



Safety conclusions depend on the approved population, dose and monitoring. See the full prescribing information.

Cornea verticillata

Predictable, reversible after treatment cessation and not associated with impaired visual acuity in the cited dataset.

Safe Use Depends on Patient Selection and Monitoring

The long half-life makes pre-treatment screening especially important.

SCREEN BEFORE DOSING



G6PD status

Contraindicated in G6PD deficiency or unknown G6PD status.



Pregnancy / lactation

Pregnancy testing is recommended; restrictions apply when fetal or infant G6PD status may be deficient or unknown.



Psychotic disorders

Contraindicated with a history of psychotic disorders or current psychotic symptoms.

MONITOR DURING AND AFTER DOSING

Hemolysis

Monitor for clinical or laboratory evidence of hemolytic anemia.

Methemoglobinemia

Average increase of ~2.4% in the cited prophylaxis dataset; no symptomatic values or values >10% were observed.

Delayed effects

The long half-life can delay hemolytic, psychiatric, hypersensitivity and methemoglobin effects.

PRACTICAL COUNSELING

With food

Administer with food to improve gastrointestinal tolerability.

Drug interactions

Avoid coadministration with OCT2 or MATE transporter substrates when clinically relevant.

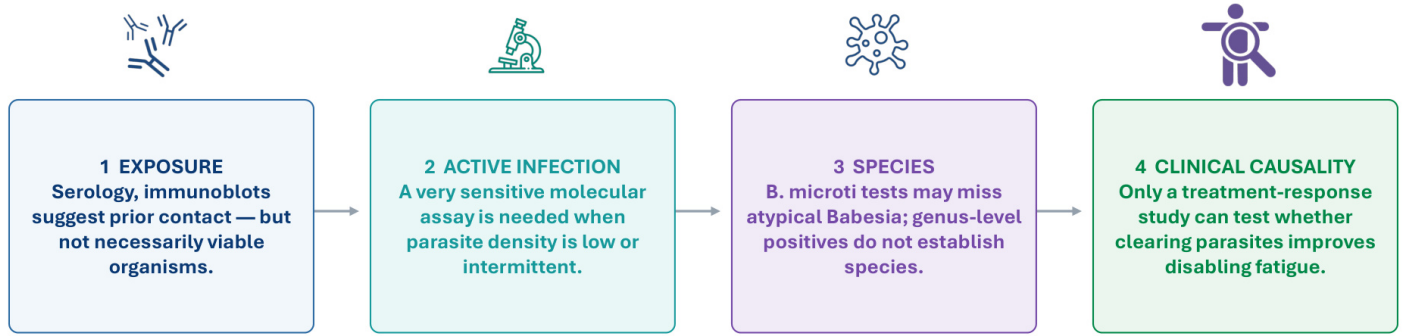
Ophthalmic finding

Cornea verticillata is reversible; no serious retinal toxicity signal was seen in the cited program.

This is a summary, not complete prescribing information.

Chronic Babesiosis: The Diagnostic-Development Bottleneck

The clinical question cannot be answered until exposure, active infection and species are separated.



Current bottleneck

No accepted chronic-babesiosis case definition and no commercially routine assay combines ultra-high sensitivity, broad species coverage and regulatory validation.

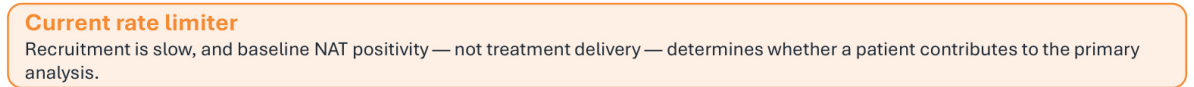
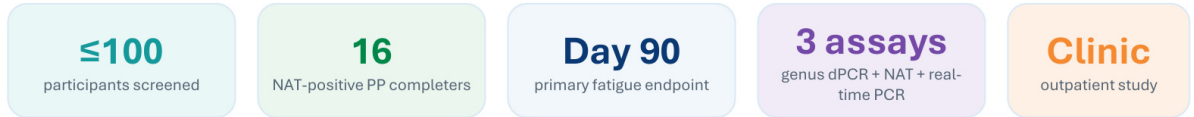
B-FREE therefore embeds diagnostic discovery inside a treatment study.

B-FREE: Phase II Open-Label Study in Chronic Babesiosis

A pragmatic design that screens broadly, but reserves the primary analysis for NAT-positive participants.



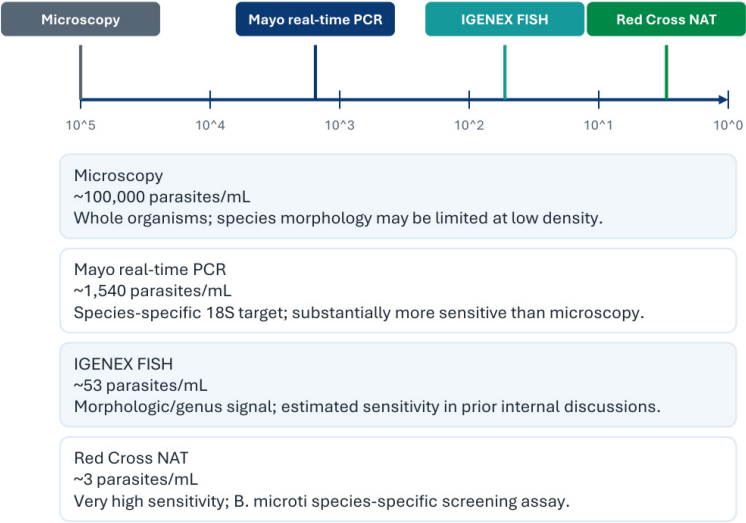
NCT06656351



Diagnostic Sensitivity Changes the Meaning of “Negative”

Different assays answer different questions — and operate across five orders of magnitude.

Approximate lower analytical sensitivity (parasites/mL; log scale)



What a test is best at

- Microscopy**
Confirms visible parasitemia and morphology, but is insensitive at low density.
- Species-specific PCR / NAT**
Strong for confirming B. microti when the target is present; may miss atypical species.
- Genus-level dPCR / FISH**
Can broaden detection, but a positive result may not establish the infecting species.

Analytical sensitivities: user-provided 2025 ILADS diagnostic slide and October 2026 internal discussion.

B-FREE Screening Update: A Genus Signal Without a Species Signal

Early screening has not yet resolved whether symptoms reflect *B. microti* or an atypical *Babesia*.

Patient	Inclusion evidence	Galaxy genus dPCR	Red Cross <i>B. microti</i> NAT	Mayo species-specific PCR	
A	≥1 IGENEX exposure assay positive	–	–	–	2/9 genus dPCR positive
B		+	–	–	
C		–	–	–	
D		–	–	–	0/9 <i>B. microti</i> NAT positive
E		–	–	–	
F		–	–	–	
G		+	–	–	0/9 Mayo species-specific PCR positive
H		–	–	–	
I		–	–	–	

Current study status

Recruitment is slow. No enrolled patient has yet qualified for the primary per-protocol analysis through a positive baseline NAT.

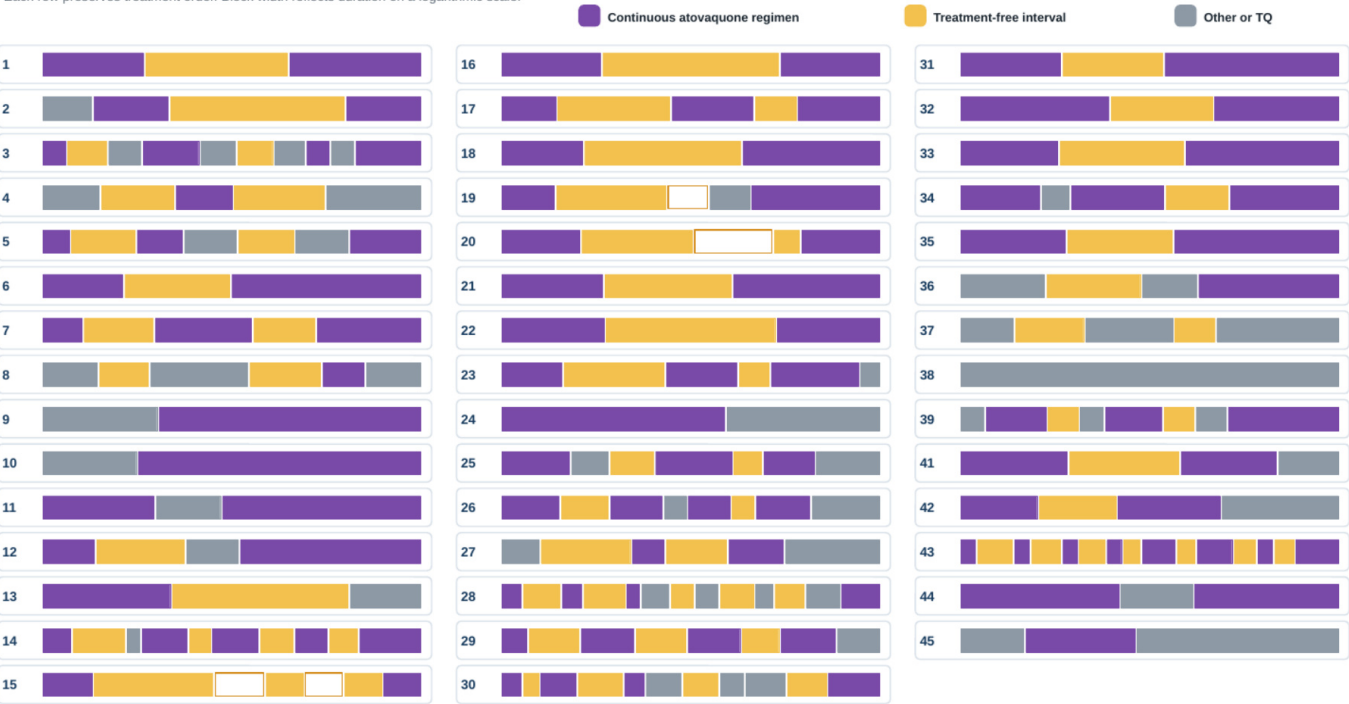
Interpretation

The data do not yet distinguish low-level *B. microti*, an atypical *Babesia*, a transient signal, or prior exposure unrelated to current symptoms.

Treatment histories across 45 published relapsing babesiosis cases

Each row preserves treatment order. Block width reflects duration on a logarithmic scale.

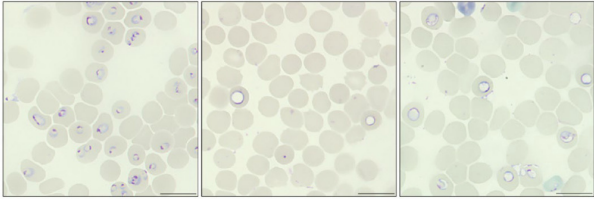
28/92 responses (30.4%)



Response = no retreatment for at least 12 weeks after treatment cessation; primary analysis retains case 20 and excludes courses with unknown post-treatment follow-up.

Why Pair Tafenoquine With Atovaquone?

Complementary oxidative mechanisms produced durable control in an immunodeficient mouse model.

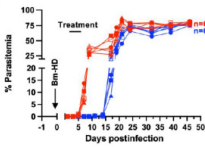


ATOVAQUONE
Disrupts parasite mitochondrial electron transport and contributes to oxidative stress.

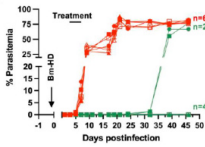
+

TAFENOQUINE
Induces parasite oxidative damage through a different mechanism.

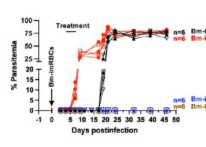
Mechanistic hypothesis
Two different sources of oxidative pressure can suppress emergence of recrudescent parasites more effectively than either drug alone.



Atovaquone relapse



Tafenoquine partial control

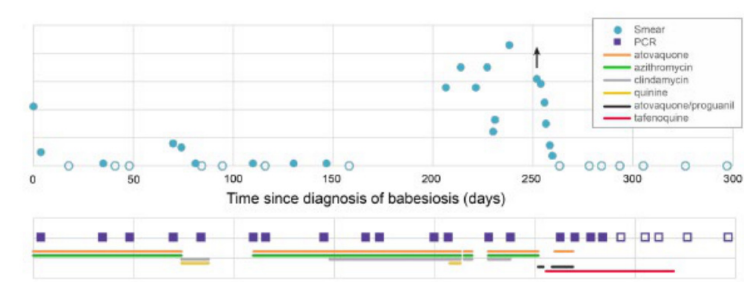


Combination durable control

Mouse-model takeaway
The combination prevented detectable recrudescence through the end of follow-up in the SCID-mouse B. microti model.

First Published Tafenoquine Case Series in Relapsing Babesiosis

Krause et al. began to define the conditions for successful use in highly immunocompromised patients.



Representative successful case

Smear parasitemia, PCR status and treatment exposure over time

4 of 5
patients achieved definitive clearance

600 mg
loading dose in the published series

Weekly maintenance
200 or 300 mg

Combination therapy
Successful cases used other antimicrobials; three included atovaquone-proguanil.

Monotherapy was not sufficient
Tafenoquine alone failed to prevent relapse in one case, supporting a combination strategy.

Published clinical signal
Clearance followed prolonged tafenoquine-containing treatment in a population with repeated prior failures.

Published tafenoquine-atovaquone treatment responses

Eligible cases received tafenoquine for at least eight weeks with concomitant atovaquone.

6/7 responses (85.7%)



Published-Case Reanalysis: Duration Predicts Response

A whole-episode Cox model tested whether longer uninterrupted treatment was followed by more durable response.

ANALYSIS FRAMEWORK

- 1

45 unique relapsing-babesiosis cases were reconstructed as treatment episodes.
- 2

Follow-up began after all treatment stopped; retreatment during the first 12 weeks was the Cox event.
- 3

One episode included all uninterrupted conventional antibabesial therapy; partner-drug changes did not split it.
- 4

The model adjusted for regimen category and earlier treatment history — not ordinal treatment position.

DURATION RESULT



Interpretation
Each doubling of uninterrupted conventional-treatment duration was associated with a lower subsequent retreatment rate during the first 12 weeks after therapy stopped.

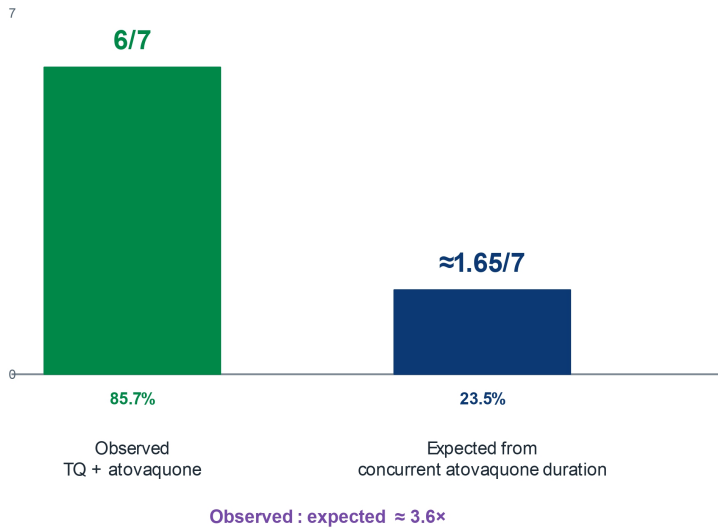
Guidance implication

Longer treatment was associated with greater post-treatment durability; the analysis does not define an optimal duration.

Tafenoquine Responses Exceeded Atovaquone Expectations

The comparison uses the duration of atovaquone actually coadministered with tafenoquine.

Observed and expected 12-week treatment-free responses among 7 published tafenoquine–atovaquone cases



Published-case counterfactual

1 Published cohort

Seven published combination cases were eligible; six achieved the 12-week endpoint. The monotherapy tafenoquine-monotherapy cases were excluded.

2 Concurrent-atovaquone model

Case-specific probabilities used the duration actually coadministered with tafenoquine, the background regimen, and recorded prior treatment history.

3 No ordinal position term

The Cox model used earlier treatment history and restart versus modification; follow-up began only after all subsequent treatment stopped.

Key observation

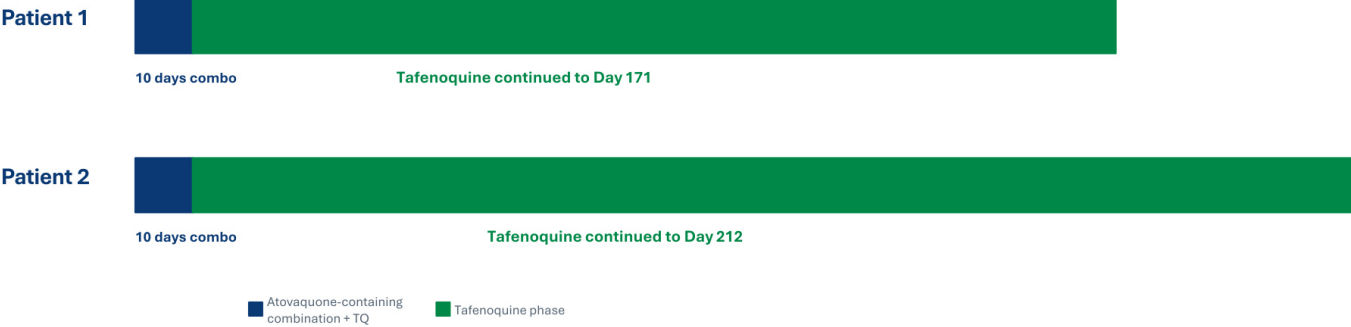
Six responses were observed versus approximately 1.65 expected (85.7% vs 23.5%). In an exploratory cox model, $p = 0.019$.

Osakwe & Wormser: Brief Atovaquone, Long Tafenoquine

Two additional cures used a deliberate two-phase strategy.

Two-phase regimen

Only the first 10 days of tafenoquine were given with an atovaquone-containing combination; tafenoquine then continued alone for months.



Dosing

200 mg daily for 3 days, then 200 mg weekly

Stopping rule

PCR negativity intentionally extended beyond the ~120-day erythrocyte lifespan

Outcome

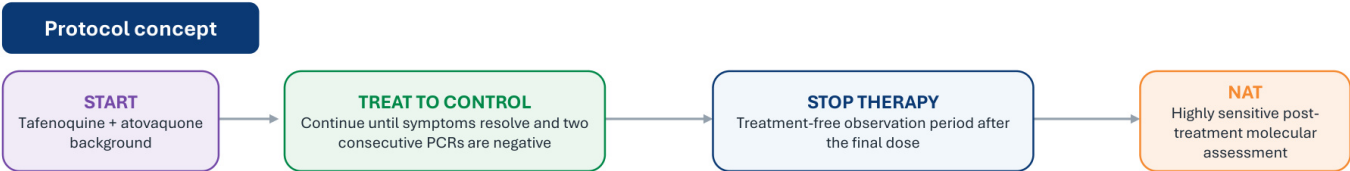
Both patients were reported cured with sustained molecular negativity

Osakwe N, Wormser GP. Pathogens. 2026;15:960. Two case reports; no control group.

Expanded Access: Three Confirmed Cures; Two Outcomes Pending

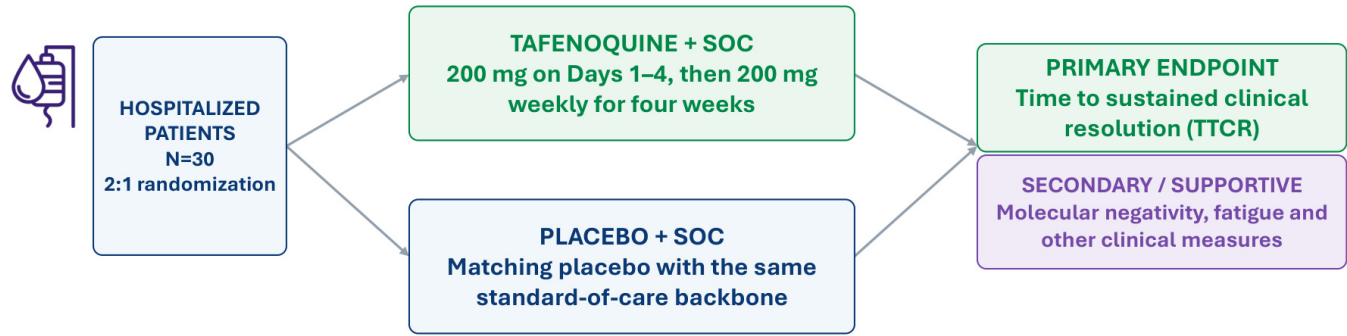
A post-treatment NAT is used to test durable parasite clearance.

CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASES 6 & 7
NAT-negative	NAT-negative	NAT-negative	OUTCOME TBD NOV 2026	OUTCOME TBD NOV 2026	Ongoing
Completed treatment and post-treatment NAT	Completed treatment and post-treatment NAT	Completed treatment and post-treatment NAT	Placeholder for final disclosure	Placeholder for final disclosure	Enrolled / follow-up in progress



Randomized Hospital Study: Designed to Measure Faster Recovery

The study remains blinded; no unblinded efficacy result is shown here.



30

subjects enrolled as of 10/1/2026

Early Jan

follow-up complete and unblinding planned

Blinded

efficacy allocation remains unknown

No safety signal

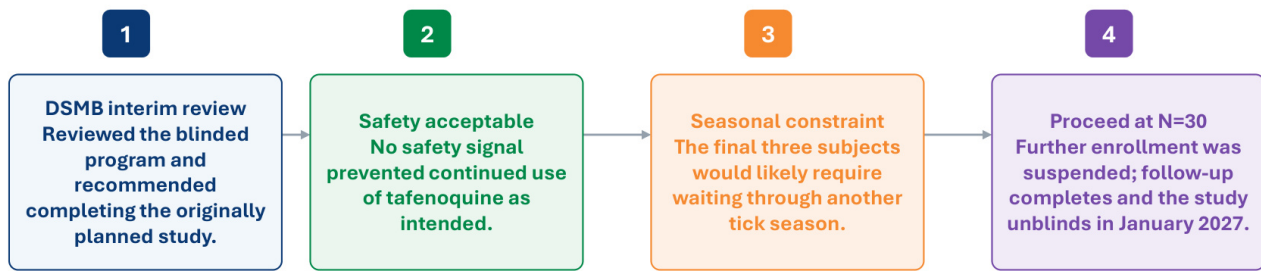
DSMB safety concern preventing continued use

~1 year

delay for final 3

What the Interim Review Changed — and What It Did Not

The study remains blinded, but the operational decision is now clear.



Statistical trade-off

Statistical assessment suggested that three additional subjects would provide limited incremental information relative to the approximately one-year delay.

What remains unknown

Because the study is still blinded, the direction and magnitude of the treatment effect remain unknown until unblinding.

Decision: complete follow-up → lock and unblind → use the result to select the regulatory path.

Two Regulatory Paths After the Hospital Study Unblinds

The same evidence base supports either route; the randomized result determines the lead strategy.

COMMON EVIDENCE BASE

Marketed-drug safety • nonclinical combination activity • published cases • expanded-access outcomes • hospital study

REGULAR sNDA

If the randomized hospital study is positive

- 1 Randomized efficacy**
Tafenoquine + SOC versus placebo + SOC in hospitalized patients.
- 2 Clinical endpoint**
Shorter time to sustained clinical resolution.
- 3 Supportive package**
Published cases, expanded access and nonclinical combination data strengthen the totality of evidence.

ACCELERATED APPROVAL

If the hospital study is not independently pivotal

- 1 Refractory evidence**
Expanded-access cures supported by the published relapsing-disease literature.
- 2 Potential surrogate**
Propose post-treatment NAT negativity as a marker of durable parasite clearance.
- 3 Confirmatory commitment**
Align with FDA on a post-marketing study to verify clinical benefit.

FDA alignment point

A pre-sNDA meeting is planned for late January 2027 after the hospital study unblinds and the expanded-access package is updated.

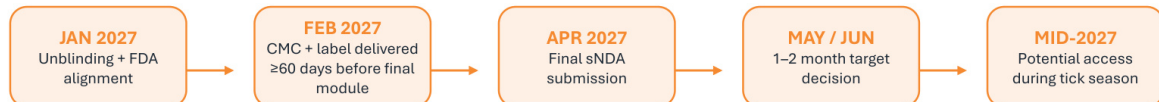
A CNPV Could Move a Potential Decision Into the 2027 Tick Season

Illustrative timing — dependent on FDA alignment, dossier completeness and review needs.

BASE PLAN



CNPV PATH



What the voucher changes

FDA describes a target review clock of approximately 1–2 months, supported by enhanced communication, rolling review and a presubmission period.

What it does not change

A CNPV accelerates the decision; it does not lower the statutory standard for safety, effectiveness or manufacturing quality.

Clinicians: Help Define Pediatric Babesiosis Care

Share your experience in a 10–15 minute survey focused on diagnosis, neuropsychiatric manifestations, treatment and unmet need.



WHY YOUR VOICE MATTERS

60 Degrees Pharmaceuticals is gathering clinician experience to better understand how pediatric babesiosis is diagnosed and treated—especially neuropsychiatric symptoms, treatment practices and unmet medical needs.

THE SURVEY WILL EXPLORE

- Clinical experience, diagnostic approaches and neuropsychiatric manifestations
- Treatment approaches, observed outcomes and unmet medical needs
- Experience with tafenoquine, including outcomes and safety considerations

Upon survey completion, **\$500** will be donated to ILADEF.

TAKE THE SURVEY



SCAN THE QR CODE

Estimated completion time: 10–15 minutes

Participation is voluntary and intended for clinicians with prescribing authority.
Please do not include patient-identifying information.