H.C. Wainwright Presentation

60 Degrees Pharmaceuticals, Inc.

September 2025

Sixty Degrees Pharma

Targeted therapies for vector-borne disease

Investment focus

A marketed antimalarial platform creates a path to potential indication expansion in babesiosis

- **Commercial base**
  ARAKODA® malaria prophylaxis
- **Clinical vector**
  Babesiosis development program
- **Regulatory arc**
  sNDA strategy + milestones

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Investment Thesis

A marketed antimalarial platform creates a staged path to potential indication expansion in babesiosis.

Core thesis

Label expansion of ARAKODA® / tafenoquine from malaria prevention into high-need tick-borne disease opportunities, led by babesiosis.

Investment setup: existing product + mechanistic rationale + human signals + near-term regulatory engagement.

Potential sNDA strategy anchor

1 Commercial base

ARAKODA® is already marketed for malaria prophylaxis, providing product familiarity and a safety database.

2 Lead expansion

Babesiosis is the focused development opportunity, with severe, persistent, and chronic unmet-need segments.

3 Evidence package

Non-clinical proof-of-concept, case-series signals, expanded access, and active studies support FDA dialogue.

4 Milestone path

Interim analysis, pre-sNDA interaction, sNDA filing, and potential launch create a staged catalyst sequence.

Focus: build toward a potential tafenoquine sNDA in babesiosis while leveraging the ARAKODA® platform.

Financial Snapshot

Q2 2026 results + July financing / Knight conversion

Q2 10-Q filed Aug. 14, 2026

COMMON OUTSTANDING/MARKET CAP

~3.51M/ ~4M

Pro forma at Jul. 31: 2.659M base + 658.6k Knight conversion + 191.6k common issued in financing. Excludes pre-funded warrants.

PREFERRED OUTSTANDING

68,080

Series A non-voting convertible preferred post-Knight conversion; 6% cumulative dividend.

COMMON WARRANTS

~3.09M

Approx. legacy/common warrants plus July Series AB warrants and placement-agent warrants. Excludes pre-funded warrants.

PRE-FUNDED WARRANTS

383.1k

Issued in July 2026 private placement; nominal $0.001 exercise price; shown separately from common.

ARAKODA® Sales Snapshot

Q2 2026 product revenue / gross profit

Q2 net product revenue

$208k +106% YoY

Gross profit on product revenue

$57k ~27% gross margin

Commercial product now contributes a measurable revenue/gross-profit line while babesiosis development remains the capital driver.

Financing & Runway

liquidity after July financing

~$1.0M
cash & equivalents
June 30, 2026

~$5.0M
operating cash use
6 months ended Jun. 30

Early Oct. 2026
runway

Last financing: July 31, 2026 private placement

$1.0M gross • priced at $1.74 per share / pre-funded warrant + accompanying warrants

Common warrant exercise price: $1.49 • PA warrants: 43.1k at $2.175

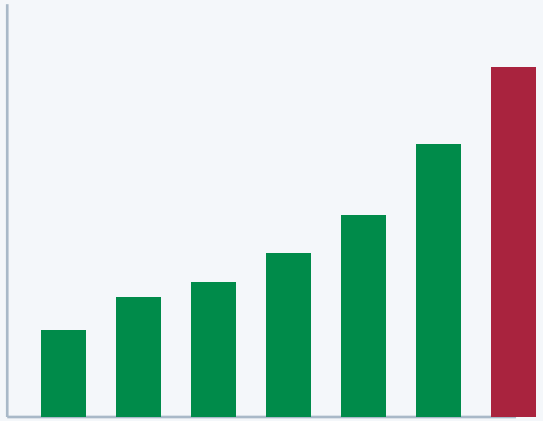
Notes: common outstanding is shown pro forma as of July 31, 2026 and excludes pre-funded warrants. Preferred outstanding reflects post-Knight conversion Series A balance. Warrant counts are approximate and exclude as-converted preferred impact.

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.

ER visits for tick bites

RECORD LEVELS THIS YEAR (113,000+)



More bites → more clinical encounters

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

Critical Unmet Need in Selected Tick-Borne and Tick-Associated Diseases

High burden, limited approved options, and a clear rationale for small-molecule repositioning

Babesiosis
Parasitic red-blood-cell infection

B

≥25k claims / yr

U.S. medical insurance claims associated with babesiosis[2]

- No FDA-approved treatment specifically for babesiosis
- Existing treatments ≤ 30% effect in relapsing disease, high mortality and long recovery time in severe cases

UNMET NEED approved, durable treatment option

Post-Treatment Lyme Disease
Chronic disease following acute infection

PT

≈50k–95k / yr

Potential new PTLD cases in U.S.[1]

- No FDA-approved treatments
- Extended antibiotic treatment believed by patients to help but is controversial

UNMET NEED validated treatment strategy

Alpha-Gal Syndrome
Red meat allergy triggered by Lone star tick bites

α

up to 45k / yr

Potential new / diagnosed cases in U.S.

- Delayed reactions can be severe or life-threatening
- Management consists of lifestyle changes to avoid exposure to mammalian meat products

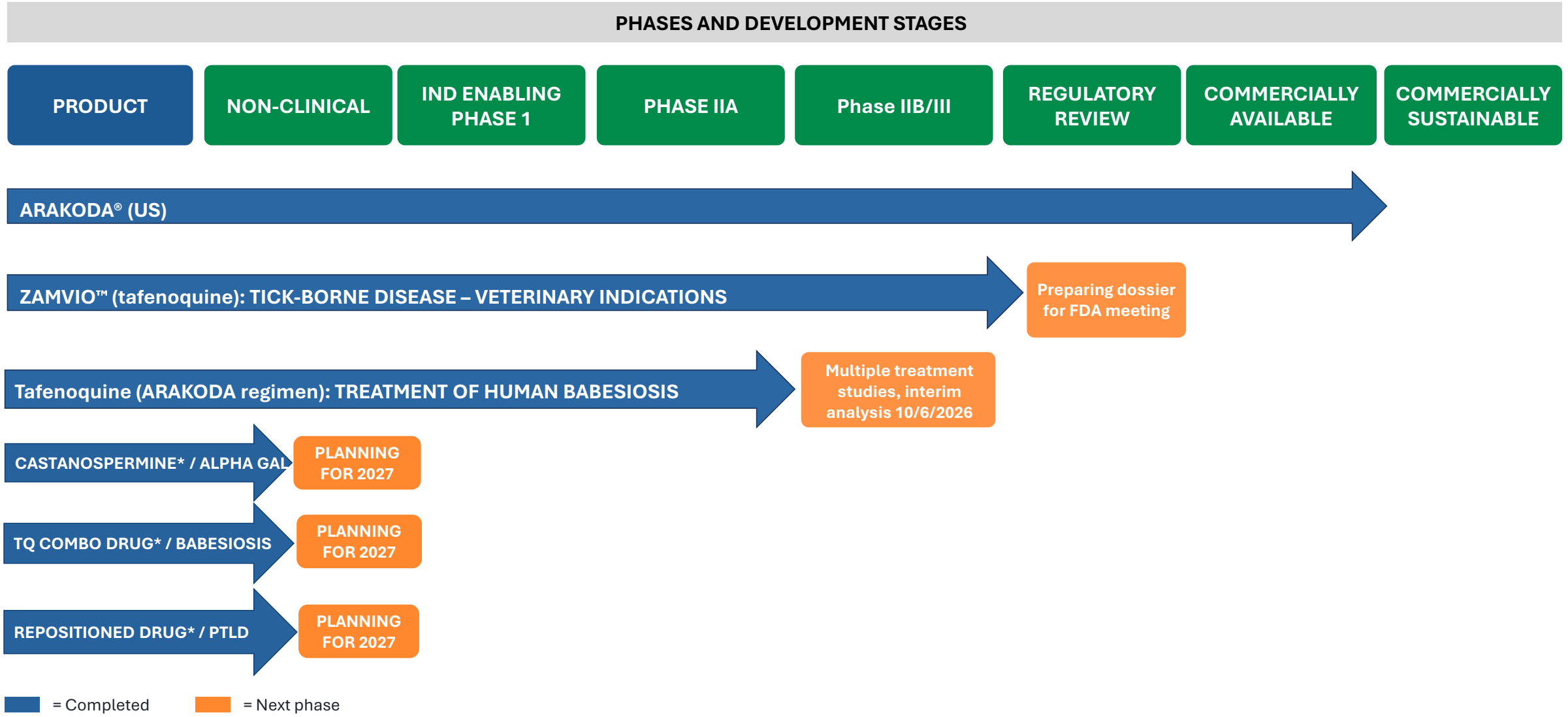
UNMET NEED prevention + disease-modifying approach

Strategic implication: a cluster of underserved indications where repositioned small molecules can shorten development timelines.

[1] CDC/NIH: ~476k Lyme diagnoses/yr; 10–20% PTLDS estimate.

[2] Unpublished company market research.

Portfolio August 2026



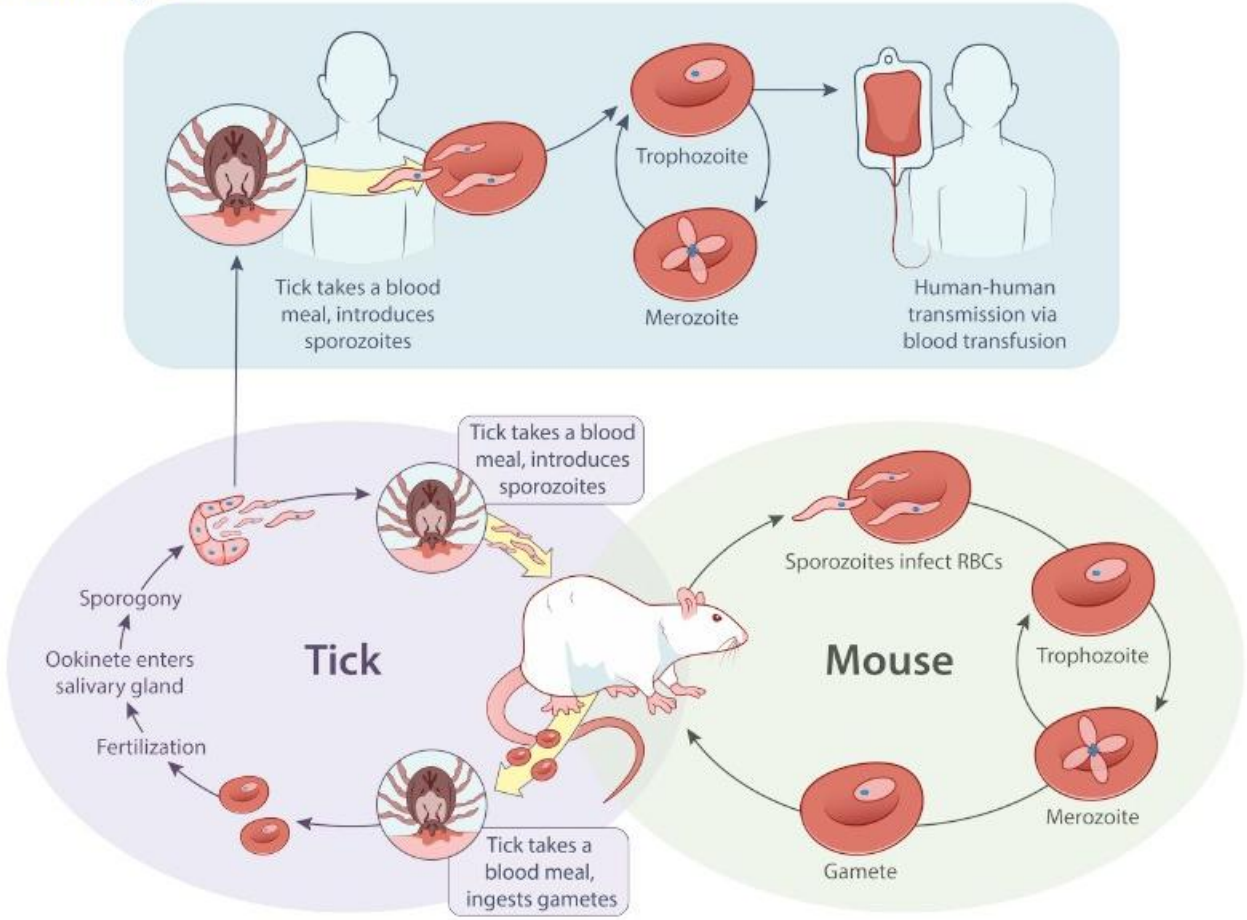
*Licensing arrangements or FTO analysis pending

From tick bite to red-blood-cell infection

Transmission pathways + symptoms that drive clinical urgency

RBC parasite • Tick-borne • Transfusion risk

Transmission cycle



Symptoms to highlight

Often asymptomatic — but symptomatic cases can resemble severe flu

Flu-like	Fever, chills, sweats, headache, body aches
Systemic	Fatigue, weakness, loss of appetite, nausea
RBC injury	Hemolytic anemia → jaundice or dark urine
Severe risk	Older adults, asplenia, immunocompromised patients
Chronic / severe fatigue	Persistent fatigue may drive prolonged recovery

Source: CDC signs/symptoms of babesiosis.

Babesiosis Treatment Gap

Current regimens leave a high-need refractory segment with limited evidence and no FDA-approved options.

STANDARD OF CARE TODAY

First-line treatment

Atovaquone + azithromycin

↓

Treatment-refractory disease

- Atovaquone + azithromycin + clindamycin
- Atovaquone + clindamycin
- Atovaquone/proguanil + azithromycin
- Atovaquone + azithromycin + clindamycin + quinine

**Higher azithromycin dose may be considered*

WHY THIS MATTERS

<30%

cure rate of atovaquone-based regimens in treatment-refractory patients*

0

specific FDA-approved regimens for refractory disease listed by IDSA

! Clinical problem

- Refractory patients often require prolonged, multi-drug therapy
- Evidence base is limited and dominated by case experience
- A repositioned oral small molecule could address the evidence and access gap

Unmet need creates room for a differentiated, approvable regimen.

REPOSITIONING RATIONALE

New treatment option needed

Tafenoquine has a plausible repositioning rationale because it is already FDA-approved for malaria prophylaxis and targets intra-erythrocytic parasites.

Sets up ARAKODA® label expansion story

Babesiosis: An Orphan Disease With Three Distinct Unmet Need Segments

Hospitalized acute disease, refractory immunosuppressed disease, and chronic/persistent symptoms create multiple treatment opportunities.

Severe Disease

Hospitalization

1.6%
mortality in immunocompetent hospitalized patients

7.0%
mortality in high-risk patients

- Long recovery times
- Clinical urgency in older / high-risk patients

UNMET NEED reduced morbidity / faster recovery

Persistent Disease

Immunosuppressed patients

Months–years
duration in refractory cases

≤30%
curative rate of atovaquone/azithromycin*

- Multiple regimens may be required
- Drug resistance and relapse reported

UNMET NEED durable parasite clearance

Chronic Disease

Poorly characterized

Fatigue
and chronic symptoms

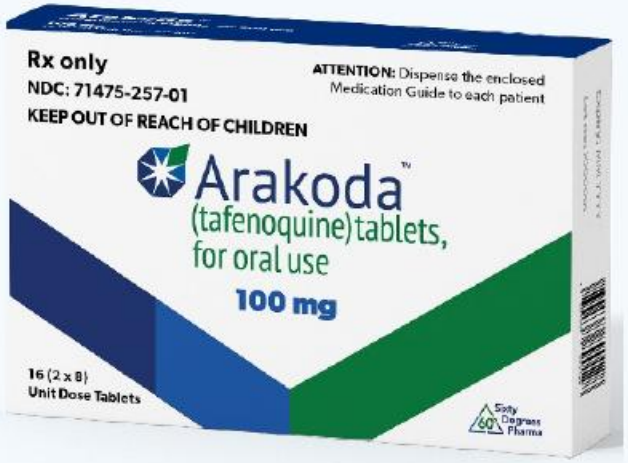
0
FDA-approved diagnostics

- Babesia infection hypothesize to prolong recovery from post-infectious illness
- Underserved and under-studied patient segment

UNMET NEED Formal case definition, FDA-cleared diagnostics & benchmarked therapeutics

ARAKODA®: FDA-Approved Tafenoquine Platform

A marketed antimalarial with weekly dosing and a safety database that supports label expansion for Babesia.



2018
US FDA approval

2019
commercially available

Indicated for prophylaxis of malaria in adults

KEY PRODUCT ATTRIBUTES

✓ **All stages**	Protection against all malaria parasite stages
✓ **No resistance**	No drug resistance observed/reported in deck claim
✓ **Weekly**	Convenient weekly dosing
✓ **CDC**	Recommended without geographic restrictions

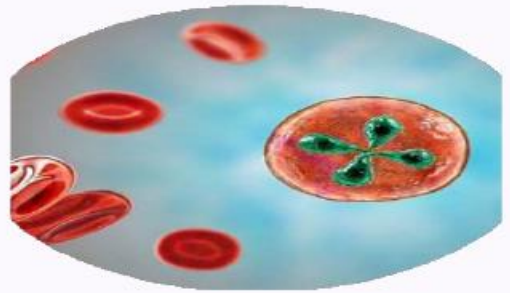
SAFETY PROFILE

8 studies

>1,100 patients

52 weeks
AE rate comparable to placebo; G6PD screening required.

WHY REPOSITIONING IS PLAUSIBLE



Babesia and malaria both involve intra-erythrocytic parasite biology.

→

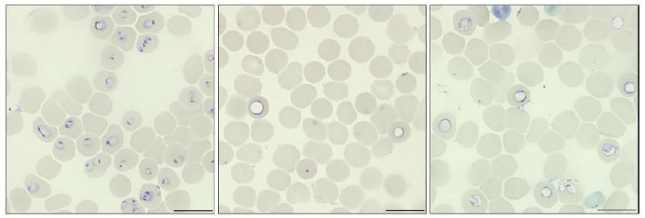
sets up non-clinical POC

Existing product + known dosing + safety database

Tafenoquine & Babesiosis: Non-Clinical Proof of Concept

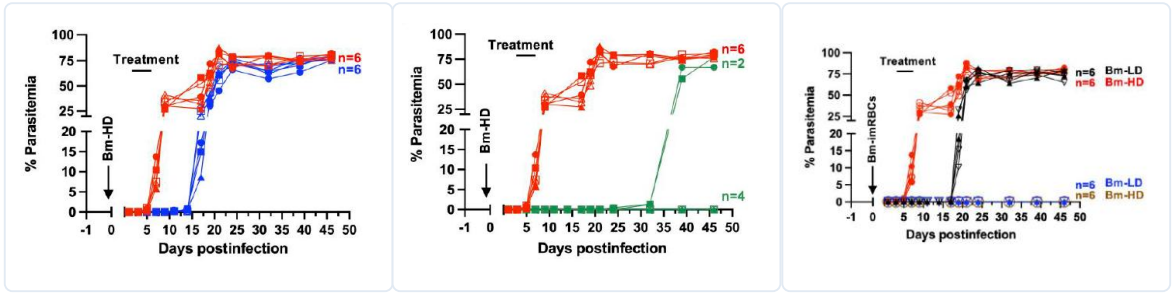
Blood-smear phenotype plus SCID-mouse combination data support repositioning into Babesia.

BLOOD-SMEAR PHENOTYPE (LIU ET AL.)



Giemsa-stained blood smears from B. rodhaini-infected mice; 24 hours post single-dose tafenoquine vs. vehicle; H_2O_2 in vitro comparator.

SCID-MOUSE COMBINATION ADDITIVITY (VYDYAM ET AL.)



Atovaquone | **Tafenoquine** | **Atovaquone + Tafenoquine**

Source: Vydyam et al., J Infect Dis. 2024;229(1):161–172. SCID mouse B. microti high-dose model.

MECHANISTIC + COMBINATION TAKEAWAYS

1 Blood-smear signal

Tafenoquine-treated Babesia showed a distinct RBC phenotype consistent with oxidative-stress biology.

2 Combination additivity

SCID mouse data support tafenoquine + atovaquone activity and durability beyond either agent alone.

3 Clinical bridge

Distinct biology plus combination activity supports the refractory babesiosis repositioning strategy.

Supports move from antimalarial product → Babesia combination development

Treatment-Refractory Babesiosis: Human Case-Series Signal

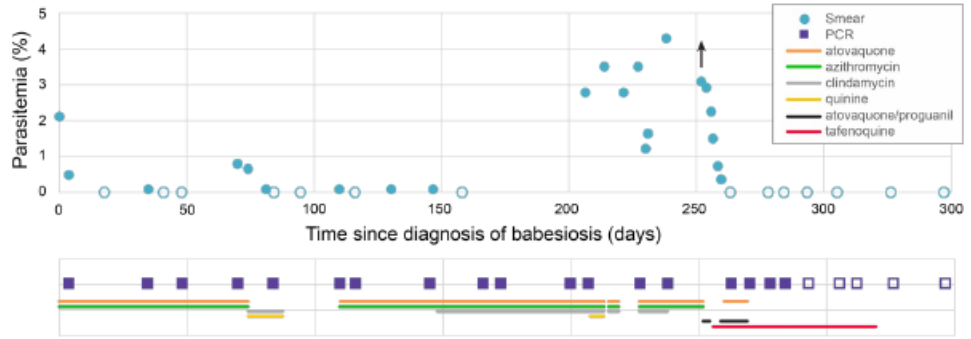
Tafenoquine combinations cured 4 of 4 immunosuppressed patients when administered concurrently for >8 weeks.

4 / 4
immunosuppressed refractory patients cured

100%
cure rate (95% CI: 51–100%)*

>8 wks
concurrent tafenoquine + atovaquone + antibiotic combinations

Representative case timeline



WHAT THE CASE SERIES CONTRIBUTES

1. **Human signal**
   Cure observed in difficult-to-treat immunosuppressed patients with refractory B. microti disease.
2. **Combination context**
   Tafenoquine was administered with atovaquone-based therapy and antibiotics.
3. **Regulatory use**
   Provides potentially supportive data for an NDA package
4. **Development rationale**
   Provided the rationale for the Company's tafenoquine babesiosis development plan

Babesiosis Could Triple the ARAKODA® Asset Opportunity

Patient exclusivity creates two ways to expand the same marketed antimalarial platform: treated patients and treatment-course value.

PATIENT CASELOAD OPPORTUNITY

Maximum cumulative addressable market (2026Q3–2035)

Malaria Prevention

450,000
trips / patients

*Max possible prescriptions for three weeks of travel**

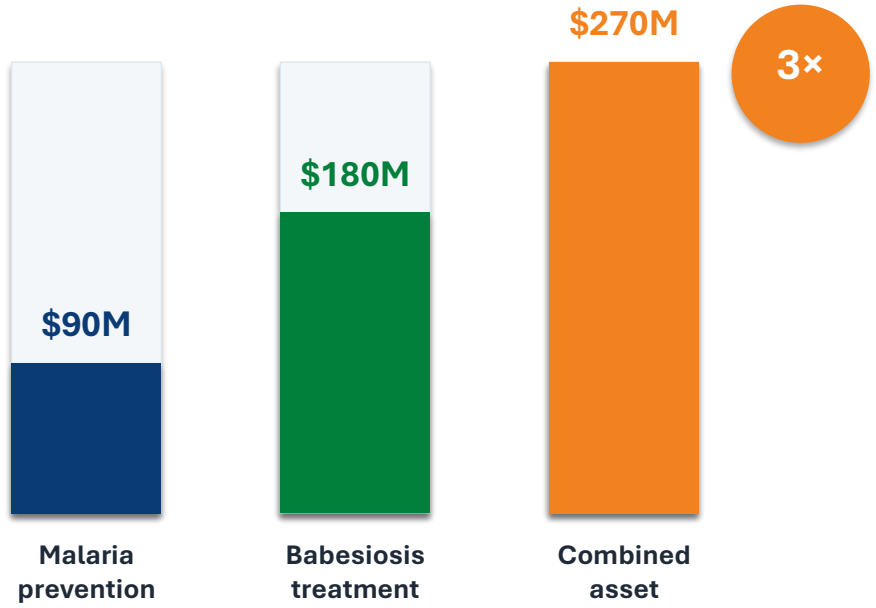
Treatment of Babesiosis

350,000
trips / patients

*Max possible patients treated post-FDA approval***

VALUE OPPORTUNITY AT CURRENT WAC

Maximum WAC-value opportunity



Same product platform; babesiosis opportunity adds treatment demand and longer-course economics. Value reflects current WAC

Pursuit of babesiosis potentially triples the value of the asset.

ARAKODA® for Babesiosis: Clinical Development Plan

Three active studies plus prevalence work support the sNDA strategy and near-term FDA engagement.

Randomized Placebo-Controlled Study

NCT06207370

Hospitalized babesiosis patients

Tafenoquine + SOC vs placebo + SOC

TQ dose: 200 mg × 4, then 200 mg weekly for 4 weeks

- Primary: TTSCR*
- Secondary: TTMC

28 enrolled @ Jul. 9; interim before 10/6/26

Expanded Use Study

NCT06478641

Relapsing immunosuppressed patients

Open-label tafenoquine + atovaquone-containing SOC

NAT test used to define cure

- Load 200 mg × 4
- Weekly dosing 200 mg

3 cured; 2 more enrolled May 2026; complete before 2/2027

Phase II Open-Label Study

NCT06656351

Chronic babesiosis

Open-label tafenoquine through Day 90

- Load 200 mg × 4
- 200 mg weekly following the load through Day 90

9 enrolled; 22% diagnostic confirmation by Galaxy dPCR

Advice meeting with FDA completed Jan. 2024 • Earliest feasible sNDA submission: April 2027 • Interim-analysis outcome to be disclosed before 10/30/26

*TTSCR = time to sustained clinical resolution; TTMC = time to molecular cure.

Default Regulatory Strategy: Accelerated Approval Pathway

Use refractory-disease evidence and a surrogate relapse marker discussion to seek an efficient pathway.

1 Supporting Data

- Literature case reports (N=44)
- Atovaquone-combination failure rate >70%
- Tafenoquine-atovaquone combo >8 weeks: 100% cure rate

2 Pivotal Evidence Base

- Expanded access case reports
- 3 completed patients cured
- 2 additional expected completion 11/26–2/27

3 Potential Surrogate

- Cure defined as negative nucleic acid test 2–3 months after drug cessation
- NAT proposed as relapse marker

4 FDA Discussion

- Q4 2026 meeting
- Priority review
- Confirmatory study design

Objective: Align with FDA on NAT as a relapse surrogate and a confirmatory-study path that can support indication expansion.

Regulatory Precedent: sNDA Without Randomized Trial Data

Leucovorin approval illustrates a totality-of-evidence approach for rare disease where randomized trials may be impractical.

LEUCOVORIN CALCIUM PRECEDENT

N — 1952

Original NDA approval

High-dose methotrexate rescue; toxicity reduction; fluorouracil potentiation

S — Mar. 2026

sNDA approval

Treatment of cerebral folate deficiency in genetically confirmed FOLR1 variants

L — Label focus

Rare genetic disorder

Label excludes treatment of autism despite symptom overlap

APPROVAL BASIS: TOTALITY OF EVIDENCE

- ✓ **Literature + case reports**
- ✓ **Natural history of disease**
- ✓ **Mechanistic plausibility**
- ! **No randomized trials required**
- ✓ **Safety database**

Implication for SXTP: a carefully framed sNDA package can be built around rare/high-need disease evidence, biological plausibility, and a marketed-drug safety base.

Sources: FDA press announcement and supplemental approval materials for Wellcovorin/leucovorin calcium (Mar. 2026).

Derisked Regulatory Pathway: Regular sNDA

Hospital study efficacy plus expanded access cure data could support lower risk regulatory approval pathway

SUPPORTING DATA PACKAGE

1. **Literature case reports**

   High cure rate with tafenoquine-atovaquone combinations in refractory immunosuppressed patients

2. **Expanded-access study**

   High cure rate confirmed in 5 patients: 3 cured + 2 enrolled

3. **Non-clinical additivity**

   Literature supports additivity of tafenoquine and atovaquone

POTENTIALLY PIVOTAL DATA

Randomized hospitalized-patient study

Tafenoquine + SOC vs **Placebo + SOC**

Shorten time to sustained clinical resolution

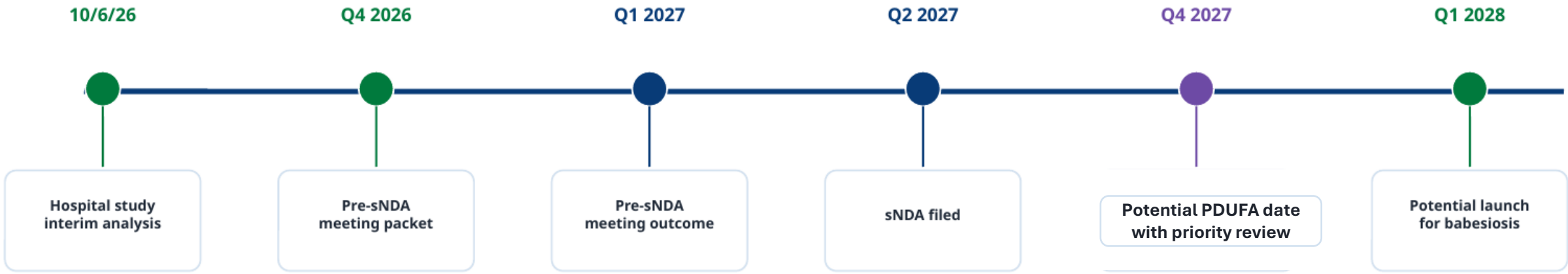
Q4 2026 FDA meeting: data requirements for potential sNDA

Milestones Through Q1 2028: Catalysts That Could Derisk the Plan

Near-term study and regulatory events create a staged path from interim analysis to potential launch.

OTHER ANTICIPATED MILESTONES

New product collaborations • market updates • other product research updates



The investment setup is milestone-driven: clinical signal first, then regulatory alignment, filing, review, and launch execution.