

July 2024



Developing and commercializing
new products that address the
unmet medical need associated
with infectious diseases

Corporate Presentation

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 warrant 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.

The forward-looking statements contained in this communication are based on knowledge of the environment in which the Company currently operates and are subject to change based on various important factors that may affect the Company’s operations, growth strategies, financial results and cash flows, and as well as other factors beyond the Company’s control as of the date of this presentation.

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 provide for the commercialization of non-malaria prevention indications for Tafenoquine (Arakoda or other regimen) or Celgosivir 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 of bringing our 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 (SEC), including our Annual Report on Form 10-K and our 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 at www.sec.gov. As a result of these matters, changes in fact, assumptions not being realized or other circumstances, the Company’s actual results may differ materially from the expected results discussed in the forward-looking statements contained 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.



60 Degrees Pharma (NASDAQ: SOTP) Investment Thesis

- FDA approved in 2018
- An 8-aminoquinoline antimalarial active against all stages of *Plasmodium* species
- Single dose convenience
- Robust US distribution network



Mission

Developing and commercializing new products that address the unmet medical need associated with infectious diseases



Proven Expertise

Commercially available differentiated malaria prevention product addressing \$50-70M market in US alone (ARAKODA® approved 2018, available 2019)



Strong & Growing IP Portfolio

Three Orange Book listed patents expiring December 2035; 42 other patents filed/pending or optioned



Pipeline Advancing Treatment in Tick-Borne Disease

Pivotal trial launched for treatment of acute babesiosis (FDA Orphan Drug status assigned); planned program for chronic babesiosis



Growing Commercial Revenues & Expansion Potential

Targeting profitability by Q4 2026 based on:

- Continued commercial growth in malaria prevention and achieving supplemental indication for babesiosis, enabling expansion to a 2M patient market



Leadership Team with Decades of Successful Clinical Development and Launch Experience



Geoffrey Dow, Chief Executive, President & Director

Geoffrey Dow is the CEO, President, and sole Director of 60 Degrees Pharmaceuticals, Inc. He has over 20 years of experience in product development for tropical diseases and a strong publication and patent history. He has 13 years of leadership and advisory experience in the antimalarial drug development program at the Walter Reed Army Institute of Research and the US Army Medical Materiel Development Activity. Dr. Dow co-founded 60 Degrees Pharmaceuticals in 2010 and has been instrumental in various projects including securing FDA-regulatory approval for ARAKODA® (tafenoquine) for malaria prophylaxis, managing post-marketing regulatory commitments, and ensuring the company adheres to GMP, quality, and pharmacovigilance requirements.



Bryan Smith, Chief Medical Officer

Bryan Smith is the Chief Medical Officer of 60 Degrees Pharmaceuticals, Inc. He is a medical doctor with expertise in clinical pharmacology, pharmacovigilance, regulatory strategy development, and translational medicine. He has over 30 years of experience in governmental research and leadership and is a retired military colonel. He joined the company in 2016 and works with the senior management team to establish all functional areas, including compliance with laws and regulations and overseeing research and development projects. Dr. Smith is also a Senior Medical Director, Clinical and Regulatory Affairs at Fast-Track Drugs & Biologics, LLC since 2019, where he is responsible for developing clinical development plans, managing clinical and regulatory projects, and designing and writing clinical trial protocols.



Kristen Landon, Chief Commercial Officer

Kristen Landon is the Chief Commercial Officer. Ms. Landon joined us in 2024 and brings over 26 years' experience building and transforming pharmaceutical brands in both start-up and large multinational companies. Ms. Landon has launched and relaunched over a dozen brands, many with peak revenues in excess of \$100 million across therapeutic categories including women's health, infectious disease, dermatology, nephrology, and hematology/oncology.



Tyrone Miller, Chief Financial Officer

Tyrone Miller is the Chief Financial Officer of 60 Degrees Pharmaceuticals, Inc. He joined the company in 2014 and has held various roles. He raised over \$6 million in external financing and established a multinational financial reporting system. He provides strategic advice in areas of financing and business planning to the company.



ARAKODA® (tafenoquine)

- US FDA approval August 8, 2018, commercially available 2019
- Indicated for the prophylaxis of malaria in patients aged 18 years and older
- Key Product Attributes
 - ARAKODA is the only prophylactic therapy to provide protection against all stages of malaria
 - Recommended by CDC
 - Convenient weekly dosing
- Established Safety Profile
 - 8 published clinical studies involving > 1,100 patients
 - Overall adverse event rate of tafenoquine 200 mg weekly for 52 weeks is comparable to placebo
 - G6PD screening required prior to use
 - See paper in *Travel Medicine & Infectious Disease* (Long-term safety of the tafenoquine antimalarial chemoprophylaxis regimen: A 12-month, randomized, double-blind, placebo-controlled trial)¹



1. Novitt-Moreno A, et al. *Travel Med Infect Dis.* 2022;45:102211. doi:10.1016/j.tmaid.2021.102211

The Burden of Malaria and Impact on US Travelers



Malaria is a life-threatening disease caused by mosquito-transmitted parasites of the genus *Plasmodium* (there are five species)



Globally in 2022, an estimated 249 million malaria cases and 608,000 malaria deaths were reported in 85 tropical countries

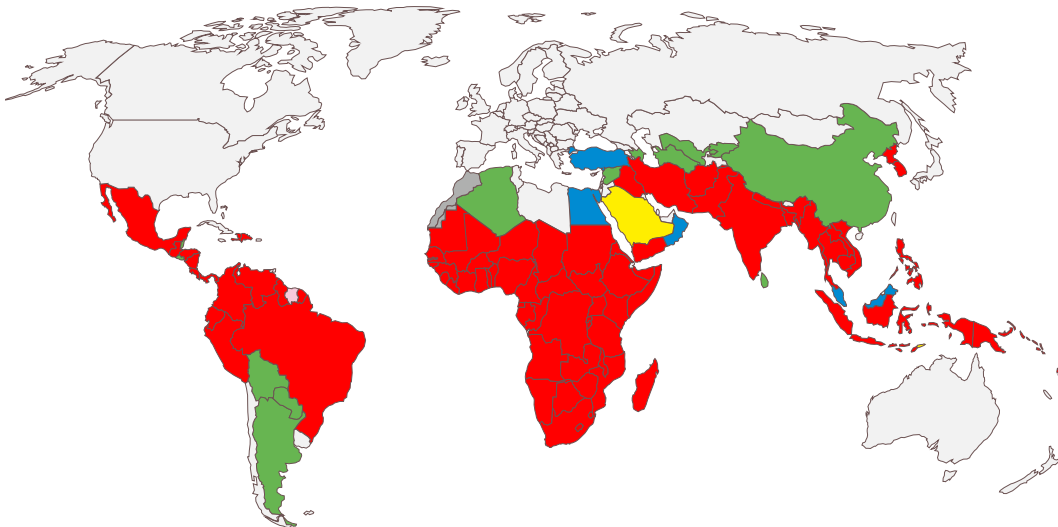


Cases of malaria among returning travelers are increasing



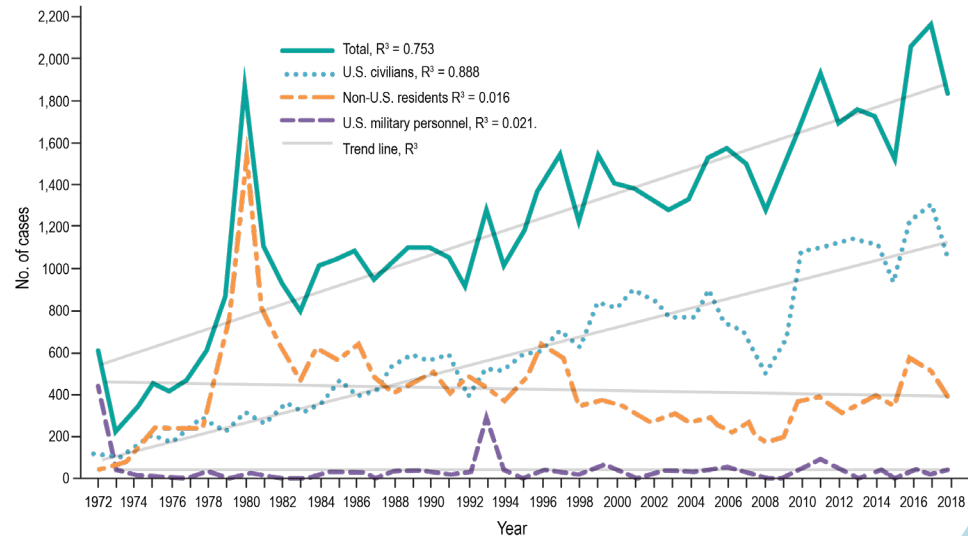
Local transmission of malaria was reported in 3 US states in 2023

Global Distribution of Malaria

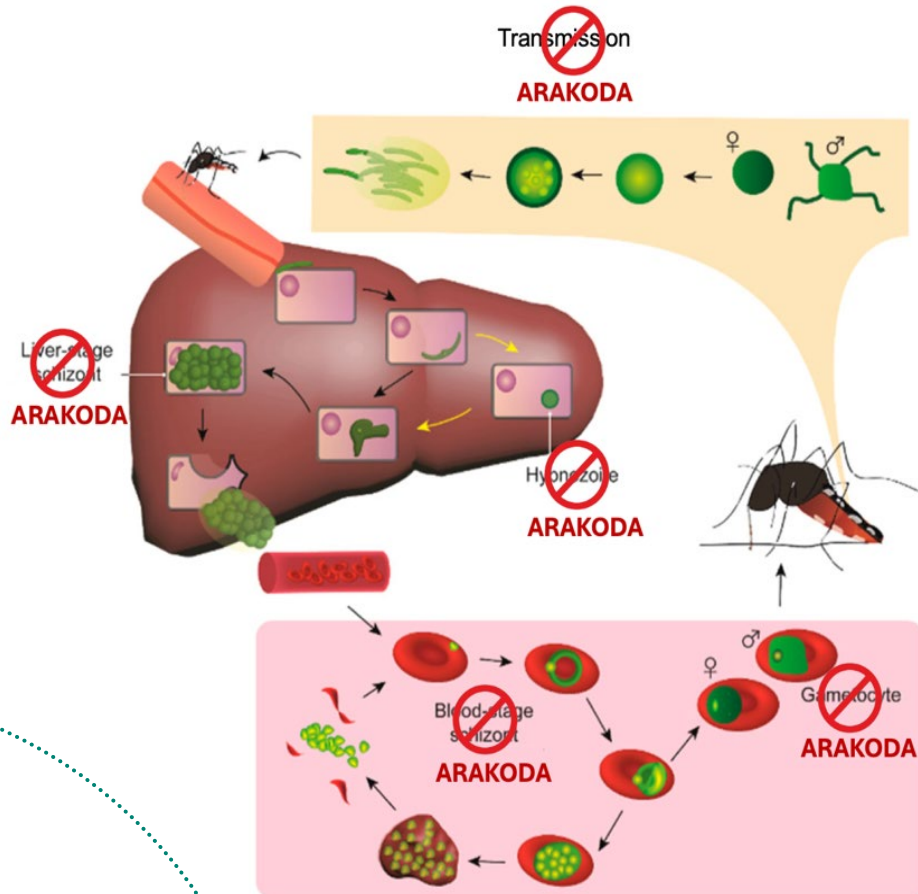


- One or more indigenous cases
- Zero indigenous cases 2021-2022
- Zero indigenous cases 2022
- Zero indigenous cases (>3 years) in 2022
- Certified malaria free after 2000
- No malaria
- Not applicable

Increasing Cases of Malaria Among Returning US Travelers



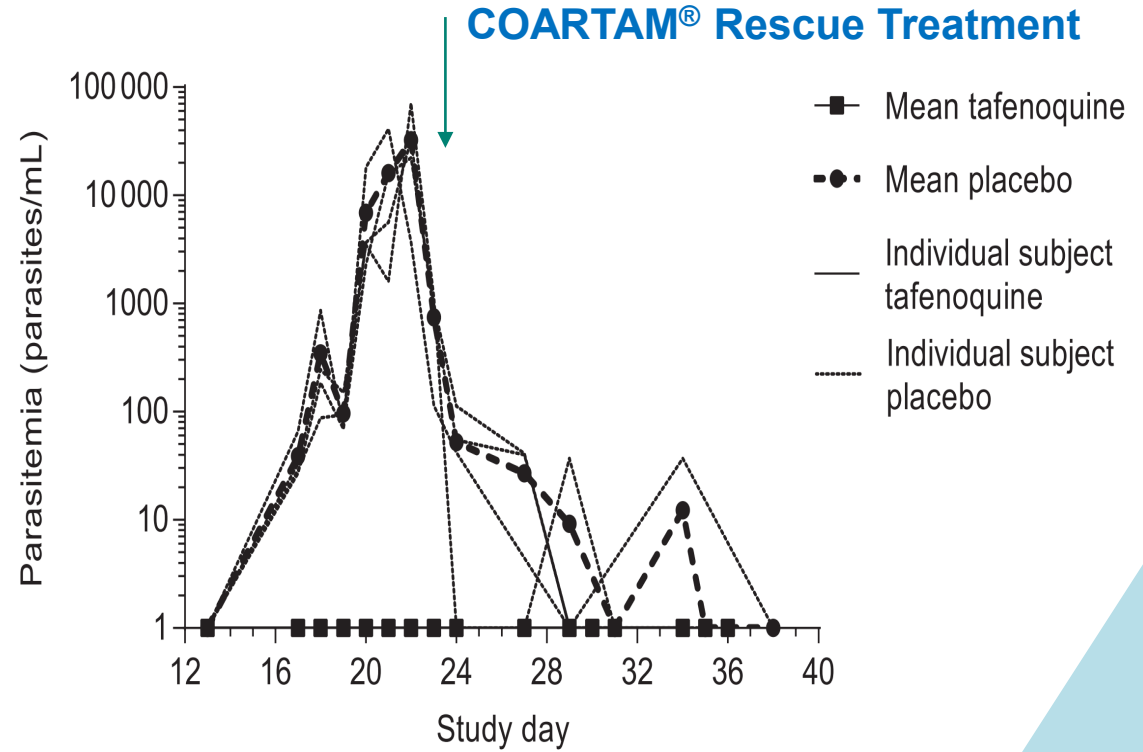
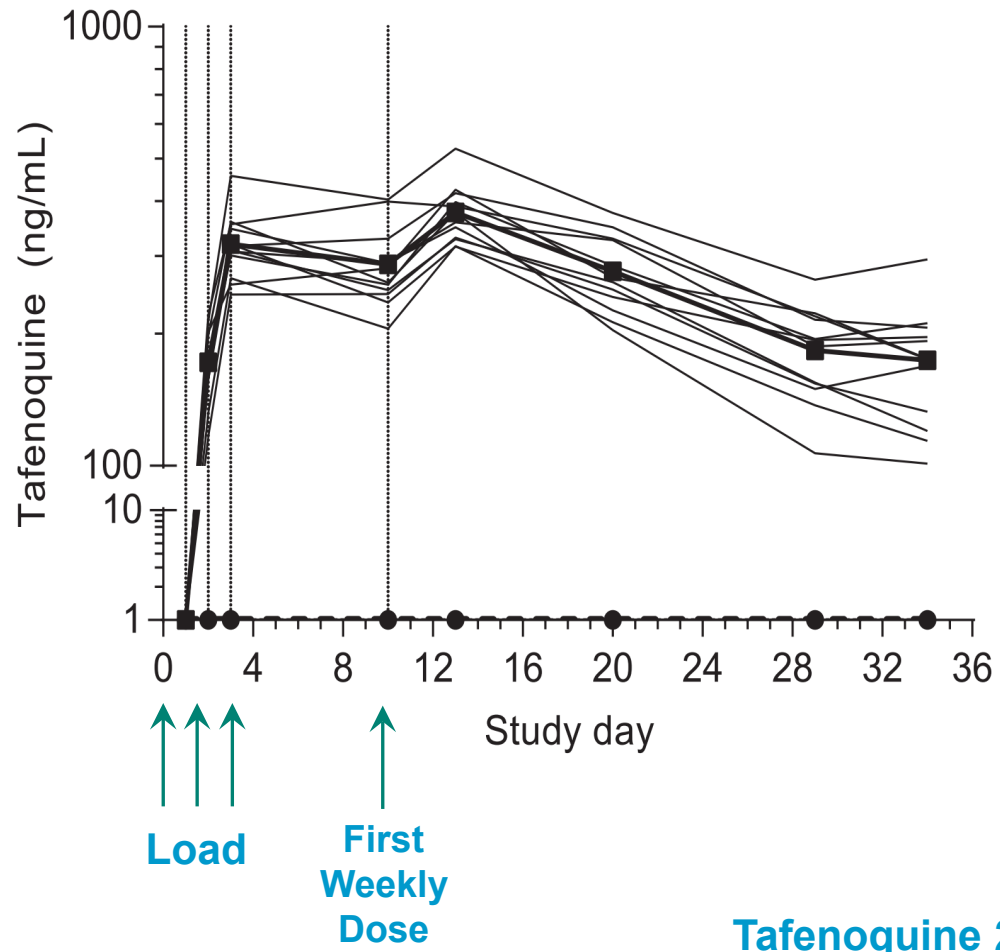
ARAKODA® Has Broad-Spectrum Activity at Several Life-cycle Stages for All *Plasmodium* Species With Convenient Weekly Dosing



Drug	Acts on blood stage	Acts on liver stage	Eliminates dormant liver stage	Weekly dosing
Chloroquine	✓	–	–	✓
Doxycycline	✓	–	–	–
Mefloquine	✓	–	–	✓
Malarone®	✓	✓	–	–
ARAKODA®	✓	✓	✓	✓

Tafenoquine 100% Protective Efficacy Against Malaria Naïve Target Population

Load then Once Per Week Dosing¹




1. McCarthy JS, et al. Clin Infect Dis. 2019;69(3):480-486. doi:10.1093/cid/ciy939

Evolving Commercial Strategy



Drive Commercial Growth
Build awareness and utilization of ARAKODA® in the malaria prevention market



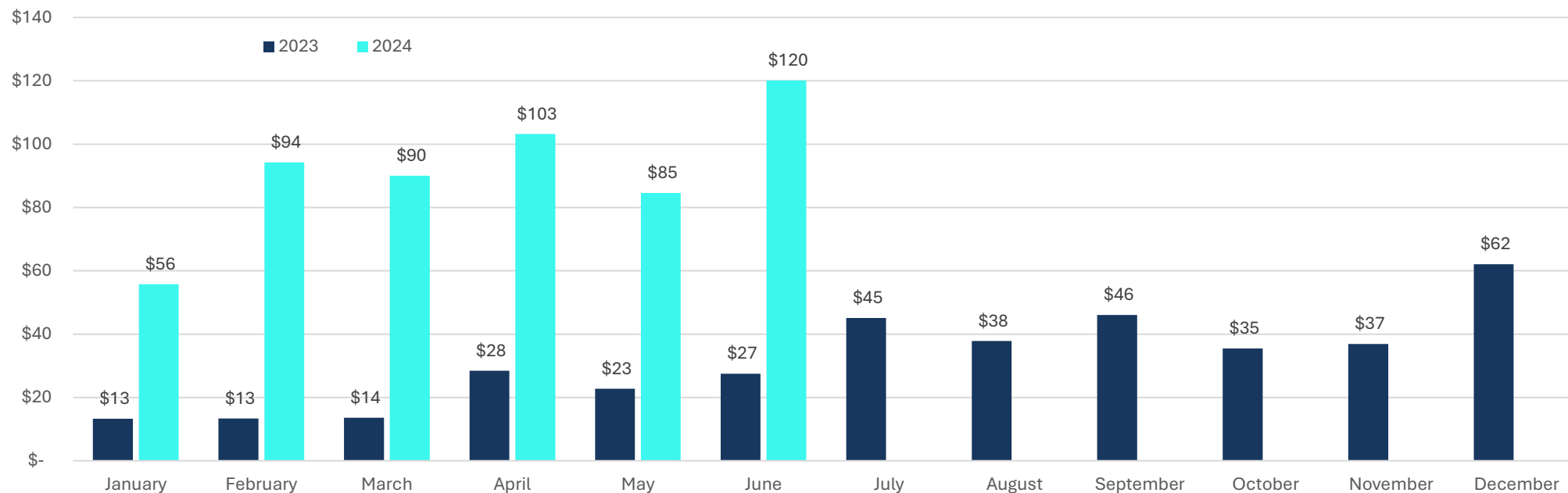
Capture Upside with RD –Derisked Clinical Development
Develop ARAKODA for babesiosis
Opportunity for label update and the only player in the space



Grow Commercial Revenue
Targeting Q4 2026 for profitability

ARAKODA® Growing With Limited Commercial Effort to Date*

Gross Sales (1,000's)



*Based on IQVIA data, this growth in sales volume appears to be driven primarily by organic growth in the Lyme disease community, whose prescribers utilize Arakoda for the treatment of babesiosis.



Commercial Plans for Malaria Indication 2024 & Beyond

Driving ARAKODA® Utilization & Addressing Access Barriers



Increase Awareness and Differentiate ARAKODA

Differentiate ARAKODA from the generic competition with a clear and compelling value story



Drive ARAKODA Trial & Usage

Convince HCPs to prescribe ARAKODA based on its brand value



Facilitate Access & Affordability

- Pharmacist education on ARAKODA order process to reduce switching at the pharmacy
- Manage high OOP costs with co-pay assistance program

Babesiosis¹

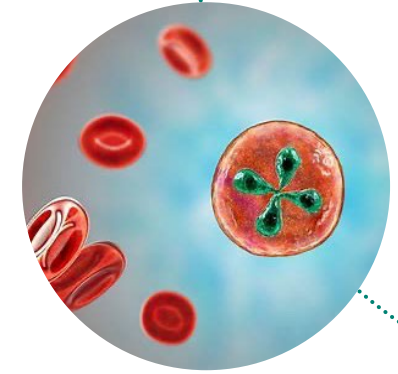
Tick-borne disease caused by protozoan parasites of the genus *Babesia*

Acute disease (*B microti* in US)

- Non-specific flu-like symptoms, anemia, but may be severe
- Mortality rate is 1.6% in hospitalized patients (10% in those with cardiac complications)
- May be refractory to treatment in immunosuppressed patients
- 38,000 symptomatic cases per year (650+ presenting to hospitals)
- Increasing in prevalence globally
- Microscopy or PCR required to confirm diagnosis prior to treatment
- Major scientific society: Infectious Diseases Society of America (IDSA)

Chronic Disease

- *Babesia* is transmitted by the same ticks as Lyme disease and is a common coinfection among patients with post-treatment Lyme disease syndrome (10-52% coinfection rate)
- Diagnosis is based on clinical presentation (e.g.; fatigue, history of tick-borne disease)
- Laboratory test confirmation not required to initiate treatment
- Total cumulative prevalence is up to 1,000,000 cases in the US
- Major scientific society: International Lyme and Associated Diseases Society (ILADS)



1. Centers for Disease Control and Prevention. Babesiosis. June 3, 2024. www.cdc.gov/dpdx/babesiosis/index.html

Current Treatments for Acute Babesiosis Have “Limited Evidence of Efficacy”¹

Atovaquone + azithromycin* + clindamycin

Atovaquone + clindamycin

Atovaquone/proguanil + azithromycin*

Atovaquone + azithromycin* + clindamycin + quinine

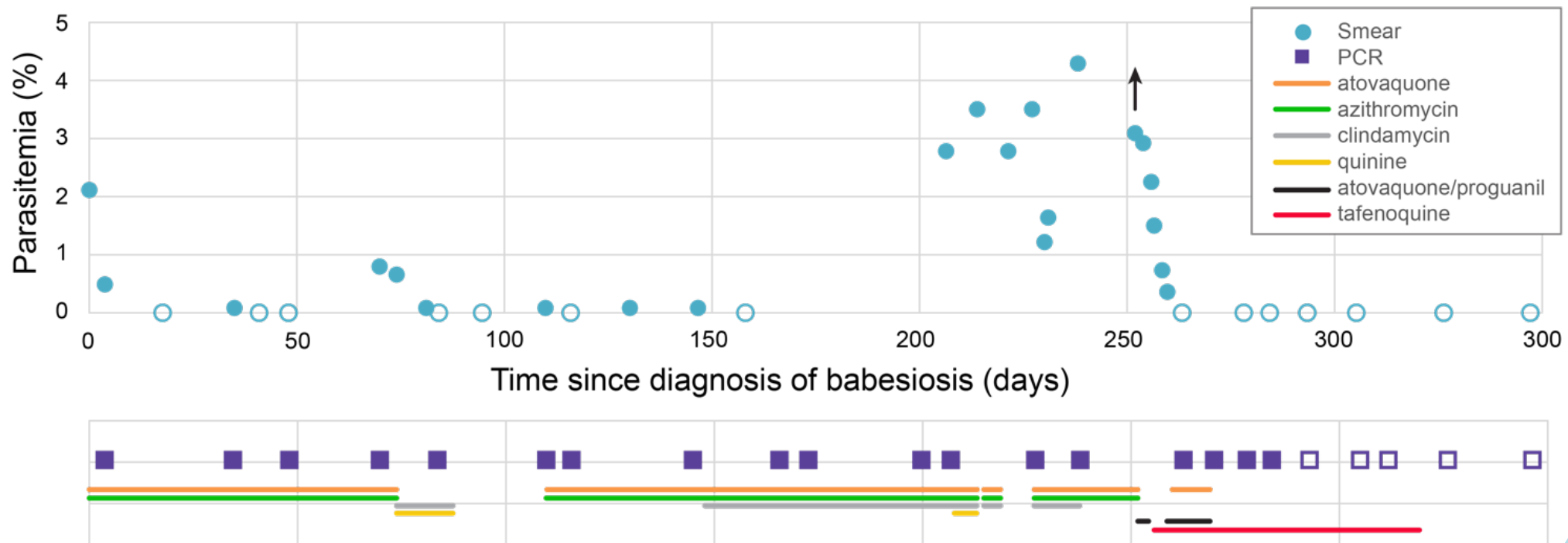
* When azithromycin is used, a 500–1000 mg daily dose should be considered.

- None of these recommended regimens is approved by the United States Food and Drug Administration
- Resistance and relapsing/persistent disease occur frequently in immunosuppressed patients
- None of these recommended regimens has been studied in chronic disease

1. Krause PJ, et al. IDSA: 2020 Guideline on Babesiosis. *Clin Infect Dis*. 2021;72(2):e49-e64. doi:10.1093/cid/ciaa1216

Tafenoquine Had an 80% Cure Rate in 5 Immunosuppressed Babesiosis Patients With Weekly Dosing Plus Standard of Care¹

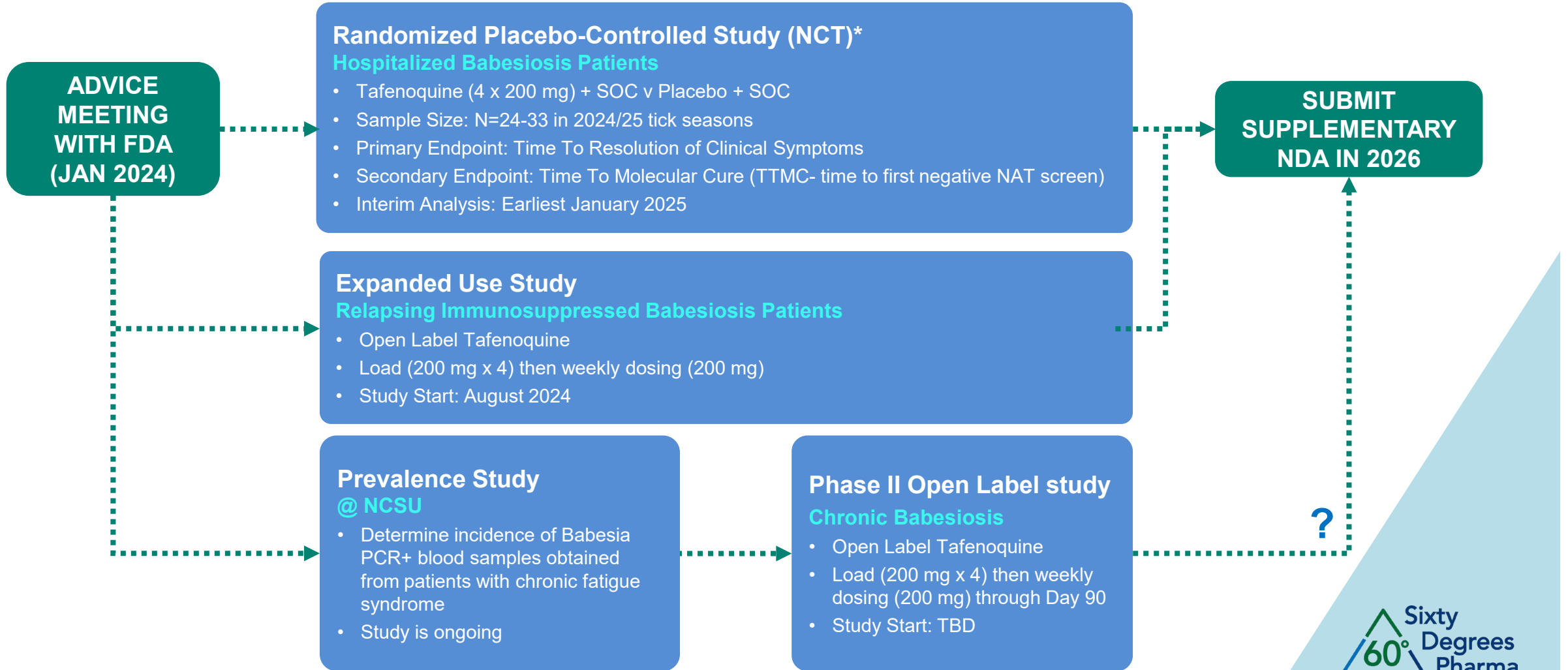
Representative Case:



1. Krause PJ, et al. Clin Infect Dis. doi:10.1093/cid/ciae238

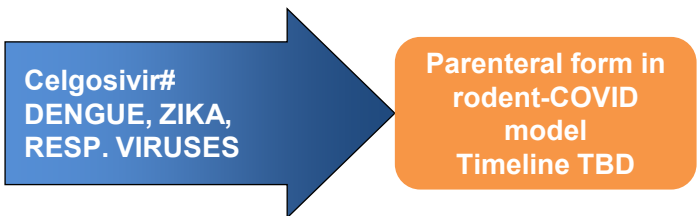
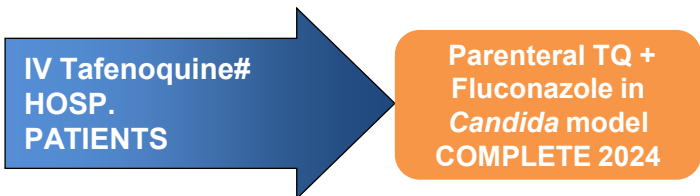
Babesiosis Clinical Development Plan

Indication: Treatment of Babesiosis



Portfolio June 2024

PHASES AND DEVELOPMENT STAGES



█ = Completed █ = Next phase



Tafenoquine in Patients Hospitalized for Acute Babesiosis

See [NCT06207370: Study Details | Oral Tafenoquine Plus Standard of Care Versus Placebo Plus Standard of Care for Babesiosis | ClinicalTrials.gov](#)



A Phase II/III, Double-Blind, Randomized study to Evaluate Oral Tafenoquine Plus Standard of Care Versus Placebo Plus Standard of Care for Babesiosis



Patients: Hospitalized patients with laboratory confirmed *Babesia* infection

Sample Size/Analysis: Will enroll N=33, before conducting an interim analysis/sample size reanalysis (if needed)



Tafenoquine Dose: 200 mg/day on Days 1,2,3 and 4, with dosing initiated within 48 h of hospitalization

Standard of Care: IDSA recommended course of atovaquone-azithromycin



Primary Endpoint: Time to (patient reported) sustained clinical resolution of the following symptoms of babesiosis over 90 days (\pm one week): sweats, joint aches, cough, loss of appetite, muscle aches, headache, chills or shivering, feeling hot or feverish, nausea, fatigue (low energy or tiredness), vomiting



Key Secondary Endpoint: Time to molecular cure (TTMC) as assessed using longitudinal NAT testing through Day 90 days (\pm one week). NAT test is an FDA-approved RNA-based test used by US blood banks to reduce risk of transmission through blood donation. Detects *B. microti* with 95% confidence at 3 copies/ml

Expanded Use of Tafenoquine in High-Risk Patients with Relapsing Babesiosis

[See [NCT06478641: Study Details | Expanded Use in Persistent \(B. Microti\) Babesiosis | ClinicalTrials.gov](#)]



Expanded Access Protocol: Use of Tafenoquine for Treatment of Babesiosis in Immunocompromised Patients With Persistent *Babesia Microti* Despite Prior Treatment



Patients: Immunosuppressed patients with lab-confirmed relapsing babesiosis caused by *B. microti*
Sample Size/Analysis: Up to ten patients per year



Tafenoquine Dose: 200 mg/day on Days 1,2,3 and 4, then 200 mg weekly for up to 12 months
Co-administered Standard of Care: IDSA recommended course of antimalarial/antimicrobial regimens



Metrics of Interest: Cure rate (regular PCR and NAT), severe adverse events, symptom resolution



Setting: Outpatient

Phase II Open Label Study of Tafenoquine - Chronic Babesiosis*



A Phase II Open Label Study of Tafenoquine in Chronic Babesiosis Patients



Patients: Diagnosis of chronic babesiosis and severe disabling fatigue with substantial functional impairment, present for at least six months

Number of Participants: Up to 40 patients per year



Tafenoquine: 200 mg/day on Days 1,2,3 and 4, then 200 mg weekly through Day 89. Modified loading dose or lower regimen acceptable in patients who do not tolerate antimicrobial or antimalarial medications

SOC: No concomitant med exclusions except quinine or per tafenoquine PI



Primary Endpoint: Change from base-line through Day 90 in patient-reported MFI – Physical Activity Score

PP Analysis Population: All patients taking 8 x 100 mg tablets who complete the Day 90 MFI survey

Secondary Endpoints: MFI subscales, Babesia PCR at baseline and Day 90, severe adverse events, herxing



Setting: Outpatient:

**Draft - Subject to change based on KOL, regulator and/or IRB feedback*

TAM for ARAKODA® for Malaria and Acute & Chronic Babesiosis

Indications	Cumulative Addressable Market Through End of Malaria Patent Exclusivity (2024-2034) (Total Trips or Patients)
Malaria Prevention*	1,700,000
Babesiosis Treatment** Chronic – ILADS-affiliated prescribers*** Acute – IDSA-affiliated prescribers If <i>Babesia</i> is a common infection in ME/CFS patients****	350,000+ 38,000 TBD

* Prescriptions for three weeks of travel (0.75 ARAKODA boxes)

** Patients

*** Based on extrapolation from existing off-label sales

**** TBD based on epidemiology study being conducted at NCSU (ME/CFS=myalgic encephalomyelitis/chronic fatigue syndrome)



Intellectual Property & Licensing

60 Degrees Pharmaceuticals has freedom to operate

- **US ARAKODA Patents (4 issued/9 in progress)**
 - Tafenoquine for malaria prevention patent family: Earliest expiration December 2035
 - Orange Book Listed
 - Tafenoquine for non-viral tick-borne diseases: Pending
 - Tafenoquine for lung Infections/COVID Treatment: Earliest expiration March 2041
- **US Celgosivir Patents**
 - Dengue/RSV (4 issued/1 in progress)
 - COVID-19 – Optioned from FSU (1 issued/1 in progress)
 - Zika: - Optioned from FSU (2 issued)
- **International Patents**
 - 6/6 for Celgosivir issued/in progress, 2/12 for tafenoquine issued/in progress
- **Clinical, non-clinical and manufacturing information**
 - Worldwide rights for all indications [except *P. vivax* malaria] licensed from US Army

Revenue Generating License & Distribution Agreements

Territory	Partner
Europe	Scandinavian Biopharma
Australia, NZ, Pacific Islands	Bioclect



Robust Supply Chain With Flexibility for Growth

API & Tablets



Piramal, India

Packaging



PCI, Philadelphia, PA, US

3PL Title Model



ICS, Brooks, KY, US

Distributors



ASB, Two Other US
Prime Vendors

PBMs
Various



60 DEGREES PHARMACEUTICALS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current Assets:		
Cash	\$ 1,576,602	\$ 2,142,485
Accounts Receivable	296,370	231,332
Prepaid and Other Assets	1,458,293	4,402,602
Deferred Offering Costs	5,860	-
Inventory (Note 3)	426,020	466,169
Total Current Assets	3,763,145	7,242,588
Property and Equipment, net (Note 4)	159,591	57,761
Other Assets:		
Right of Use Asset (Note 11)	-	13,517
Long-Term Prepaid Expense	154,412	242,647
Intangible Assets, net (Note 5)	250,103	227,258
Total Other Assets	404,515	483,422
Total Assets	\$ 4,327,251	\$ 7,783,771
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable and Accrued Expenses	\$ 643,375	\$ 506,206
Lease Liability (Note 11)	-	13,650
SBA EIDL (including accrued interest) (Note 7)	8,772	8,772
Derivative Liabilities (Note 8)	567,050	2,306,796
Total Current Liabilities:	1,219,197	2,835,424
Long-Term Liabilities:		
SBA EIDL (including accrued interest) (Note 7)	148,670	150,251
Total Long-Term Liabilities	148,670	150,251
Total Liabilities	1,367,867	2,985,675
Commitments and Contingencies (Note 11)		
SHAREHOLDERS' DEFICIT:		
Series A Preferred Stock, \$0.0001 par value, 1,000,000 shares authorized; 78,803 and 78,803 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively (Note 6)	9,858,040	9,858,040
Common Stock, \$0.0001 par value, 150,000,000 shares authorized; 1,017,198 and 484,187 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively ⁽¹⁾ (Note 6)	102	48
Additional Paid-in Capital ⁽¹⁾	29,365,567	27,457,335
Accumulated Other Comprehensive Income	134,804	135,561
Accumulated Deficit	(36,323,135)	(32,580,850)
60P Shareholders' Equity:	3,035,378	4,870,134
Noncontrolling Interest	(75,994)	(72,038)
Total Shareholders' Equity	2,959,384	4,798,096
Total Liabilities and Shareholders' Equity	\$ 4,327,251	\$ 7,783,771

Financial Overview (as of June 30, 2024)

Ask & Use of Proceeds

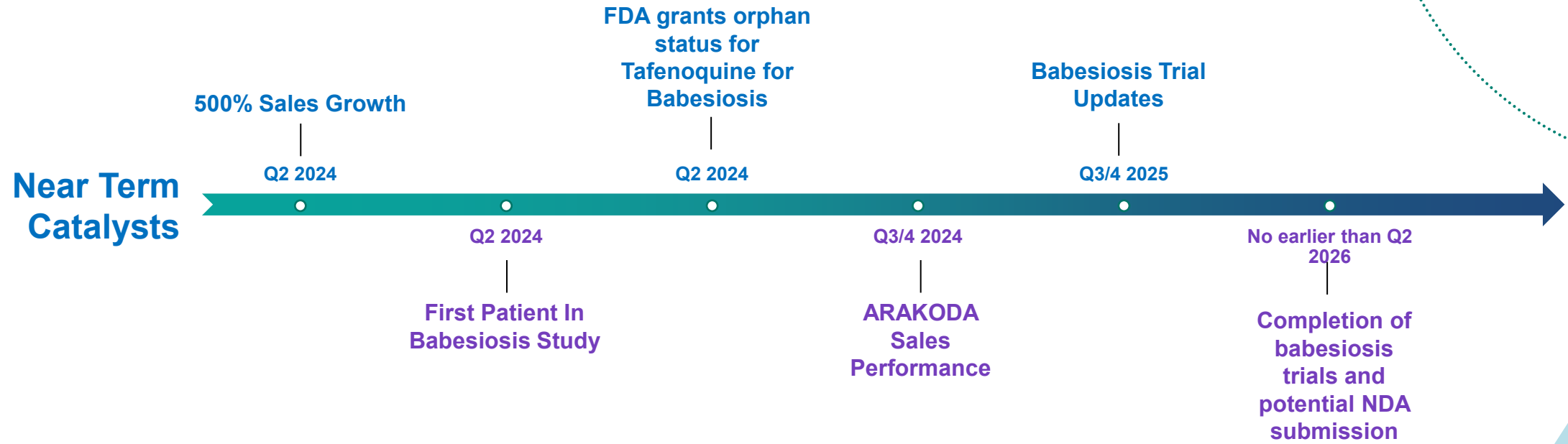
- 60P recently raised \$1.94 million off an S3
- 60P is looking to raise an additional \$8.0M to reach a cash flow positive position

Use of Proceeds

- Commercialization \$3M
 - Malaria Pilot, then Ongoing Commercialization
 - Babesiosis Market Development
- Development \$3M
 - Trial 1 – Hospitalized babesiosis patients
 - Trial 2 – Expanded use immunosuppressed patients
 - Trial 3 – Expanded use in chronic disease
 - Miscellaneous other
- Other Corporate Costs \$4M



2024/25 Milestones



Other Anticipated Milestones



Market updates



Outcomes from research pilot studies



Trade & scientific conferences



New product development collaborations



60 Degrees Pharma (NASDAQ: SOTP) Investment Thesis



- **Proven Expertise:** Commercially available differentiated malaria prevention product addressing \$50-70M market in US alone
- **Strong & Growing IP Portfolio:** 3 Orange Book listed patents expiring December 2035
- **Pipeline Advancing Treatment in Tick-Borne Disease:** Pivotal trial ongoing for treatment of acute babesiosis (FDA Orphan Drug status assigned), and planned program for chronic babesiosis
- **Growing Commercial Revenues & Expansion Potential:** Targeting profitability by Q4 2026 based on continued commercial growth in malaria prevention, and positive Babesiosis outcome



Officers & Directors



Geoffrey Dow, MBA, PHD, CEO & Chairman

- Affiliations: WRAIR, USAMMDA
- Founded & led 60P from 2010-2023
- Industry Project Leader on Arakoda NDA



Tyrone Miller, CFO

- CPA
- CFO since 2014
- Over 20 years in private practice



Bryan Smith, MD, Chief Medical Officer

- Retired US Army Colonel/30+ years experience
- Two successful NDAs as a Chief Medical Officer
- Medical affairs/regulatory expert in GxP environment



Kristen Landon, Chief Commercial Officer

- 26 years industry experience
- Led 11 brand launches
- Experience in Commercial strategy & BD



Cheryl Xu, Director

- First PhRMA representative to China
- Senior Advisor to multinationals (market access and expansion)
- Project Leader (multiple public health projects)



Stephen Toovey, MD, PHD Director

- Affiliations: Roche, Pegasus Research, WHO Collaborating Centre for Vaccines and Travel Medicine, London, UK
- Tropical medicine subject matter expert
- Respiratory virus subject matter expert



Paul Field, Director

- Affiliations: GARDP, Immunexus, Marinova
- 30 years global biotech business development experience
- Previously investment specialist at Austrade, focused on tropical medicine and NTDs



Charles Allen, Director

- Affiliations: BTCS & GBV
- CEO & Chairman of NASDAQ listed company
- Managing Director, several boutique investment banks
- Broad business experience across multiple sectors





Developing and commercializing new products that address the unmet medical need associated with infectious diseases

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