MERIDIAN BIOSYSTEMS

SBIR Phase I Project Proposal

Project Title: Next-Generation Microfluidic Optoelectronic Biosensor for Rapid Point-of-Care Pathogen Detection

Agency: NSF SBIR Phase I
Topic ID: BT1.2 Biological Tech
Budget: $275,000
Duration: 6 Months
Date: October 2026

Applicant Firm Details

Company Name: Meridian BioSystems Inc.
DUNS / UEI: K9X8J2M4L7V1
Principal Investigator: Dr. Eleanor Vance, Ph.D.
Location: Cambridge Innovation Center, MA
Contact Email: evance@meridianbio.com
Commercial Track: Medical Diagnostics

Key Performance Metrics

Target Assay Time: < 15 Minutes
Limit of Detection (LOD): < 100 CFU/mL
Sample Matrix: Whole Blood / Plasma
Target Unit Cost: $< \$12.50$
IP Protection: 2 Provisionals Filed (2025/2026)
Phase II Target: $500k Match Funding

Executive Summary & Technical Abstract:
Hospital-acquired infections and bloodstream pathogens account for over 270,000 annual fatalities in the United States, largely driven by diagnostic delays of 24–48 hours required for standard microbial blood culture. Meridian BioSystems proposes a novel microfluidic optoelectronic biosensor platform (*OptoDx*) that enables fully automated multiplexed pathogen detection directly from whole blood in under 15 minutes. Phase I research will establish feasibility by optimizing functionalized plasmonic microchannels, achieving sub-picomolar target capture efficiency, and demonstrating benchtop detection of *Staphylococcus aureus* and *Escherichia coli* at < 100 CFU/mL without prior sample enrichment.

1 Identification and Significance of the Innovation

1.1 Market Need and Technical Problem

Current clinical diagnostic protocols for bloodstream infections rely on time-intensive enrichment cultures followed by automated mass spectrometry (MALDI-TOF) or polymerase chain reaction (PCR). While highly specific, these workflow pipelines suffer from three fundamental bottlenecks:

- **Diagnostic Delay:** Turnaround times of 24 to 72 hours force clinicians to prescribe broad-spectrum empiric antibiotics, accelerating drug-resistant strain emergence.
- **Sample Preparation Complexity:** PCR and nucleic acid amplification methods demand labor-intensive extraction, centrifugation, and skilled laboratory staff.
- **Point-of-Care Incompatibility:** Centralized testing infrastructure cannot support decentralization to urgent care clinics, emergency departments, or rural triage centers.

1.2 The Meridian OptoDx Platform Innovation

Meridian BioSystems addresses these limitations by coupling nanostructure-enhanced surface plasmon resonance (SPR) optics with self-driven microfluidic arrays. The core innovation comprises a multi-layered cyclic olefin copolymer (COC) cartridge coated with localized gold nanostar arrays functionalized with high-affinity synthetic aptamers.

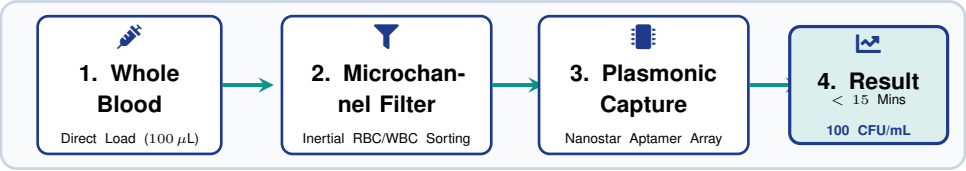

Figure 1: Architectural Overview of the Meridian *OptoDx* Sample-to-Answer Microfluidic Pipeline.

1.3 Transformative Technical & Commercial Potential

Unlike optical fluorescence sensors requiring laser excitation and cooling systems, the *OptoDx* reader utilizes solid-state LED sources paired with complementary metal-oxide-semiconductor (CMOS) detector arrays. This architectural reduction decreases instrument manufacturing cost by an estimated 78% relative to benchtop PCR systems while retaining single-cell sensitivity thresholds.

2 Phase I Technical Objectives and R&D Plan

The goal of this Phase I research program is to demonstrate technical feasibility of the *OptoDx* platform in a laboratory environment (TRL 4). Research tasks focus on chip functionalization, optical calibration, and biological validation in spiked human blood matrix.

2.1 Phase I Research Objectives

1. **Objective 1 (Cartridge Optimization):** Fabricate and validate gold-nanostar microfluidic channels achieving $> 92\%$ analyte capture efficiency under continuous capillary flow rates ($15\ \mu$L/min).
2. **Objective 2 (Optical Sensor Calibration):** Calibrate multi-wavelength CMOS optoelectronic reader to yield a signal-to-noise ratio (SNR) > 15 dB at target pathogen concentration of 50 CFU/mL.
3. **Objective 3 (Whole-Blood Assay Validation):** Perform multiplexed detection of *S. aureus* and *E. coli* in spiked human blood samples with coefficient of variation (CV) $< 6.5\%$.

2.2 Detailed Work Plan & Experimental Tasks

Task 1: Surface Functionalization & Microfluidic Channel Fabrication (Months 1–2) *Lead: Dr. Marcus Lin.* Microchannels will be injection-molded in COC substrates using precision micro-milling dies produced by manufacturing partner Apex Precision Tech. Channel surfaces will be activated via oxygen plasma treatment followed by silanization with (3-aminopropyl)triethoxysilane (APTES). Thiol-terminated aptamer sequences specific to surface proteins of *S. aureus* (Apt-Sa1) and *E. coli* (Apt-Ec3) will be conjugated to gold nanostars via self-assembled monolayer chemistry.

Task 2: Optoelectronic Subsystem Assembly & Detector Tuning (Months 3–4) *Lead: Sarah Jenkins.* Dual-wavelength illumination LEDs (530 nm and 650 nm) will be coupled with custom bandpass filters and a 5-megapixel CMOS sensor. Signal extraction algorithms will apply spatial fast Fourier transforms (FFT) to filter baseline dark currents and ambient optical noise.

Task 3: Biological Assay Benchmark & Matrix Interference Testing (Months 5–6) *Lead: Dr. Eleanor Vance.* De-identified human donor blood samples will be spiked with heat-inactivated bacterial strains across concentrations ranging from 10^1 to 10^5 CFU/mL. Assay performance will be cross-checked against quantitative PCR (qPCR) standard curves.

2.3 Project Milestones and Verification Metrics

Table 1: Phase I Project Milestones, Target Specifications, and Risk Mitigation.

Milestone	Deliverable Description	Month	Success Criteria	Risk Mitigation Strategy
M1.1	Functionalized COC Microchips	M2	Capture efficiency $> 90\%$	Fallback to planar gold films with PEG
M1.2	Aptamer Conjugation Density	M3	Surface density $> 10^{12}/\text{cm}^2$	Adjust pH and ionic strength in buffer
M2.1	Optoelectronic Reader Assembly	M4	Noise level < 0.5 mV	Implement differential photodiode topology
M3.1	Single-Pathogen LOD Test	M5	LOD < 100 CFU/mL	Increase LED illumination pulse power
M3.2	Multiplex Whole-Blood Validation	M6	Assay CV $< 6.5\%$ ($n = 30$)	Refine inertial filter micropillar design

3 Commercial Opportunity and Business Strategy

3.1 Target Market and Commercial Viability

The global market for rapid point-of-care infectious disease diagnostics was valued at $14.2 Billion in 2025 and is projected to reach $24.8 Billion by 2032 (CAGR 8.3%). Meridian BioSystems will initially target hospital emergency departments and intensive care units where rapid diagnostic results directly reduce patient length of stay and intensive care costs.

Figure 2: Market Size Partitioning (TAM / SAM / SOM) for Meridian BioSystems.

3.2 Competitive Landscape Analysis

Existing commercial diagnostic systems exhibit distinct trade-offs between speed, cost, and complexity. As summarized in Table 2, Meridian's *OptoDx* platform combines the rapid assay time of lateral flow tests with the sensitivity of PCR.

Table 2: Competitive Comparison of Diagnostic Platform Technologies.

Performance Metric	Meridian OptoDx	Standard PCR	Blood Culture	Lateral Flow
Time-to-Result	< 15 **Mins**	2–4 Hours	24–48 Hours	15–30 Mins
Limit of Detection	< 100 **CFU/mL**	10–50 CFU/mL	1 CFU/mL	$> 10^5$ CFU/mL
Sample Preparation	**Automated On-Chip**	Manual Extraction	Automated Incubation	None
Instrument Cost	**$4,500**	$45,000–$90,000	$60,000	None (Visual)
Consumable Unit Cost	**$12.50**	$35.00–$75.00	$18.00	$5.00–$10.00

3.3 Intellectual Property & Regulatory Strategy

Meridian BioSystems holds exclusive global commercial rights to two provisional patents filed with the USPTO:

- **US Prov. App. 63/892,104:** *Plasmonic Nanostructure Arrays for Microfluidic Optoelectronic Sensing* (Filed Nov 2025).
- **US Prov. App. 63/941,512:** *Inertial Microfluidic Particle Separation in Viscous Biological Fluids* (Filed Mar 2026).

The regulatory path will follow the FDA 510(k) clearance process utilizing a predicate Class II point-of-care molecular diagnostic device. Meridian will seek Clinical Laboratory Improvement Amendments (CLIA) waiver status to allow deployment in decentralized clinical settings.

3.4 Phase II Transition and Commercial Partners

Upon successful completion of Phase I feasibility milestones, Meridian will submit an NSF Phase II proposal for $1,200,000 in funding. To accelerate commercial scale-up, Meridian has secured non-binding Letters of Intent (LOIs) from:

1. **Apex Precision Tech Inc.:** Contract manufacturing partner for high-volume injection molding of microfluidic cartridges.
2. **Synapse Health Network:** Regional health system providing clinical access for prospective 200-patient validation trials during Phase II.

4 Key Personnel, Facilities, and Budget Justification

4.1 Key Personnel Qualifications

- **Dr. Eleanor Vance, Ph.D. (Principal Investigator):** Former Senior Research Scientist at Harvard Wyss Institute. 12+ years experience in microfluidics, biosensors, and translational diagnostics. Author of 24 peer-reviewed publications and inventor on 5 patents.
- **Dr. Marcus Lin, Ph.D. (Lead Surface Chemist):** Ph.D. in Materials Chemistry from MIT. Expert in self-assembled monolayers, gold nanoparticle synthesis, and aptamer functionalization chemistry.
- **Sarah Jenkins, M.S. (Chief Systems Engineer):** 10+ years commercial experience in optoelectronic instrument design and embedded signal processing at Vertex Biomedical.

4.2 Facilities and Equipment Resources

Meridian BioSystems operates a $2,400$ sq ft laboratory facility at the Cambridge Innovation Center, equipped with:

- Class 1000 (ISO 6) cleanroom for microfluidic device prototype assembly.
- BSL-2 cell culture laboratory equipped with Class II Type A2 biosafety cabinets, incubators, and refrigerated centrifuges.
- Optical characterization suite with ocean optics spectrometers, epi-fluorescence microscope, and RF sputtering system.

4.3 Phase I Budget Breakdown and Cost Realism

The requested total direct and indirect cost budget for the 6-month Phase I project is $275,000. Costs have been estimated based on audited labor rates and quotes from qualified vendor suppliers.

Table 3: Detailed Phase I Budget Allocation by Cost Category.

Cost Category	Description & Itemization	Cost ($)	Share (%)
Senior Personnel	PI Dr. Vance (2.5 Mos) & Dr. Lin (2.0 Mos)	$112,500	40.9%
Engineering Staff	Systems Engineer S. Jenkins (1.5 Mos)	$36,000	13.1%
Materials & Supplies	Microfluidic COC substrates, aptamers, gold nanostars	$38,500	14.0%
Subcontractor Services	Apex Precision Tech (Precision Mold Die Tooling)	$32,000	11.6%
Analytical Testing	Third-party SEM/AFM surface characterization	$9,500	3.5%
Indirect Costs (F&A)	Overhead calculated at 32% of Direct Labor	$46,500	16.9%
Total Requested Budget	**NSF Phase I Small Business Innovation Research**	**$275,000**	**100.0%**

Compliance Statement:
Meridian BioSystems Inc. certifies that it is a small business concern meeting all eligibility criteria set forth by the National Science Foundation SBIR/STTR Phase I solicitation guidelines. All research work detailed in this proposal will be performed within the United States at Meridian's facilities and designated subcontractor sites.