Mission

Provide Clinicians, Patients and Payors with a Point-of-Care Diagnostic Solution Coupling Clinically Relevant Performance with Unparalleled Ease-of-Use and Cost Effectiveness
**Product:** Point-of-care immunoassay system yielding rapid lab-quality quantitative blood test results with unprecedented ease-of-use.

**Technology**
- Proprietary microfluidics and amplification chemistry
- Pre-loaded reagents
- Sensitive single marker or multiplex assays
- Wide bandwidth of accuracy
- Flexibility of testing media
- Inexpensive

**Platform technology / Harvard University / Dr. George Whitesides**

**Initial target application:** Diagnostics panel for prostate cancer
- Large market / Est. reimbursement

**Secondary Application:** Multiple verticals / Multiple assays

**Strong IP Portfolio**

**Highly regarded / Active Medical Advisory Board**

**Market driven need**
OPKO POC Diagnostics Technology Applications

Urologist Office
- PSA Panel: • total-PSA • free-PSA • Testosterone
- Panel Tests: • Pre-term bleed • Fertility • Menopause

Ob/Gyn Office

Emergency Room
- Cardio Panel: • CTnl • BNP • D-dimer

Clinic and Blood Bank
- STD Panel: • HIV • Hepatitis B • Syphilis

General Practitioner
- Key Tests: • TSH, T4 • Vitamin D

Setting

Product

Liquid Sample Capabilities

<table>
<thead>
<tr>
<th>Whole Blood</th>
<th>Semen</th>
<th>Spinal Fluid</th>
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<tbody>
<tr>
<td>Serum</td>
<td>Saliva</td>
<td>Tears</td>
</tr>
<tr>
<td>Urine</td>
<td>Amniotic Fluid</td>
<td>Sweat</td>
</tr>
</tbody>
</table>
Overview of OPKO Diagnostics Technology

Key Attributes – High Quantitative Performance / Low Cost

- **Inexpensive Disposable**
  - Injection-molded microfluidics
  - Storage / delivery of multiple reagents
  - Multiplex platform

- **Robust Signal Detection**
  - Sensitive proprietary amplification chemistry for microfluidics

- **Inexpensive Hardware Unit**
  - Reliable standard optics

- **Ease of Use and Safety**
  - No sample prep
  - User-friendly sample introduction
  - Biohazard containment
OPKO / Claros 1 Point-of-Care Platform
Sandwich Immunoassays in Microfluidics

Assay Formats

ELISA Assay

Sample → Second Antibody

Au

Enzymatic Detection

Ag

Reagents

OPKO / Claros Assay

Sample

ELISA: Enzyme-Linked Immunosorbent Assay
OPKO’s Claros 1 Assay / Disposable Configuration

- Reagent storage and delivery
  - Multiple fluid plugs
  - No valves – complex fluid handling
  - Automated delivery
  - Simple geometry
  - Optical feedback / active control
  - Multiplex format validation
Industrial Design
Analyzer / Disposable / Interface

- **Analyzer**
  - Design minimizes counter space
  - Intuitive touch screen interface / menu
  - USB printer and EMR output
  - Easy insertion / removal of cassette
  - Cleanable surfaces

- **Disposable: Blood Collector – Cassette / Ease-of-Use**
  - Guided attachment to cassette / snaps permanently into place
  - One-handed operation / fill-window for blood loading

**Simple User Steps:**
1. Collect blood
2. Snap into cassette
3. Insert into analyzer
4. Read result
OPKO Diagnostics

Physician Logistics / Value Proposition

- General Operations Management / Alleviate Need...
  - Reacquaint to case / call patient with results
  - Scheduling / significant distraction - time drain

- Physician Direct Reimbursement Value

- Patient Results Expedience
  - Connect patient visit w/ current lab results

- Minimize Physician Liability
  - Failure to notify patient of abnormal results

- Payors
  - Efficient diagnostics & therapeutics
  - No sample ship cost
  - Minimize sample risks
    - Loss / contamination / degradation due to prolonged storage
OPKO Platform for Infectious Disease / Global Health Collaboration with Sam Sia, Ph.D., Claros Co-Founder / Columbia Univ.

- Simultaneous Detection of 3 Infectious Diseases
  - **Multiplex Panel:** HIV, Hepatitis C, Syphilis

- Optimized for Low-Resource Settings
  - Portable / low power / single-button operation
  - Field testing in Rwanda

- Gates Foundation Grant ($3MM)
  - Commons Capital / Research Triangle Institute (RTI)
Key Operational Points

- Quality System / Manufacturing
- Regulatory / Clinical Affairs
- Financial / Business Model
- Sales Channel
- Business Development
**OPKO Technology Expansion / Business Development**

- **Worldwide Applicability**
  - High quantitative performance / low cost / multiplex / etc.
  - Address specific challenges for all segments of healthcare
  - Significant business development / industry interest

<table>
<thead>
<tr>
<th>Example Applications</th>
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<tbody>
<tr>
<td><strong>Settings</strong></td>
</tr>
<tr>
<td>Developed (USA, Europe, Asia)</td>
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<tr>
<td>Emerging (Brazil, China, India)</td>
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<tr>
<td>Developing</td>
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### POC Diagnostics Attribute Realization

**High Performance / Quantitative Immunoassay Platform**

<table>
<thead>
<tr>
<th>Market Requirements</th>
<th>OPKO / Claros Design Features</th>
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<tbody>
<tr>
<td>Simple sample acquisition</td>
<td>Finger-stick of whole blood</td>
</tr>
<tr>
<td>No sample preparation</td>
<td>No separation of blood cells</td>
</tr>
<tr>
<td>Automation of all assay steps</td>
<td>- On-cassette reagent storage</td>
</tr>
<tr>
<td></td>
<td>- Automated reagent delivery</td>
</tr>
<tr>
<td>Reliable and fail-safe operations</td>
<td>- On-cassette controls</td>
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<tr>
<td></td>
<td>- Intelligent quality control</td>
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<tr>
<td></td>
<td>- User-interface / ease-of-use</td>
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<tr>
<td></td>
<td>- Waste containment for liquids</td>
</tr>
<tr>
<td>Patient data retrieval</td>
<td>- Hardcopy or EMR capability</td>
</tr>
<tr>
<td>Attractive capital cost</td>
<td>- Inexpensive optics</td>
</tr>
<tr>
<td></td>
<td>- Standard sub-systems</td>
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<tr>
<td>Attractive recurring cost</td>
<td>- Cassette by injection molding</td>
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<tr>
<td></td>
<td>- No moving parts in the cassette</td>
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OPKO Diagnostics

Next Generation CaP Index / Urology Practice Integration

Current Std of Care

TRUS Needle Biopsy
- ~1.2MM U.S. Bx/Yr
- Morbidity
- 750K Unnecessary Bx/Yr
- $2.5B+ Expenditures

Active Surveillance
- Aggressive Tx Indolent Tumors
- Morbidity
- Healthcare Costs

GP Baseline / Urologist Validation
- Elevated PSA
- PSA Velocity
- Abnormal DRE

Next Generation
OPKO Index
- Predict Initial Bx Result
- Dramatic Reduction
  - Unnecessary Bx Rates
  - Morbidity
  - Aggressive Tx Indolent Tumors
  - Healthcare Costs

TRUS Needle Biopsy
- Validated Need

Intervention

PSA Monitoring

PSA Monitoring

TRUS Needle Biopsy

Active Surveillance

Intervention

Current Std of Care
Value Proposition Highlights

- Attractive point-of-care diagnostics space
- Opportunity for high margin disposable device business
- Clear regulatory path
- Established reimbursement
- Strong IP foundation / know-how / trade-secrets
- Market-driven need validated
- Internal / external manufacturing expertise
- Distribution / channel partner diligence
- Technical execution foundation / capabilities
- **Platform** point-of-care diagnostics applications
  - Urology, infectious disease, cardiology, women’s health, etc.