

Industry Medical Device

Product Description AI Solutions for precision colon cancer screening
 [1]PolypSense (polyp detection),
 [2]PolypSect (polyp resection),
 [3] CapsuleNet (small bowel disease detection)

Management Team

Jacob Nye, Technical Lead (B.S., M.S., Biomedical Engineering – Columbia University) | Former A.I. Engineer at Tempus Labs

Bina Bansinath, Operations Lead (B.S. Biomedical Engineering – Columbia University) | Former NIH brain-computer interface researcher

Drew Afromsky, Co-Founder (B.S., M.S. Biomedical Engineering – Columbia University) | Founder of Adam’s Heart

Advisors

Katherine Reuther, Scientific, PhD, MBA – Director of Columbia University BiomedX

Markos Koutsos, Clinical, MD – Gastroenterologist (25+ years of experience) affiliated with New York Presbyterian – Brooklyn Methodist Hospital

Craig Kenesky, Legal, PhD, JD – Wilson Sonsini, Goodrich, & Rosati

Lori Lonczak, Industry, RPH, MBA (20+ years of experience at Johnson & Johnson in Strategic Marketing and Corporate Strategy)

Legal

Provisional Patent filed & in the process of filing for utility

Financing Sought: \$500,000 convertible note with a \$5 million valuation cap, a 20% discount rate, & conversion on \$2+ million

Use of Funds: [1] Pilot Study (\$290K), [2] IP (\$100K), [3] Founder’s Salary (\$60K), [4] R&D (\$50K)

Revenue Model: \$25 fee per colonoscopy (based on Endocuff comparable) | average of 1000 procedures performed per

Company History Colonai was founded in 2018 to improve colonoscopy to reduce mortality from colorectal cancer (2nd leading cause of cancer-related deaths in the U.S. and 3rd leading cause globally). With our proprietary artificial-intelligence-based software solutions, Colonai enables gastroenterologists (GIs) to perform higher quality colonoscopies with fewer missed and incompletely tumors. High-quality colonoscopy significantly reduces the risk of colorectal cancer-related mortality

Unmet Need/Market Opportunity Gastrointestinal-related procedures such as colonoscopy and wireless video capsule endoscopy (WVCE) are the gold standard in detecting and treating diseases of the large and small intestine. Colorectal tumors known as polyps or adenomas are difficult to find and fully remove during colonoscopy; with 27% missed and 10% incompletely removed (*Gastrointestinal Endoscopy 2018*). According to iData Research, 19M colonoscopies are performed annually in the U.S., which is a \$450M domestic market based on our \$25 per use business model. The American Cancer Society reports that 60% of adults in the U.S. that need to be screened get screened with a colonoscopy, with the goal to increase that number to 80%. This yields an estimated future market of 31M colonoscopies and a \$775M total addressable market. Of our four competitors, none of them have addressed the incompletely removed polyp problem. Additionally, we are working on a high-risk tumor detection module which our competitors hold as an exclusion criteria. No one is currently in the market.

Our product – seamlessly integrated into existing workflow Using artificial intelligence, Colonai, has developed three proprietary software products that identify missed polyps, incompletely removed polyps, and detect small bowel disease lesions. PolypSense and PolypSect are patent-pending.

- **PolypSense** is our cutting-edge deep learning algorithm that functions as a second set of eyes for the physician, better highlighting suspicious areas in the colon that may have a tumor in the field of view and covers the physician’s blind spots.
- **PolypSect** is a deep learning algorithm that helps doctors define the margins between tumors and healthy tissue, to aid in achieving a complete resection.
- **CapsuleNet** is a third deep learning algorithm that retrospectively analyzes capsule endoscopy footage, 37 min. faster than manually, detecting and localizing lesions in the small intestine.

Commercial/ Technical Milestones

March 2019 - Achieved sensitivity of 98.1% and specificity of 97.45% for colon polyp detection on validation set of 2,391 colonoscopy images labeled by gastroenterologists comparable to our competitors Docbot (95% sensitivity, 98% specificity) and Wision A.I. (94% sensitivity, 96% specificity).

April 2019 - Finalist at the Rice Business Plan Competition and runner-up prize (OFW Law)

May 2019 – Completed working prototype of CapsuleNet that can detect and localize inflammation and bleeding in the small intestine in wireless capsule endoscopy images in 59% of time required for manual reading.

September 2019 – Redesigned CapsuleNet network architecture and improved mean accuracy (both sensitivity and specificity) above 80% for all disease classes with 96.0% global accuracy.

August 2020 – Complete pilot study with clinical collaborator demonstrating ADR improvement. Accepted into Columbia Almadworks Accelerator – Fall 2019 Cohort.

April 2020 - Finalists in Columbia Venture Competition, and began talks with VP, Global M&A Lead/Business Development at Olympus (potential acquisition partner)

August 2020 – Complete pilot study with clinical collaborator demonstrating ADR improvement

December 2021 – Complete 1-year 300-patient feasibility study demonstrating ADR improvement to receive FDA clearance in 2nd half of 2022.

Financial Projections

Year	2022	2023	2024	2026
Revenue	\$5.61M	\$63.4M	\$81.4M	\$104.35M
Gross Profit	\$3.65M	\$4.23M	\$54.54M	\$73.05M
# of G.I.s	1, 919	2, 534	3,256	4, 174