

Curiva, LLC.
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Industry: Diagnostics, Digital Health

Management:
 Eydis Lima, MSc.
 Entrepreneurship, CEO, Founder,
 Former Process Development Associate at Abbvie

Advisory Board:
 James Thompson, MSc, Associate VP of Innovation, University of Notre Dame

Gil Mor, MD/PhD, Vice Chair for Research, Department of Obstetrics and Gynecology, Wayne State University

Elizabeth Jennings, Principal, Venture Atlas Labs

Jesse Hsieh, MD, Primary Care Physician, Michiana VIP MD, Chairman of the Board Beacon Health System

Patricia Sigmon, CEO, David Advisory Group,

Seeking additional members

Number of Employees: 4

Finance:
 Accounting/Tax: Marcum LLP

Funding to Date:
 Founder: \$25,000
 NSF I-Corps Grant: \$25,000
 Total: \$50,000

Financing Sought: \$2M
 Proof of concept studies
 IP portfolio
 MVP
 Human pilot IRB
 FDA documentation
 Operating costs

IP: DZ Buschmann Law
 Provisional patent submitted
 Licensing agreements in negotiations

Legal: TBD

Business Description / Company Background:

Curiva is a startup developing and commercializing a wearable diagnostics patch for gynecologic malignancies detection - **diapatch™**. Curiva's flagship product allows doctors, healthcare professionals and their patients to accurately test for high-risk biomarkers that forecast the onset of cervical cancer. The idea of diapatch™ surfaced when the founder participated at a Healthcare Hackathon - Yale University while doing ovarian cancer research.

Market Opportunity / Unmet Need:

The total market size for the startup is \$14.1B with a CAGR of 5.6%, wherein the Serviceable Obtainable Market is \$15M for detection of pre-cancerous cervical intraepithelial neoplasia as the initial area of indication, followed by the Serviceable Addressable Market of \$3.9B encompassing cervical cancer screening. In total, 39M women in the US are infected with the human papilloma virus (HPV) - the primary cause of cervical cancer. The standard of care is the Pap smear, which has a sensitivity and specificity of 55.4% and 96.85% respectively. The cost for a Pap smear test is \$40, with an additional \$50-\$100 for an HPV test and results can be received in days to weeks. 14,800 women are diagnosed with invasive cervical cancer and an estimated 4,290 die from the disease every year - leading to \$1.7B for HPV and cervical cancer related costs.

Products / Services – Launched & Pipeline:

diapatch™ is a novel patent-pending molecular diagnostic medical device. Our diagnostic patch is non-invasive and able to detect high-risk, pre-cancerous biomarkers. Our initial product, diapatch_{CER}™ effectively forecasts the onset of pre-cancerous lesions. The follow-on product, diapatch_{HPV}™ later supports the screening population. Patients are sampled via diapatch™ using microneedles. Our novel assay of detection gives results within 30 to 45 minutes - equivalent to the length of a clinical visit, and costing between \$100 to \$350 per patch. The signal obtained is digitized and our algorithms provide follow-up clinical insights to practitioners, healthcare professionals, and their patients via our protected patient health information app, ELLE™.

Commercial / Technical Milestones:

Achieved: NSF I-Corps (Q1/Q2 2019); Created an LLC (Q1 2021); IP provisional patent filing (Q2 2021); collaboration with microneedles supplier (Q1 2021).

Pending – proof of concept showing microneedles can sample biomarkers of interest (Q3/Q4 2021); application to NIH SBIR (Q3/Q4 2021); securing 2 licensing agreements (Q3/Q4 2021) and file additional 3 patents (Q1/Q2 2022); launch date (Q1 2023).

Competition / Competitive Advantages / Customer Benefits:

Roche Diagnostics, one of the global market leaders in cervical cancer detection, is the main manufacturer of the reagents utilized for the Pap Smear test. Roche's HPV primary screening test was substantially more sensitive in detecting cervical cancer disease than Pap cytology (96.1% vs. 53%). The total cervical cancer market has a multitude of major players, with Roche accounting for 3.31%, followed by Becton, Dickinson, 2.78%, and Hologic, 3.86% in 2019. We believe these markets are similarly sized today and projected to maintain a growing trend into 2025. Our startup differentiates by entering the untapped market of digital health gynecologic oncology diagnostics. It will streamline physicians' workflow and improve patient compliance. Curiva's smart wearable diapatch™ generates high test accuracy, sensitivity rates ranging from 98% to 99% and a specificity of 99.5% or above. Our product entirely differentiates by being the only tool to be utilized for the indication of pre-cancerous lesions, after a series of abnormal Pap Smears and before a Colposcopy is necessary.

Financial Forecast:

Curiva has two paths to revenue: (1) Clinical sales direct to health systems starting in Year 1 of sales (2) Sales to health insurers and distributors from Year 2 onwards. Curiva offers 2 products from Year 2 onwards and the added service of our secure app ELLE™.

Year	Year 1	Year 2	Year 3	Year 4	Year 5
Growth Rate	0%	312%	110%	84%	144%
Gross Profits	\$1.9M	\$15.9M	\$35.7M	\$73.7M	\$181.9M
Revenue	\$10.4M	\$43.0M	\$90.2M	\$165.7M	\$404.2M
Gross Margins	19%	37%	40%	44%	45%