

# EPI ONE INC.

## FORM C-AR — ANNUAL REPORT

For the Fiscal Year Ended December 31, 2025

Filed Pursuant to Regulation Crowdfunding §227.202

### 1. Company Information

Legal Name: Epi One, Inc.

Jurisdiction: Delaware

Date of Incorporation: June 16, 2016

Principal Office: 760 Parkside Ave, Suite 213, Brooklyn, NY 11226

### 2. Description of the Business

Epi One is a development-stage molecular diagnostics company focused on advancing early cancer detection through epigenetic biomarker analysis. The Company is currently engaged in research and development activities and does not have any commercially available products or generate revenue.

The Company utilizes a proprietary computational discovery platform to identify epigenetic biomarkers that may be measured using standard polymerase chain reaction (PCR)-based assays, in contrast to approaches that rely on next-generation sequencing (NGS). The Company believes this approach may support the development of diagnostic tests with shorter turnaround times, lower expected costs relative to next-generation sequencing-based methods, and compatibility with existing clinical laboratory workflows; however, these capabilities have not yet been clinically validated.

During fiscal year 2025, the Company concentrated its efforts on validating its Multi-Cancer Early Detection (MCED) biomarker panel, advancing preclinical studies, and strengthening its intellectual property portfolio. These activities represent foundational steps toward future clinical validation and potential commercialization.

The Company intends to develop and offer laboratory-developed tests (LDTs) following the completion of additional validation activities and the establishment of a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory. The Company may also pursue additional regulatory pathways, including review by the U.S. Food and Drug Administration, depending on its development strategy and intended use of its tests.

The Company expects to generate future revenue from diagnostic testing services performed in its planned CLIA-certified laboratory and may explore partnerships or other commercialization arrangements. The timing of these activities, including the establishment of laboratory operations and the initiation of clinical validation studies, is dependent on the Company's ability to obtain additional financing, including a planned Series A offering.

### **3. Risk Factors**

#### **Early-Stage Company with No Commercial Products or Revenue**

The Company is a development-stage enterprise and has not generated any revenue to date. It does not have any commercially available products and remains in the research and preclinical validation stage. As a result, the Company is subject to all of the risks inherent in early-stage companies, including uncertainty of product development, lack of operating history, and the need for substantial additional capital. There can be no assurance that the Company will successfully develop, validate, or commercialize any of its diagnostic candidates, or that it will ever achieve profitability.

#### **R&D Focus on Multi-Cancer Early Detection (MCED)**

During the 2025 fiscal year, the Company concentrated its R&D efforts on the validation of MCED biomarkers and preclinical studies. MCED technology is inherently complex and requires the ability to demonstrate sensitivity, specificity and clinical utility across multiple cancer types and disease stages. The Company's success depends on its ability to validate these biomarkers in larger and more diverse sample sets. There can be no assurance that preliminary performance observed in internal or limited data sets will be replicated in broader studies. Failure to achieve acceptable analytical or clinical performance, particularly in detecting early-stage (Stage I and II) cancers could materially harm the Company's business prospects.

#### **Sample Acquisition and Biobank Dependency**

The development of assays requires access to large numbers of high-quality clinical samples, including cancer-positive specimens, longitudinal follow-up samples, and pre-diagnosis samples. The Company may face challenges in securing sufficient sample volumes, maintaining sample diversity (to ensure cross-population accuracy), or obtaining samples with appropriate clinical annotation. Competition for these samples is intense. Delays or limitations in sample acquisition could slow development timelines, reduce statistical power, or impair the Company's ability to demonstrate clinical validity to regulators and payers.

#### **Intellectual Property and Patent Prosecution Risks**

The Company is in the process of preparing and filing patent applications related to its biomarker discoveries and computational methods. The Company's ability to compete may depend, in part, on the strength and scope of its intellectual property. There can be no assurance that any patent applications will be granted or that issued patents will provide meaningful protection or competitive advantage. In addition, the Company may face risks of third-party intellectual property claims, including infringement allegations from existing market participants.

### **Regulatory Uncertainty and Oversight of Laboratory Developed Tests (LDTs)**

The regulatory environment for laboratory developed tests (LDTs) remains uncertain and subject to change. In 2024, the U.S. Food and Drug Administration (FDA) issued a final rule to regulate LDTs as medical devices. However, in March 2025, a federal court vacated the rule, and the FDA subsequently rescinded it in September 2025, restoring the prior framework under which LDTs are primarily regulated under the Clinical Laboratory Improvement Amendments (CLIA), with the FDA exercising enforcement discretion.

There can be no assurance that this framework will remain in place. The FDA, Congress, or other authorities may impose new or modified requirements in the future, including premarket review, additional validation, or quality system regulations. Such changes could increase costs, require operational adjustments, or delay commercialization.

In addition, certain states impose their own requirements. For example, the New York State Department of Health, through its Clinical Laboratory Evaluation Program, requires separate approval of laboratory-developed tests before they may be offered to patients in New York. This process may require additional validation and review time and could delay or limit the Company's ability to commercialize its tests in that market. This includes the potential passage of federal legislation, such as the VALID Act, which would provide the FDA with explicit statutory authority to regulate LDTs.

### **Operational Risks: Establishment of a CLIA and CLEP-Certified Laboratory**

The Company's future success depends on transitioning from a research-focused environment to a fully operational, high-complexity clinical laboratory. This shift involves significant operational risks, including facility build-out, equipment procurement and validation, and implementation of a Quality Management System.

To generate revenue, the Company must obtain and maintain certification under the Clinical Laboratory Improvement Amendments (CLIA) and comply with the more stringent requirements of the New York State Department of Health through its Clinical Laboratory Evaluation Program. These requirements include test-specific approvals, enhanced validation standards, and ongoing inspections.

The Company must also recruit and retain highly specialized personnel, including a qualified laboratory director holding a New York State Certificate of Qualification. Failure to secure or retain such personnel could prevent the Company from offering testing services in New York.

In addition, the Company faces risks related to supply chain reliability, laboratory operations, and ongoing regulatory compliance. Any delays in laboratory build-out, certification, or inspection approval could delay commercialization, increase operating costs, and adversely affect the Company's ability to generate revenue.

### **Dependence on Additional Financing**

The Company did not conduct formal fundraising activities during the 2025 fiscal year and is currently funded by prior capital raises. As a development-stage company, it has ongoing

operating losses and expects to require substantial additional capital to continue research and development activities, establish laboratory operations, and conduct clinical validation studies. There can be no assurance that additional financing will be available on acceptable terms, or at all. If the Company is unable to obtain sufficient funding, it may be required to delay, reduce, or discontinue its operations.

### **Transition to Multi-Cancer Platform and Commercialization Risks**

The Company has expanded its focus from a single-indication diagnostic test to a broader multi-cancer detection platform. This transition increases technical, operational, and clinical validation complexity. In addition, successful commercialization will depend on factors including clinical utility, physician adoption, and reimbursement by third-party payers. There can be no assurance that the Company will be able to demonstrate sufficient clinical utility or achieve market acceptance, even if its assays demonstrate analytical performance.

### **No Public Market**

There is currently no public market for the Company's securities, and an active market may never develop. Investors should be prepared to hold their securities indefinitely, as they may not be able to resell them due to liquidity constraints and transfer restrictions under federal securities laws.

## **4. Management's Discussion and Analysis of Financial Condition and Results of Operations**

### **Revenue**

The Company did not generate any operating revenue during fiscal years 2024 or 2025. The Company remains in the development stage and has not yet commercialized its diagnostic assays or established clinical laboratory operations.

The Company recorded non-operating income during fiscal year 2025 consisting primarily of interest income earned on cash balances. The Company did not generate any revenue from operations during either fiscal year.

### **Cost of Sales**

The Company did not record any cost of sales during fiscal years 2024 or 2025. As the Company has not commenced commercial operations or product sales, no costs of goods sold were incurred. All laboratory-related expenditures were classified as research and development expenses.

### **Gross Margin**

The Company did not generate gross margin during fiscal years 2024 or 2025 due to the absence of revenue. Gross margin is not considered a meaningful performance metric at the Company's current stage of development.

### **Operating Expenses**

Operating expenses increased from \$974,909.47 in fiscal year 2024 to \$1,029,175.23 in fiscal year 2025, representing an increase of approximately 5.6%.

The increase was primarily driven by expanded research and development activities, including assay optimization, biomarker research, and development of laboratory workflows, as well as laboratory expansion costs such as materials, equipment-related expenditures, and higher professional fees, including legal and accounting services.

During fiscal year 2024, operating expenses included costs associated with Regulation Crowdfunding and private placement fundraising activities, including marketing, advertising, platform fees, legal, and accounting expenses, in addition to personnel costs and research and development activities.

During fiscal year 2025, operating expenses were primarily attributable to research and development activities related to Multi-Cancer Early Detection (MCED) biomarker validation, intellectual property development and patent preparation activities, and continued personnel and infrastructure costs supporting operations.

### **Liquidity and Capital Resources**

As of December 31, 2025, the Company had cash and cash equivalents of \$1,548,540.10 compared to \$2,598,461.60 as of December 31, 2024. The decrease in cash was primarily due to the funding of operating activities during fiscal year 2025.

Total assets were \$2,102,408.72 as of December 31, 2025, compared to \$2,994,950.82 as of December 31, 2024. The decrease in total assets was primarily attributable to the use of cash to fund operations.

The Company has historically funded its operations through equity financing, including its 2024 Regulation Crowdfunding offering and private placements. The Company has not generated revenue and continues to rely on external financing to support operations.

The Company expects that additional capital will be required to fund ongoing research and development activities, establish clinical laboratory operations, and advance validation studies. There can be no assurance that such financing will be available on acceptable terms, or at all. If the Company is unable to obtain sufficient financing, it may be required to delay, reduce, or discontinue certain development activities.

### **Cash Flows and Outlook**

The Company has incurred net losses of \$1,812,887.48 in fiscal year 2024 and \$2,839,261.62 in fiscal year 2025. These losses reflect investments in research and development, intellectual property development, and operational infrastructure.

Historical cash flows have primarily resulted from equity financing activities and expenditures associated with research and development and capital raising efforts. These historical results are not indicative of future operating performance.

The Company's future ability to generate cash flow will depend on its ability to obtain additional financing and successfully develop and commercialize its diagnostic technologies. There can be no assurance that the Company will achieve these objectives.

## 5. Indebtedness

As of December 31, 2025, the Company had the following outstanding indebtedness:

### Credit Card Payables

- Capital One, N.A.: \$18,087.34 under a revolving credit facility. The obligation is unsecured, carries a variable interest rate, and is payable on demand.
- JPMorgan Chase Bank, N.A.: \$1,338.47 under a revolving credit facility. The obligation is unsecured, carries a variable interest rate, and is payable on demand.

The Company had no outstanding bank loans, notes payable, convertible instruments, or other debt obligations as of December 31, 2025.

## 6. Related-Party Transactions

During the year ended December 31, 2025, the Company did not engage in any related-party financing transactions. All equity issued during the year was sold to investors through a Regulation D private placement and a Regulation Crowdfunding offering. No founders, officers, or directors made personal capital contributions outside of these offerings.

The Company did not enter into any related-party debt arrangements or non-arm's-length service agreements during the period.

All related-party transactions were approved by management and were conducted at terms intended to be consistent with fair market value.

## 7. Directors and Executive Officers

The following table sets forth the Company's directors and executive officers as of December 31, 2025:

Fang Fang

Co-Chief Executive Officer, Chief Scientific Officer, Director

Service: 2016–Present

Responsibilities: Oversees scientific strategy, biomarker discovery, and research and development activities, including computational and laboratory-based assay development.

John J. Meduri

Co-Chief Executive Officer, Principal Financial Officer

Service: 2026–Present

Responsibilities: Responsible for corporate strategy, financial management, capital formation, and business development activities, including partnership development and fundraising strategy.

Neng Yang

Senior Vice President, Research and Development; Secretary

Service: 2016–Present

Responsibilities: Oversees laboratory operations, assay development and optimization, and biomarker validation activities, and supports corporate governance functions in the role of Secretary.

Michael Marquardt (Former Officer)

Former Chief Executive Officer and Director (June 2023 – January 2026)

Responsibilities (during tenure): Led investor relations and fundraising activities.

The former officer resigned from his executive and director roles effective January 2026.

## **8. Principal Security Holders**

The following table sets forth information regarding beneficial ownership of the Company's voting securities by persons who beneficially own more than 20% of the Company's outstanding common stock as of the most recent practicable date.

Fang Fang

- Number of Shares Owned: 3,430,000
- Type of Security: Common Stock
- Percentage Ownership: 52.67%

This individual is considered a principal stockholder of the Company due to ownership exceeding 50% of outstanding voting securities.

## **9. Outstanding Securities**

The following summarizes the Company's outstanding securities as of December 31, 2025:

### **Common Stock (Class A)**

- Authorized: 8,900,000 shares
- Outstanding: 5,338,984 shares
- Voting Rights: One vote per share
- Liquidation Rights: None

### **Common Stock (Class B – Non-Voting)**

- Authorized: 1,100,000 shares
- Outstanding: 330,133 shares
- Voting Rights: None
- Liquidation Rights: None

### **Series Seed Preferred Stock**

- Authorized: 1,041,666 shares
- Outstanding: 843,622 shares
- Voting Rights: As provided in the Company's certificate of incorporation
- Liquidation Preference: 1x preference over common stock

## **Convertible Securities**

- Convertible Notes: None outstanding
- SAFE Agreements: None outstanding

## **10. Securities Issuances in the Last Three Fiscal Years**

### **Equity Offering #1**

- Security Type: Common Stock
- Amount Raised: \$2,000,000.00
- Shares Issued: 402,927
- Date: May 5, 2024
- Exemption: Regulation D, Rule 506(b)
- Use of Proceeds: General corporate purposes, including laboratory infrastructure expansion, operating expenses, and preclinical research and development activities.

### **Equity Offering #2**

- Security Type: Class B Common Stock (Non-Voting)
- Amount Raised: \$2,078,185.80
- Net Cash Proceeds Received: \$1,745,021.59
- Shares Issued: 330,133
- Date: December 4, 2024
- Exemption: Section 4(a)(6)
- Use of Proceeds: Research and development activities, laboratory operations, and general working capital.

The Company did not conduct any securities offerings during the fiscal year ended December 31, 2025.

## **11. Corporate Actions**

The Company did not undertake any corporate actions during the fiscal year ended December 31, 2025, including stock splits, stock dividends, conversions, recapitalizations, or other similar equity restructuring events.

## **12. Signatures**

This report has been signed by the following officers of the Company in their respective capacities:

Fang Fang  
Co-Chief Executive Officer and Chair of the Board

John Meduri  
Co-Chief Executive Officer and Principal Financial Officer

Neng Yang  
Secretary and Member of the Board of Directors

## CEO FINANCIAL CERTIFICATION

I, Fang Fang, the Co-Chief Executive Officer of Epi One, Inc., hereby certify that the financial statements of Epi One, Inc. and the notes thereto for the periods ending December 31, 2024 and December 31, 2025 included in this Form C-AR are true and complete in all material respects and that the information presented is consistent with the information reported on the Company's federal income tax returns.

IN WITNESS THEREOF, this Principal Executive Officer's Financial Statement Certification has been executed as of April 25, 2026.

  
\_\_\_\_\_ (Signature)

Co-Chief Executive Officer

April 25, 2026