

✦ INDUSTRY FIRST · FDA DE NOVO GRANTED · DEN250007

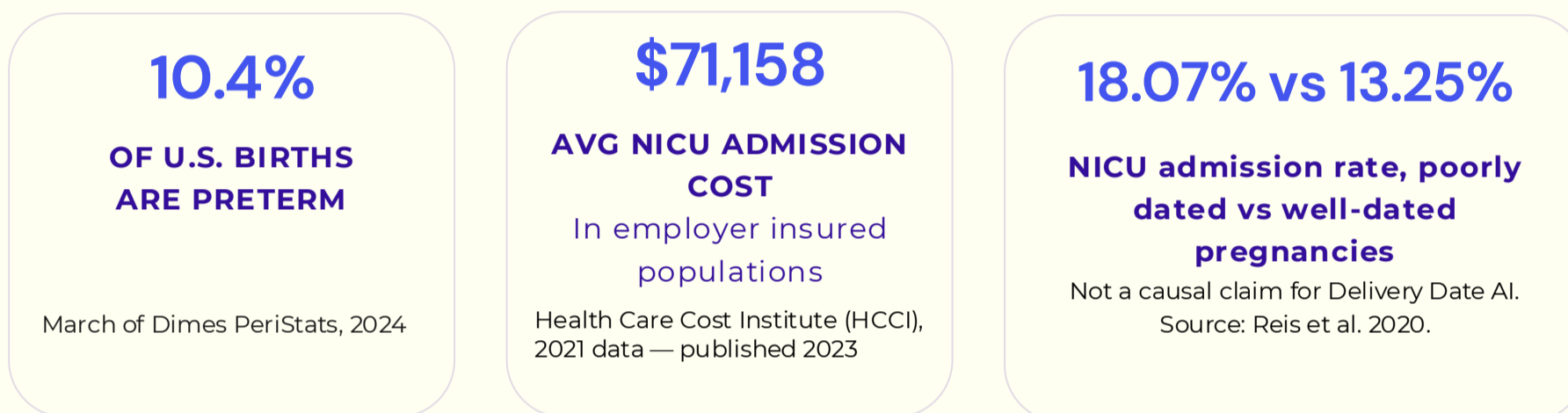
## The first FDA De Novo Granted AI that predicts actual delivery timing from routine ultrasound images

**Delivery Date AI™** uses routine ultrasound images to predict actual delivery timing — helping clinicians identify pregnancies that may require earlier intervention, surveillance, or delivery planning.

Validated across 5,714 pregnancies with  $R^2 = 0.92$  for delivery timing prediction.

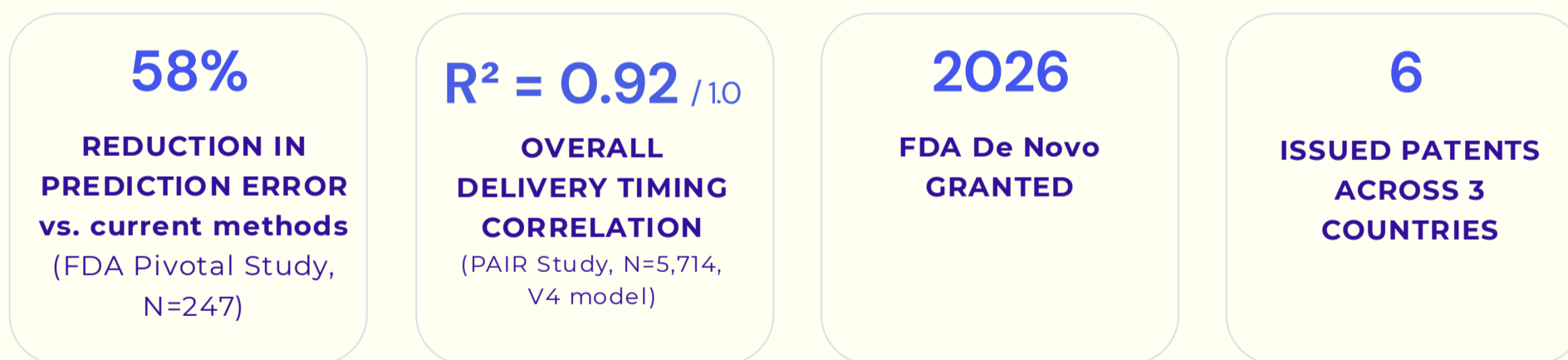
### 01 THE PROBLEM · NO RELIABLE DELIVERY TIMING

Incorrect or uncertain delivery dating can delay interventions, impair fetal surveillance, increase NICU utilization, and contribute to avoidable maternal and neonatal complications. **Delivery Date AI was built to provide an additional Predicted Delivery Date from routine ultrasound.**

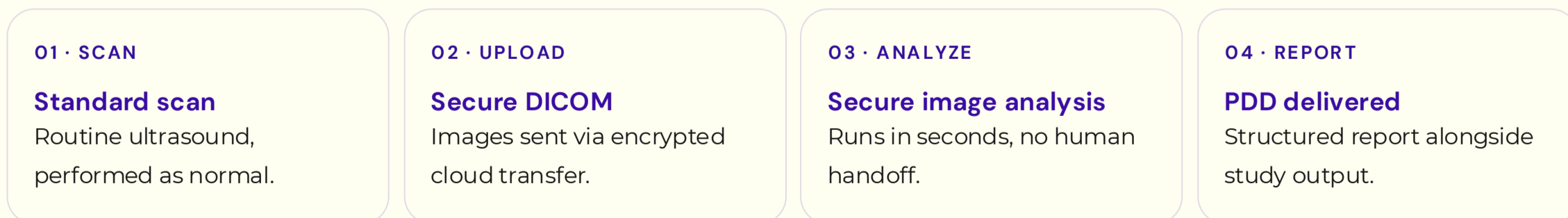


### 02 THE SOLUTION **Delivery Date AI™**

FDA De Novo-granted (DEN250007) AI for image-based delivery prediction. Image-only — no extra views, no blood draw, no new hardware.



### 03 HOW IT WORKS · ECONOMICS



**~8.7x** **Base-case payer ROI (modeled scenario)**

In a modeled 10,000 birth population:  
 \$3M screening spend → ~\$23.1M net savings on a 10K-birth population.  
 Modeled estimate; actual results will vary by population and institution.

## 04 ABOUT ULTRASOUND AI

|                 |   |
|-----------------|---|
| <b>FOUNDED</b>  | 2019  |
| <b>EVIDENCE</b> | PAIR Study · 5,714 pregnancies · $R^2 = 0.92^1$                                 |
| <b>U.S. FDA</b> | De Novo Granted Feb 11, 2026 · DEN250007 · code SHE                             |
| <b>MARKETS</b>  | U.S. (FDA), Brazil (ANVISA 82499100004) · Chile: R&D only, no ISP registration  |
| <b>IP</b>       | 6 patents issued across 3 countries (U.S., Israel, Singapore); EU/CN/KR pending |
| <b>TEAM</b>     | R. Bunn (Founder) · M. Davis (CEO) · A. Newhouse (COO/GC) · Dr. R. Dardik (CMO) |

## 05 WHY THIS CATEGORY IS

### Proprietary data moat

One of the largest proprietary obstetric ultrasound AI datasets assembled globally. Exceptionally difficult to replicate. Every new clinical scan widens the gap.

### FDA De Novo Granted

The first FDA-cleared software category for image-based delivery date prediction. Establishes a regulatory moat competitors must navigate to enter this market.

### Platform Vision

*AI prediction of future clinical outcomes directly from medical imaging.*

## 06 MARKET OPPORTUNITY · MATERNAL-HEALTH IMAGING

### TAM

**\$8B**

Global obstetric AI

### SAM

**\$3-4B**

Global addressable markets

### 2-5-YR SOM

**~\$1B**

Plan target capture

## 07 2026 INITIATIVES

### 01

#### Market land-grab

Direct enterprise sales to top-50 U.S. health systems; target run-rate ARR within 24 months.

### 02

#### OEM platform embedding

Integrations with global ultrasound OEMs for scaled distribution.

### 03

#### Reimbursement pathway

Health-economic studies with payers to convert 8.7x ROI into reimbursement codes.

### 04

#### Future investigational modules (not FDA-authorized)

Future investigational modules may evaluate additional maternal-health applications. These modules are not FDA-authorized and not for clinical use.

## 08 THE RAISE

### RAISING

**\$25M**

Series A

### USE OF FUNDS

|                           |     |
|---------------------------|-----|
| Market land-grab          | 50% |
| Reimbursement & evidence  | 20% |
| Pipeline expansion        | 15% |
| Operations, quality & G&A | 15% |

## Learn more.

Fundraise discussion · product demo · diligence materials

[ultrasound.ai](https://ultrasound.ai) · [bob@ultrasound.ai](mailto:bob@ultrasound.ai) · 720.545.8055

DEN250007 · UN AI for Good · PAIR Study, JMFNM 2025

**U.S. regulatory note (DEN250007):** In the United States, Delivery Date AI™ is authorized as an aid to clinical judgment for women 18+ with singleton pregnancies at 14 0/7–36 6/7 weeks gestation lacking a reliable EDD. Per FDA labeling requirements, the output is not intended to predict or assess the risk of preterm birth. Preterm AI and other pipeline modules referenced herein are **not FDA-authorized** and not for clinical use. Product availability, indications, and permitted claims vary by jurisdiction; Brazil (ANVISA) operates under separate local authorization. Chile is R&D only — no ISP registration has been obtained.

<sup>1</sup> **PAIR Study:** Patel N, O'Brien J, Bunn R, Schanbacher B, Bauer J, Lam GK. *J Matern Fetal Neonatal Med.* 2025;38(1):2532099. Single-institution academic medical center; generalizability to all practice settings has not been established. Dr. Lam has a stock interest in Ultrasound AI; Robert Bunn is President and Founder of Ultrasound AI. <sup>2</sup> **Proprietary dataset** reflects total internal training corpus across studies; PAIR validation set comprised 877,141 de-identified images. Population statistics: CDC / March of Dimes (2024).