



## EXECUTIVE SUMMARY

Lactation Innovations is developing a medical device, Manoula, that accurately measures the quantity of breastmilk consumed by an infant in the first days of life to critically improve the current state of infant postpartum care.

### Contact:

Jayne Coates, Co-Founder  
357 Bingham Rd  
Canterbury, CT 06331  
(860) 778-8249  
jayme@lactationinnovations.com  
www.lactationinnovations.com

### Industry: Medical Device

### Manoula Medical Device:

Simple device providing immediate breastmilk consumption feedback data that addresses current detrimental gaps in the mother-to-child postpartum standard of care.

### Executive Leadership:

**Jayne Coates**, MBA, MS BME, Co-founder with 15+ years' experience developing over 100 unique medical devices both for design, mfg & testing.

**Brittany Molkenhain**, BSN, RN, Co-founder, is a pediatric intensive care nurse at CCMC; and a 2020 Pediatric Primary Care Nurse Practitioner master's candidate.

### Advisory Board:

**Kevin Bouley**, MBA, President Nerac

**Christine Meehan**, BSN, MA, Founder and Former CEO CAD Implant, Member, Goldenseeds

**Marisa Merlo**, RN, IBCLC, International Board-Certified Lactation Consultant and Nurse UCONN Health

**Robert Parker**, DO, Pediatric Intensivist and Assist. Prof. of Pediatrics at CCMC

### Fundraising:

**Raised:** \$34,500 Self-funded; \$100k seed patent support

**Seeking:** Pre-Seed \$500k

**Use of proceeds:** MVP, Pre-clinical supplies & testing, Regulatory Strategy & Reporting

**Milestone:** MVP Clinical Data

**Date:** September 2020

### OPPORTUNITY OVERVIEW

Insufficient milk consumption results in 500,000 infant re-hospitalizations in the USA at a cost of \$519M per year<sup>1</sup>. According to the surgeon general, despite the many benefits of breastfeeding, 50% of mothers stop within 2 weeks due to anxiety that their baby is not receiving enough milk<sup>2</sup>. Current technologies continue to produce unsuccessful outcomes for over 20.6M breastfeeding mothers annually, despite healthcare initiatives that focus on the most critical first days and weeks of infant care.

### SOLUTION

Manoula is a safe, convenient, non-invasive medical device that accurately detects the volume of milk in an infant's stomach using patent pending sensor technology. Manoula will be used in hospital settings to augment postpartum care between infants and mothers. Lactation consultants will continue to guide mothers with at-home-monitoring. Manoula provides actionable information allowing providers to give decisive remedial support, while increasing a mother's confidence in breastfeeding. Ultimately, Manoula will reduce the number of hospital stays, the rehospitalization of infants from dehydration or malnutrition, and improve quality of infant health with more successful rates of breastfeeding.

### COMPETITIVE LANDSCAPE

Manoula disrupts the current standard of care for breastfeeding mothers where existing products do not have an impact. The current standard of care uses qualitative measures for breastfeeding performance or lagging indicators such as baby weight. These measures are not efficient in mitigating infant dehydration or alleviating the growing anxiety for an uncertain mother. Hospital-based milk scales measure baby after each feeding and can show error rates up to 300%<sup>3</sup>, specifically for lower birth-weight classes. Other at-home products attempt to quantify breastmilk before each feeding. These devices maybe more accurate than baby-scales but are cumbersome to use and disrupt the mom-baby bonding experience. Manoula is non-invasive, simple to use, and bolsters support from clinicians. The measurements captured by the Manoula device have a <1% error rate, providing accurate and actionable data, resulting in better health outcomes.

### DEVELOPMENT MILESTONES

**Feasibility Clinical Data:** MVP, Preliminary Clinical Results, Regulatory Strategy & Pre-Submission FDA Meeting. ETA October 2020; \$500k (Pre-Seed Funds)

**Clinical Study:** Clinical Device & Data, Regulatory submission, Market and Reimbursement, Team building. ETA April 2021; \$1.3M (Seed Funds)

**Manufacturing and FDA Submission:** Manufacturable device, App and Cloud Development, Team building, V&V, FDA submission. ETA October 2021; \$5.2M (Series A)

**FDA Approval and Pilot:** FDA Approval, Pilot testing in 3 hospitals, marketing for commercial release. ETA May 2022; \$3.2M (Series B)

### FINANCIAL PROJECTIONS

Manoula will be sold to baby friendly hospitals in the US in strategic geographical regions followed by increased penetration and outreach throughout the US. After initial 5 years, sales will continue into all birthing hospitals in the US & global markets. Reimbursement by insurance will be pursued. Secondary markets include birthing centers, NICU transitioning patients, and IBCLC direct sales. Device price: \$300; COGS: \$90. It will be manufactured by a contract manufacturer.

	Y1: 2023	Y2: 2024	Y3: 2025	Y4: 2026	Y5: 2027
<b>Total Revenues (M)</b>	\$ 12.41	\$ 44.05	\$ 90.82	\$ 119.49	\$ 179.89
<b>Gross Profit (M)</b>	\$ 7.44	\$ 28.63	\$ 59.03	\$ 83.64	\$ 134.91
<b>Gross Margin (%)</b>	60%	65%	65%	70%	75%

<sup>1</sup> Del Castillo- Hegyi, C. (2018). Hypernatremic dehydration is common and occurs to a third of healthy newborns. Retrieved from <https://fedisbest.org/2018/07/hypernatremic-dehydration-common-occurs-third-healthy-newborns/>; <sup>2</sup>US Department of Health and Human Services. (2011). The Surgeon General's Call to Action to Support Breastfeeding. Washington, DC: Department of Health and Human Services, Office of the Surgeon General.; <sup>3</sup>Savenije, O., & Brand, P. (2006). Accuracy and precision of test weighing to assess milk intake in infants. *Archives of Disease in Childhood Fetal Neonatal Education*, 91(5), 330-332. doi: 10.1136/adc.2005.091876; <http://betterdoctor.com/assets/img/blog/baby.jpg>