

BIOMILQ

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Bio manufacturing human milk components to improve early-life nutrition

BIOMILQ is bridging the gap between infant formula and breast milk by producing high-value ingredients from human mammary epithelial cells.

It was while on maternity leave that cell biologist Leila Strickland, now CEO and co-founder of BIOMILQ, first had the idea of growing human mammary cells outside breast tissue to make milk. Like many new mothers, she was surprised by how difficult breast feeding can be and by the lack of options available for feeding her child.

"Breast milk is widely considered the optimal food for infants, but there are lots of reasons that may prevent access to it, so having more options is really critical," said Zack Holmes, bioinformatician and head of product development at BIOMILQ. In the USA, only a quarter of babies receive the recommended 6 months of exclusive breastfeeding¹.

Infant formulas are life-saving products, but fall short in delivering some of the benefits of breast milk. Most are based on cow's milk, goat's milk or soy proteins and lack many of the functional components that are unique to human breast milk. By combining the emerging understanding of breast milk with innovative biotechnology, BIOMILQ offers the early-life nutrition industry an opportunity to access the beneficial components of breast milk in new ways.

"We are only just starting to understand what breast milk really is," said Strickland. The application of advanced biochemical methods and omics technologies to breast milk is allowing researchers to analyze its composition and determine which components are key mediators of infant growth and development.

With seed funding from venture capital firms, Strickland was able to start turning her idea into reality. In 2020, BIOMILQ began operations in Research Triangle Park, North Carolina, to produce human milk ingredients from human mammary epithelial cells. The company is swiftly advancing towards commercialization of its first products, which will demonstrate the advantages of BIOMILQ's platform (Fig. 1).

Central to BIOMILQ's unique bio manufacturing technology platform is a proprietary bank of human mammary epithelial cells, isolated from breast milk generously donated by women from diverse backgrounds. "Our cell bank contains cells from over 60 women at all lactation stages," Strickland explained. "It is a treasure trove of potential since every cell has different attributes and capabilities."

Researchers at BIOMILQ have been characterizing and optimizing these cells and looking for growth conditions that will enable them to produce functionally important human milk components.

Some simple milk components can be directly extracted from cow's milk or easily produced in yeast or microbial precision-fermentation systems.

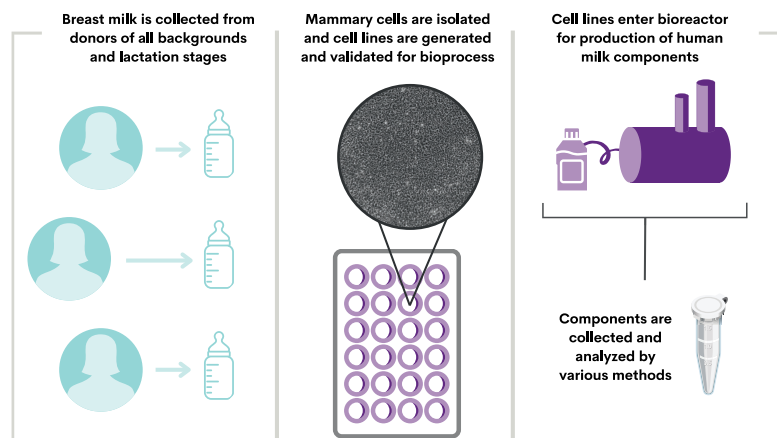


Fig. 1 | BIOMILQ's production platform. Steps in sequence for the process of human milk ingredients.

BIOMILQ is focusing on components with complex biosynthetic pathways that benefit from being made in the metabolic environment of the human mammary epithelial cell.

"Mammary epithelial cells have the cellular machinery to make almost anything that is in human milk, but we want to direct their metabolism towards producing potent functional molecules that can't be made on any other production platform," Holmes said.

Bio manufacturing human osteopontin

Human milk osteopontin (OPN) is a bioactive protein found in breast milk that undergoes extensive post-translational processing to achieve its functionality. There is strong evidence that OPN in breast milk regulates developmental, immunological and physiological processes in infants². Interestingly, the version of OPN made by human mammary epithelial cells is unlike that made by other cell types in the body and bovine OPN.

Bovine OPN, recently approved for use as a novel food in infant formula by the European Food Safety Authorities (EFSA), has a different amino-acid sequence and phosphorylation profile to human OPN. Because it is produced in the native production system, BIOMILQ's OPN is more similar to human OPN. The company is conducting research to show that it behaves in the body similarly to human OPN.

"The post-translational modifications of human OPN are very difficult to make outside a human mammary epithelial cell; the OPN produced by our cells has a much more bio-authentic phosphorylation signature, which could have important implications for its function and regulatory approval," Holmes said.

Partnering to bring breast milk's benefits to more babies

BIOMILQ's work to date has focused on producing specific, high-value breast milk components consistently through an economically feasible and scalable process. The company is seeking global partners in the early-life nutrition and ingredients industries to develop downstream-processing approaches that will enable the incorporation of bio-authentic human milk components into infant formula.

"In the next year, we are planning on making rapid progress on product and platform development," Strickland said. "We are looking for partners that will help us analyze, test and scale-up production of specific compounds from the molecular library of breast milk ingredients produced by our bio manufacturing technology platform."

The introduction of potent functional components that have tightly evolved to mediate infant development—such as human OPN—into infant formula will mark a significant advance in bringing the nutritional profile closer to breast milk.

- Centers for Disease Control and Prevention. Breastfeeding Report Card, United States, 2022. <https://www.cdc.gov/breastfeeding/data/reportcard.htm>
- Sørensen, E. S. et al. *Nutrients* **15**, 2423 (2023). <https://doi.org/10.3390/nu1512423>

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