

# ImmuCell

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FOR IMMEDIATE RELEASE:

## **ImmuCell Commences Manufacture of Nisin Necessary for Approval of Mast Out<sup>®</sup>**

*Necessary facility upgrades completed;  
Process validation and optimization to complete manufacturing objectives of regulatory submission initiated*

**Contact:** Michael F. Brigham, President and CEO  
(207) 878-2770

Joe Diaz, Robert Blum and Joe Dorame  
Lytham Partners, LLC  
(602) 889-9700  
iccc@lythampartners.com

PORTLAND, Maine – July 9, 2014 -- **ImmuCell Corporation (NasdaqCM: ICCC)** a growing animal health company that is developing, manufacturing and selling products that improve animal health and productivity in the dairy and beef industries, announced today that it has completed modifications to its manufacturing facility to produce pharmaceutical-grade Nisin, the active ingredient in its **Mast Out<sup>®</sup>** product, to address subclinical mastitis in lactating dairy cows.

ImmuCell (the Company) will commence validation and testing of the new facility and processing equipment to complete the manufacturing requirements of the New Animal Drug Application (NADA) submission to the Food and Drug Administration (FDA). Once this data has been compiled, the Company expects to make its first submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section to the FDA around the end of calendar year 2014. At the same time, Company scientists are working with the FDA to transfer the analytical method to detect Nisin in milk to an FDA laboratory. Once this method is successfully transferred, the Company expects to receive the Human Food Safety Technical Section Complete Letter from the FDA. These are the final two steps in the NADA process, as **Mast Out<sup>®</sup>** has previously received the following from the FDA:

- The Environmental Impact Technical Section Complete Letter;
- The Target Animal Safety Technical Section Complete Letter;
- The Effectiveness Technical Section Complete Letter; and
- A zero milk discard and zero meat withhold claim.

The Company anticipates two, six-month reviews of the CMC Technical Section submission by the FDA during 2015, setting up potential NADA approval from the FDA during 2016. This would allow test marketing of **Mast Out<sup>®</sup>** in 2016.

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Michael F. Brigham, President and CEO of ImmuCell, commented, “We are pleased with the progress achieved during the first half of fiscal 2014 in completing the necessary modifications to our manufacturing facilities on time and on budget. We will now begin to utilize the newly installed equipment and space to demonstrate to the FDA our ability to effectively produce pharmaceutical-grade Nisin while verifying process yields.”

Mastitis is considered the costliest disease to the U.S. dairy industry and major dairy producing regions of the world. Annual losses are presently estimated to be upwards of \$2 Billion in the United States alone. These losses are comprised of reduced milk production, discarded milk, replacement animals, labor, drug treatments and veterinarian services. Mastitis refers to an inflammation of the udder, most commonly caused by a bacterial infection. This infection is commonly treated with traditional antibiotics. **Mast Out**<sup>®</sup>, an intramammary infusion product containing Nisin, is under development as an alternative to traditional antibiotics for the treatment of subclinical mastitis in lactating cows. The safety profile of Nisin may allow for the use of **Mast Out**<sup>®</sup> in the United States without “milk discard” or “meat withhold” requirements.

In late 2013, the Company announced a \$3 Million capital improvement investment, allocating approximately half of this total to build out modifications of its facility and acquire equipment necessary to produce pharmaceutical-grade Nisin for **Mast Out**<sup>®</sup>. The remaining amount has been allocated to a 7,100 square foot facility addition intended to increase production capacity for current products, maintain compliance with current Good Manufacturing Practice (cGMP) regulations in all operations and integrate the production of pharmaceutical-grade Nisin. The Company is preparing to break ground on this second project during the third quarter of 2014.

### **About ImmuCell**

ImmuCell Corporation's (NasdaqCM: ICCG) purpose is to create scientifically-proven and practical products that improve animal health and productivity in the dairy and beef industries. ImmuCell has developed products that provide significant immediate immunity to newborn dairy and beef livestock. The Company has also developed products that address mastitis, the most significant cause of economic loss to the dairy industry. Press releases and other information about the Company are available at our web-site, (<http://www.immucell.com>).

### **Safe Harbor Statement:**

*This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; the future adequacy of our working capital and the availability of third party financing; the outcome of pending or anticipated applications for future regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, pharmaceutical-grade Nisin manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors.*

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