

## **ImmuCell Announces Strategic Focus on First Defense® After Receiving an FDA Incomplete Letter for Re-Tain®**

PORTLAND, Maine, Dec. 24, 2025 (GLOBE NEWSWIRE) — **ImmuCell Corporation (Nasdaq: ICC)** (“ImmuCell”), an animal health company that develops, manufactures and markets products that improve cattle health and productivity today announced that it received an Incomplete Letter from the United States Food and Drug Administration (FDA) on December 23, 2025 for its **Re-Tain®** New Animal Drug Application (NADA), and simultaneously that it is increasing its **First Defense®** field sales force by 50% and expanding its **First Defense®** manufacturing capabilities.

In seeking FDA approval to bring its innovative **Re-Tain®** product to market, ImmuCell received Complete Letters from the FDA for four of the five Technical Sections required for NADA approval. It pursued a two-pronged manufacturing approach to reduce capital expenditure and limit technical risk for the remaining fifth Technical Section pertaining to manufacturing. ImmuCell manufactured the active pharmaceutical ingredient using a proprietary process in its own facility and hired an experienced contract manufacturer with FDA approvals for animal health products for the aseptic filling of the product into syringes. ImmuCell passed FDA inspection of its own facility in 2024. It is ImmuCell’s understanding that the FDA is now declining to approve the NADA because the contract manufacturer has not satisfactorily addressed inspectional deficiencies.

After considering the practical implications of the resulting delays, including the pending expiration of ImmuCell’s contract with the manufacturer in March 2026, ImmuCell has decided to pause further investment in **Re-Tain®** and increase its investment in its market leading **First Defense®** franchise, which it believes to have significant revenue and profit growth capacity.

ImmuCell will complete ongoing investigational studies with **Re-Tain®** to assess opportunities for an improved set of claims for preventing and treating mastitis in dairy cows. It will seek to license the product to interested parties or, depending on the outcome of the studies, may seek to partner with a global manufacturer. Neither approach would require further capital investment or in-house manufacturing capability, meaning that ImmuCell will prioritize cash and other resources for maximizing the value of its market leading **First Defense®** franchise.

“While it is disappointing news that we will be unable to achieve NADA approval with this contract manufacturer, this has only strengthened our resolve to allocate our resources to our highest return opportunity, namely **First Defense®**,” said Olivier te Boekhorst, President and Chief Executive Officer of ImmuCell. “We will focus on maximizing our opportunities in

the estimated \$900 million worldwide Total Addressable Market for preventing scours in calves. Based on feedback from customers about our products and our ongoing internal assessment of potential manufacturing efficiencies, we believe there is significant runway for top-line growth and margin expansion for **First Defense**<sup>®</sup> that would drive sustainable profit growth for ImmuCell.”

ImmuCell’s **First Defense**<sup>®</sup> product line is based on proprietary colostrum hyper-immunization technology, offering a unique range of products with considerable growth potential. The brand holds strong leadership in the U.S. market, shown by its #1 ranking for scour-prevention in the 2025 Hoard’s Dairyman Continuing Market Study and its 29% share of U.S. spend on scours prevention, and targets a sector where high calf values present significant opportunities in dairy and beef industries. ImmuCell believes it is in a favorable position to expand sales internationally and to develop new products by harnessing the special antibody-rich and bioactive properties of colostrum.

“As a result of this strategic change in focus, ImmuCell expects to record a non-cash impairment write-down of property, plant and equipment during the fourth quarter of 2025. As previously disclosed, net book value of **Re-Tain**<sup>®</sup> assets was approximately \$15.5 million as of September 30, 2025. We are anticipating adjustments to laboratory and manufacturing equipment and construction in progress, resulting in an estimated non-cash impact to profit of approximately \$2.3 million. The final figure for this non-cash expense will be determined after a review of alternate purposing and net realizable value is completed as part of the financial closing for the quarter and year ending December 31, 2025,” says Timothy Fiori, Chief Financial Officer. “We plan to repurpose facilities and a large portion of the equipment for the expansion of **First Defense**<sup>®</sup> capacity to maximize return on these assets.”

“We are pleased to announce immediate steps toward **First Defense**<sup>®</sup> commercial and manufacturing expansion,” added Mr. te Boekhorst. “We have created two new sales territories in the U.S., and we are hiring a senior dairy executive to execute our international strategy. We have also started a multi-year manufacturing improvement program to lower product costs, improve manufacturing yields, and execute our next phase of capacity expansion. Customer feedback and our own market assessments give us confidence that this is the right time for further investment in **First Defense**<sup>®</sup>.”

David S. Tomsche, DVM, Chair of the ImmuCell Board of Directors, commented, “Fifteen years ago, ImmuCell established a small field team that grew **First Defense**<sup>®</sup> annual revenue from approximately \$4.4 million then to approximately \$27.8 million in the trailing twelve-month period ended September 30, 2025. **First Defense**<sup>®</sup>’s record of more than 13% compounded growth per year for more than a decade gives us confidence that focusing on

and investing more in **First Defense**<sup>®</sup> can deliver strong shareholder value.”

ImmuCell expects to announce its topline revenue results for the quarter and year ending December 31, 2025 on Thursday, January 8, 2026. ImmuCell expects to host a conference call to discuss revenue results and certain balance sheet activities on Friday, January 9, 2026 at 9:00 AM ET. ImmuCell expects to announce its full financial results for the year ending December 31, 2025 on Wednesday, February 25, 2026. ImmuCell expects to host a conference call to discuss its financial results for the year ending December 31, 2025 on Thursday, February 26, 2026 at 9:00 AM ET.

### **Cautionary Note Regarding Forward-Looking Statements (Safe Harbor Statement):**

This Press Release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts and often include words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts”, “seeks” and similar words and expressions. Such statements include, but are not limited to, any forward-looking statements relating to: our plans, goals and strategies for our business; the expected timing of key future events; future operational performance and financial results; future demand for our products; the timing and outcome of pending or anticipated applications for regulatory approvals; and any other statements that are not historical facts. Such statements involve known and unknown risks and uncertainties that may cause ImmuCell’s actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

### **About ImmuCell:**

ImmuCell Corporation’s (**Nasdaq: ICCC**) purpose is to create scientifically proven and practical products that improve the health and productivity of dairy and beef cattle. ImmuCell manufactures and markets **First Defense**<sup>®</sup>, which provides **Immediate Immunity**<sup>™</sup> to newborn dairy and beef calves. Press releases and other information about ImmuCell are available at: <http://www.immuCell.com>.

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