ImmuCell

ImmuCell Makes Important Regulatory Submission and Announces Unaudited Financial Results for the Year Ended December 31, 2020

For Immediate Release

PORTLAND, Maine – February 22, 2021 – ImmuCell Corporation (Nasdaq: ICCC) ("ImmuCell" or the "Company"), a growing animal health company that develops, manufactures and markets scientifically proven and practical products that improve the health and productivity of dairy and beef cattle, today announced submission of a critical filing to the FDA related to **Re-Tain**™ and the Company's unaudited financial results for the year ended December 31, 2020.

Update on Regulatory Status of Re-Tain™:

The Company recently submitted the last of five significant technical sections required to achieve FDA approval to market **Re-Tain**™, the Company's mastitis product under development. A response from the FDA to this Chemistry, Manufacturing and Controls Technical Section is expected during the third quarter of 2021 after the statutory six-month review period. If the FDA issues a Technical Section Complete Letter, the Company would be able to begin initial, limited sales of **Re-Tain**™ during the fourth quarter of 2021 after the final sixty-day administrative review period. If the FDA issues a Technical Section Incomplete Letter, the Company would re-submit for another six-month review after responding to the FDA inquiries leading to potential market launch during the second quarter of 2022. The Company is taking a prudent approach and planning for a mass market launch during 2022.

Product Sales Results:

- As previously announced, total product sales increased by $1.6 million, or 12%, to $15.3 million during the year ended December 31, 2020 compared to the year ended December 31, 2019.
- Sales of the **First Defense**® product line increased by 14% during the year ended December 31, 2020 compared to the year ended December 31, 2019.
- Total product sales increased by $111,000, or 3%, to $3.7 million during the three-month period ended December 31, 2020 compared to the three-month period ended December 31, 2019.

Backlog of Orders:

The Company reported a backlog of orders worth approximately $1.8 million as of December 31, 2020 compared to no backlog as of December 31, 2019. The Company projects that, during the first quarter of 2021, it may sell product equivalent to approximately 92% of the $4.1 million that it estimates to be its current production capacity per quarter, resulting in a sales decrease during the first quarter of 2021 compared to the first quarter 2020. The COVID-19 pandemic affects everyone personally and at work in many tragic ways around the world. It has contributed to the

Company's backlog challenge through staff disruptions, complications with equipment fabrication and interruptions in component supply. The Company is working through it, as efficiently as it can. The Company's investment to increase its annual production capacity from approximately $16.5 million to approximately $23 million is proceeding on budget and on time for completion during the second quarter of 2021. After fulfilling the backlog and meeting on-going strong demand, the Company plans to build inventory during the second half of 2021 to prepare for peak season sales during the first quarter of 2022 without risk of backlog.

Management's Discussion:

"Our team did an outstanding job compiling a very extensive and detailed submission to the FDA for **Re-Tain**™," commented Michael F. Brigham, President and CEO. "That completes the bulk of the regulatory submission work on our end. Now we continue to maintain our production and quality systems and prepare to respond to any FDA queries and ongoing site inspections."

"The **First Defense**® product line continues to help fund the **Re-Tain**™ regulatory investment with strong growth over the prior year," Mr. Brigham concluded. "During 2020, we sold product equivalent to about 93% of the $16.5 million that we estimate to be our current annual production capacity, which was about $1.8 million less than what our customers sought to purchase from us. We are experiencing some growing pains during the first quarter of 2021 while available product is constrained, but by increasing our annual production capacity to approximately $23 million, we can return to a growth mode during the second half of the year and thereafter."

Other Financial Results:

- Gross margin earned was 45% and 49% of product sales during the years ended December 31, 2020 and 2019, respectively. This decrease is largely due to an increase in fixed manufacturing costs that were incurred during 2020 before the benefits of the increased production output are realized and a shift in product mix in favor of **First Defense Tri-Shield**®, which delivers more gross margin per dose at a lower percentage of sales.
- Product development expenses increased by $667,000, or 18%, to $4,355,000 during the year ended December 31, 2020 compared to the year ended December 31, 2019. The increase in this expense was budgeted for and necessary to complete the development work related to **Re-Tain**™. These expenses included $1.5 million of non-cash depreciation expense during both the years ended December 31, 2020 and 2019.
- The 2020 financial results benefited from $938,000 in other income from the forgiveness of the Company's Paycheck Protection Program loan from the federal government during the fourth quarter of 2020.
- Net loss was $1,022,000, or $0.14 per share, during the year ended December 31, 2020 compared to net loss of $1,296,000, or $0.19 per share, during the year ended December 31, 2019.
- EBITDA (a non-GAAP financial measure described on page 5 of this press release) increased to $1,893,000 during the year ended December 31, 2020 compared to $1,432,000 during the year ended December 31, 2019.

Conference Call:

The Company will host a conference call on Tuesday, February 23, 2021 to discuss the financial results for the year ended December 31, 2020. Interested parties can access the conference call by dialing (844) 855-9502 (toll free) or (412) 317-5499 (international) at 9:00 AM ET. A teleconference replay of the call will be available for seven days at (877) 344-7529 (toll free) or (412) 317-0088 (international), utilizing confirmation #10151096. Investors are encouraged to review the Company's updated Corporate Presentation slide deck that provides an overview of the Company's business and is available under the "Investors" tab of the Company's website at www.immucell.com, or by request to the Company. The Company expects to file its Annual Report on Form 10-K on or about March 30, 2021.

About ImmuCell (Nasdaq: ICCC):

ImmuCell Corporation's 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**®, providing **Immediate Immunity**™ to newborn dairy and beef calves, and is in the late stages of developing **Re-Tain**™, a novel treatment for subclinical mastitis without a milk discard requirement that provides an alternative to traditional antibiotics. Press releases and other information about the Company are available at: http://www.immucell.com.

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Condensed Statements of Operations (Unaudited)

(In thousands, except per share amounts)	During the Three-Month Periods Ended December 31, 2020	2019	During the Years Ended December 31, 2020	2019
Product sales	$3,743	$3,632	$15,342	$13,723
Costs of goods sold	2,122	1,794	8,479	6,983
Gross margin	1,621	1,838	6,863	6,740
Product development expenses	1,170	972	4,354	3,688
Sales, marketing and administrative expenses	1,085	1,108	3,889	4,006
Operating expenses	2,255	2,080	8,243	7,694
NET OPERATING LOSS	(634)	(242)	(1,380)	(954)
Other (income) expenses, net	(827)	72	(348)	314
INCOME (LOSS) BEFORE INCOME TAXES	193	(314)	(1,032)	(1,268)
Income tax expense (benefit)	4	(4)	(10)	28
NET INCOME (LOSS)	$189	($310)	($1,022)	($1,296)
Basic weighted average common shares Outstanding	7,215	7,210	7,213	6,819
Basic net income (loss) per share	$0.03	($0.04)	($0.14)	($0.19)
Diluted weighted average common shares outstanding	7,215	7,210	7,213	6,819
Diluted net income (loss) per share	$0.03	($0.04)	($0.14)	($0.19)

Selected Balance Sheet Data (In thousands) (Unaudited)

	As of December 31, 2020	As of December 31, 2019
Cash, cash equivalents and short-term investments	$7,946	$8,774
Net working capital	9,946	10,694
Total assets	40,350	38,692
Stockholders' equity	$28,266	$28,991

Non-GAAP Measures:

Generally, a non-GAAP financial measure is a numerical measure of a company's performance, financial position or cash flow that either excludes or includes amounts that are not normally excluded or included in the most directly comparable measure calculated and presented in accordance with GAAP. The non-GAAP measures included in this press release, however, should be considered in addition to, and not as a substitute for or superior to, the comparable measure prepared in accordance with GAAP. We believe that considering the non-GAAP income before income taxes and certain non-cash expenses assists management and investors by looking at our performance across reporting periods on a consistent basis excluding these certain charges that are not uses of cash from our reported loss before income taxes. We start with our reported loss before income taxes because presently we are not paying cash for income taxes and do not anticipate paying cash for income taxes in the near-term future. We calculate non-GAAP income before income taxes and certain non-cash expenses as indicated in the table below:

	During the Years Ended December 31,	
(In thousands)	**2020**	**2019**
Loss before income taxes	($1,032)	($1,267)
Depreciation	2,328	2,248
Amortization	122	36
Stock-based compensation	253	313
Income before income taxes and certain non-cash expenses	$1,671	$1,330

Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) increased to $1,893,000 during the year ended December 31, 2020 compared to $1,432,000 during the year ended December 31, 2019. The figures reported in the table above differ from the calculation of EBITDA in the following two significant ways:

1) We have not added back interest expense or interest rate swap termination fees because we do pay cash for these expenses; and

2) We have added back stock-based compensation expense because this is a non-cash expense that is not added back to the calculation of EBITDA.

Cautionary Note Regarding Forward-Looking Statements (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: our plans and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; the extent, nature and duration of the COVID-19 pandemic and its consequences, and their direct and indirect impacts on the Company's production activities, operating results and financial condition and on the customers and markets the Company serves; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis and producers' level of interest in treating subclinical mastitis given the current economic and market conditions; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the impacts of backlogs on customer relationships; the anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; the continuing availability to us on reasonable terms of third-party providers of critical products or services; the robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield, which are highly subject to biological variability and the product format mix of our sales; the future adequacy of our working capital and the availability and cost of third-party financing; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our current operations and attaining such compliance for the facility to produce the Nisin Drug Substance; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; anticipated 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", "seeks" 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 (including the **First Defense**® product line and **Re-Tain™**), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs or excess inventory buildup), our reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making and delays by regulatory authorities, currency values and fluctuations and other risks detailed from time to time in filings we make with the SEC, 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 involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized above.