

ImmuCell

ImmuCell Announces Unaudited Financial Results for the Year Ended December 31, 2022

PORTLAND, Maine – February 21, 2023 – ImmuCell Corporation (Nasdaq: ICC) (“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 its unaudited financial results for the year ended December 31, 2022.

Management’s Discussion:

“Our unaudited, preliminary product sales were first reported on January 9, 2023,” commented Michael F. Brigham, President and CEO of ImmuCell. “We have no changes to those figures.”

“Unfortunately, we are experiencing a second contamination event in our production process,” continued Mr. Brigham. “Our entire manufacturing team, along with technical support from experienced members of our sales team, are fully engaged in the remediation of this problem.”

In 2018, it became clear that demand for **Tri-Shield First Defense**[®] was outpacing production. Despite growing sales, the Company saw backlogs of approximately \$1.8 million, \$2.4 million and \$2.5 million as of December 31, 2020, 2021 and 2022, respectively. In response to this increasing demand, the Company began a series of investments during 2019 to increase its production capacity to over \$30 million per year. The necessary facility expansions and new equipment to increase production capacity were in place by the end of 2022.

As this increased production capacity was coming online, a product contamination event was detected by standard in-process quality control testing around the end of the third quarter of 2022. Immediate steps to address the contamination were taken, and production ran without issue during the balance of the fourth quarter of 2022.

During the first quarter of 2023, a second contamination event was detected, also by standard in-process quality control testing. This is resulting in a slowdown of production output as necessary steps are taken to assess and remediate the issues and ensure that any product that is put to market meets all quality standards. The Company believes that the ongoing implementation of its capacity expansion plans and the corrective actions being taken in response to these contamination events should allow for operations at the higher level of production output going forward without further significant contaminations.

This slowdown in first quarter production output has, in part, contributed to a more than doubling of the order backlog since the end of 2022. The Company expects to report reduced sales during the first quarter of 2023 and a large, increased backlog as of March 31, 2023. Due to

the loss in earned gross margin that is being incurred during the first quarter of 2023, the Company has made the decision to defer, for the time being, completion of an incremental planned investment to increase its production capacity further to over \$40 million per year. While the Company has not yet fully capitalized on the increased demand for the **First Defense**[®] product line, it does believe that it is making the right investments to achieve this growth as it navigates through this prolonged period of short supply.

“The increase in sales demand for **First Defense**[®] is both exciting and difficult. At the same time, we are preparing all the data required to make our third submission of the CMC Technical Section, approval of which is required to market **Re-Tain**[®]. This submission would be subject to a six-month review by the FDA,” concluded Mr. Brigham. “We aim to re-submit during the first quarter of 2023, subject to completion of several critical path items that require results from external laboratories. We remain poised and excited to revolutionize the way that subclinical mastitis is treated. Mastitis is a disease that causes about \$2 billion in economic harm to the U.S. dairy industry per year.”

Certain Financial Results:

- Gross margin earned was 41% and 45% of product sales during the years ended December 31, 2022 and 2021, respectively. The less than normal gross margin during 2022 was largely the result of product contamination events in the production processes that resulted in a write-off of the affected inventory. Remediation measures are being implemented to reduce the opportunity for recurrence.
- Net operating (loss) was (\$2.3) million during the year ended December 31, 2022 in contrast to a net operating income of \$257,000 during the year ended December 31, 2021.
- Net (loss) was (\$2.5) million, or (\$0.32) per basic share, during the year ended December 31, 2022 in comparison to a net (loss) of (\$78,000), or (\$0.01) per basic share, during the year ended December 31, 2021.
- EBITDA (a non-GAAP financial measure described on page 5 of this press release) decreased to approximately \$350,000 during the year ended December 31, 2022 from \$2,706,000 during the year ended December 31, 2021.

Balance Sheet Data as of December 31, 2022:

- Cash and cash equivalents decreased to \$5.8 million as of December 31, 2022 from \$10.2 million as of December 31, 2021.
- Net working capital decreased to approximately \$10.9 million as of December 31, 2022 from \$13.7 million as of December 31, 2021.
- Stockholders' equity decreased to \$30.4 million as of December 31, 2022 from \$32.6 million as of December 31, 2021.

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

This Press Release and the statements to be made in the accompanying earnings conference call referenced herein contain “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 will 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 and strategies for our business; projections of future financial or operational performance; the timing and outcome of pending or anticipated applications for regulatory approvals; future demand for our products; 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 per unit; the 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 efficacy or timeline to complete our contamination remediation efforts; the likelihood, severity or impact of future contamination efforts; 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 robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield; future expense ratios and margins; the efficacy of our investments in our business; anticipated changes in our manufacturing capabilities and efficiencies; projections about depreciation expense and its impact on income for book and tax return purposes; and any other statements that are not historical facts. These statements are intended to provide management’s current expectation of future events as of the date of this earnings release, are based on management’s estimates, projections, beliefs and assumptions as of the date hereof; and are not guarantees of future performance. Such statements involve known and unknown risks and uncertainties that may cause the Company’s actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements, 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), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer and supplier relationships, commercial and operational risks relating to our current and planned expansion of production capacity, and other risks and uncertainties detailed from time to time in filings we make with the Securities and Exchange Commission (SEC), including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. In addition, there can be no assurance that future risks, uncertainties or developments affecting us will be those that we anticipate. 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.

Condensed Statements of Operations (Unaudited)

(In thousands, except per share amounts)	During the Years Ended December 31,	
	2022	2021
Product sales	\$18,568	\$19,243
Costs of goods sold	10,919	10,587
Gross margin	7,649	8,656
Product development expenses	4,494	4,169
Sales, marketing and administrative expenses	5,454	4,230
Operating expenses	9,948	8,399
NET OPERATING (LOSS) INCOME	(2,299)	257
Other expenses, net	187	326
(LOSS) BEFORE INCOME TAXES	(2,486)	(69)
Income tax expense	8	9
NET (LOSS)	(\$2,494)	(\$78)
Basic weighted average common shares outstanding	7,745	7,592
Basic net (loss) per share	(\$0.32)	(\$0.01)
Diluted weighted average common shares outstanding	7,745	7,592
Diluted net (loss) per share	(\$0.32)	(\$0.01)

Selected Balance Sheet Data (In thousands) (Unaudited)

	As of December 31, 2022	As of December 31, 2021
Cash and cash equivalents	\$5,792	\$10,185
Net working capital	10,923	13,730
Total assets	44,861	44,466
Stockholders' equity	\$30,380	\$32,577

Non-GAAP Financial 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 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 measures of Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) and 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 calculate EBITDA as described in the following table:

(In thousands)	During the Years Ended December 31,	
	2022	2021
(Loss) before income taxes	(\$2,486)	(\$69)
Interest Expense	341	306
Depreciation	2,468	2,442
Amortization and write-off of debt issuance costs	27	27
EBITDA	<u>\$350</u>	<u>\$2,706</u>

To calculate income before income taxes and certain non-cash expenses, we start with our reported (loss) before income taxes because presently we are not paying significant cash for income taxes and do not anticipate paying significant cash for income taxes in the near-term future. Cash payments to satisfy debt principal repayment obligations or to make capital investments have not been factored into this calculation. The figures reported in the table below differ from the calculation of EBITDA in the following two significant ways: 1) we have included payments for interest expense 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. We calculate non-GAAP income before income taxes and certain non-cash expenses as indicated in the table below:

(In thousands)	During the Years Ended December 31,	
	2022	2021
(Loss) before income taxes	(\$2,486)	(\$69)
Depreciation	2,468	2,442
Amortization and write-off of debt issuance costs	27	27
Stock-based compensation	266	144
Income before income taxes and certain non-cash expenses	<u>\$275</u>	<u>\$2,544</u>

Conference Call:

The Company will host a conference call on Wednesday, February 22, 2023 at 9:00 AM ET to discuss the full unaudited financial results for the year ended December 31, 2022. Interested parties can access the conference call by dialing (844) 855-9502 (toll free) or (412) 317-5499 (international). A teleconference replay of the call will be available until March 1, 2023 at (877) 344-7529 (toll free) or (412) 317-0088 (international), utilizing replay access code #1239083. 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.

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**[®], 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 in dairy cows 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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