

IMMUCELL CORP /DE/
Form 424B5
March 26, 2019

This preliminary prospectus supplement relates to an effective registration statement under the Securities Act of 1933, but the information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed Pursuant to Rule 424(b)(5)

Registration No.: 333-228479

SUBJECT TO COMPLETION, DATED MARCH 26, 2019

PRELIMINARY PROSPECTUS SUPPLEMENT

(To Prospectus dated November 29, 2018)

\$ of Shares of Common Stock

ImmuCell Corporation

We are offering \$ of shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus. Our common stock is listed on The NASDAQ Capital Market under the symbol "ICCC". On March 25, 2019, the last reported sale price of our common stock on The NASDAQ Capital Market was \$6.9052 per share.

| | Per Share | Total |
|--------------------------------------|----------------------|--------------|
| Public offering price | \$ | \$ |
| Underwriting discount ⁽¹⁾ | \$ | \$ |
| Proceeds, before expenses, to us | \$ | \$ |

⁽¹⁾ We refer you to the section entitled "Underwriting" of this prospectus supplement for additional information regarding total underwriting compensation.

As of January 29, 2019, the aggregate market value of our outstanding common equity held by non-affiliates was approximately \$37,378,737 based on 5,568,962 of outstanding common stock, of which 4,620,363 shares are held by non-affiliates, and a price of \$8.09 per share, which was the last reported sale price of our common stock on The Nasdaq Capital Market on January 29, 2019. As of the date of this prospectus supplement, we have not sold any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12-calendar month period that ends on, and includes, the date of this prospectus supplement.

Investing in our securities involves certain risks. Before deciding whether to invest in our securities, you should review carefully the information described under the heading “Risk Factors” beginning on page S- of this prospectus supplement, on page 6 of the accompanying prospectus, and in our Annual Report on Form 10-K for the year ended December 31, 2018 .

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter expects to deliver the shares of our common stock on or about March , 2019, subject to customary closing conditions.

Craig-Hallum Capital Group

The date of this prospectus supplement is March __, 2019.

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Prospectus

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a “shelf” registration process. Under this process, we may sell from time to time in one or more offerings up to an aggregate of \$20,000,000 of our securities described in the accompanying prospectus.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus. The second part is the accompanying prospectus, which provides general information, some of which may not apply to this offering. If information in this prospectus supplement is inconsistent with the accompanying prospectus, you should rely on this prospectus supplement.

You should rely only on the information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriter has not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are making an offer to sell common stock only in jurisdictions where offers and sales are permitted. You should assume that the information appearing in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference is accurate only as of their respective dates or other dates which are specified in those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

It is important for you to read and consider all of the information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus in making your investment decision. See “Where You Can Find More Information” on page S- of this prospectus supplement and “Where You Can Find Additional Information” on page 5 of the accompanying prospectus.

Unless the context otherwise requires, references in this prospectus supplement to “ImmuCell”, the “Company”, “we”, “us” and “our”, or similar terms, refer to ImmuCell Corporation.

FORWARD-LOOKING STATEMENTS

Some of the statements contained in or incorporated by reference in this prospectus supplement and in the accompanying prospectus that are not historical facts constitute “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. These statements relate to future events concerning our business and to our future revenues, operating results and financial condition,

and involve a number of known and unknown risks, uncertainties and other factors that could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “could”, “would”, “should”, “expect”, “plan”, “anticipate”, “aim”, “intend”, “believe”, “forecast”, “predict”, “project”, “propose”, “potential”, “seek” or “continue”, or the negative of those terms or other comparable terminology.

These statements are only estimates or predictions of future events based on information currently available to our management and management’s current beliefs about the potential outcome of future events. There are a number of important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements, including the following:

Our reliance on sales of our existing products;

Our dependence on a small number of significant customers and the concentration of our existing product sales;

Our ability to complete the development of (including obtaining required regulatory approvals for), and to achieve successful commercialization of, a key new product;

The risk of cost overruns or delays in expanding our manufacturing facilities for our **First Defense®** product line and our **Re-Tain™** mastitis product, including inadequacy of available funding for these projects;

Uncertainties arising from the volatile economics of the dairy and beef cattle industries;

Risks related to ongoing regulatory compliance and associated substantial costs;

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Our dependence on third parties for raw materials and manufacturing services, including the loss or interruption of such services and the risk of consequent delays in bringing our **Re-Tain™** mastitis product to market;

Risks of sales order backlogs and possible loss of key customers due to product delivery issues or concerns;

Competitive pressures from larger and better capitalized competitors;

Possible technical obsolescence or loss of cost competitiveness of our products;

Our small size and dependence on key personnel;

Risks of product recalls and product liability claims;

Risks associated with the substantial additional indebtedness we incurred to fund our recently completed Nisin manufacturing facilities expansion;

Our reliance on our intellectual property rights and risks associated with protecting such rights; and

Other risks listed in Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2018, which is incorporated by reference in this prospectus supplement and the accompanying prospectus.

Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. Forward-looking statements contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus present our views only as of the date of the applicable document containing such forward-looking statements. We do not assume any obligation, and do not intend, to update any forward-looking statement except as required by law. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary statements.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained in or incorporated by reference in this prospectus supplement. It does not contain all the information you should consider before investing in shares of our common stock. Before deciding to invest in shares of our common stock, you should carefully read this entire prospectus supplement, the accompanying prospectus and the documents incorporated herein and therein by reference, including the “Risk Factors” beginning on page S- of this prospectus supplement, our financial statements and the related notes and other information that is incorporated by reference in this prospectus supplement.

Overview

ImmuCell Corporation is a growing animal health company focused on developing, manufacturing and delivering scientifically-proven, practical and effective products that improve the health and productivity of dairy and beef cattle. Our lead product, **First Defense®**, is derived from colostrum collected from dairy cows and provides significant, immediate immunity against scours in newborn dairy and beef cattle. On November 13, 2017, we received approved licensure from the USDA, Center for Veterinary Biologics, for a new product, **Tri-Shield First Defense®**, the first calf-level scours preventative with claims against all three newborn calf scours-causing pathogens: *E. coli*, coronavirus and rotavirus, and have begun marketing this product. We are in the late stages of developing and securing final regulatory approvals for **Re-Tain™**, an intramammary treatment for subclinical mastitis in lactating dairy cows, the active ingredient of which is Nisin, an antibacterial peptide that has been demonstrated in clinical studies to be an effective aid in the reduction of mastitis-causing organisms in dairy cows. We currently expect to be in a position to commence commercial sales of **Re-Tain™** in the United States in 2020 (subject to receipt of final approvals from the U.S. Food and Drug Administration’s Center for Veterinary Medicine (FDA) and reaching agreement with our existing third party manufacturer on an amendment of our existing agreement or, alternatively, entering into a comparable agreement with another third party manufacturer who can provide the needed services without delay).

Across all product lines, our product sales during the year ended December 31, 2018 increased by 5%, or \$555,000, to \$10,986,000 from \$10,431,000 for the year ended December 31, 2017, and gross margin as a percentage of product sales was 47% during the year ended December 31, 2018, as compared to 50% during the year ended December 31, 2017. Sales of the **First Defense®** product line aggregated 97% and 94% of our total product sales during the year ended December 31, 2018 and the year ended December 31, 2017, respectively. Sales of the **First Defense®** product line increased by 9% and 11% during the years ended December 31, 2018 and December 31, 2017, respectively, in comparison to the corresponding prior years.

First Defense® Product Line

First Defense® is manufactured from hyper-immune cows' colostrum (the milk that a cow produces immediately after giving birth) utilizing our proprietary vaccine and milk protein purification technologies. The target disease, bovine enteritis (calf scours), causes diarrhea and dehydration in newborn calves and often leads to serious sickness and even death. **First Defense®** is the only orally delivered scours preventative product on the market for calves that is licensed by the U.S. Department of Agriculture (USDA) with claims against *E. coli* K99 and coronavirus (two leading causes of scours). On November 13, 2017, we received approved licensure from the USDA, Center for Veterinary Biologics, for a new product, **Tri-Shield First Defense®**, the first calf-level scours preventative with claims against all three newborn calf scours-causing pathogens: *E. coli*, coronavirus and rotavirus. No other calf-level product in the market contains all three claims in a one-time preventative dose. With this expanded claim set, we believe that we can compete more effectively against dam-level scours vaccine products that are given to the cow to improve the quality of her colostrum (first milk) that is fed to the newborn calf. It is generally believed that only 80% of cows respond to a vaccine, leaving approximately 20% of calves treated in this manner unprotected against scours. Also, we believe that vaccine treatment protocols are often not adhered to, leaving even more calves unprotected. **First Defense®** provides bovine antibodies that newborn calves need but are unable to produce on their own immediately after birth. Our milk antibody products provide **Immediate Immunity™** during the first few critical days of life when calves need this protection most. Studies have shown that calves that scour are more susceptible to other diseases later in life and under-perform calves that do not contract scours. We estimate that scours causes approximately \$740 million in economic losses to the U.S. dairy and beef industries per year. We believe that the U.S. market for calf-level scours prevention products is approximately \$18 million and that the market for dam-level scours prevention products is approximately twice that size. With the new rotavirus claim for our product (**Tri-Shield First Defense®**) we are now competing against dam-level vaccine products that are given to the mother cow to increase the antibody level against scours-causing pathogens in the colostrum that she produces for her newborn. Those products are sold by Elanco (Scour Bos™), Merck (Guardian®) and Zoetis (ScourGuard®). Despite the best-managed dam vaccine program, colostrum quality is naturally variable and newborn calves do not always get the antibodies they need from maternal colostrum. We believe that the guaranteed dose of antibodies in our product provides more consistent protection than such vaccine products.

When compared to the other USDA-approved calf-level scours preventatives, we believe we are first in sales dollars and second in volume. This product category is comprised of five primary brands (increased from four during the fourth quarter of 2016) that are given either orally or intra-nasally to newborn dairy and beef calves immediately after birth. Market research that we subscribe to suggests that our product comprised approximately 34% and 33% of the total doses sold in this product category (one dose equates to one calf, according to label administration on all products) during 2018 and 2017, respectively. These estimates are down from 36% during 2016 and 40% during 2015, when the product category included only four primary brands (one of which experienced lack of supply to the market during late 2014 and into the middle of 2015). This market share estimate is slightly up from 32% in 2014 and up from 26% and 22% in 2013 and 2012, respectively, as the total volume in the product category has steadily increased. These estimates do not include sales of vaccine products that are given to the dam (mother cow), which is discussed below. The third quarter of 2018 marked the 27th anniversary of the original USDA approval of this product in 1991. During the fourth quarter of 2018, our cumulative sales of **First Defense®** since inception exceeded 22,000,000 doses. We believe that these milestones demonstrate the value of our technology and the long-term market acceptance of our product.

The majority of our international sales are to Canada. We price our products in U.S. dollars. To the extent that the value of the dollar declines with respect to any other currency, our competitive position may be enhanced. Conversely, an increase in the value of the dollar in any country in which we sell products may have the effect of increasing the local price of our products, thereby leading to a potential reduction in demand. Generally, our international sales have been generated through relationships with in-country distributors that have knowledge of the local regulatory and marketing requirements. We are initiating our plan to expand the number of countries to which our **First Defense®** product line is approved for export. Generally, it is our intent to be the holder of these product registrations for each country rather than rely on distribution partners to gain and hold these registrations. This is a long regulatory process but allows us to maximize the use of our product label claims and avoid long-term exclusive distribution agreements. We continue our efforts to grow sales of the **First Defense®** product line in North America, where there are approximately 41,300,000 dairy and beef cows in the United States and 4,645,000 dairy and beef cows in Canada. We believe that even greater market opportunities exist in other international territories. There are estimated to be approximately 67,400,000 dairy and beef cows in China, 35,450,000 in the European Union, 18,470,000 in Australia and New Zealand, 11,150,000 in Mexico, 1,700,000 in South Korea and 1,470,000 in Japan. The statistics above are provided by an industry compilation of USDA data for 2019. However, industry practices, economic conditions, cause of disease, distribution channels and regulatory requirements may differ in these international markets from what we experience in North America making it more difficult or costly for us to generate and sustain sales volumes at profitable margins in these markets.

Novel Treatment for Subclinical Mastitis (Re-Tain™)

The majority of our product development budget since 2000 has been focused on the development of **Re-Tain™**, a Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. Mastitis is a very common infection in dairy cows that results in inflammation of the mammary gland. It is the largest single cause of economic harm to the U.S. dairy industry, with an estimated cost of approximately \$2 billion per year, including approximately \$300 million in discarded milk from cows that have been treated with traditional antibiotic mastitis drugs. During the period that began on January 1, 2000 (the year we began the development of **Re-Tain™**) and ended on December 31, 2018, we invested an aggregate of approximately \$15.5 million in the development of this product (excluding depreciation and the capital cost (\$20.8 million) of our Nisin production facility). This estimated allocation of product development expenses reflects only direct expenditures and includes no allocation of product development or administrative overhead expenses. Approximately \$2.9 million of this investment was offset by related product licensing revenues and grant income.

Nisin is an antibacterial peptide that has been demonstrated in clinical studies to be an effective aid in the reduction of mastitis-causing organisms in dairy cows. Because dairy producers are required to discard milk for a period of time during and after treatment with all currently marketed mastitis treatment products due to concerns about antibiotic residue in milk, it is generally current practice to only treat mastitis when the disease has progressed to the clinical stage where the milk from an infected cow cannot be sold. We believe that **Re-Tain™** could revolutionize the way that mastitis is treated in the United States by making earlier treatment of subclinically infected cows economically feasible by not requiring a milk discard during, or for a period of time after, treatment. No other FDA-approved

mastitis treatment product on the market can offer this value proposition. Growing concerns about the presence of traditional antibiotics in our food supply, we believe, will aid in the marketing of our product and growth in its sales.

Based on publicly available information on the size of the U.S. dairy herd, the incidence of mastitis and likely mastitis treatment protocols, we have estimated that the market potential for **Re-Tain™** could be \$5.8 million during the first year of sales with potential growth for the fifth year to \$36.1 million. Our near-term sales goal is to double our current sales through continued growth in sales of the **First Defense®** product line and a successful launch of **Re-Tain™** as soon as possible. As market penetration is achieved and additional resources are dedicated to sales, marketing and technical services, our longer term goal is to triple our current sales as soon as possible during the five-year period after market launch of **Re-Tain™**.

Commercial introduction of our product in the United States is subject to approval of our New Animal Drug Application by the FDA, which approval cannot be assured. We have received FDA Complete Letters with respect to four of the five principal Technical Sections required for FDA approval of commercial sales of **Re-Tain™**. During the first quarter of 2019, we made the first of two phased Drug Substance submissions to the FDA relating to the fifth Technical Section – Chemistry, Manufacturing and Controls (CMC). This Technical Section includes data from the Nisin Drug Substance Registration Batches produced at commercial scale in our new manufacturing facility. This submission is subject to a six-month review period. A successful FDA inspection of our Nisin manufacturing facility must also be achieved. The second phased Drug Product submission for the CMC Technical Section (which will include responses to the FDA’s review of the first phased submission and detailed information about the manufacturing process and controls for the sterile Nisin Drug Product) is also subject to a six-month review period, and will not be made in time to achieve product approval by our original goal of December 2019. After FDA approval of the CMC Technical Section, there is a sixty (60) day FDA administrative review before the anticipated product license approval can be issued and commercial sales of **Re-Tain™** can begin. Foreign regulatory approvals would be required for sales of **Re-Tain™** in key markets outside of the United States, which would involve some similar and some different requirements, likely including some milk discard requirements.

Since 2010, we have been a party to a long-term exclusive product development and contract manufacturing services agreement with Norbrook Laboratories Limited of Newry, Northern Ireland, an FDA-approved Drug Product manufacturer, covering the final formulation, aseptic filling and final packaging services for **Re-Tain™**. Norbrook has provided services to us under this contract throughout the FDA process for use in all of our pivotal studies. During the fourth quarter of 2015, this agreement was amended and restated to, among other things, extend the term of the agreement to January 1, 2024. It has been our expectation that we would have these services available through both the remainder of the development process and approximately the first four years of commercial sales of **Re-Tain™**. However, the agreement includes a provision potentially entitling Norbrook to terminate the agreement if we do not receive FDA approval for **Re-Tain™** by mid-December 2019. Due to unexpected difficulties and delays encountered by Norbrook during this late stage of the development and the usual FDA timeline for processing CMC Technical Sections, we do not expect to receive FDA approval by the December 2019 date.

In anticipation of this potential issue, we have made requests to Norbrook to amend the existing agreement to avoid early termination, including proposing a shorter term and increased payments to Norbrook. However, we have not yet reached resolution on an amendment, and it remains unclear whether we will be able to reach agreement on a suitable amendment, or if we do, for how long we will continue to have access to Norbrook's services. Consequently, we have been actively investigating multiple alternatives, including securing an agreement for such services with another qualified third party and performing the services in-house by constructing an aseptic filling capability within our new Drug Substance production facility. Because both of these alternatives would likely delay our commencement of commercial sales of **Re-Tain™** to at least 2021, we believe, in the case of transitioning to a new third party manufacturer, and to at least 2022, we estimate, in the case of constructing our own facilities and performing these services in-house, our strong preference would be to reach at least an interim arrangement with Norbrook, while we pursue the implementation of the chosen alternative in parallel. If we are unable to reach an arrangement with Norbrook, our alternative approach would be to seek an interim agreement for such services with another qualified third party while we proceed to construct and equip our own drug product manufacturing facility in order to reduce or avoid a delay in commencing sales of **Re-Tain™** or an interruption of such sales after commencement. Due to the unique requirements associated with manufacturing **Re-Tain™** (the facility cannot also handle products containing traditional antibiotics), there can be no assurance that we will be able to locate and reach agreement with a suitable alternative third-party provider. In light of the challenges and risks associated with reliance on third-party services, it is likely that we will take the steps necessary to become self-sufficient with respect to the manufacturing process for **Re-Tain™**, and will utilize these third-party arrangements, if available to us, as a necessary but temporary solution pending the completion of our own facilities; however, whether and when we implement those steps will depend, in part, on developments in the upcoming weeks or months with respect to third party arrangements with Norbrook or another provider.

First Defense® Facilities Expansion

We have decided to undertake an expansion of our **First Defense**® manufacturing facilities to better assure our ability to meet growing market demand for this product line. We first experienced a prolonged period of order backlog for our **First Defense**® product line (which began early in 2015 and extended through the middle of 2016), which disrupted our normal product shipping patterns. In response, we completed investments necessary to increase our liquid processing capacity by 50% during the fourth quarter of 2015 and our freeze drying capacity by 100% during the first quarter of 2016. With this expanded production capacity, we can now produce **First Defense**® product with an annual sales value of approximately \$18 million. The actual value of the production output will vary subject to product yields, selling price and product format mix. Since the third quarter of 2016 and through most of 2017, we had sufficient available inventory and were shipping in accordance with the current demand of our distributors. However, we quickly sold out of our initial launch quantities of **Tri-Shield First Defense**® soon after regulatory approval was obtained during the fourth quarter of 2017. Presently, we are only accepting purchase orders for **Tri-Shield First Defense**® from customers to match available inventory, which requires a careful allocation of product supply directly to certain farms. Production of this new product format has not kept pace with demand primarily because of our inability to produce enough of the new, complex rotavirus vaccine that is used to immunize our source cows in this time frame. Recent production improvements in our vaccine laboratory will allow us to immunize more source cows, but the increased supply of finished product will not be available for sale in a significant way until the second half of 2019. While this product shortage is a problem and has adversely impacted customer relations and resulted in lost sales, it is also a positive indication that the market is accepting our new product offering.

During the first quarter of 2018, sales demand for **Dual-Force**™ **First Defense**® also exceeded available inventory, resulting in a backlog of orders worth approximately \$901,000 as of March 31, 2018, which was filled during the second quarter of 2018. The estimated value of this backlog was calculated by multiplying the number of units for which customer orders had been received but were not shipped at the end of the period by the expected selling price. In order to produce more doses quickly to clear the 2015/2016 order backlog, we significantly increased the quantity of our supply of colostrum at the same time that we were making the investments to increase our production capacity, discussed above. The 2018 backlog problem was largely caused by a reduction in the biological yield from this new colostrum supply. To address the inherent variability in our biological yields, among other process improvements, we have optimized and standardized the mix of early milk that is rich with antibodies and later milk that contains less antibodies but is required to run our production process. As we rebuild target inventory levels of **Dual-Force**™, we are confident that we will again consistently supply product to the market because of the improved production methods to increase yields and the enhanced manufacturing redundancies that we have implemented.

Given the strength of what we are seeing for potential demand for the **First Defense®** product line in North America, we plan to further increase our liquid processing capacity by 100% and our freeze drying capacity by 50%. Our very preliminary estimate of the cost of this investment is approximately \$3 million. We anticipate finalizing the plans for this expansion, contracting for the necessary equipment and construction services, and commencing work in mid-2019 and, based on that expected start time, completing this project in the fourth quarter of 2020.

Re-Tain™ Facilities Expansion

As discussed above, it is becoming increasingly likely that we will determine that our long-term interests will be best served by developing our own drug product manufacturing facilities and capability for **Re-Tain™**, and ending our reliance on third-party services for the **Re-Tain™** manufacturing process. We expect that this shift to internal manufacturing will result in operating cost savings relative to the expected cost of third-party services. We believe that the elimination of the risk of interruption or loss of third-party services or substantial cost increases for those services together with these anticipated operating cost savings justify the estimated \$4 million of capital expenditures we expect to incur to develop this facility.

We estimate that this project, once commenced, would likely require approximately three years to complete and be approved by the FDA. Therefore, during the coming weeks and months, we intend to continue our efforts to amend our existing agreement with Norbrook or secure an agreement for alternative third-party manufacturing services, and will assess on an on-going basis whether such efforts seem likely to produce a favorable outcome and, in that light, when and whether to proceed with planning, designing, constructing and equipping this facility on our existing premises, in order to reduce the period during which we remain dependent on third-party manufacturing services or to minimize any delay in commencing sales of **Re-Tain™** resulting from the unavailability of such third-party services.

During the third quarter of 2018, at a total cost of approximately \$20.8 million, we completed a new manufacturing facility that enables us to generate our own Nisin supply at commercial scale, with sufficient capacity to achieve approximately \$10.0 million in annual sales. Our facility, as originally designed and constructed, included enough room for a second production line to be purchased and installed to effectively double our Nisin production output. However, the **Re-Tain™** drug product manufacturing facility discussed above would, if constructed, occupy the space in our new Nisin production facility that we had originally intended to use to double our Nisin production capacity if warranted by **Re-Tain™** sales volumes during the initial years following product launch, thus limiting the maximum production capacity of our new **Re-Tain™** facilities. This could possibly leave us unable to meet growing customer demand for **Re-Tain™** until and unless we are able to expand that capacity elsewhere or otherwise relocate certain manufacturing activities to enable the expansion to occur.

Recent Developments

We are in the process of finalizing our results for the three-month and twelve-month periods ended March 31, 2019.

Based on currently available information, we estimate that, as of and for the three-month and twelve-month periods ended March 31, 2019:

Product sales during the three-month period ended March 31, 2019 are anticipated to be approximately \$4,252,000, compared to \$2,881,000 during the three-month period ended March 31, 2018, an increase of \$1,371,000 or 48%; Product sales during the twelve-month period ended March 31, 2019 are anticipated to be approximately \$12,357,000 compared to \$9,768,000 during the twelve-month period ended March 31, 2018, an increase of \$2,589,000 or 26%; Cash, cash equivalents and short-term investments are anticipated to be approximately \$2,410,000 as of March 31, 2019, as compared to \$3,060,470 as of March 31, 2018.

This unaudited preliminary financial information for the three-month and twelve-month periods ended March 31, 2019 is based upon our estimates and subject to completion of our financial closing procedures. Moreover, these data have been prepared solely on the basis of currently available information by, and are the responsibility of, management. This preliminary financial information is not a comprehensive statement of our financial results for these periods, and our actual results may differ materially from these estimates due to the completion of our financial closing procedures, final adjustments, and other developments that may arise between now and the time the closing procedures for the quarter are completed. There can be no assurance that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within our control. In addition, product sales during the three-month and twelve-month periods ended March 31, 2018 were adversely affected by a \$1,245,000 backlog in filling **First Defense**® orders that occurred in the first quarter of 2018, as compared to an estimated backlog of \$185,000 as of March 31, 2019. Backlog for **Tri-Shield First Defense**® was \$344,000 as of March 31, 2018, compared to \$185,000 as of March 31, 2019. The estimated product sales data for the three-month and twelve-month periods ended March 31, 2019 includes a revised estimate of \$668,000 of **Tri-Shield First Defense**® sales in the first quarter of 2019, as compared to our previous estimate of \$795,000. Our operating results are subject to seasonal fluctuations and variations; therefore, these estimated results may not be representative of results in the ensuing quarters. Under our bank covenants, we are required to maintain a cash balance of at least \$2 million as of the end of any calendar quarter, thus limiting our ability to utilize these funds.

Summary Historical and Pro Forma Balance Sheet Data

The table below presents audited summary balance sheet data as of December 31, 2018 on both a historical basis and on an as adjusted basis (assuming that the proceeds of this offering had been received as of December 31, 2018). The summary financial data has been derived from our audited financial statements, which are incorporated by reference in this prospectus supplement. The as adjusted summary financial data is not necessarily indicative of what our financial position or results of operations would have been if this offering had been completed as of the date indicated, nor is such data necessarily indicative of our financial position for any future date. The following summary and as adjusted financial data should be read in conjunction with, and are qualified in their entirety by reference to: “Use of Proceeds”, “Summary Financial Data” and our financial statements and the related notes included elsewhere in this prospectus supplement or incorporated by reference herein.

| | As of December 31, 2018 (Actual) | As of December 31, 2018 (As Adjusted) |
|---|---|--|
| <u>Assets</u> | | |
| Total current assets | \$6,420,836 | \$ |
| Property, plant and equipment, net | 26,027,549 | 26,027,549 |
| Intangible Assets, net | 133,728 | 133,728 |
| Goodwill | 95,557 | 95,557 |
| Interest Rate Swaps | 40,209 | 40,209 |
| Other assets | 12,953 | 12,953 |
| Total Assets | \$32,730,832 | \$ |
| <u>Liabilities and Stockholders' Equity</u> | | |
| Total current liabilities | \$2,565,011 | \$2,565,011 |
| Total long-term liabilities | 8,421,487 | 8,421,487 |
| Total Liabilities | 10,986,498 | 10,986,498 |
| Total Stockholders' Equity | 21,744,334 | |
| Total Liabilities and Stockholders' Equity | \$32,730,832 | \$ |

Corporate Information

We are a growing animal health company that develops, manufactures and markets scientifically-proven products that improve the health and productivity of dairy and beef cattle. We were originally incorporated in Maine in 1982 and reincorporated in Delaware in 1987, in conjunction with our initial public offering of common stock. Our principal executive offices are located at 56 Evergreen Drive, Portland, Maine 04103. Our telephone number is (207) 878-2770. We maintain an Internet website at www.immucell.com. The information contained in, or accessible from, our website

is not a part of this prospectus supplement or the accompanying prospectus.

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The Offering

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus supplement.

Common stock offered by us shares of common stock, par value \$0.10 per share.

Common stock outstanding immediately after this offering⁽¹⁾ shares of common stock.

Use of proceeds The net proceeds from this offering will be approximately \$, after deducting underwriting discounts and our estimated expenses related to the offering. We intend to use the net proceeds from this offering of common stock to fund certain critical investments and possibly to reduce indebtedness or increase working capital. See “Use of Proceeds.”

Risk Factors See the information described under the heading “Risk Factors” beginning on page S- of this prospectus supplement and other information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should consider carefully before investing in our common stock.

Nasdaq Capital Market symbol ICCC

⁽¹⁾ The number of shares of common stock that will be outstanding immediately after this offering is based on 5,573,231 shares outstanding as of March 25, 2019, and excludes 377,000 shares of our common stock reserved for future issuance upon the exercise of outstanding options (of which options with respect to 45,000 shares are currently exercisable) at a weighted average exercise price of \$6.51 per share.

SUMMARY FINANCIAL DATA

The following table sets forth, for the periods and dates indicated, our summary financial data. The summary financial data has been derived from our audited historical consolidated financial statements and accompanying notes for the year ended December 31, 2018 and the year ended December 31, 2017. The results included in this table are not necessarily indicative of future performance. The following table should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the audited historical financial statements and accompanying notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2018, which are incorporated by reference in this prospectus supplement and the accompanying prospectus.

| (In thousands, except per share amounts) | Year Ended | |
|--|-------------------|-------------------|
| | December 31, 2018 | December 31, 2017 |
| Product sales | \$10,986 | \$10,431 |
| Costs of goods sold | 5,792 | 5,210 |
| Gross margin | 5,194 | 5,221 |
| Selling and administrative expenses | 3,824 | 3,418 |
| Product development expenses | 3,517 | 2,046 |
| Gain on sale of assets | 700 | — |
| Operating Expenses | 6,641 | 5,464 |
| Net operating income (loss) | (1,447) | (243) |
| Other expenses, net | 413 | 195 |
| (Loss)before income taxes | (1,860) | (438) |
| Income tax expense (benefit) | 462 | (270) |
| Net (loss) | \$(2,322) | \$(168) |
| Weighted average common shares outstanding | | |
| Basic | 5,486 | 4,949 |
| Diluted | 5,486 | 4,949 |
| Net (loss) per share | | |
| Basic | \$(0.42) | (0.03) |
| Diluted | \$(0.42) | \$(0.03) |

RISK FACTORS

An investment in our securities involves risk. You should consider carefully the risk factors described below and set forth in the “Risk Factors” sections of the Annual Report on Form 10-K for the year ended December 31, 2018, together with the other information contained in our financial statements and the related notes, which is incorporated by reference herein, before deciding to invest in our common stock. We operate in a changing environment that involves numerous known and unknown risks and uncertainties that could materially adversely affect our operations. If any of such risks materialize, our business, financial condition, results of operations and the value of our common stock could be materially and adversely affected. In such case, you may lose all or part of your investment in our common stock. Please also refer to the section above entitled “Forward-Looking Statements” regarding forward-looking statements included or incorporated herein by reference.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. If you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$ per share in the net tangible book value of the common stock. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

Our common stock has had limited trading.

Trading in our common stock has historically been thin. Because of the thinness of the market for our stock, the price of our common stock may be subject to manipulation and may be volatile. This limited trading may adversely affect the liquidity of our common stock, in terms of the number of shares that can be bought and sold at a given price. As a result, there could be a larger spread between the bid and the ask prices of our common stock and investors may not be able to sell shares of our common stock when or at prices they desire.

Fluctuations in the price of our common stock, including as a result of actual or anticipated sales of shares by stockholders, may make our common stock more difficult to resell.

The market price and trading volume of our common stock have been and may continue to be subject to significant fluctuations due not only to general stock market conditions, but also to a change in sentiment in the market regarding

the industry in which we operate, our operations, business prospects or liquidity or this offering. During the period from January 1, 2016 to March , 2019, our common stock has fluctuated from a low of \$4.76 per share to a high of \$9.30 per share. In addition to the risk factors discussed in our periodic reports and in this prospectus supplement, the price and volume volatility of our common stock may be affected by actual or anticipated sales of common stock by existing stockholders, including the shares purchased in this offering, whether in the market or in subsequent public offerings. Stock markets in general have experienced extreme volatility recently that has at times been unrelated to the operating performance of particular companies or industries. These broad market fluctuations may adversely affect the trading price of our common stock, regardless of our operating results. As a result, these fluctuations in the market price and trading volume of our common stock may make it difficult to predict the market price of our common stock in the future, cause the value of your investment to decline and make it more difficult to resell our common stock.

Our stockholders may experience further dilution if we issue additional shares of common stock in the future.

Any additional future issuances of common stock by us will reduce the percentage of our common stock owned by investors purchasing shares in this offering who do not participate in such future issuances. In most circumstances stockholders will not be entitled to vote on whether or not we issue additional common stock. In addition, depending on the terms and pricing of an additional offering of our common stock and the value of our assets, our stockholders may experience dilution in both the book value and the market value of their shares.

We are not restricted from issuing additional common stock, including securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. We are offering shares of common stock. The issuance of additional shares of our common stock in this offering or other issuances of our common stock or convertible or other equity linked securities, including options and warrants, or otherwise, in connection with capital raising transactions or for employee compensation or other purposes will dilute the ownership interest of our common stockholders. As of March 25, 2019, we 5,573,231 outstanding shares of common stock, which excludes 377,000 shares of common stock issuable upon the exercise of outstanding stock options.

Sales of a substantial number of shares of our common stock or other equity-related securities in the public market could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the effect that future sales of our common stock or other equity-related securities would have on the market price of our common stock.

We are not currently paying dividends and will likely continue not paying dividends for the foreseeable future.

We have never paid or declared any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to repay indebtedness and to fund the development and expansion of our business, and we do not anticipate paying any cash dividends or repurchasing shares of our common stock in the foreseeable future. In addition, the terms of our existing credit agreements restrict the payment of cash dividends on our common stock and the repurchase by us of our common stock. Any future determination to pay dividends or to repurchase stock will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, contractual restrictions and other factors that our board of directors deems relevant.

Provisions in our rights plan and in Delaware law could make it more difficult for a third party to acquire us, discourage a takeover and adversely affect existing stockholders.

Our board of directors adopted in 1995 a common stock rights plan under which, if the rights issued thereunder are not redeemed by the board and the board has not approved the acquisition by a prospective acquirer of 20% or more of our outstanding common stock, the holders of such rights (other than such prospective acquirer) have the right, in effect, to purchase additional shares of our common stock for each right held at a substantial discount from the market price of such stock, immediately preceding the prospective acquirer's acquisition of such ownership (or announcement of an offer to acquire such ownership).

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which could prevent us from engaging in a "business combination" with a 15% or greater stockholder for a period of three years from the date such person acquired that status unless appropriate board or stockholder approvals are obtained.

These provisions could deter unsolicited takeovers or delay or prevent changes in our control or management, including transactions in which stockholders might otherwise receive a premium for their shares over the then current market price. These provisions may also limit the ability of stockholders to approve transactions that they may deem to be in their best interests.

We could experience higher than anticipated costs, cost over-runs, longer completion time frames or delays in completing our expanded manufacturing facilities, and we could fail to access necessary funding for the expansion projects.

As noted above, and in “Use of Proceeds”, we presently intend to apply a portion of the net proceeds of this offering to fund at least a substantial portion of the costs of expanding our existing manufacturing facilities for our **First Defense®** product line, and we believe it is likely that we will construct and equip our own drug product manufacturing facility for **Re-Tain™**, our mastitis product, also using a portion of the net proceeds of this offering. The preliminary cost estimates set forth in this prospectus supplement for those projects have been prepared internally and are not based on any bids or quotes from contractors or equipment suppliers. Also, our estimated timelines for those projects, similarly, are preliminary, internally prepared and not based on quotes, proposals or other reliable third-party information. Actual bids and binding agreements could result in longer time frames for completion and in higher actual costs, which may outstrip our available resources, and even those actual bids could understate actual costs, such as due to change orders, delays or other unforeseen events, in any of which instances actual project costs could exceed our current estimates. In addition, completion of either project could be delayed due to factors outside our control, including equipment delivery delays or delays in obtaining FDA approvals for **Re-Tain™**. Also, our ability to fund the completion of those projects may depend on, in addition to the proceeds from this offering, cash flow from future operations, which may not materialize or be available at the needed levels.

USE OF PROCEEDS

The net proceeds of this offering to us will be approximately \$ after deducting our estimated offering expenses. We intend to use the net proceeds from this offering to fund certain critical investments, and possibly to pay down indebtedness and add to our working capital.

· As noted under “Prospectus Supplement Summary – **First Defense**® Facilities Expansion”, our existing manufacturing capacity for our **First Defense**® product line supports an estimated annual sales volume of approximately \$18 million. Due to increasing customer demand we have encountered backlogs for these products in recent months, and have had to delay and reduce the scope of our rollout of our **Tri-Shield First Defense**® product to avoid further backlogs. To alleviate these constraints and to enable us to expand **First Defense**® production to support annual sales of approximately \$30 million, we plan to install or construct, during 2019 and 2020, a third freeze dryer and additional liquid processing equipment at a total preliminary estimated cost of \$3 million, which estimate is based on internally-generated calculations using, among other things, actual costs incurred in previous equipment acquisitions and installations for our **First Defense**® manufacturing facilities.

· As described above under “Prospectus Supplement Summary – **Re-Tain**™ Facilities Expansion”, while we have Nisin manufacturing capacity in our own facilities sufficient to support annual sales of **Re-Tain**™ of approximately \$10 million, we will at least initially remain dependent on a third-party for drug product manufacturing services for that product. Due to the risks and uncertainties associated with that dependency, as well as the added cost of using third-party manufacturing services over the long-term, it is increasingly likely that we will construct and equip our own drug product manufacturing facilities in the hope of avoiding or reducing delays in commercial sales of **Re-Tain**™ following receipt of FDA approval resulting from the loss or unavailability of those third-party services. Based on publicly available information and our recent experience in constructing and equipping our Nisin production facility, we preliminarily estimate the cost of this facility to be \$4 million.

For the funding of these two projects, we intend to complement the \$ of net proceeds from this offering with an additional \$ of revenues from ongoing operations.

If we were to decide not to proceed with the drug product manufacturing facilities for **Re-Tain**™ due to unanticipated circumstances (such as obtaining a favorable long-term manufacturing services contract with a suitable third-party, or encountering adverse developments in the pending FDA approval process), we would apply the unexpended portion of the net proceeds from this offering to reduction of indebtedness and/or additions to our working capital.

PRICE RANGE OF OUR COMMON STOCK

Our common stock is traded on The NASDAQ Capital Market under the symbol “ICCC”. The last reported sales price of our common stock on The NASDAQ Capital Market on March 25, 2019 was \$6.9052 per share.

The following table sets forth, for the periods indicated, the high and low sale prices for our common stock.

| | HIGH | LOW |
|--|-------------|------------|
| First Quarter of 2019 (through March 25, 2019) | \$ 8.09 | \$ 6.7028 |
| Year ending December 31, 2018 | | |
| First Quarter | \$ 8.79 | \$ 6.70 |
| Second Quarter | 8.65 | 6.74 |
| Third Quarter | 9.24 | 6.50 |
| Fourth Quarter | 9.30 | 6.38 |
| Year ended December 31, 2017 | &n | |