IMMUCELL CORP /DE/
Form 8-K
July 16, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report: July 16, 2014
(Date of earliest event reported)
ImmuCell Corporation
(Exact name of registrant as specified in its charter)

DE	**001-12934**	**01-0382980**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

56 Evergreen Drive

Portland, Maine
(Address of principal executive offices)

04103
(Zip Code)

207-878-2770
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure

The Company has recently engaged an investor relations firm to introduce the Company more broadly to the investment community. In response to inquiries for more detailed information about the potential market for the Company's products, **First Defense®** and **Mast Out®**, the Company is furnishing this public disclosure in accordance with Regulation FD and under the forward-looking statement disclaimer provided at the end of this document.

First Defense®:

First Defense® is derived from bovine colostrum and is delivered orally immediately after birth with USDA-approved claims to protect the newborn calves from scours (bovine enteritis or diarrhea) caused by *E. coli* and coronavirus. Based on the Company's internal best estimates and calculations and some available published literature, it is the Company's opinion that scours causes approximately $761,000,000 in economic losses (primarily related to deaths, treatments and reduced productivity) to the U.S. dairy and beef calf industries annually.

First Defense® competes primarily with two products on the market today, Calf-Guard (Zoetis) and Bovine Ecolizer and Bovine Ecolizer +C (Novartis). There are other products and methods to reduce losses due to scours, but the Company's sales team focuses directly on these two competitive products which together with **First Defense®** are used to treat approximately 3.0 million calves per year. This estimate represents approximately 8% of the 37,054,000 calves born alive each year. Approximately 8,500,000 calves per year are diagnosed with scours, representing approximately 23% of all live births. This segment has been growing in recent years by 3-5% and **First Defense®** has consistently grown its share of market in the segment with an estimated 25% market share in 2013 up from 22% in 2012. First half 2014 results continue to show strengthening performance as **First Defense®** is projected to attain ~ 28% share of market based on internal estimates. We believe that there is an opportunity for growth in this product category as progressive producers adopt proactive preventative protocols over a treatment mentality. This information is approximated but does give the investor some indication of the market potential for **First Defense®**.

Mast Out®:

Mast Out® is a Nisin-based treatment for subclinical mastitis in lactating dairy cows, subject to FDA approval. It is widely understood that mastitis is the largest cause of economic harm to the U.S. dairy industry, estimated at approximately $2,000,000,000 per year.

It is very difficult to accurately assess the market potential for this product because currently subclinical mastitis is generally not treated due to the cost of discarded milk, which is required with the use of all traditional antibiotic

treatments. With a zero milk discard claim in the U.S. market, the Company expects to revolutionize current mastitis treatment practices by making the treatment of subclinical infection economical. Over the past two to three years, the Company has examined many different sales models and discussed the market potential for this product with several potential marketing partners. By our best estimate, we project potential retail sales for

Mast Out® of approximately $5,400,000 during the first year after market launch and approximately $31,700,000 during the tenth year after market launch. The actual sales level achieved could be significantly higher or lower depending on many different variables. The critical assumptions underlying these estimates are as follows:

# of U.S. cows in lactation: 7,868,000

Projected % of cows treated with **Mast Out®** over first ten years after market launch: 0.40% during first quarter after market launch to 3.37% during 40th quarter after market launch.

Each cow has four quarters (teats) per udder. Some cows are infected in more than one quarter. The average number of quarters treated with **Mast Out®** per cow: 1.15

of **Mast Out®** doses per treatment: three

Suggested retail price per dose: $8.99

This data was derived from our best interpretation of industry reports and our own understandings and projections.

Forward-looking statement disclaimer:

This presentation contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the scope and timing of future product development work and commercialization of our products; the outcome of pending or anticipated applications for future regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", “hopes”, "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, the uncertainties associated with product development, pharmaceutical-grade Nisin manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory

authorities and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: July 16, 2014 **IMMUCELL CORPORATION**

By: /s/Michael F Brigham
Michael F. Brigham
President, Chief Executive Officer
and Principal Financial Officer