

IMMUCELL CORP /DE/
Form 8-K
September 26, 2018

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: September 25, 2018

(Date of earliest event reported)

ImmuCell Corporation

(Exact name of registrant as specified in its charter)

DE

(State or other jurisdiction
of incorporation)

001-12934

(Commission File Number)

01-0382980

(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)

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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:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On September 25, 2018, ImmuCell announced that the FDA issued a Technical Section Complete Letter for the Human Food Safety Technical Section of ImmuCell's New Animal Drug Application ("NADA") for its Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. There are five major Technical Sections to a NADA with the FDA. ImmuCell previously received three of the five Technical Section Complete Letters required for NADA approval. This fourth Complete Letter leaves just the manufacturing technical section (known as the Chemistry, Manufacturing and Controls ("CMC") Technical Section) remaining for product approval and market launch.

Additional information is provided in today's press release that is attached as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1	<u>Press Release of ImmuCell Corporation, dated September 25, 2018.</u>
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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.

IMMUCELL CORPORATION

Date: September 25, 2018 By: /s/ Michael F. Brigham
Michael F. Brigham
President and Chief Executive Officer

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release of ImmuCell Corporation, dated September 25, 2018.