

IMMUCELL CORP /DE/
Form 8-K
November 19, 2004

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

November 17, 2004

(Date of earliest event reported)

IMMUCELL CORPORATION

(Exact name of registrant as specified in its charter)

0-15507

(Commission file number)

DELAWARE
(State or other jurisdiction
of incorporation)

01-0382980
(I.R.S. Employer
Identification No.)

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56 Evergreen Drive

Portland, ME 04103

(Address of principal executive offices and zip code)

(207) 878-2770

(Registrant's telephone number, including area code)

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

- .. Written communications pursuant to Rule 425 under the Securities Act
 - .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act
 - .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
 - .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act
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ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT

On November 17, 2004 ImmuCell Corporation (ImmuCell or the Company) entered into an amended license agreement with Nutrition 21, Inc. for Mast Out[®]. ImmuCell is developing Mast Out[®] as an alternative to traditional antibiotics used in the treatment of mastitis in dairy cows. The product contains Nisin, the same active ingredient in the Company's Wipe Out[®] Dairy Wipes. Nutrition 21 (f/k/a AMBI Inc.) holds various rights to Nisin and is a party to three different license agreements with ImmuCell.

ImmuCell's license agreement for Mast Out[®] was originally entered into in April 2000. The agreement would have required the Company to pay \$150,000 to Nutrition 21 upon FDA approval of Mast Out[®], and \$50,000 upon each of the first three regulatory approvals outside of the United States. No regulatory approvals have yet been obtained. The agreement also would have required ImmuCell to pay royalties to Nutrition 21 of 3% to 5% of Mast Out[®] sales, with annual minimums of up to \$75,000 per year in royalties. The 2000 license agreement also contained similar provisions relating to so-called Nisin option products, defined to include any future products containing Nisin for use as preventatives or treatments (other than as food additives) for animal diseases other than mastitis, and any other future veterinary products (other than as food additives). ImmuCell's rights under the 2000 license agreement generally were not sublicensable without Nutrition 21's consent.

The recent amendment eliminates these periodic payment obligations and allows ImmuCell fully paid-up, perpetual, exclusive, world-wide, sublicensable rights to develop, manufacture, have manufactured, use, sell, market, or distribute Mast Out[®] and any Nisin option products.

Simultaneously, the parties have amended a December 1999 license agreement for skin sanitizers and environmental sanitizers containing Nisin. The amendment revises the royalty period on these products to cover the five-year period beginning as of the date of the amendment and reduces the royalty rate from 10% of sales to 3% to 5%. As part of this same amendment, ImmuCell is to obtain approximately \$35,000 worth of Nisin inventory from Nutrition 21 and (at ImmuCell's option, but subject to third-party consents) may become the designated Nisin supplier under two contracts held by Nutrition 21.

In return for these amendments to the 2000 and 1999 license agreements, ImmuCell has paid approximately \$1,000,000 to Nutrition 21. The payment was made from cash on hand.

These amendments do not materially affect the Company's prior rights to develop and market Nisin-based teat dip products outside of North America, Mexico and Puerto Rico (licensed under a February 2002 agreement with Nutrition 21). These products continue to be subject to future royalties equal to 3% to 5% of sales over a five-year period beginning upon product launch in each relevant country.

ITEM 7.01 REGULATION FD DISCLOSURE

On November 17, 2004, ImmuCell issued a press release announcing amendments to its license agreements with Nutrition 21, Inc. The full text of the press release is furnished as Exhibit 99.1 to this report.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

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(c) Exhibits

10.1 License and Sublicense Agreement between the Registrant and Nutrition 21, Inc. (f/k/a AMBI Inc.), dated as of April 12, 2000, as amended (conformed copy)

99.1 Press Release of the Registrant dated November 17, 2004 (furnished pursuant to Item 7.01)

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: November 19, 2004

IMMUCELL CORPORATION

By: /s/ Michael F. Brigham

Michael F. Brigham
President and Chief Executive Officer