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ALFACELL CORP Form 8-K January 18, 2008

# 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 (Date of earliest event reported): January 14, 2008

## **Alfacell Corporation**

(Exact name of registrant as specified in its charter)

#### 0-11088

(Commission File Number)

#### **Delaware**

(State or other jurisdiction of incorporation)

#### 22-2369085

(I.R.S. Employer Identification No.)

## 300 Atrium Drive, Somerset, NJ 08873

(Address of principal executive offices, with zip code)

### (732) 652-4525

(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 obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

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

## Item 1.01 Entry into Material Definitive Agreements.

On January 14, 2008, Alfacell Corporation ([Alfacell[]) entered into a License Agreement and a Supply Agreement with Par Pharmaceutical, Inc., a subsidiary of Par Pharmaceutical Companies, Inc. Under the terms of the License Agreement, Strativa Pharmaceuticals ([Strativa[]), the proprietary products division of Par Pharmaceutical will have exclusive marketing, sales and distribution rights to Alfacell[]s product, ONCONASE, for the treatment of cancer in the United States and its territories. ONCONASE is currently being evaluated as a treatment for unresectable malignant mesothelioma (UMM) in a confirmatory Phase IIIb clinical trial. Alfacell will retain all rights and obligations for product manufacturing, clinical development and obtaining regulatory approvals, as well as all rights for non-U.S. jurisdictions where Alfacell does not currently have partnerships. Joint oversight committees with members from Alfacell and Strativa will manage the alliance. Alfacell will supply all of Strativa[]s requirements for ONCONASE pursuant to the Supply Agreement with Par Pharmaceutical, Inc.

Alfacell received a cash payment of \$5 million upon the signing of the License Agreement and will be entitled to an additional cash payment of up to \$30 million upon FDA approval of ONCONASE for UMM. Alfacell will, in consultation with Strativa, and at Alfacell scost, pursue the development of ONCONASE for additional cancer indications in the United States. Alfacell will be entitled to receive up to \$190 million in additional development and sales milestone payments. Alfacell will have the option to co-promote ONCONASE in the United States upon the approval of ONCONASE for a cancer indication in addition to UMM, with support from Strativa. Strativa will provide technical expertise for a future Alfacell oncology sales force, as well as funding for certain associated costs. Under certain circumstances, Alfacell will have the right to co-promote ONCONASE, at Alfacell sole cost, prior to the time ONCONASE is approved for any such additional cancer indication.

Strativa will have the right to terminate the License Agreement if ONCONASE does not receive marketing approval by the FDA on or before January 1, 2012 or receives a not approvable communication from the FDA with respect to the primary UMM indication. In the case of termination of the License Agreement for any reason, Alfacell will retain all rights to ONCONASE.

On January 14, 2008, Alfacell also entered into a Purchase and Supply Agreement (the [Supply Agreement]) with Scientific Protein Laboratories LLC ([SPL]). Under the Supply Agreement, SPL will manufacture and be Alfacell[Sexclusive supplier for the bulk drug substance used to make ONCONASE. The term of the Supply Agreement shall be ten years. Alfacell shall have the right to terminate the Supply Agreement at any time without cause on two years prior notice to SPL.

The foregoing descriptions are qualified in its entirety by reference to the License Agreement and Supply Agreement, which will be filed as exhibits to Alfacell\[]s next quarterly report on Form 10-Q. A copy of the press releases announcing the License Agreement and the Supply Agreement are attached hereto as Exhibit 99.1 and 99.2 respectively, which are incorporated herein by reference.

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#### Item 8.01 Other Events.

On January 17, 2008, Alfacell announced that its board of directors has appointed David Sidransky, M.D., chairman. Dr. Sidransky has served as Alfacell□s vice chairman since January 2007 and as a director since May 2004. He succeeds Kuslima Shogen, Alfacell□s chairman since 1996. Ms. Shogen continues to serve as Alfacell□s chief executive officer and a director.

A copy of the press release announcing Dr. Sidransky\[ \] s appointment is attached hereto as Exhibit 99.3, which is incorporated herein by reference.

## Item 9.01 Financial Statements and Exhibits.

## (d) Exhibits.

Exhibit No.	<u>Description</u>
99.1	Press Release of Alfacell Corporation dated January 15, 2008.
99.2	Press Release of Alfacell Corporation dated January 18, 2008.
99.3	Press Release of Alfacell Corporation dated January 17, 2008.

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## **SIGNATURES**

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.

## **ALFACELL CORPORATION**

Date: January 18, 2008 By: <u>/s/ Lawrence A. Kenyon</u>

Lawrence A. Kenyon

Executive Vice President, Chief Financial

Officer, Chief Operating Officer and

Corporate Secretary