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AKORN INC Form 8-K September 27, 2004 Edgar Filing: AKORN INC - Form 8-K

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

Date of Report: September 27, 2004 (Date of Earliest Event Reported)

Akorn, Inc.

(Exact Name of Registrant as Specified in its Charter)

Louisiana	0-13976	72-0717400
(State or other	(Commission	(I.R.S. Employer
Jurisdiction of	File Number)	Identification No.)
Incorporation)		

2500 MILLBROOK DRIVE BUFFALO GROVE, ILLINOIS

(Address of principal executive offices)

(847) 279-6100

(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 (See General Instruction A.2. below):

- o Written communication pursuant to Rule 425 under the Securities Ac (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240. 13e-4(c))

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

On April 21, 2004, Akorn, Inc. (Akorn) announced that it had signed a Memo of Understanding (MOU) with Strides Arcolab Limited, a pharmaceutical manufacturer based in India (Strides). As a result of negotiations following the execution of the MOU, on September 22, 2004, Akorn and Strides entered into certain agreements providing for a joint venture for the development, manufacturing and marketing of grandfathered products, patent-challenging products and abbreviated new drug applications (ANDA) products for the U.S. Hospital and retail markets.

The joint venture will operate in the form of a new Delaware limited liability company, Akorn-Strides, LLC (the A-S) under the terms of a Limited Liability Company Agreement (the LLC Agreement) between Akorn and Strides. Strides will be responsible for developing, manufacturing and supplying products under an OEM Agreement (the OEM Agreement) between Strides and A-S. Akorn will be responsible for sales and marketing of the products under an exclusive Sales and Marketing Agreement with A-S (the Sales and Marketing Agreement) between Akorn and A-S.

Akorn and Strides will each own 50% of A-S and will each appoint one of its two managers. Each will contribute \$1,250,000 in capital, to be used to finance the preparation of ANDAs by Strides. Akorn will also loan an additional \$1,250,000 to A-S that will be advanced to Strides to finance its capital contribution.

Under the OEM Agreement, these funds will be paid to Strides to finance the preparation, development and filing with the Food and Drug Administration (FDA) of ANDAs for generic drugs based on a mutually agreed development schedule. A-S will have exclusive rights to FDA approved generic drugs within the United States hospital, medical clinic, physician group and other wholesale drug markets. A-S has identified 20 generic injectable drugs slated for the first phase of development projects.

If within a mutually agreed time period, Strides manufacturing facilities in India have not received a satisfactory current good manufacturing practices (cGMP) inspection by the FDA, which remains current, and twelve ANDAs for products developed under the OEM Agreement have not been submitted to the FDA, Akorn will have certain special rights. Akorn will become the sole owner of A-S and A-S will be entitled to draw on a \$1,250,000 letter of credit from an Indian Bank that is confirmed by a United States Bank. On the other hand, if these conditions are met, and if both managers agree, Akorn and Strides may make additional equivalent capital contributions to finance subsequent ANDA preparation costs under a similar arrangement to our initial capital contributions, including an additional loan by us to A-S to finance Strides capital contribution. Strides shall repay such advances by crediting A-S an amount equal to 35% of all payments due for products provided under the OEM Agreement.

Under the Sales and Marketing Agreement, Akorn will market, advertise and sell FDA approved generic drugs in the United States supplied to A-S by Strides under the OEM Agreement. Akorn will be required to achieve, with respect to each generic drug, a minimum market share in the United States in order to preserve our exclusive marketing rights. Akorn will be paid a commission on the sales of these drugs.

Item 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

- (c) Exhibits.
- 10.1 Limited Liability Company Agreement dated September 22, 2004 between Akorn and Strides (confidential treatment has been requested for Exhibit A of Exhibit D, consisting of 9 pages, and Exhibit B of Exhibit D, consisting of 2 pages, which have been omitted and filed separately with the Securities and Exchange Commission).
- 10.2 OEM Agreement dated September 22, 2004 between A-S and Strides (confidential treatment has been requested for Exhibit A, consisting of 9 pages, and Exhibit B, consisting of 2 pages, which have been omitted and filed separately with the Securities and Exchange Commission).
- 10.3 Sales and Marketing Agreement dated September 22, 2004 between Akorn and A-S.
- 10.4 Promissory Note dated September 22, 2004 executed by A-S for the benefit of Akorn.
- 10.5 Capital Contribution Agreement dated September 22, 2004 executed by Strides for the benefit of A-S.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Current Report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Akorn, Inc.

By: /s/ Jeffrey A. Whitnell

Jeffrey A. Whitnell Chief Financial Officer, Treasurer and Secretary

Date: September 27, 2004