

INHALE THERAPEUTIC SYSTEMS INC
Form 8-K
January 08, 2002

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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 7, 2002**

Inhale Therapeutic Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-23556

(Commission File No.)

94-3134940

(IRS Employer Identification No.)

**150 Industrial Road
San Carlos, CA 94070**

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 631-3100**

Item 5. Other Events

Effective January 7, 2002, Inhale Therapeutic Systems, Inc. ("Inhale") announced that it has entered into a broad strategic alliance with Enzon, Inc. ("Enzon") that will serve to enhance each company's business model. As more fully described below, the most significant terms of the alliance are:

Inhale and Enzon will collaborate to develop three products to be specified over time based on the Inhale Inhance pulmonary delivery platform and SEDS supercritical fluids platform. The collaboration will have a particular focus on the development of products in the oncology field. Enzon will be responsible for commercialization and clinical development of the products while Inhale will be responsible for product development and manufacturing.

Inhale will be solely responsible for licensing Enzon's PEG patents, which include over 40 U.S. patents, to third parties. Inhale will also have the option to license Enzon's PEG patents for use in Inhale's proprietary products. Enzon will receive a royalty or a share of profits on final product sales of any products that are subject to a license under Enzon's PEG patents,

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including its branched PEG patents. Enzon retains the right to use its PEG technology for its own proprietary products and those it may develop with co-commercialization partners.

Enzon will have the option to license Inhale's PEGylation patents for Enzon's proprietary products and Inhale will receive royalties on sales of any such products.

Enzon and Inhale will explore the development of non-invasive delivery of single-chain antibody (SCA®) products via the pulmonary route. Inhale will become the exclusive pulmonary technology provider for Enzon's single-chain antibody technology using Inhale's proprietary Inhance pulmonary drug delivery technology for at least three years assuming success in the initial proof of concept program.

Enzon purchased \$40 million of newly issued Inhale convertible preferred stock.

Enzon and Inhale have agreed to settlement of the patent infringement litigation filed by Enzon against Shearwater Corporation, Inhale's wholly-owned subsidiary.

Product Development Agreements

Enzon and Inhale will jointly develop up to three products using Inhale's platform technologies: the Inhance pulmonary delivery platform and SEDS supercritical fluids platform. The two companies will collaborate to identify product candidates. Inhale will be responsible for formulation development, delivery system supply, and in some cases, early clinical development. Enzon will have responsibility for most clinical development and for commercialization.

The two companies have agreed to collaborate on realizing the significant therapeutic and competitive potential offered by single-chain antibody (SCA®) products when administered by the pulmonary route. The two companies will initially focus on exploring the utility of the Inhale pulmonary platform for single-chain antibodies and then move to develop single-chain products that will complement the current use of antibodies through the injectable route. Single-chain antibodies are genetically engineered proteins designed to expand on the therapeutic and diagnostic applications possible with monoclonal antibodies. Enzon retains all rights to its SCA products while Inhale retains all rights to its own technology. Inhale will become the exclusive pulmonary technology provider for Enzon's single-chain antibody technology using Inhale's Inhance pulmonary drug delivery technology for at least the next three years assuming a successful initial proof-of-concept program.

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Technology Licensing

Enzon will grant to Inhale the exclusive right to grant sublicenses under Enzon's PEG patents to third parties. Enzon will receive a share of profits for certain products that currently incorporate branched PEG technology and royalties on sales of products that are subject to new sublicenses that Inhale grants to its partners under Enzon's PEG Patents. With respect to Pegasys, it is anticipated that Enzon will receive 0.5% or less of Inhale's current partner's sales, which represents equal profit sharing with Inhale on this product. With respect to certain other products in Inhale's current product pipeline that use branched PEG technology, Inhale has advised Enzon that it expects to receive a higher percentage of partner sales in the form of royalty and manufacturing revenues. For such products, Inhale and Enzon will have a profit sharing relationship, but the extent of Enzon's participation in such profit-sharing on a percentage basis is expected to be considerably less than for Pegasys, since Inhale anticipates receiving a higher percentage of partner sales with respect to such products. Enzon retains the right to use all of its PEG technology for its own product portfolio, as well as for those products it develops in co-commercialization collaborations with third parties. It is the intent of the parties that Inhale will be responsible for marketing PEG services and Enzon and Inhale PEG technology to third parties.

Enzon will have an option to license Inhale's PEGylation technology for use with its own portfolio products. Inhale will receive royalties on any sales of Enzon PEGylation products using Inhale technology. Enzon will have the ability to request PEGylation supply and services from Inhale.

Certain drug molecules will be excluded from both the product collaboration and PEG licensing agreements.

Settlement Agreement

In addition to establishing this alliance, the two companies have agreed to settle the patent infringement suit related to Enzon's branched PEG technology filed in 1998 by Enzon against Shearwater Corporation, Inhale's wholly-owned subsidiary. Inhale will receive licensing access to the contested patents under the cross-license agreement described above. Enzon will receive a \$3 million payment from Inhale to cover expenses incurred in connection with defending the branched PEG patents that both companies will now commercially exploit.

Preferred Stock Purchase

In connection with the strategic alliance, Inhale and Enzon also entered into a Preferred Stock Purchase Agreement (the "Purchase Agreement"), pursuant to which Inhale sold to Enzon and Enzon purchased from Inhale forty thousand (40,000) shares of non-voting Series B Convertible Preferred Stock (the "Preferred Stock") at a purchase price of one thousand dollars (\$1,000) per share of Preferred Stock for an aggregate purchase price of forty million dollars (\$40,000,000). The description contained in this Item 5 of the terms of the Purchase Agreement and the rights, privileges and preferences of the Preferred Stock is qualified in its entirety by reference to the full text of the Purchase Agreement, the form of which is attached hereto as **Exhibit 4.21** and the Certificate of Designation, setting forth the rights, privileges and preferences of the Preferred Stock, the form of which is attached hereto as **Exhibit 3.5**.

Pursuant to the Certificate of Designation, the Preferred Stock does not have voting rights and the consent of the holders of the Preferred Stock is not required (except to the extent required by law or otherwise expressly stated in the Certificate of Designation) for taking any corporate action.

The Preferred Stock is convertible, in whole or in part, into that number of shares of common stock (the "Conversion Shares") equal to the quotient of \$1,000 per share divided by the Conversion Price. The "Conversion Price" shall initially be equal to \$22.79 per share or 125% of the Closing Price

and at no time can the Preferred Stock convert into shares of Common Stock at a discount to the Closing Price. The "Closing Price" equals \$18.23 per share and was based upon the average of the Company's closing bid prices as listed on the Nasdaq National Market for the twenty (20) trading days preceding the date of the closing of the transaction.

The Preferred Stock is convertible at the option of the holder after the first anniversary of the original issuance of the Preferred Stock (the "Original Issue Date") or, if earlier, upon a Change in Control (as defined in the Certificate of Designation). Except with respect to an automatic conversion as described below, the Conversion Price shall be equal to 125% of the Closing Price until the third anniversary of the Original Issue Date. Upon the third anniversary of the Original Issue Date, the Conversion Price shall be adjusted to be equal to either (i) the Closing Price, in the event that the average of the closing bid prices of Inhale's Common Stock as quoted on the Nasdaq National Market for the twenty (20) trading days preceding the third anniversary of the original issuance (the "Future Price") is less than or equal to the Closing Price; (ii) the Future Price (as defined above) if the Future Price is greater than the Closing Price but less than 125% of the Closing Price; or (iii) 125% of the Closing Price if the Future Price is equal to or greater than 125% of the Closing Price.

To the extent not previously converted, the Preferred Stock will automatically convert into shares of Inhale Common Stock, based on the then effective Conversion Price, upon the earliest of (i) the fourth anniversary of the Original Issue Date; (ii) immediately prior to an Asset Transfer or Acquisition (as defined in the Certificate of Designation); or (iii) with the consent of the holders of a majority of the then outstanding Series B Preferred Stock immediately prior to a liquidation, dissolution or winding up of Inhale. In the event of an automatic conversion pursuant to an Asset Transfer, Acquisition or liquidation, the adjustment mechanism described above will be applied immediately prior to the automatic conversion.

Pursuant to the terms of the Purchase Agreement, Inhale has agreed to register the shares of common stock issuable upon conversion of the Preferred Stock for resale under certain circumstances.

The Preferred Stock was issued in a private placement exempt from the registration requirements of the Securities Act of 1933 (the "Act") pursuant to an exemption under Section 4(2) of the Act.

This report contains forward-looking statements that reflect Inhale management's current views as to the company's business strategy, this strategic alliance, future products, product developments, clinical trials, manufacturing scale-up, and other future events and operations relating to the company and its subsidiaries. The forward-looking statements also involve uncertainties and risks that are detailed in Inhale's reports and other filings with the Securities and Exchange Commission, including its Form 10-K as amended for the year ending December 31, 2000 and its Form 10-Q for the quarter ended September 30, 2001. Actual results could differ materially from these forward-looking statements.

