

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

SEPTEMBER 5, 2000

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Date of Report (Date of earliest event reported)

INHALE THERAPEUTIC SYSTEMS, INC.

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(Exact name of registrant as specified in its charter)

Delaware

023556

94-3134940

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(State or other jurisdiction of  
incorporation)

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(Commission  
File Number)

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

150 Industrial Road  
SAN CARLOS, CA 94070

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(Address of principal executive offices)

(650) 631-3100

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(Registrant's telephone number, including area code)

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(Former name, if changed since last report)

ITEM 5. OTHER EVENTS

On September 5, 2000, Inhale Therapeutic Systems, Inc. ("Inhale") announced its re-initiation with Eli Lilly and Company ("Lilly") of the development and License Agreement of an inhaled formulation of Forteo-TM-recombinant parathyroid hormone (PTH). Inhale also announced that Lilly has decided to discontinue work on an unspecified inhaleable protein product that was in pre-clinical development with Inhale. A press release relating to these matters is attached hereto as Exhibit 99.1.

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS

(c) Exhibits

99.1 Press Release dated September 5, 2000

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.

INHALE THERAPEUTIC SYSTEMS, INC.

Dated: September 5, 2000

By: /s/ AJIT S. GILL

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Ajit S. Gill,  
President and Chief Executive Officer

CONTACT: Joyce Strand (Inhale) (650) 631-3138

Inhale Reinitiates Development of Inhaleable Form of Forteo with Lilly

SECOND PRE-CLINICAL COLLABORATION DISCONTINUED

SAN CARLOS, CALIF., SEPTEMBER 5, 2000 - Inhale Therapeutic Systems, Inc. (Nasdaq:INHL) announced today that the company has reinitiated a development program with Eli Lilly and Company (NYSE:LLY) for an inhaleable formulation of Forteo-TM- recombinant parathyroid hormone (PTH). Lilly and Inhale plan to develop the pulmonary form of Forteo with Inhale's Inhance -TM- drug delivery platform and anticipate that this inhaleable product will be the first to use Inhale's new pocketsize Solo-TM- inhaler technology.

Inhale also announced that Lilly has decided to discontinue work on an unspecified inhaleable protein product that was in pre-clinical development with Inhale. Inhale will be free to develop the product further on its own or with another partner. "Given the technical progress we have made during our collaboration with Lilly, we plan to continue work on this molecule and will seek another partner for commercializing it," said Robert Chess, chairman of Inhale.

INHALEABLE FORM OF FORTEO

Forteo is a bone forming agent that is being developed by Lilly as a treatment for osteoporosis, a disease that results from a loss of bone mass and deterioration of bone tissue. Osteoporosis can lead to enhanced bone fragility and an increase in the risk of fracture. Unlike antiresorptive agents that work to reduce bone loss, clinical trials with Forteo - a bone anabolic - suggest that the agent appears to rapidly stimulate new bone formation.

"An inhaled formulation of Forteo could greatly benefit patients by providing a convenient pulmonary delivery alternative," said Richard D. DiMarchi, Ph.D., vice president, research technologies and product development, for Lilly. "Further, we are pleased to be working with Inhale as they have a breadth of expertise and experience that spans discovery, development and manufacturing of pulmonary systems."

"We believe that Forteo is potentially a leading new treatment for osteoporosis, a disease that is growing as our population ages," said Robert Chess, chairman of Inhale. "By working with Lilly, a leader in the development of innovative products in the field of endocrinology, Inhale will be positioned to play a major role in helping to treat osteoporosis in a patient-friendly way."

Chess continued, "We are also pleased that Lilly anticipates that pulmonary Forteo will be the first to use Inhale's new pocketsize Solo-TM- inhaler technology. We are developing this product as part of our family of inhalers to be offered in our Inhance drug delivery platform."

Inhale's new Solo technology will result in a pocket-size, patient-driven inhaler designed to maximize patient reproducible inhaleable therapeutics by automatically compensating for breathing differences among patients through built-in flow control. The Solo inhaler will be an optimal product solution where smaller device size, shorter-term use and larger drug payloads are preferred without sacrificing consistent dosing. In addition to an inhaler, the pulmonary Forteo product will use the powder processing and formulation products of the Inhance platform.

Osteoporosis threatens approximately 23 million American women and has often been referred to as a "silent" disease because it typically progresses without symptoms until fractures occur.<sup>1</sup> More than 1.5 million fractures are associated with osteoporosis each year.<sup>1</sup>

Inhale is pioneering drug delivery systems designed to easily deliver a range of inhaleable drugs, including peptides, proteins and small molecules, to the deep lung for treatment of systemic and respiratory diseases. Inhale's Inhance drug delivery platform technology combines innovations in powder technology and inhaler delivery systems that should enable efficient and reproducible delivery of inhaleable drugs.

This release contains forward-looking statements that reflect Inhale management's current views as to the company's future products, product developments, and other future events and operations. These forward-looking statements involve uncertainties and other risks that are detailed in Inhale's reports and other filings with the SEC, including its latest Form 10-Q dated August 2000. Actual results could differ materially from these forward-looking statements.

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1 1996 AND 2015 OSTEOPOROSIS PREVALENCE FIGURES. STATE-BY-STATE REPORT. Washington, D.C.: National Osteoporosis Foundation; 1997: Executive Summary, 1,2.

Forteo-TM- (teriparatide, Lilly)