

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

February 6, 1997

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Date of Report (Date of earliest event reported)

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INHALE THERAPEUTIC SYSTEMS

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(Exact name of registrant as specified in its charter)

California

0-23556

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.)

1060 East Meadow Circle  
Palo Alto, CA 94303

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(Address of principal executive offices)

(415) 354-0700

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(Registrant's telephone number, including area code)

## ITEM 5. OTHER EVENTS.

THE FOLLOWING DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISK AND UNCERTAINTIES. THE COMPANY'S ACTUAL RESULTS COULD DIFFER MATERIALLY FROM THOSE DISCUSSED HERE. FACTORS THAT COULD CAUSE OR CONTRIBUTE TO SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO THOSE DISCUSSED UNDER THE HEADING "RISK FACTORS" IN THE COMPANY'S REGISTRATION STATEMENT ON FORM S-3 (NO. 333-20787). READERS ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH REFLECT MANAGEMENT'S ANALYSIS ONLY AS OF THE DATE HEREOF. THE COMPANY UNDERTAKES NO OBLIGATION TO RELEASE THE RESULTS OF ANY REVISION TO THESE FORWARD-LOOKING STATEMENTS WHICH MAY BE MADE TO REFLECT EVENTS OR CIRCUMSTANCES OCCURRING AFTER THE DATE HEREOF OR TO REFLECT THE OCCURRENCE OF UNANTICIPATED EVENTS.

### RECENT DEVELOPMENTS

During the past 12 months, Inhale has entered into strategic relationships with four new collaborative partners, moved the pulmonary insulin product development program into a Phase IIb clinical trial and two additional product development programs into Phase I testing, strengthened its balance sheet by adding \$25 million of equity financing from corporate partners and expanded its technology and manufacturing development activities as well as its management team.

### COLLABORATIVE PARTNERS

In March 1996, Inhale and Baxter Healthcare Corporation (a subsidiary of Baxter International) ("Baxter") entered into a broad strategic partnership to use Inhale's dry powder pulmonary delivery system as a technology platform for developing and launching therapeutic products. In April 1996, Baxter made a \$20 million equity investment in Inhale at a 25% market premium based on the average market price prior to the signing of the agreement. Baxter will receive worldwide commercialization rights in exchange for research and development funding and milestone payments for the first four molecules, estimated at up to \$60 million. Baxter also has an option to add molecules to the collaboration that could result in additional funding and milestone payments to Inhale. Inhale will receive royalties and manufacturing revenue on sales of products that are successfully commercialized as a result of this collaboration.

In July 1996, the Company entered into an agreement with Genzyme Corporation to examine the feasibility of developing dry powder formulations of gene vectors for pulmonary applications.

In January 1997, Inhale and Centeon (a company of Armour and Behring) entered into a collaboration to develop a pulmonary formulation of alpha-1 proteinase inhibitor to treat patients with alpha-1 antitrypsin deficiency, a genetic disorder which can lead to emphysema. Centeon will receive commercialization rights worldwide with the exception of Japan, and Inhale will receive royalties and manufacturing revenue on product sales, an up-front signing fee and up to an estimated \$15 million in research and development funding and milestone payments. Inhale and Centeon completed preclinical work indicating that Inhale's dry powder formulation of Centeon's

alpha-1 proteinase inhibitor has the potential to significantly improve the efficiency of delivery compared to current infusion therapy.

Also in January 1997, Inhale and Eli Lilly and Company ("Lilly") entered into a development and license agreement to develop a pulmonary delivered product for an osteoporosis drug. Inhale will receive up to an estimated \$20 million in initial fees, research funding and milestone payments. Lilly will receive global commercialization rights for the pulmonary delivery of the products with Inhale receiving royalties and manufacturing revenue on any marketed products. Inhale successfully completed the Phase I clinical trial of this drug conducted with ALZA that indicated that the drug was systematically absorbed when delivered with Inhale's system.

Each of the foregoing collaborative arrangements are terminable by the partner. Therefore, there can be no assurance that the Company will receive additional payments as described.

#### CLINICAL TRIALS

In March 1996, Pfizer Inc. ("Pfizer") began Phase II clinical trials of pulmonary insulin using Inhale's pulmonary delivery system. Pfizer advanced these trials to the next step in late October 1996 by initiating a multi-site outpatient trial that may include up to 240 patients. At that time, Pfizer made an additional \$5 million equity investment in Inhale at a 25% premium to the market price of Inhale stock at the time. Pfizer had made an initial \$5 million equity investment in February 1995, also at a 25% premium to market price.

In May 1996, Inhale announced the start of a Phase I clinical trial of an aerosolized form of a drug to treat osteoporosis using Inhale's pulmonary delivery system as part of a collaboration with ALZA. In early January 1997, Inhale announced the completion of that trial.

In July 1996, Inhale initiated a Phase I clinical trial of an aerosolized form of salmon calcitonin as a potential treatment for osteoporosis, Paget's disease, hypercalcemia, and other bone diseases.

#### TECHNOLOGY DEVELOPMENT AND MANUFACTURING SCALE-UP

Inhale continued to advance the development of its core technologies and manufacturing capabilities in 1996. The Company developed a prototype device suitable for the home clinical trials and also scaled-up its powder processing and automated powder filling systems for production of later stage clinical supplies. In late 1996, the Company entered into a 15-year lease agreement on a third facility. The Company intends to consolidate its operations into this facility over the next eighteen months and intends to use the facility as its early commercial manufacturing site.

#### MANAGEMENT TEAM

Inhale expanded its management team in 1996. Judi R. Lum joined the Company in the fourth quarter to become Inhale's Chief Financial Officer. Judi most recently served as Vice President of Finance and Administration for an ophthalmic start-up company and previously was Director of Corporate Development for GenPharm International. She also served as Director of Finance for the Industrial Sector of Raychem Corporation, Pilot Operations Manager for

Advanced Cardiovascular Systems, and an Assistant Vice President of Crocker National Bank. She received her B.A. and M.B.A. degrees from Stanford University.

Lynn Van Campen, Ph.D., joined the Company as Vice President, Pharmaceutical Development. She previously was Director of Pharmaceuticals for Boehringer Ingelheim Pharmaceuticals, Inc. Christopher L. Searcy, Pharm. D., joined the company as Vice President, New Business Opportunities. Prior to joining Inhale, Dr. Searcy was Vice President of Business Development at GalaGen, Inc., and served as Director, Licensing and Development for Pfizer.

Promotions and changes of responsibilities in the executive staff during the past year included: Ajit Gill, former CFO, became Executive Vice President of Technical Operations. Mr. Gill, who has a vast amount of experience in building new businesses, will focus on managing Inhale's growth. Stephen L. Hurst, J.D., Vice President of Intellectual Property and Licensing, took on additional responsibility for Business Development following the departure of Jack Anthony. Mr. Michael Glembourtt was recently promoted to Vice President, Project Management. Mr. Glembourtt has held a variety of project management and research positions at Syntex Development Research (now Roche Biosciences), California Biotechnology (now Scios Corporation), Cetus Corporation (now Chiron Corporation), and the Stanford University School of Medicine.

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

Dated: February 6, 1997

By: /s/ Robert B. Chess  
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Robert B. Chess  
President and Chief Executive  
Officer