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): June 20, 2001

Inhale Therapeutic Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

000-23556

94-3134940

(Commission File No.)

(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

On June 20, 2001, Inhale Therapeutic Systems, Inc. ("Inhale") announced the English High Court of Justice ruled that Inhale's European patent covering room-temperature stable glassy materials will no longer be valid in the United Kingdom. The revocation has no effect outside the United Kingdom and does not limit in any way Inhale's ability to use glass stabilization.

Inhale's press release, dated June 20, 2001, titled "Inhale Announces Decision of English Court Concerning Validity of a Glass Stabilization Patent in the United Kingdom" is attached hereto as Exhibit 99.1.

Item 7. Financial Statements and Exhibits

(c)

Exhibits

Exhibit Number Description

99.1 Press Release titled "Inhale Announces Decision of English Court Concerning Validity of a Glass Stabilization Patent in the United Kingdom" dated June 20, 2001.

2

SIGNATURE

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: June 20, 2001 By: /s/ Brigid A. Makes

Brigid A. Makes

Chief Financial Officer and Vice President (Principal Financial and Accounting Officer)

QuickLinks

<u>Item 5. Other Events</u> <u>Item 7. Financial Statements and Exhibits</u> <u>SIGNATURE</u>

Exhibit 99.1

CONTACTS: Joyce Strand, Inhale 650 631-3138

INHALE ANNOUNCES DECISION OF ENGLISH COURT CONCERNING VALIDITY OF A GLASS STABILIZATION PATENT IN THE UNITED KINGDOM

San Carlos, Calif., June 20, 2001—Inhale Therapeutic Systems, Inc. (Nasdaq:INHL) today announced the English High Court of Justice ruled that Inhale's European patent covering room-temperature stable glassy materials is not valid in the United Kingdom. The revocation, which has been stayed pending appeal, has no effect outside the United Kingdom and does not limit in any way Inhale's ability to use glass stabilization.

"We have several additional patent families that provide protection for our glass stabilization and room temperature stable powder technologies. This ruling has no bearing on Inhale's ability to practice this technology or on our partners' ability to conduct their inhaleable drug programs. It affects only one aspect of our protection in the United Kingdom only. We believe we have a good case for restoring this United Kingdom patent and are reviewing our options," said Stephen L. Hurst, Inhale's general counsel.

The patent that was the subject of the ruling provided coverage for one aspect of Inhale's glass stabilization technology on the use of glass forming excipients with a glass transition temperature at or above 20 degrees centigrade. Based on the claims of the patent, Inhale filed an infringement action in the English High Court of Justice against Quadrant Healthcare PLC, Nottingham, England on November 1, 1999. Quadrant challenged the validity of this patent as part of its defense of the infringement suit. Inhale successfully defended the validity of this patent, with minor amendments, against Quadrant and three other challengers in the European Patent Office in December 1999. The English Court ruling today does not invalidate the European patent in other European countries.

In addition to the patent that was the subject of this ruling, Inhale has several other patent families covering its room-temperature stable powder technologies, including a group that cover the use of spray drying drugs into a fine powder and preparing powders for the filling of drugs. Room-temperature stable formulations of powdered drugs including macromolecules for inhalation provides improved patient convenience by eliminating the need for refrigeration. It is one of several technologies pioneered by Inhale to enable inhaleable delivery of macromolecules and other drugs for systemic and local lung diseases.

Inhale Therapeutic Systems, Inc. develops advanced drug delivery solutions for the biopharmaceutical industry. The Company is focused on two main opportunities: improved delivery of macromolecules, including peptides and proteins, and improved performance of drug powders. To address these opportunities, Inhale is pioneering inhaleable delivery of macromolecules, supercritical fluids processing for powder particle production and, upon approval of the acquisition of Shearwater, advanced PEGylation. The Company is currently collaborating with major pharmaceutical and biotechnology companies, including AstraZeneca, Biogen, Bristol-Myers Squibb, GlaxoSmithKline, Lilly and Pfizer.

This release contains forward-looking statements that reflect Inhale management's current views as to the company's business strategy, future products, product developments, and other future events and operations relating to the company. 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 March 31, 2001. Actual results could differ materially from these forward-looking statements.

QuickLinks

Exhibit 99.1