

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): **October 24, 2001**

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

On October 24, 2001, Inhale Therapeutic Systems, Inc., a Delaware corporation (the "Company"), announced its financial results for the third quarter and nine months ended September 30, 2001 and provided additional information with respect to the status of certain of its collaborative arrangements. A copy of the press release issued by the Company is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 7. Financial Statements and Exhibits

(c)

Exhibits

**Exhibit
Number**

Description

99.1	Press Release titled "Inhale Announces Third Quarter 2001 Results" dated October 24, 2001.
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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: October 24, 2001

By: _____ /s/ Brigid A. Makes

/s/ Brigid A. Makes
Chief Financial Officer and Vice President (Principal Financial and
Accounting Officer)

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[SIGNATURE](#)

Inhale Announces Third Quarter 2001 Results

SAN CARLOS, Calif.—Oct. 24, 2001—Inhale Therapeutic Systems, Inc. (Nasdaq:INHL-news) today announced its financial results for the third quarter and nine months ended September 30, 2001.

The Company reported revenue of \$22.4 million for the three months ended September 30, 2001, compared to \$14.1 million in the same period in 2000—an increase of 59%. For the nine months ended September 30, 2001, revenue was \$53.3 million, compared to \$38.5 million during the first nine months of 2000. The increase in revenue reported is due to expanded activities under the Company's existing collaborative agreements and the inclusion of Shearwater Corporation product sales this quarter as a result of completing the previously announced acquisition.

For the three months ended September 30, 2001, the Company reported a net loss of \$26.9 million or \$(0.49) per share. On an adjusted basis, the Company reported a net loss of \$18.2 million or \$(0.33) per share for the third quarter. The adjusted net loss for the third quarter excludes non-cash charges for the amortization of goodwill and other intangible assets of \$8.7 million related to the acquisitions of Shearwater Corporation and Bradford Particle Design plc this year. For the same period ending September 30, 2000, the Company reported a net loss of \$13.2 million or \$(0.31) per share. The adjusted net loss during the corresponding period of 2000 was \$12.2 million or \$(0.29) per share, which excluded a non-cash compensation charge of \$1.0 million associated with accounting for stock options.

For the nine months ended September 30, 2001, on an adjusted basis the Company reported a net loss of \$51.1 million or \$(0.97) per share. The nine-month adjusted net loss excludes purchased in-process research and development of \$146.3 million associated with the acquisitions of Shearwater and Bradford Particle Design plc, non-cash charges relating to the amortization of goodwill and other intangible assets of \$15.9 million and non-cash compensation charges of \$0.5 million. Net loss as reported for the nine months ended September 30, 2001 was \$213.8 million or \$(4.07) per share. The Company's adjusted net loss for the nine months ending September 30, 2000 was \$35.1 million or \$(0.86) per share. The adjusted net loss for the nine months ended September 30, 2000 excludes a one-time net interest charge of \$15.2 million paid as a premium to convert \$98.7 million of debentures into 6.2 million shares of common stock, a charge of \$2.3 million for the purchased in-process research and development, and charges for non-cash compensation of \$5.2 million.

The increase in expenses and net operating loss in the first nine months of 2001 over the prior year is primarily attributed to increased spending related to the development effort for both partner and internally funded programs, the scale-up of technologies and the continuing development of global manufacturing capabilities for both inhalation devices and drug powders in order to support inhaleable insulin clinical trials and commercial operations as well as the addition of Shearwater and Bradford to our operations through acquisitions during 2001.

At September 30, 2001, the Company reported cash and investments totaling approximately \$353 million.

Summary of Recent Events

Inhale has made several announcements during the last month illustrating the applicability of its Inhance pulmonary drug delivery technology platform to inhaleable small-molecule delivery, including:

- a collaboration with two subsidiaries of Johnson & Johnson for multiple inhaleable small molecules;
 - favorable results from a clinical study of inhaleable tobramycin, an anti-infective small-molecule drug used to treat lung infections, showing that powdered tobramycin developed with Inhale's Inhance(TM) PulmoSphere(TM) powder processing technology delivered the tobramycin to the lung with an efficiency 3.5 times higher than from a liquid solution via nebulization. The powdered drug was also delivered 2.2 times more reproducibly than the nebulized dose;
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- favorable results from a clinical study of inhaleable budesonide, a small-molecule drug used in the treatment of asthma, showing that powdered budesonide prepared with the Inhance PulmoSphere powder processing technology achieved a greater than two-fold improvement in lung deposition over a currently approved product.

"The Inhance pulmonary delivery solution is a recognized leading technology platform for macromolecule inhaleable delivery. Over the last few years, Inhale has expanded the platform to enable us to provide our partners with advanced solutions for small molecule delivery as well. We believe these clinical results and our newly signed collaboration with Johnson & Johnson provide strong validation for the applicability of our platform to small-molecule inhaleables," said Ajit Gill, president and CEO.

In addition, Inhale also announced other data recently presented at the 2001 AAPS Annual Meeting & Exposition, October 21-25, 2001 that provided validation of a variety of applications for the Bradford Particle Design SEDS(TM) supercritical fluids processing technology including the use of SEDS as a particle engineering process for poorly soluble drugs and specifically for a variety of molecules, such as, fluticasone, terbutaline and fenoterol powders.

Clinical Pipeline Update

Inhale's product pipeline now includes 21 products using the company's technology that have completed or are in human clinical testing. Most of the programs are being conducted with partners. Two of these products are marketed in the United States, 3 are filed for approval, and 16 more are in various stages of clinical testing. PEGASYS®, a PEGylated form of interferon alpha being developed by Roche for hepatitis C, was approved for marketing in Switzerland in August.

Concerning one of the Phase I programs, inhaleable Forteo for osteoporosis, Inhale partner Eli Lilly and Company has told Inhale that the program will not be funded in 2002 and that other than perhaps on-going stability work, other activities will be suspended. President and CEO Ajit Gill commented, "This project has

made excellent progress over the last year. We understand that this suspension is a result of Lilly's decision on funding priorities for the next year, not due to any technical issues."

Gill continued, "We are pleased with the overall breadth and diversity of our product pipeline. Through the end of 2002, we expect several programs to start pivotal trials and several more to enter human clinical testing. We are hopeful that some or all of the products currently filed with the FDA will gain approval next year. We believe our strong pipeline combined with our leading positions in inhalation, PEGylation, and supercritical fluid processing positions us well to achieve our long-term goal of becoming the leading provider of drug delivery solutions."

Inhale Therapeutic Systems, Inc. develops advanced drug delivery solutions for the biopharmaceutical industry. The Inhance pulmonary drug delivery solution combines innovations in powder technology and pulmonary inhalers to enable efficient and reproducible delivery of a range of drugs—including peptides, proteins, and small molecules—for treatment of systemic and respiratory diseases. The Inhance PulmoSphere powder processing technology used to develop the powdered budesonide and tobramycin is a lipid-based emulsion process that produces particles in the optimal range of 1 to 5 microns for pulmonary delivery.

SEDS(TM) is a novel new method of engineering drug particles with specifically selected or preferred properties and changes the traditional multi-step manufacturing methods into a single-stage process. Inhale also offers the Shearwater advanced PEGylation technology which enhances the injectable delivery performance of most major drug classes, including macromolecules such as peptides and proteins, small molecules, and other drugs.

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The company is collaborating with major pharmaceutical and biotechnology companies, including Amgen, AstraZeneca, Aventis Behring, Biogen, Bristol-Myers Squibb, GlaxoSmithKline, Lilly, Pfizer, Pharmacia, and Roche.

This release contains forward-looking statements that reflect Inhale management's current views as to its 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 Securities and Exchange Commission, including its Form 10-K as amended for the year ending Dec. 31, 2000 and Form 10-Q for the quarter ending June 30, 2001. Actual results could differ materially from these forward-looking statements.

Inhance and PulmoSphere are trademarks of Inhale Therapeutic Systems, Inc.

Forteo is a trademark of Eli Lilly and Company.

PEGASYS® is a registered trademark of Hoffman-La Roche Ltd.

Robert Chess, Inhale Chairman, will host a conference call for analysts and investors beginning at 2:00 p.m. Pacific Time today, October 24, to further discuss the Company's financial results.

Investors can access a live Webcast through a link that will be posted on Inhale's Web site at www.inhale.com. The Web broadcast of the conference call will be available for replay through November 7, 2001.

All callers can access the conference call live via telephone by dialing (212) 896-6123.

An audio replay will be available shortly following the call through November 7, 2001 and can be accessed by dialing (800) 633-8284(US) or (858) 812-6440 (outside the US) and then entering the Reservation Number: 19848289.

See attached tables—

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INHALE THERAPEUTIC SYSTEMS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	Sept. 30, 2001 (unaudited)	Dec. 31, 2000 (a)
ASSETS		
Current assets:		
Cash, cash equivalents and short-term investments	\$ 353,382	\$ 484,841
Other current assets	16,070	8,202
Total current assets	369,452	493,043
Property and equipment, net	138,837	110,457
Marketable equity securities	964	9,140
Goodwill & other intangibles	162,631	4,969
Deposits and other assets	13,799	11,931
	\$ 685,683	\$ 629,540
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 36,161	\$ 24,313

Current portion of capital lease obligations	977	977
Deferred revenue	7,774	4,913
Total current liabilities	44,912	30,203
Convertible subordinated debentures	299,149	299,149
Accrued rent	2,131	2,010
Capital lease obligations	29,611	15,269
Other long-term liabilities	7,297	5,026
Stockholders' equity:		
Common stock	710,946	465,598
Deferred compensation	(1,109)	(1,827)
Accumulated other comprehensive gain/(loss)	(1,629)	5,981
Accumulated deficit	(405,625)	(191,869)
Total stockholders' equity	302,583	277,883
	\$ 685,683	\$ 629,540

(a)

The consolidated balance sheet at December 31, 2000 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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INHALE THERAPEUTIC SYSTEMS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share information)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2000	2001	2000
	(unaudited)		(unaudited)	
Contract research revenue	\$ 17,236	\$ 14,061	\$ 48,132	\$ 38,483
Product sales	5,169	—	5,169	—
Total revenue	22,405	14,061	53,301	38,483
Operating costs and expenses:				
Cost of goods sold	1,979	—	1,979	—
Research and development	34,212	26,739	98,542	74,232
General and administrative	5,762	3,066	14,200	9,696
Purchased in-process research and development	—	—	146,260	2,292
Amortization of goodwill and intangible assets	8,943	194	16,478	565
Total operating costs and expenses	50,896	29,999	277,459	86,785
Loss from operations	(28,491)	(15,938)	(224,158)	(48,302)
Other income/(expense)	(263)	752	(603)	752
Debt conversion premium, net	—	—	—	(15,157)
Interest income/(expense), net	1,833	1,971	11,005	4,913
Net loss	\$ (26,921)	\$ (13,215)	\$ (213,756)	\$ (57,794)
Basic and diluted net loss per common share	\$ (0.49)	\$ (0.31)	\$ (4.07)	\$ (1.42)
Shares used in computing basic and diluted net loss per common share	54,845	42,266	52,513	40,742
Note: Detail of unusual charges				
Purchased in-process research & development	\$ —	\$ —	\$ 146,260	\$ 2,292
Amortization of goodwill & intangibles related to 2001 acquisitions	8,743	—	15,877	—
Non-cash compensation charges	3	973	480	5,240
Debt conversion premium, net	—	—	—	15,157
Total	\$ 8,746	\$ 973	\$ 162,617	\$ 22,689

Contact:

Inhale Therapeutic Systems, Inc.
Joyce Strand, 650/631-3138

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 June 30, 2001. Actual results could differ materially from these forward-looking statements.

QuickLinks

[Exhibit 99.1](#)