UNITED STATES
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): December 30, 2024

INOGEN, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36309**	**33-0989359**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
859 Ward Drive Goleta, California		**93111**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (805) 562-0500

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	INGN	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 30, 2024, Inogen, Inc. (the "Company") issued a press release announcing U.S. Food and Drug Administration ("FDA") 510(k) clearance of its Simeox 200 device intended to promote airway clearance and to improve bronchial drainage. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On December 30, 2024, the Company announced FDA 510(k) clearance of its Simeox 200 device intended to promote airway clearance and to improve bronchial drainage. Upon FDA 510(k) clearance of the Simeox 200 device, the Company became obligated to make a $13 million cash earnout milestone payment (the "Physio-Assist Milestone Payment") pursuant to the Share Purchase Agreement, dated July 10, 2023, by and among the Company and Mr. Adrien Mithalal, Mr. Jean-Sébastien Lantz, Mrs. Anne Reiser, CAAP Creation, Societe De Capital Risque Provencale Et Corse, Region Sud Investissement, Mérieux Participations 2, Relyens Innovation Santé and certain holders of exercisable securities identified therein (collectively, the "Sellers"). The Physio-Assist Milestone Payment must be made to the Sellers no later than ten business days following the date of the FDA 510(k) clearance.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated December 30, 2024.
104	The cover page of this Current Report on Form 8-K, formatted in Inline XBRL.

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 thereunto duly authorized.

INOGEN, INC.

Date: December 30, 2024

By: /s/ Michael Bourque
Michael Bourque
Executive Vice President
Chief Financial Officer
Treasurer
(Principal Accounting and Financial Officer)

Exhibit 99.1

Inogen Receives FDA 510(k) Clearance for SIMEOX 200 Airway Clearance Device

GOLETA, Calif., – December 30, 2024 – Inogen, Inc. (Nasdaq: INGN), a medical technology company offering innovative respiratory products for use in the homecare setting, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the SIMEOX 200 Airway Clearance Device, expanding the company's ability to market and meet the various needs of patients with chronic respiratory diseases in the U.S.

SIMEOX 200 is the next-generation of the original Simeox (currently available in select international markets). It is intended to promote and improve bronchial drainage by enhancing mobilization of bronchial secretions via high frequency oscillatory vibrations and intermittent negative pressure to the airway during exhalation. The device is intended to be prescribed for use in patients capable of independently generating cough. SIMEOX 200 is predominantly aimed to help patients with chronic lung diseases associated with mucus hypersecretion and mucus retention, such as Bronchiectasis, COPD (Chronic Obstructive Pulmonary Diseases), Cystic Fibrosis or Primary Ciliary Dyskinesia.

"We are very excited to receive FDA clearance for the innovative SIMEOX 200 therapy for patients in the U.S.," said Kevin Smith, President and Chief Executive Officer. "By tapping into our well-established network of healthcare providers, B2B partners, and our Direct-to-Patient team, we aim to bring this next-generation airway clearance device to patients within the next year and significantly expand our reach over time."

Traditional airway clearance therapies can be time consuming and constraining with mixed results. SIMEOX 200 provides an innovative alternative, delivering efficient bronchial drainage, specifically in low lung volumes, that can be administered in healthcare centers and institutions, as well as at home.

Inogen plans to pursue a limited launch of SIMEOX 200 in targeted sites in 2025.

About Inogen
Inogen, Inc. (Nasdaq: INGN) is a leading global medical technology company offering innovative respiratory products for use in the homecare setting. Inogen supports patient respiratory care by developing, manufacturing, and marketing innovative best-in-class respiratory therapy devices used to deliver care to patients suffering from chronic respiratory conditions. Inogen partners with patients, prescribers, home medical equipment providers, and distributors to make its respiratory therapy products widely available, allowing patients the chance to manage the impact of their disease.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this communication that are not historical facts, including, but not limited to, statements regarding Inogen's future business plans, market opportunities, financial outlook, growth strategies, and anticipated operational results, are forward-looking statements. Words such as "aims," "believes," "anticipates," "plans," "expects," "will,"

“intends,” “potential,” “possible,” and similar expressions are intended to identify forward-looking statements. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including but not limited to, risks and uncertainties relating to market acceptance of its products; competition; its sales, marketing and distribution capabilities; its planned sales, marketing, and research and development activities; interruptions or delays in the supply of components or materials for, or manufacturing of, its products; seasonal variations; unanticipated increases in costs or expenses; risks associated with international operations; and the possibility that Inogen will not realize anticipated revenue from recent or future technology acquisitions or that expenses and costs related thereto will exceed Inogen’s expectations. For a detailed discussion of these and other risks that could impact Inogen’s operations and financial performance, please refer to the “Risk Factors” section of its Annual Report on Form 10-K for the period ended December 31, 2023, its Quarterly Report on Form 10-Q for the calendar quarter ended March 31, 2024 and in its other filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. Inogen disclaims any obligation to update these forward-looking statements except as may be required by law.

For more information, please visit www.inogen.com.

Inogen has used, and intends to continue to use, its Investor Relations website, http://investor.inogen.com/, as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD.

Contact:
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