

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):

February 25, 2025

**INNOVATE CORP.**

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-35210</u> (Commission File Number)	<u>54-1708481</u> (I.R.S. Employer Identification No.)
295 Madison Ave, 12th Fl New York, NY		10017
(Address of principal executive offices)		(Zip Code)
Registrant's telephone number, including area code:		(212) 235-2691

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 (see General Instruction A.2. below):

- 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	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	VATE	New York Stock Exchange
Preferred Stock Purchase Rights	N/A	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 8.01 Other Events

On February 25, 2025, INNOVATE Corp. issued a press release announcing that the National Medical Products Administration (“NMPA”) in China has approved the MediBeacon® Transdermal GFR Monitor and TGFR Sensor for the assessment of kidney function in patients with normal or impaired renal function. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Current Report on Form 8-K, including the exhibit attached hereto, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, unless such subsequent filing specifically references this Form 8-K.

## Item 9.01 Financial Statements and Exhibits.

### (d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release dated February 25, 2025, titled “MediBeacon® Transdermal GFR Receives Device Approval in China”</a>
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

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## 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.

Date: February 25, 2025

**INNOVATE Corp.** (Registrant)

By: /s/ Michael J. Sena

Name: Michael J. Sena

Title: Chief Financial Officer

**MediBeacon® Transdermal GFR System receives device approval in China  
Peer-reviewed articles on MediBeacon technology published**

- **Transdermal GFR System (TGFR) is a first-in-kind product for point of care assessment of kidney function in patients with normal or impaired renal function.**
- **The Clinical Kidney Journal in February published MediBeacon study results on measured GFR (mGFR) using relmapirazin versus estimated GFR (eGFR) for the purpose of classifying patient Chronic Kidney Disease (CKD) stages.**
- **MediBeacon TGFR study results have been posted online in the February ahead of print section in the Journal of the American Society of Nephrology (JASN).**

NEW YORK, February 25, 2025 - INNOVATE Corp. (NYSE: VATE) (“INNOVATE” or the “Company”) announced today the National Medical Products Administration (NMPA) in China has approved the MediBeacon® TGFR Monitor and TGFR Sensor for the assessment of kidney function in patients with normal or impaired renal function. Lumitrace® (relmapirazin) injection, categorized as a drug in China, is under review and is targeted for approval in late 2025. The transdermal GFR technology includes Lumitrace® (relmapirazin) injection, a non-radioactive, non-iodinated fluorescent GFR tracer agent, which together with the TGFR Monitor and TGFR Sensor allow assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the body.

In 2021, the NMPA granted the TGFR Innovative Medical Device Designation. Only 10% of applications are granted this designation. Benefits of this registration route including early product promotion are considerable.

In February, the Clinical Kidney Journal published MediBeacon data in an article on Chronic Kidney Disease (CKD) stage misclassification via estimated GFR (eGFR) compared to measured GFR (mGFR) using relmapirazin. In a stable CKD population, more than one-third of the subjects had an actual mGFR (relmapirazin) that differed by at least one CKD stage from their estimated GFR (eGFR).<sup>1</sup> Relmapirazin is indicated for use with the TGFR.

“The *Clinical Kidney Journal* study raises serious concerns about how chronic kidney disease is diagnosed today,” said Dr. Ira Kurtz, Chief of the Division of Nephrology at UCLA Medical Center. “Researchers found that current eGFR methods misclassified 35% of patients, leading to potentially incorrect treatments and delayed interventions.”

In the February ahead of print section in the Journal of the American Society of Nephrology (JASN), MediBeacon clinical study data from the use of transdermal detection of relmapirazin in patients with normal to impaired kidney function across a range of skin color types was posted online.<sup>2</sup> JASN publishes high-impact research to advance the understanding and treatment of kidney diseases.<sup>3</sup>

In addition to his leadership role at UCLA Medical Center, Dr. Kurtz is active in the development of an artificial kidney and artificial intelligence in the training and practice of nephrology.

Dr. Kurtz commented that: “The study in the *Journal of the American Society of Nephrology* introduces a wearable, transdermal device that assesses GFR without the need for blood samples. The fluorescence-based test, developed by MediBeacon, demonstrated an exceptional correlation ( $r^2 = 0.90$ ) with plasma mGFR across all skin types, paving the way for more equitable and accurate kidney function assessment. These two new studies have reshaped the landscape of kidney disease diagnostics, offering both a cutting-edge innovation and a stark warning about current practices. The findings underscore the urgent need for

<sup>1</sup> CKD stage misclassification between estimated GFR and measured GFR in a clinical study of chronic kidney patients, *Clinical Kidney Journal*, Dorshow, Richard B. et al., 2025 Jan 9;18(2):sfaf006. DOI: 10.1093/ckj/sfaf006

<sup>2</sup> Glomerular Filtration Rate Measurement Utilizing Transdermal Detection Methodology, *Journal of the American Society of Nephrology (JASN)*, Dorshow, Richard B. et al., February 7, 2025, DOI: 10.1681/ASN.000000639

<sup>3</sup> <https://www.asn-online.org/publications/>

improved kidney function assessment tools, with non-invasive, point of care GFR measurement emerging as a game-changing solution.”

“Awareness of kidney disease is relatively low despite the fact that it is the 7th leading risk factor for mortality worldwide.<sup>4</sup> MediBeacon is pleased to have the opportunity to aid in the assessment of kidney function in China,” said Steve Hanley CEO of MediBeacon. “NMPA approval is the culmination of a rigorous device application process that required close collaboration of the MediBeacon and Huadong Medicine teams. We look forward to the next phase of our partnership with Huadong Medicine and eagerly anticipate Lumitrace approval in China later this year.”

The TGFR, which includes Lumitrace (relmapirazin), was approved on January 17<sup>th</sup> by the U.S. Food and Drug Administration (FDA). MediBeacon continues development of future TGFR products including a next-generation TGFR Sensor with updated software and algorithms.

#### **About INNOVATE**

INNOVATE Corp. is a portfolio of best-in-class assets in three key areas of the new economy – Infrastructure, Life Sciences and Spectrum. Dedicated to stakeholder capitalism, INNOVATE employs approximately 4,000 people across its subsidiaries. For more information, please visit: [www.INNOVATECorp.com](http://www.INNOVATECorp.com).

#### **About MediBeacon Inc.**

MediBeacon is a medical technology company specializing in the advancement of fluorescent tracer agents and their transdermal detection. MediBeacon’s use of proprietary fluorescent tracer agents coupled with transdermal detection technology focuses on providing vital and actionable measurement of organ function. MediBeacon owns over 55 granted U.S. patents and over 215 granted patents worldwide that provide extensive coverage of the MediBeacon® TGFR, including Lumitrace® injection, the sensor and algorithms, as well as other strategic uses of its proprietary pyrazine platform and sensor technology. The TGFR is approved for human use. Potential technology applications in gastroenterology, ophthalmology and surgery are in various stages of clinical development. MediBeacon is based in St. Louis, Missouri, with additional operations in Mannheim, Germany. For more information, please visit: [www.medibeacon.com](http://www.medibeacon.com).

#### **About Lumitrace® (relmapirazin) injection**

Relmapirazin is a non-radioactive, non-iodinated pyrazine-based compound, which has been engineered to be inert, highly fluorescent, and have the clearance properties of a GFR tracer agent in the body. The unique photophysical characteristics of Lumitrace have been designed to enable the collection of fluorescence data via a photodetector sensor placed on the skin. Data collected by the sensor measures the change in the intensity of Lumitrace fluorescence over time and is converted into a transdermal GFR (tGFR) by proprietary algorithms. In a phase 2 investigational study mGFR deduced from Lumitrace matched that of mGFR deduced from iohexol over a range of GFR values. See the peer reviewed article published in the October 2024 issue of *Kidney International* by Dorshow et al.<sup>5</sup>

#### **About MediBeacon® Transdermal GFR System (TGFR)**

The TGFR is comprised of the TGFR Sensor, TGFR Monitor, and Lumitrace® (relmapirazin), which together allow assessment of kidney function by measuring the clearance rate of the fluorescent agent as it leaves the body. The system records Lumitrace fluorescence intensity transdermally as a function of time via a sensor placed on the skin. The TGFR Sensor records 2.5 fluorescent readings per second and the TGFR Monitor will display the average session tGFR reading at the patient’s bedside or in the outpatient setting.

#### **Forward-Looking Statements**

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the federal securities laws. Forward-looking statements generally relate to future events. You are cautioned that such statements are not guarantees of future performance and that INNOVATE’s actual results may

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<sup>4</sup> Chronic kidney disease and the global public health agenda: an international consensus, *Nature Reviews Nephrology*, 20, 473-485 (2024), doi.org/10.1038/s41581-024-00820-6

<sup>5</sup> Clinical validation of the novel fluorescent glomerular filtration rate tracer agent relmapirazin (MB-102), *Kidney International*, Volume 106, Issue 4, P679-687, October 2024, DOI: 10.1016/j.kint.2024.06.012

differ materially from those set forth in the forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that may change at any time. Factors that could cause INNOVATE's actual expectations to differ materially from these forward-looking statements include INNOVATE's ability to continue to comply with applicable listing standards of the NYSE and the other factors under the heading "Risk Factors" set forth in INNOVATE's Annual Report on Form 10-K, as supplemented by INNOVATE's quarterly reports on Form 10-Q. Such filings are available on our website or at [www.sec.gov](http://www.sec.gov). You should not place undue reliance on these forward-looking statements, which are made only as of the date of this press release. INNOVATE undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent developments, events, or circumstances, except as may be required under applicable securities laws.

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**IMPORTANT SAFETY INFORMATION FOR TGFR (U.S. FDA)**

**Indication for Use:**

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15ml/min/1.73m<sup>2</sup>, GFR >120ml/min/1.73m<sup>2</sup>, patients on dialysis or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Sensor and exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Sensor is a single use device intended to attach to the patient's skin and excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

**Contraindications:**

There are no known contraindications.

**Warnings and Precautions:**

- See [ifu.medibeacon.com](http://ifu.medibeacon.com) for full instructions, warnings, and cautions.
- In clinical studies no serious or severe adverse events have been observed.
- Lumitrace® injection has light absorbance at 266nm and 435nm, and broad fluorescent emission at ~560nm when excited at ~440nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.
- Lumitrace injection may interfere with clinical laboratory tests. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system (up to 72 hours for renally-impaired patients). The presence of Lumitrace decreased B-Type Natriuretic Peptide (BNP) results by around 20% in limited testing.
- Bolus infusions may impact the GFR assessment temporarily while the vasculature-tissue equilibrium is re-established.

- During a TGFR session, the patient should be as still as possible, especially during the “Establishing Baseline” stage. The current system is designed to compensate for light activity such as reading or eating after the Baseline stage.