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): July 27, 2026

FREENOME, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-42126	98-1783595
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Genesis Marina, 3300 Marina Blvd,
Brisbane, CA 94005
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 446-6630

PERCEPTIVE CAPITAL SOLUTIONS CORP
51 Astor Place, 10th Floor
New York, NY 10003

(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	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**FRNM**	**The Nasdaq Capital Market**

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 July 27, 2026, Freenome, Inc. (the "Company") issued a press release titled "FDA Approves Freenome's SimpleScreen™ CRC Blood-Based Screening Test; Abbott to Commercialize in the U.S." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On July 27, 2026, the Company announced that the U.S. Food and Drug Administration ("FDA") has approved SimpleScreen™ CRC, a new blood-based screening option for colorectal cancer ("CRC") in adults 45 and older who are at average risk for the disease.

Colorectal cancer is the second-leading cause of cancer-related death in the U.S., but it is highly preventable and treatable when detected early through screening. Up to 60 million Americans remain overdue for recommended screening, underscoring the need for additional convenient screening approaches that can help reach more people.

SimpleScreen CRC detects signals associated with colorectal cancer from cell-free DNA in the blood. FDA approval reflects years of clinical research, AI/ML-driven technology development and extensive collaboration with investigators, healthcare providers and partners.

SimpleScreen CRC was evaluated in PREEMPT CRC, the largest prospective clinical validation study ever conducted for a blood-based colorectal cancer screening test. Conducted at over 200 sites, PREEMPT CRC enrolled more than 48,000 asymptomatic, average-risk adults between the ages of 45 and 85 who were scheduled for a screening colonoscopy. In a prespecified analysis adjusted to match the U.S. Census, SimpleScreen CRC detected colorectal cancer with 81.1% sensitivity and advanced precancerous lesions ("APLs") with 13.7% sensitivity, including 30.7% for APLs with high-grade dysplasia. The test showed 90.4% specificity for advanced colorectal neoplasia. In practical terms, the test correctly detected about 8 in 10 colorectal cancers while correctly producing negative results for 9 of 10 people without colorectal cancer or advanced precancerous lesions.

With FDA approval, SimpleScreen CRC meets the coverage criteria for Medicare and is expected to be incorporated into the American Cancer Society guidelines by name. Together, we believe these milestones will help expand access to blood-based CRC screening for eligible adults.

Under the terms of the commercial agreement signed between Freenome and Abbott in August 2025, Freenome will receive a $100 million milestone payment from Abbott for this FDA approval. Abbott will exclusively commercialize SimpleScreen CRC in the U.S., building on the provider relationships, reimbursement expertise and patient support programs it has developed through Cologuard®. The company's established CRC infrastructure – including its Nexus platform – will help connect more people to screening and support adoption across the healthcare system.

For Freenome, the approval marks the first commercial milestone in Freenome's Personalized Cancer Detection approach, which combines risk-based screening with test performance optimized and tailored to specific indications, all through a single blood draw. The Company also plans to incorporate SimpleScreen CRC into its broader SimpleScreen portfolio, while continuing to advance additional single- and multi-cancer tests, built on the same multiomics platform.

Forward-Looking Statements

Statements we make in this report may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will" and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are making this statement for purposes of complying with those safe harbor provisions. Any statements in this report that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, express or implied statements regarding SimpleScreen CRC's impact and ability to reach additional patients; the impact of FDA approval including with respect to Medicare and ACS guidelines; Freenome's partnership with Abbott and the expected results and benefits thereof; and Freenome's business and strategy, including its plans with respect to its broader SimpleScreen portfolio and multiomics platform. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks related to the approval of Freenome's products and tests and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive products and tests; ability to obtain sufficient supply of materials; ability to obtain additional financing; ability to attract and retain qualified personnel; global economic and political conditions; legal and regulatory changes; the outcome of any legal proceedings that may be instituted against Freenome; the effects of competition on Freenome's future business; as well as those set forth in the Form S-4 that was filed with the SEC, as updated by our subsequently filed SEC filings. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release issued by Freenome, Inc., dated July 27, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FREENOME, INC.

By:	/s/ Aaron Elliott
Name:	Aaron Elliott
Title:	Chief Executive Officer

Date: July 27, 2026

Exhibit 99.1

FDA Approves Freenome's SimpleScreen™ CRC Blood-Based Screening Test; Abbott to Commercialize in the U.S.

– Approval expands colorectal cancer screening options for the up to 60 million Americans who are overdue for screening –

– Medicare coverage and American Cancer Society guidance support broader access to blood-based colorectal cancer screening –

BRISBANE, Calif. and ABBOTT PARK, Ill. (July 27, 2026) — Freenome, Inc. (Nasdaq: FRNM), an early cancer detection company developing blood-based screening tests, and Abbott (NYSE: ABT) today announced that the U.S. Food and Drug Administration (FDA) has approved SimpleScreen™ CRC, a new blood-based screening option for colorectal cancer (CRC) in adults 45 and older who are at average risk for the disease. Abbott will exclusively commercialize the test in the U.S. this fall, expanding its CRC screening portfolio with a new option that requires only a simple blood draw.

Colorectal cancer is the second-leading cause of cancer-related death in the U.S., but it is highly preventable and treatable when detected early through screening. Up to 60 million Americans remain overdue for recommended screening,[1] underscoring the need for additional convenient screening approaches that can help reach more people.

"The most effective screening test is the one a person will actually complete," said Aasma Shaukat, M.D., M.P.H., professor of medicine at NYU Grossman School of Medicine and a co-lead principal investigator on the PREEMPT CRC® study.[2] "Many people who should be screened for colorectal cancer simply aren't. A blood-based test provides another way to reach unscreened patients, and bringing more people into the screening fold leads to earlier detection and better outcomes."

SimpleScreen CRC detects signals associated with colorectal cancer from cell-free DNA (cfDNA) in the blood. FDA approval reflects years of clinical research, AI/ML-driven technology development and extensive collaboration with investigators, healthcare providers and partners.

SimpleScreen CRC was evaluated in PREEMPT CRC, the largest prospective clinical validation study ever conducted for a blood-based colorectal cancer screening test. Conducted at over 200 sites, PREEMPT CRC enrolled more than 48,000 asymptomatic, average-risk adults between the ages of 45 and 85 who were scheduled for a screening colonoscopy. In a prespecified analysis adjusted to match the U.S. Census, SimpleScreen CRC detected colorectal cancer with 81.1% sensitivity and advanced precancerous lesions (APLs) with 13.7% sensitivity, including 30.7% for APLs with high-grade dysplasia. The test showed 90.4% specificity for advanced colorectal neoplasia. In practical terms, the test correctly detected about 8 in 10 colorectal cancers while correctly producing negative results for 9 of 10 people without colorectal cancer or advanced precancerous lesions.

"Today's approval is an important validation of the scientific vision we've spent more than a decade building," said Aaron Elliott, Ph.D., CEO of Freenome. "SimpleScreen CRC is the first commercial realization of our Personalized Cancer Detection strategy, built on base-level cfDNA methylation and AI enhanced accuracy. We believe this common technology foundation will power our expanding portfolio of cancer screening tests, continuous performance improvements and future product generations as our platform continues to learn."

“The fact is that 90% of colorectal cancer deaths are preventable, yet the disease will still claim more than 55,000 lives in the U.S. this year alone,” added Anjee Davis, MPAA, CEO of Fight Colorectal Cancer. “Regular screening is the key to reversing that trend, and new, minimally invasive screening options that help more people get screened are a critical part of that process. Colorectal cancer is increasingly affecting younger adults, and a screening test that fits into a routine visit, accompanied by prompt follow-up in response to an abnormal result, can play an important role in driving earlier treatment and prevention.”

With FDA approval, SimpleScreen CRC meets the coverage criteria for Medicare and is expected to be incorporated into the American Cancer Society guidelines by name. Together, these milestones help expand access to blood-based CRC screening for eligible adults.

Under the terms of the commercial agreement signed between Freenome and Abbott in August 2025, Freenome will receive a $100 million milestone payment from Abbott for this FDA approval. Abbott will exclusively commercialize SimpleScreen CRC in the U.S., building on the provider relationships, reimbursement expertise and patient support programs it has developed through Cologuard®. The company’s established CRC infrastructure – including its Nexus platform – will help connect more people to screening and support adoption across the healthcare system.

“FDA approval is a significant milestone in our mission to help more people get screened, detect colorectal cancer earlier and ultimately help save lives,” said Jake Orville, senior vice president of Abbott’s cancer diagnostics business. “No single screening option will reach every patient. By adding SimpleScreen CRC alongside Cologuard, we are expanding the choices available to healthcare providers and helping remove barriers that keep too many people from getting screened.”

For Freenome, the approval marks the first commercial milestone in Freenome’s Personalized Cancer Detection approach, which combines risk-based screening with test performance optimized and tailored to specific indications, all through a single blood draw. The company also plans to incorporate SimpleScreen CRC into its broader SimpleScreen portfolio, while continuing to advance additional single- and multi-cancer tests, built on the same multiomics platform.

About SimpleScreen CRC

SimpleScreen CRC is a cancer screening option for colorectal cancer. It uses a simple blood draw and detects signals associated with CRC from cell-free DNA (cfDNA) in the blood. The test is indicated for adults aged 45 years and older who are at average risk for CRC and referred by a healthcare provider for CRC screening. A positive result indicates a signal was detected that may suggest the presence of colorectal cancer or advanced precancerous lesions and should be followed by colonoscopy. SimpleScreen CRC is not a replacement for diagnostic colonoscopy or for surveillance colonoscopy in high-risk individuals.

About Freenome

Freenome is an early cancer detection company developing blood-based screening tests to identify cancer in its earliest, most treatable stages. The company's proprietary multiomics discovery platform analyzes circulating cell-free DNA methylation patterns at single-base resolution alongside additional biomarkers to detect multiple cancers. Freenome's development of SimpleScreen™ CRC for colorectal cancer screening, with clinical validation through the PREEMPT CRC Study, and a pipeline of tests for lung cancer and additional indications is designed to increase cancer screening participation among millions of at-risk individuals. For more information, visit www.freenome.com.

About Abbott

Abbott is a global healthcare leader that helps people live more fully at all stages of life. Our portfolio of life-changing technologies spans the spectrum of healthcare, with leading businesses and products in diagnostics, medical devices, nutritionals, and branded generic medicines. Our 122,000 colleagues serve people in more than 160 countries. Connect with us at abbott.com and on LinkedIn, Facebook, Instagram, X and YouTube. Learn more at www.abbott.com

Forward-Looking Statements

Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will” and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are making this statement for purposes of complying with those safe harbor provisions. Any statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, express or implied statements regarding SimpleScreen CRC’s impact and ability to reach additional patients; the impact of FDA approval including with respect to Medicare and ACS guidelines; Freenome’s partnership with Abbott and the expected results and benefits thereof; and Freenome’s business and strategy, including its plans with respect to its broader SimpleScreen portfolio and multiomics platform. These forward-looking statements reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks related to the approval of Freenome’s products and tests and the timing of expected regulatory and business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive products and tests; ability to obtain sufficient supply of materials; ability to obtain additional financing; ability to attract and retain qualified personnel; global economic and political conditions; legal and regulatory changes; the outcome of any legal proceedings that may be instituted against Freenome; the effects of competition on Freenome’s future business; as well as those set forth in the Form S-4 that was filed with the SEC, as updated by our subsequently filed SEC filings. We assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

References

1. Ebner DW, Kisiel JB, Fendrick AM, et al. Estimated Average-Risk Colorectal Cancer Screening-Eligible Population in the US. JAMA Netw Open. 2024;7(3):e245537.
2. Shaukat A, Burke CA, Chan AT, et al. Clinical Validation of a Circulating Tumor DNA-Based Blood Test to Screen for Colorectal Cancer. JAMA. Published online June 2, 2025. doi: 10.1001/jama.2025.7515.

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