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): November 14, 2022

EXAGEN INC.
(Exact name of registrant as specified in its charter)

Delaware	001-39049	20-0434866
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1261 Liberty Way
Vista, CA 92081
(Address of principal executive offices) (Zip Code)

(760) 560-1501
(Registrant's telephone number, including area code)

N/A
(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, par value $0.001 per share	**XGN**	**The Nasdaq Global 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 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Exagen Inc. (the "Company") reported its financial results for the three and nine months ended September 30, 2022. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this report.

The information furnished with Item 2.02 of this report, including Exhibit 99.1, is being 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 into any other filings under the Exchange Act or under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such a filing.

Item 4.02 – Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

(a)

On November 13, 2022, the Audit Committee (the "Audit Committee") of the Board of Directors of the Company, after discussion with the Company's management, determined that the Company made certain errors in the manner in which it recognized revenue related to changes in billing practices specific to its transition to the use of the PLA code for AVISE CTD. The errors were due to the inadequate design and implementation and precision of internal controls and procedures designed to evaluate and monitor the accounting for revenue recognition. As a result, revenue and accounts receivable were overstated and other liabilities was understated for the quarter and year to date periods ended June 30, 2022. Accordingly, the Company's financial statements as of and for the three and six months ended June 30, 2022 (the "Non-Reliance Period") included in the associated Form 10-Q for the period ended June 30, 2022, filed with the Securities Exchange Commission (the "SEC"), (1) should no longer be relied upon due to such errors, and (2) will require restatement. The Company will file an amendment to its Form 10-Q for the three and six months ended June 30, 2022 to restate the previously issued financial statements. Similarly, any previously issued or filed reports, press releases, earnings releases, and investor presentations or other communications describing the Company's financial statements and other related financial information covering the Non-Reliance Period should no longer be relied upon. The Company expects to file an extension on Form 12b-25 for its Quarterly Report for the period ended September 30, 2022.

The effect of these errors is an overstatement of revenue and accounts receivable in the amount of $1.4 million and $0.9 million, respectively, and an understatement of other liabilities in the amount of $0.5 million for the three and six months ended June 30, 2022. The Company is working to complete the restatement of its financial statements for the Non-Reliance Period. The Company intends to restate the financial statements for the Non-Reliance Period as soon as practicable, and will include therein the correction of any other, immaterial errors. Accordingly, investors and others should rely only on financial information and other disclosures regarding the Non-Reliance Period once the Company restates its financial statements for the Non-Reliance Period and not rely on any previously issued or filed earnings press releases, investor presentations or other communications related thereto covering the Non-Reliance Period.

Management is assessing the effect of these restatements on the Company's internal control over financial reporting and its disclosure controls and procedures. The Company expects to report at least one material weakness following completion of its analysis of the cause of these restatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. The existence of one or more material weaknesses precludes a conclusion by management that the Company's disclosure controls and procedures and internal control over financial reporting are effective. As a result of the material weakness or material weaknesses expected to be reported, the Company believes that its internal control over financial reporting was not effective and its disclosure controls and procedures were not effective for the Non-Reliance Period.

The Company's management and the Audit Committee have discussed the matters disclosed in this Item 4.02(a) with the Company's independent registered accounting firm, BDO USA, LLP.

Forward-Looking Statements: This Current Report on Form 8-K contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on expectations and estimates of management of the Company which may differ from any actual results and consequently you should not rely on these forward-looking statements as predictions of future events. Forward-looking statements include, without limitation, the Company's plans related to the restatement of the financial statements as of and for the three and six months ended June 30,

2022, including that it will it will timely file its Form 10-Q for the quarter ended September 30, 2022 by the extended filing date pursuant to Rule 12b-25 and the Company's plan of remediation with respect to the one or more material weaknesses in internal controls over financial reporting the Company expects to identify. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those implied by forward-looking statements, including the outcome of the Company's completion of the quantification and evaluation of the specific impact of the errors in the Company's financial results and previously issued financial statements, including the possibility of material adjustments thereto; the discovery of additional and unanticipated information during the procedures required to be completed before the Company is able to file its required reports; the application of accounting or tax principles in an unanticipated manner; and other risks and uncertainties set forth in the Company's periodic filings with the SEC, including, but not limited to, those risks and uncertainties listed in the section entitled "Risk Factors," in the Company's Annual Report on Form 10-K filed with the SEC on March 22, 2022. All forward-looking statements in this Current Report on Form 8-K are based on information available to the Company as of the date of this filing. The Company expressly disclaims any obligation to update or alter its forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Item 9.01. Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

EXAGEN INC.

Date: November 14, 2022

By: /s/ Kamal Adawi

Kamal Adawi
Chief Financial Officer

Exagen Inc. Reports Third Quarter 2022 Results

Medicare Reimbursement Returns

November 14, 2022

SAN DIEGO – Exagen Inc. (Nasdaq: XGN), a leading provider of autoimmune testing solutions, today reported financial results for the quarter ended September 30, 2022.

Third Quarter Highlights:

- Total revenue of $14.7 million recognized in the third quarter of 2022. Our flagship AVISE® CTD test, including AVISE® Lupus, recognized revenue of $12.8 million in the third quarter of 2022.
- Delivered 35,569 AVISE® CTD tests, including AVISE® Lupus, in the third quarter of 2022, a 12% increase over the third quarter of 2021. Since the launch of AVISE® CTD in 2012 through the third quarter of 2022, we have delivered over 700,000 of these tests.
- Number of ordering healthcare providers totaled 2,287 in the third quarter of 2022, an increase of 16% over the third quarter of 2021.
- Medicare resumed reimbursement dating back to Q2 for AVISE Lupus claims.
- Increasing full year 2022 revenue guidance, range of $40 million to $43 million.

“I’m very excited to be joining Exagen, as President and CEO,” said John Aballi. “Exagen has developed a leadership position in one of the largest fields of medicine with our proprietary AVISE testing platform. We are the Rheumatologist’s trusted partner in diagnostics, and I look forward to working with the team to continue to build on this foundation. Having spent the majority of my career working in labs, developing and commercializing diagnostics in oncology, I’m looking forward to bringing that same successful approach to Exagen."

Third Quarter 2022 Financial Results

Total testing revenue was $14.7 million for the third quarter of 2022 (including $3.7 million that we recognized in the third quarter from AVISE Lupus Medicare claims that were submitted in the second quarter), compared to $11.9 million in the third quarter of 2021. Our revenue resulting from the Janssen Agreement contributed no revenue in the third quarter of 2022, compared to $0.4 million in the third quarter of 2021. Total revenue for the three months ended September 30, 2022 was $14.7 million,

compared with $12.3 million in the third quarter of 2021. Gross margin was 59.2% in the third quarter of 2022, compared to 55.2% in the third quarter of 2021. Testing gross margin was 59.2% in the third quarter of 2022, compared to 53.7% in the third quarter of 2021.

Operating expenses were $22.5 million in the third quarter of 2022, compared with $18.8 million in the third quarter of 2021, due to higher expenses in the following areas; employee-related expenses associated with the overall increase in headcount, marketing spend, R&D expenses, cost of revenue due to the increase in testing volumes, and public company costs.

As disclosed in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 14, 2022, the Audit Committee of the Board of Directors of the Company determined that the Company made certain errors in the manner in which it recognized revenue related to changes in billing practices specific to its transition to the use of the PLA code for AVISE CTD. The effect of these errors was an overstatement of revenue and accounts receivable in the amount of $1.4 million and $0.9 million, respectively, and an understatement of other liabilities in the amount of $0.5 million for the three months ended June 30, 2022. Accordingly, the Company will file an amendment to its Form 10-Q for the quarter ended June 30, 2022 to restate the previously issued financial statements.

For the third quarter of 2022, net loss was $8.1 million, compared to a net loss of $7.2 million for the third quarter of 2021.

Cash and cash equivalents were $68.7 million as of September 30, 2022.

2022 Guidance

For the full year 2022, we increase our revenue guidance range to $40 million to $43 million.

Conference Call

A conference call to review third quarter 2022 financial results and to provide a business update is scheduled for today November 14, 2022 at 4:30 PM Eastern Time (1:30 PM Pacific Time). Interested parties may access the conference call by dialing (201) 389-0918 (U.S.) or (877) 407-0890 (international). Additionally, a link to a live webcast of the call will be available in the Investor Relations section of Exagen's website at investors.exagen.com.

Participants are asked to join a few minutes prior to the call to register for the event. A replay of the conference call will be available until Monday, November 28, 2022 at 11:59 PM Eastern Time (8:59 PM Pacific Time). Interested parties may access the replay of the conference call by dialing (201) 612-7415 (U.S.) or (877) 660-6853 (international) using passcode 13733098. Additionally, a recording of the webcast will be available using the link on the Exagen investor relations website approximately one hour after the call concludes.

About Exagen

Exagen (Nasdaq: XGN) is a leading provider of autoimmune diagnostic, prognostic, and monitoring testing solutions. Exagen is a patient focused, discovery driven organization built on the success of AVISE testing and is investing in its product pipeline to support patients throughout their autoimmune diagnosis and treatment journeys. The goal at Exagen is to assist patients, physicians, and payors by

enabling precision medicine. Exagen is located in San Diego County with clinical and research and development laboratories in Vista, CA.

For more information, please visit Exagen.com and follow @ExagenInc on Twitter.

Forward Looking Statements

Exagen cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on Exagen's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: Exagen's goals and strategies; the potential utility and effectiveness of Exagen's services and testing solutions that are currently available or in its development pipeline and any related potential cost-savings; the expectation that Exagen's in-network agreements will drive availability of its tests, and potential revenue that may be generated by such agreements; Exagen's ability to obtain and maintain consistent reimbursement for its tests, including its reliance on third parties to process and transmit claims to payors and the adverse impact of any delay, data loss, or other disruption in processing or transmitting such claims; the expected impact and results of further investments in its business and collaborations, Exagen's future potential growth and ability to continue to sustain success; Exagen's plans related to the restatement of the financial statements as of and for the three and six months ended June 30, 2022; Exagen's plan of remediation with respect to the one or more material weaknesses in internal controls over financial reporting the Company expects to identify; and 2022 guidance. The inclusion of forward-looking statements should not be regarded as a representation by Exagen that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Exagen's business, including, without limitation: the COVID-19 pandemic may continue to adversely affect its business, financial condition and results of operations, including as a result of slowdown in its operations as well as those of its suppliers and courier services, impeding patient movement and interruptions to healthcare services causing a decrease in test volumes, disruptions to the supply chain of material needed for its tests causing an increase in cost per test, its sales and commercialization activities and its ability to receive specimens and perform or deliver the results from its tests, delays in reimbursement and coverage decisions from Medicare and third-party payors and in interactions with regulatory authorities, and delays in ongoing and planned clinical trials involving its tests; Exagen's commercial success depends upon attaining and maintaining significant market acceptance of its testing products and promoted therapeutics among rheumatologists, patients, third-party payors and others in the medical community; Exagen's ability to successfully execute on its business strategies; third-party payors not providing coverage and adequate reimbursement for Exagen's testing products or promoted therapeutics, including Exagen's ability to collect funds due; Exagen's ability to obtain and maintain intellectual property protection for its testing products; regulatory developments affecting Exagen's business; and other risks described in Exagen's prior press releases and Exagen's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in Exagen's Annual Report on Form 10-K for the year ended December 31, 2021 and any subsequent filings with the SEC. These reports contain more information about Exagen, its business and the risks affecting its business, as well as its results of operations for the periods covered by the financial results included in this press release. In particular, you are encouraged to review the company's quarterly report on Form 10-Q for the quarter ended September 30, 2022 and its amended quarterly report on Form 10-Q for the quarter ended June 30, 2022 for any revisions or updates to the information in this release. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Exagen undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the

date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Exagen Inc.

Unaudited Condensed Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 14,726	$ 12,251	$ 32,726	$ 35,610
Operating expenses:				
Costs of revenue	6,010	5,487	17,905	15,649
Selling, general and administrative expenses	14,151	11,528	39,204	32,739
Research and development expenses	2,382	1,740	7,175	5,035
Total operating expenses	22,543	18,755	64,284	53,423
Loss from operations	(7,817)	(6,504)	(31,558)	(17,813)
Interest expense	(618)	(678)	(1,822)	(1,986)
Other income, net	339	3	346	1
Net loss	$ (8,096)	$ (7,179)	$ (33,034)	$ (19,798)
Net loss per share, basic and diluted	$ (0.47)	$ (0.42)	$ (1.94)	$ (1.27)
Weighted-average number of shares used to compute net loss per share, basic and diluted	17,080,959	16,945,591	17,044,623	15,636,150

Exagen Inc.

Unaudited Condensed Balance Sheets
(in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 68,704	$ 99,442
Accounts receivable, net	10,639	9,654
Prepaid expenses and other current assets	2,717	3,638
Total current assets	82,060	112,734
Property and equipment, net	8,331	4,772
Operating lease right-of-use assets	5,114	—
Goodwill	5,506	5,506
Other assets	586	433
Total assets	$ 101,597	$ 123,445
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,669	$ 2,492
Operating lease liabilities	1,009	—
Accrued and other current liabilities	6,654	6,826
Total current liabilities	11,332	9,318
Borrowings-non-current portion, net of discounts and debt issuance costs	28,008	27,478
Non-current operating lease liabilities	4,766	—
Deferred tax liabilities	306	306
Other non-current liabilities	999	1,407
Total liabilities	45,411	38,509
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 16,305,475 and 16,164,994 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	16	16
Additional paid-in capital	297,344	293,060
Accumulated deficit	(241,174)	(208,140)
Total stockholders' equity	56,186	84,936
Total liabilities and stockholders' equity	$ 101,597	$ 123,445