

**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): January 9, 2023

EXAGEN INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39049
(Commission
File Number)

20-0434866
(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.

Cautionary Note Regarding Forward Looking Statements

All statements, other than those of historical fact, contained in this Current Report on Form 8-K, are forward-looking statements, including preliminary financial information and results of operations for the three months and year ended December 31, 2022 and the Company's estimates as to if and when it may achieve profitability. The actual results, performance or achievements of Exagen Inc. (the "Company") could differ materially from those expressed or implied by forward-looking statements the Company makes as a result of a variety of risks and uncertainties, including those related to the preliminary nature of our estimated financial information and results of operations estimates for the three months ended March 31, 2023 and the three months and year ended December 31, 2022, which are subject to completion of the Company's financial closing procedures and year-end audit; and the factors discussed in the "Risk Factors" section of the Company's most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K, as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission (the "SEC"). You are urged to carefully consider all such factors. The forward-looking statements contained herein and the exhibits hereto represent the Company's views only as of the date of this Current Report on Form 8-K and the Company does not undertake or plan to update or revise any such forward-looking statements to reflect actual results or changes in plans, prospects, assumptions, estimates or other circumstances occurring after the date of this Current Report on Form 8-K except as required by law.

Item 2.02. Results of Operations and Financial Conditions.

The Company is providing certain preliminary financial information and results of operations for the three months and year ended December 31, 2022, based on currently available information. The Company's financial closing procedures with respect to the estimated financial data provided below are not yet complete. These procedures often result in changes to accounts. As a result, the Company's final results may vary from the preliminary results presented below. The Company undertakes no obligation to update or supplement the information provided below until it releases its financial statements for the three months and year ended December 31, 2022.

The preliminary financial data included in this Current Report on Form 8-K has been prepared by, and is the responsibility of, our management. BDO USA, LLP ("BDO") has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial information and results of operations. Accordingly, BDO does not express an opinion or any other form of assurance with respect thereto.

Based on currently available information, the Company estimates that it delivered approximately 33,800 and 135,000 units of its lead testing product, AVISE® CTD, during the three months and year ended December 31, 2022, respectively.

The information provided in this Item 2.02 of this Current Report on Form 8-K 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, as amended (the "Securities Act"), except as expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

On January 9, 2023, the Company updated its corporate presentation slides (the "Corporate Presentation Slides"). A copy of the Corporate Presentation Slides are furnished herewith as Exhibit 99.1.

The information provided in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of 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 except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

The following information included in the Corporate Presentation Slides is "filed" for purposes of Section 18 of the Exchange Act:

- The information included in Item 2.02 of this Current Report on Form 8-K is incorporated by reference into this Item 8.01.
- For the three months ended March 31, 2023, the Company expects revenue to be in the range of \$8.2 million to \$9.2 million.
- Assuming a gross margin of 60%, the Company estimates that it can achieve profitability if it obtains annual revenues of \$75 million.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation
104	Cover Page Interactive Data file (formatted as 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 hereunto

EXAGEN INC.

Date: January 9, 2023

By: /s/ Kamal Adawi

Name: Kamal Adawi

Title: Chief Financial Officer

duly authorized.



Disclaimer






This presentation and all oral statements made by its officers, directors or employees in connection with this presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, the impact of the COVID-19 pandemic, current and future product offerings, reimbursement and coverage, our ability to implement an integrated testing with therapeutics strategy, the expected benefits from our partnership or promotion arrangements with third parties, research and development costs, timing and likelihood of success and plans and objectives of management for future operations, including estimations of future profitability are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These known risks and uncertainties are described in detail in our filings with the SEC from time to time, including under the heading "Risk Factors" in our Annual Report on Form 10-K and any subsequent filings with the SEC.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this presentation are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We obtained the industry, market and competitive position data used throughout this presentation from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe our own internal research is reliable, such research has not been verified by any independent source.

Key Highlights

Through the Differential **Diagnosis, Prognosis, Monitoring, and Therapeutic Selection** of Autoimmune Diseases, We Address the Unmet Needs that Patients Face

-  Large and underserved autoimmune disease market
-  IP-protected technology platforms: CB-CAPs and AVISE® RADR
-  Demonstrated clinical evidence with clinical utility and healthcare savings
-  Established commercial team servicing the rheumatology channel
-  Proprietary platform with assays covered by Medicare, achieved value-based pricing

Rheumatologists Face Significant Barriers and Diagnostic Disparities



No “smoking gun”

High rate of misdiagnosis

Overlapping manifestations



Antiquated technology and serial testing delays

24mm

Americans suffer from an autoimmune disease^[1]

100

autoimmune illnesses identified over the last few decades^[2]



Ambiguous symptoms

Lack of specificity and sensitivity

Exagen[®]

Patient Focused. Discovery Driven.

[1] Per the National Institute of Environment Health Services estimates.

[2] Autoimmune Disease: The Hidden Epidemic | <http://acbdentalce.com/courses/autoimmune-disease-the-hidden-epidemic/>

Systemic Lupus Erythematosus (SLE) is One of the Deadliest Autoimmune Diseases

SLE takes
years to
diagnose

6



63%
of patients misdiagnosed^[1]



47% by non-rheumatologists^[2]

27% by rheumatologists^[2]

[1] Lupus Foundation of America UNVEIL Survey 2014.

[2] Narain, et al., Arch Intern Med. 2004;164:2435-2441 (Table 2).

AVISE® CTD is a more
accurate frontline
diagnostic



86%
specificity, which is
a 33% increase over
antinuclear antibody
(ANA)

80%
sensitivity, which is a 48%
increase over anti-dsDNA

AVISE® CTD has the following markers:

- Cell-bound complement activation products: EC4d & BC4d
- Auto-antibodies: U1RNP, RNP70, SS-A/Ro
- Rheumatoid arthritis auto-antibodies: rheumatoid factor IgM, rheumatoid factor IgA, anticyclic citrullinated peptide IgG
- Anti-phospholipid syndrome auto-antibodies: cardiolipin IgM, cardiolipin IgG, β 2-glycoprotein 1 IgG, β 2-glycoprotein 1 IgM
- Thyroid auto-antibodies: thyroglobulin IgG, thyroid, thyroid peroxidase

The Rheumatologist's Trusted Testing Company



~ 4,500 U.S.
Rheumatologists



AVISE Test Kit

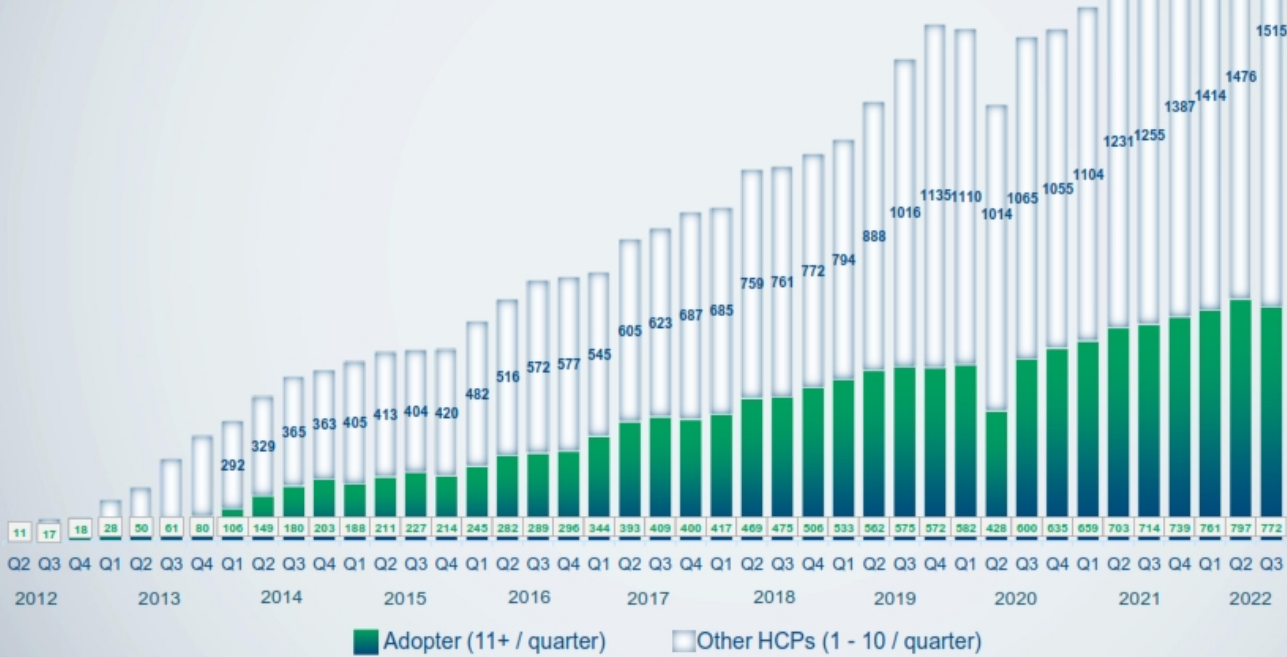


Specimen Delivered to
Exagen Lab

~750,000
AVISE® CTD
Tests Completed

Strong Adopter Base Powers HCP Growth

Number of HCPs for AVISE® CTD



Strong Growth
(Continued attraction of new prescribers)

Strong Base
(Maintaining a strong base)

The Capstone Study



Retrospective analysis of integrated EHR Records

A cohort of ~22k AVISE Lupus tested patients were compared to ~23k traditional ANA (tANA) tested patients to establish clinical utility for diagnosis and treatment of Lupus

3x

AVISE + vs. standard of care + patients were at ~3-fold increased odds of prescribing treatment for SLE Rx

6x

AVISE + vs. standard of care + patients were at ~6-fold increased odds of receiving a SLE diagnosis



Repeat testing was 3.5X higher with the standard of care vs. AVISE tested patients



Comparing AVISE negative vs. standard of care negative patients, post-test vs. pre-test outpatient lab claims decrease 2X as much in AVISE tested patients

Strategic Update

Improving Exagen's Path to Profitability



Improvement of Per Tests Costs

- Eliminate non-profitable, non-core test offerings
- Laboratory resources focused on AVISE CTD optimization
- Reduction of overhead and other fixed costs



Operating Expenses Streamlined to Support Clinical Offering

- Company re-alignment ensures we are rightsized and focused on AVISE CTD
- 40 sales territories optimized for AVISE CTD
- R&D comprised of 8 FTEs with molecular and protein assay development and bioinformatic capabilities

Growing AVISE CTD Revenue



Building Upon Strong AVISE CTD Adoption ~135k tests in 2022

- Specialty laboratory focused on rheumatology
- Establish industry leading quality, service and technology
- Strong support with community rheumatologists and large opportunity with academic institutions
- Ordering physician base has continued to grow every year since launch of AVISE CTD in 2012



Long-term Reimbursement & ASP Growth

- Optimization of revenue cycle practices
- Managed care efforts focused on medical policy expansion
- Published real-world evidence of clinical utility showing savings to healthcare costs and reduction in time to diagnosis



Product Development Criteria Process

Research & Development

- ✓ Impactful Results
 - ✓ Top customer need in rheumatology space
- ✓ Competitive Advantage
 - ✓ Proprietary technology
- ✓ Reimbursement Pathway
 - ✓ Established evidence development plan and market size

Commercialization

- ✓ Medicare Coverage
- ✓ Proprietary Value-Based Pricing
- ✓ Published Clinical Utility
- ✓ Guideline Strategy

R&D Pipeline

Research & Development criteria:

Impactful Results

Competitive Advantage

Reimbursement Pathway

Meets criteria:

AVISE® RADR (focused)

Drug response prediction for 1st-line biologic treatment for RA

AVISE® Lupus Nephritis

AI developed diagnostic score for identifying major kidney involvement due to lupus nephritis

AVISE® SLE Monitor (2.0)

AI developed score for monitoring SLE disease activity and progression

Does not meet criteria:

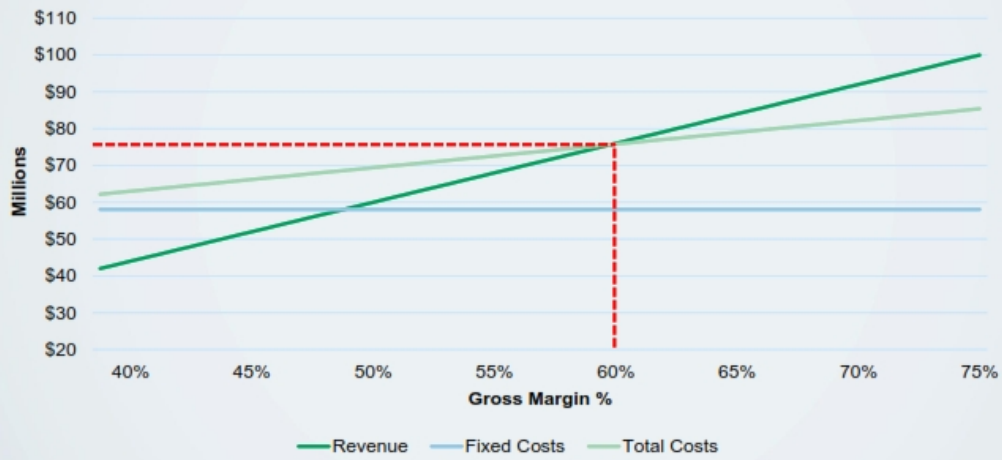
AVISE® Fibromyalgia

AVISE® IFN

AVISE® Thrombosis

Cash Flow Breakeven

Exagen estimates it can achieve profitability with annual revenue of \$75M and GM of 60%





Q4'22
 ~33,800 CTD Units



Q1'23 Guidance
 Revenue \$8.2M - \$9.2M

Key Strategic Messages



Focus on flagship product AVISE CTD – Grow revenue and reduce costs



Establish clear criteria for R&D projects and milestones for commercialization



Discontinue clinical offerings and research projects which lack defined value propositions



Align the organization with this new focus to best accomplish our goals



Execute our strategy to achieve a path to profitability

Thank You

