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 13, 2025

Commission file number 001-39482



GeneDx Holdings Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

85-1966622 (I.R.S. Employer Identification No.)

333 Ludlow Street, North Tower; 6th Floor Stamford, Connecticut 06902 (Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (888) 729-1206

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
Class A common stock, par value \$0.0001 per share	WGS	The Nasdaq Stock Market LLC
Warrants to purchase one share of Class A common stock, each at an exercise price of \$379.50 per share	WGSWW	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 \boxtimes

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.

The information set forth in Item 7.01 below is incorporated by reference into this Item 2.02.

Item 7.01 Regulation FD Disclosure.

On January 13, 2025, GeneDx Holdings Corp. (the "Company") issued a press release (the "Press Release") announcing the Company's expectations regarding its preliminary, unaudited revenue for the fourth quarter and the year ended 2024, exome and genome test result volumes for the fourth quarter and cash, cash equivalents, marketable securities and restricted cash as of December 31, 2024. A copy of the Press Release is included with this Form 8-K for convenience and attached hereto as Exhibit 99.1. Also on January 13, 2024, the Company is furnishing as Exhibit 99.2 hereto a copy of the investor presentation to be used at the 43rd Annual J.P. Morgan Healthcare Conference event.

The information furnished under Items 2.02 and 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, 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 into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No	Description
99.1	Press Release, dated January 13, 2025, regarding Preliminary 2024 Financial Results
99.2	Investor Presentation, dated January 13, 2025

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.

GENEDX HOLDINGS CORP.

Date: January 13, 2025

By: Name: Title: /s/ Katherine Stueland Katherine Stueland Chief Executive Officer



GeneDx Announces Preliminary 2024 Financial Results

Expects to exceed guidance with full year 2024 revenues¹ of at least \$299 million

Expects fourth quarter 2024 revenues¹ of at least \$92 million

Expects to exceed guidance with full year 2024 adjusted gross margin¹ of at least 64%

Expects fourth quarter 2024 adjusted gross margin¹ of at least 68%

STAMFORD, Conn., January 13, 2025 — GeneDx Holdings Corp. (Nasdaq: WGS), a leader in delivering improved health outcomes through genomic insights, today reported preliminary financial results for the fourth quarter and full year of 2024.

"2024 was a transformative year for GeneDx, as we achieved our profitability milestone of adjusted net income, released landmark studies, strengthened our products and expanded our team to set up for the opportunity ahead," said Katherine Stueland, CEO of GeneDx. "The economic burden of rare disease is estimated to be \$1 trillion annually, with the absence of early diagnosis being a major contributor to this cost and the cause for unnecessary and avoidable suffering faced by too many families. With our differentiated capabilities, GeneDx is setting the standard for the use of genetics in healthcare. We ended 2024 with momentum and are only beginning to unlock our full potential."

"Our Q4 performance reflects strong execution as we expect to deliver a second consecutive quarter of adjusted net income and our first quarter of positive operational cash flow," said Kevin Feeley, CFO of GeneDx.

Preliminary Full Year and Fourth Quarter 2024 Financial Results (Unaudited)

Management expects GeneDx to report:

Revenues

- Revenues¹ of at least \$299 million for full year 2024, an increase of 54% year-over-year (previous guidance was \$284-\$290 million).
- Revenues¹ of at least \$92 million in the fourth quarter 2024, an increase of 59% year-over-year and 20% sequentially.
- Exome and genome test revenues of at least \$75.8 million in the fourth quarter 2024, an increase of 93% year-over-year and 26% sequentially.

Gross Margin¹

- Adjusted gross margin of at least 64% for full year 2024 (previous guidance was at least 62%).
- Adjusted gross margin of at least 68% for the fourth quarter 2024, up from 64% in the third quarter of 2024.

Full year and fourth quarter 2024 revenues and adjusted gross margin includes \$6.8 million of discrete benefit in connection with a multi-year appeal recovery from a single third-party payer. The fourth quarter benefit is composed of \$5.8 million to exome genome revenues and \$1.0 million to other test lines.

Exome and genome volume

• Exome and genome test result volume of 20,676 in the fourth quarter, an increase of 32% year-over-year and 7% sequentially with exome and genome representing 38% of all tests result volume in the fourth quarter.

1. Revenue and adjusted gross margin results from continuing operations, which excludes any revenue from the exited Legacy Sema4 diagnostic testing business. Total Company Revenue for the full year and fourth quarter 2024 are expected to be at least \$302 million and \$92 million, respectively.

GeneDx has not completed the preparation of its consolidated financial statements for the year ended December 31, 2024. The preliminary, unaudited results presented in this press release for the quarter and year ended December 31, 2024, are based on current expectations and are subject to adjustment, as the company completes the preparation of its 2024 year-end consolidated financial statements and its 2024 year-end audit.

GeneDx will release financial results for the fourth quarter and full year of 2024 before the market opens on Tuesday, February 18, 2025. On the same day, management will host a conference call to discuss financial and operating results at 8:30 a.m. Eastern Time.

Investors interested in listening to the conference call are required to register online. A live and archived webcast of the event will be available on the "Events" section of the GeneDx investor relations website at https://ir.genedx.com/.

Safe Harbor Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws, including statements regarding our future performance and our market opportunity, including our preliminary, unaudited fourth quarter and full year 2024 revenue, fourth quarter and full year 2024 test result volumes, and fourth quarter 2024 operational cash flow and adjusted net income. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will be," "will continue," "will kely result," and similar expressions. Forward-looking statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including but not limited to: (i) our ability to implement business plans, goals and forecasts, and identify and realize additional opportunities, "(ii) the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, (iii) the size and growth of the market in which we operate, (iv) our ability to pursue our new strategic direction, and (v) our ability to enhance our artificial intelligence tools that we use in our clinical interpretation platform. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission (the "SEC") on February 23, 2024 and other documents. Forward-looking statements, whether as a result of new information, future events, or otherwise. We do not give any assurance that we will achieve our expectations.

About GeneDx

At GeneDx (Nasdaq: WGS), we believe that everyone deserves personalized, targeted medical care—and that it all begins with a genetic diagnosis. Fueled by one of the world's largest rare disease data sets, our industry-leading exome and genome tests translate complex genomic data into clinical answers that unlock personalized health plans, accelerate drug discovery, and improve health system efficiencies. For more information, please visit genedx.com and connect with us on LinkedIn, X, Facebook, and Instagram.

Investor Relations Contact: Investors@GeneDx.com

Media Contact: Press@GeneDx.com

GeneDx

J.P. Morgan Healthcare Conference January 2025 San Francisco, California

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Exhibit 99.2

Forward Looking Statements

This presentation contains forward-looking statements under the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that do not relate to historical facts and events and such statements and opinions pertaining to the future that, for example, contain wording such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "portinial," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about tour future performance and our market opportunity, our expectations regarding fourth quarter 2024 and full year 2024 revenue, adjusted gross margin profile and cash burn in 2024. We cannot assure that the forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

The forward-looking statements and opinions contained in this presentation are based on our management's beliefs and assumptions and are based upon information currently available to our management as of the date of this presentation and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Many factors could cause actual future events to differ materially from the forward-looking statements in this presentation, including but not limited to: (i) the ability to implement business plans, goals and forecasts, and identify and realize additional opportunities, (ii) the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, (iii) the size and growth of the market in which we operate, (iv) our ability to pursue our new strategic direction, and (v) our ability to enhance our artificial intelligence tools that we use in our clinical interpretation platform. The information, opinions and forward-looking statements contained in this announcement speak only as of its date and are subject to change without notice.

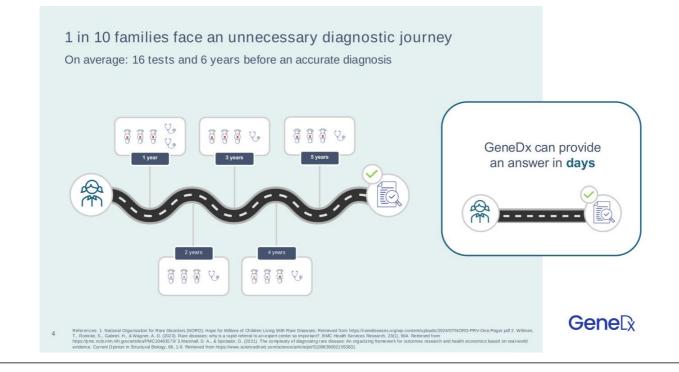
This presentation contains estimates, projections and other information concerning our industry, our business, and the markets for our products and services. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and ricumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

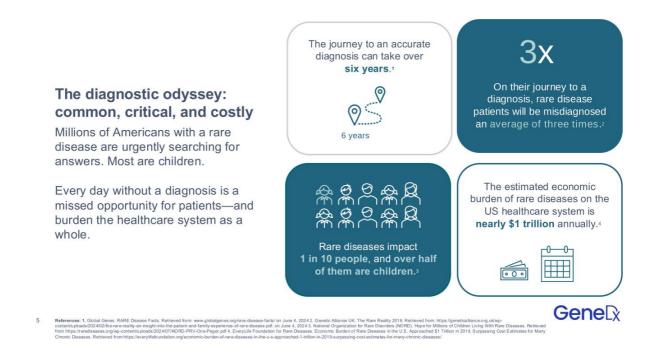
We discuss these and other risks and uncertainties in greater detail in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our periodic reports and other filings we make with the SEC from time to time. Given these uncertainties, you should not place undue reliance on the forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations. We file reports, proxy statements, and other information with the SEC. Such reports, proxy statements, and other information concerning us are available <u>www.sec.gov</u>. Requests for copies of such documents should be directed to our Investor Relations department at GeneDx Holdings Corp. 333 Ludlow Street, North Tower 6th Floor, Stamford, Connecticut, 06902. Our telephone number is 888-729-1206.



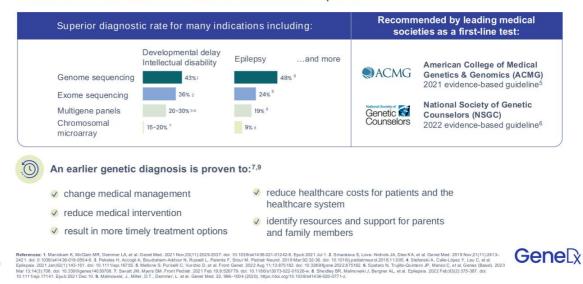
We envision a world where any genetic disorder is diagnosed quickly to prevent disease progression and ensure long and healthy lives for all.







Exome and genome testing offer answers sooner—leading to more effective treatments and more efficient healthcare spend

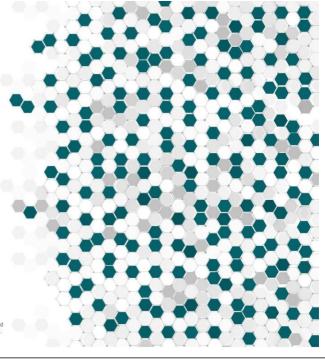


Common diseases are in fact a constellation of genetic diagnoses

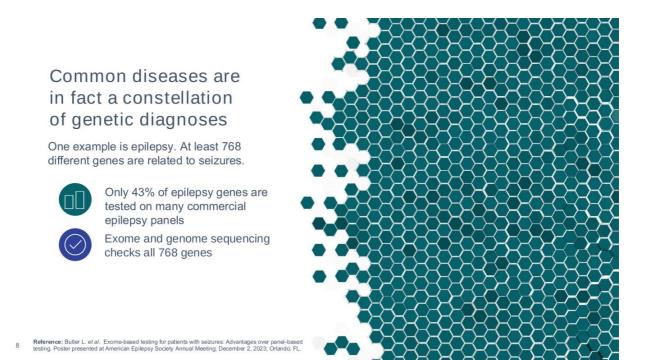
One example is epilepsy. At least 768 different genes are related to seizures.



Only 43% of epilepsy genes are tested on many commercial epilepsy panels



7 Reference: Butler L. et al. Exome-based testing for patients with seizures: Advantages over panel-based testing. Poster presented at American Epilepsy Society Annual Meeting; December 2, 2023; Orlando, FL.



GeneDx has spent over a decade solving for the limitations of the past and we're working to change the perception of exome and genome sequencing

	Then		Now
CO Turnaround time	Results take months	\rangle	GeneDx delivers results in days or weeks
\$ Cost	Tests are prohibitively expensive	\rangle	GeneDx's tests are accessible and widely covered by insurance
Interpretation	Results are confusing, filled with useless information	\rangle	Patients receive fewer variants of uncertain significance and more definitive answers
Actionability	Nothing to do or change based on the results	\rangle	Results unlock a growing number of approved therapies, clinical trials, dietary and behaviora health therapies
Value	Other testing (CT scan, MRI, gene panels) offers the same information	\rangle	Exome and genome uncover what other tests don't, which saves time & money

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Accelerating and deepening our competitive advantage with every patient

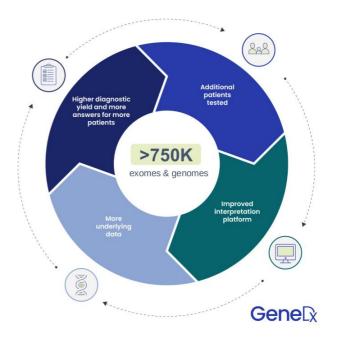
Pay it forward data strategy: the snowballing effect of data accumulated with ever patient we test drives our underlying interpretation platform to get smarter, faster, and more scalable



That's enable us to identify more than 400 new disease-gene relationships—and counting.



Patent applications have been filed to develop an IP portfolio directed to our innovative platform of genetic variant identification, clinical interpretation and innovative diagnostic tools developed using artificial intelligence.

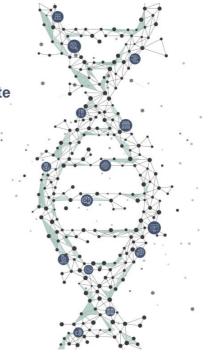


Our data is unmatched in size, breadth, and depth making it highly infeasible for competitors to recreate

- Enriched for rare disease
 Diagnosing even the rarest conditions for 25 years
- 60% of our exomes/genomes are parent/child trios Enabling *de novo* findings, sequencing asymptomatic parents
- 6 million phenotypic datapoints Bridging clinical information and genomic insights
- 10+ years of Medicaid patients tested Representing the full US population diversity

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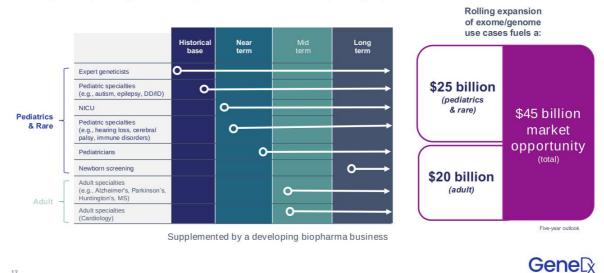
 All underpinned by expert annotation and curation Bringing answers to more patients today—without future reanalysis



•

Our market opportunity is massive and poised to expand over time

Taking a disciplined approach entering markets as reimbursement pathways open





Outpatient market expansion: Fueling growth with new indications, coverage and guidelines

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Today, GeneDx primarily targets epilepsy, autism and intellectual disability/developmental delay, congenital anomalies, and rare disease

 We have 80% market share among genetics experts, 12% among pediatric neurologists, and the rest is untapped



A disciplined approach to expand into **additional indications starting with** hearing loss, cerebral palsy and eventually adult disorders including various neurological, cardiology and other domains

Expect expanded clinical guidelines and reimbursement coverage over time

- American Academy of Pediatrics (AAP) last updated their genetic testing guidelines in 2014
- Contracted with ~80% of commercially-insured lives
- Medicaid coverage continues to expand



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Inpatient (NICU) market expansion: A clear unmet need, underscored by decades of earned trust and improved workflows



1 in 4 infants in U.S. NICUs likely have a genetic disorder1

- Genome testing is severely underutilized, currently ordered for <5% of children who could benefit²
- NICU orders represent only single digits of our current volume



GeneDx has decades of earned trust amongst children's hospitals and geneticists with 10+ years of exome/genome experience



We are expanding our enterprise sales team and implementing EPIC Aura in 2025 to begin penetrating with a more seamless experience to drive utilization

14 References: 1. Kingsmore SF, Cakici JA, Clark MM, et al. Am J Hum Genet. 2019 Oct 3:105(4):719-733. doi:10.1016/j.ajhg.2019.08.009. 2. Kingsmore SF, Notsinger R. & Ellsworth K. NPJ Genom. Med. 2024/9(17). doi:10.1038/s41525-024-04044-0.

Genetic evidence is one of the most powerful tools to improve the therapeutic development process

		Tomorrow
	Today	
The average therapeutic development cycle:		Including genetic evidence can dramatically reduce cost, shorten timelines, and improve success rates:
Costs \$2.6B		
 Up to 60% of this cost is spent in the clinical phase. 	0	Genetic evidence can reduce development costs by up to 25%.
Takes 12 years		
 Inefficient trials—driven by patient identification and recruitment challenges—extend timelines. 		Leveraging genetic data can cut development timelines by up to 5 years.
Fails 90% of the time		Drugs with supporting genetic evidence are
 Most trials fail due to safety and efficacy concerns. 	X	2.6 times more likely to succeed.

Our partnerships with biopharma companies help accelerate treatments from early discovery through commercialization

Our collaborations are impacting the lives of patients today:



We believe in a future where every newborn's genome is sequenced at birth

Every year, thousands of newborns with actionable conditions are missed by traditional newborn screening (NBS).

Federal NBS guidelines recommend testing for 37 conditions with biomarkers—measurable changes in the baby's blood that indicate the baby may have a disorder.

However, there are hundreds of actionable conditions that lack biomarkers.



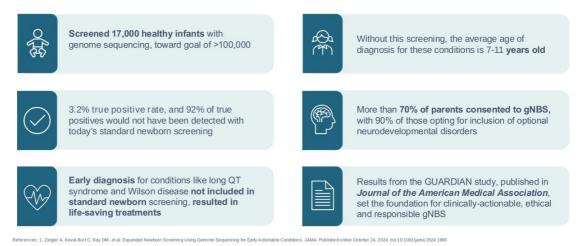
Genomic sequencing can detect conditions without biomarkers, expanding the number of conditions screened to ~450.

By supplementing traditional NBS with genomic sequencing, we can offer crucial information to improve health outcomes.

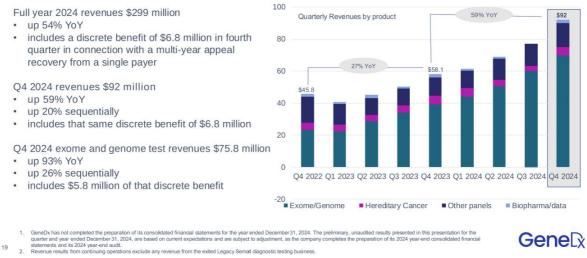
GeneDx is the leader set to revolutionize the standard approach to today's newborn screening, enabling diagnoses before symptoms even start

GeneDx has screened more newborns than any other commercial laboratory. This experience gives GeneDx a deep understanding of how to offer this testing at scale.

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Preliminary results¹ exceeded guidance: FY 2024 revenue² now expected to be \$299 million (previous guidance was \$284-290 million)



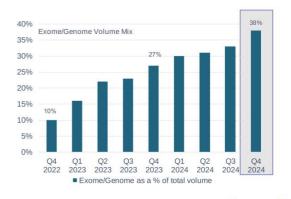
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Preliminary results¹ exceeded guidance: FY 2024 adjusted gross margin² now expected to be at least 64% for full year, 68% for Q4 (previous guidance was at least 62% for full year)

- Gross profit benefiting from all three of mix shift towards exome/genome, improved reimbursement and lower production costs
 Q4 2024 exome/genome volume up 32% year-over-year and 7% sequentially
 Exome and genome volume mix 38% of all tests' result volume







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of our ongoing business strategy exclude any revenue and cost of goods sold from the exited Legacy Sema4 g depreciation, amortization, share-based compensation and any restructuring costs.

Multiple drivers to profitable, sustainable growth	 Expanding serviceable market New use cases/ indications / call points stemming from emerging guidelines, expanding and, secular tailwinds towards greater acceptance of exome/genome The American Academy of Pediatrics last issued their genetic testing guidelines in 2014. An update in support of an exome/genome first approach for genetics, may unlock the pediatrician call point, of which there are nearly 80 thousand in the U.S.
	 Driving into the inpatient NICU setting SeqFirst and other study data supporting the clinical and economic case for a first-line approach in the NICU EPIC Aura go-live Q2 2025
	 Increasing penetration in outpatient setting GeneDx enjoys an ~80% market share of clinical exome/genome ordered in the U.S. today yet we are still only ~12% penetrated in the pediatric neurology market
	 Reducing denials improving coverage Reduction in Medicaid denials via additional states providing exome/genome reimbursement policies Reduction in third-party commercial denials through continued refinement of operational processes
	 New product launches Launch additional solutions for biopharma Alternative pathways for access and ordering Newborn screening (future)
	 Expanding margins Further cost per test declines via introduction of automation/AI across various dry-side processes Leverageable commercial spend
21	 Strong capital base Turned adj. EBITDA profitable in Q3 2024 Expecting Q4 2024 to deliver our second consecutive quarter with adjusted net income and our first quarter of positive operational cash flow

A rare opportunity to fuel seismic healthcare shifts

From years of disease progression

From unnecessary and bloated health costs

From generalized treatments

From diagnosing symptomatic disease

to

early interventions streamlined economic efficiency

precision medicines

universal genomic newborn screening



