

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 12, 2023 (January 12, 2023)**

GeneDx Holdings Corp.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

001-39482

(Commission File Number)

85-196622

(I.R.S. Employer Identification No.)

333 Ludlow Street, North Tower, 8th Floor
Stamford, Connecticut

(Address of Principal Executive Offices)

06902

(Zip Code)

(800) 298-6470

Registrant's telephone number, including area code
(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(s)	Name of each exchange on which registered
Class A common stock, par value \$0.0001 per share	WGS	The Nasdaq Global Select Market
Warrants to purchase one share of Class A common stock, each at an exercise price of \$11.50 per share	WGSWW	The Nasdaq Global Select 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 January 12, 2023, GeneDx Holdings Corp. (the "Company") is furnishing as Exhibit 99.1 hereto a copy of the investor presentation to be used at the 41st Annual J.P. Morgan Healthcare Conference event.

The information in this current report on Form 8-K and the exhibit attached hereto 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, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation, dated January 12, 2023
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 12, 2023

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

One Test: Miss Less. Discover More.
GeneDx (Nasdaq: WGS)

Katherine Stueland
President and Chief Executive Officer

41st Annual JPMorgan Healthcare Conference
January 12, 2023
San Francisco



Disclaimer

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," "potential," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained in this presentation include, but are not limited to, statements about: our future performance and our market opportunity, including our preliminary, unaudited pro forma revenue, pro forma test result volumes and pro forma adjusted gross margins for 2022, our expected full year 2023 reported revenue guidance, our expectations regarding our gross margin profile in 2023 and beyond, our use of cash for continuing operations and our cash burn in 2023 and our turning profitable in 2025, our expectations for our growth and future investment in our business, our expectations regarding our plans to pursue a new strategic direction and exit our reproductive health and somatic tumor testing businesses, including statements regarding our future performance and our market opportunity, including our preliminary, unaudited pro forma revenue, pro forma test result volumes and pro forma adjusted gross margins for 2022, our expected full year 2023 reported revenue guidance, our expectations regarding our gross margin profile in 2023 and beyond, our use of cash for continuing operations and our cash burn in 2023 and our turning profitable in 2025, our expectations for our growth and future investment in our business, our expectations regarding our plans to pursue a new strategic direction and exit our reproductive health and somatic tumor testing businesses, our addressable market, market growth, future revenue, key performance indicators, expenses, capital requirements and our needs for additional financing, our commercial launch plans, our strategic plans for our business and products, market acceptance of our products, our competitive position and developments and projections relating to our competitors, domestic and foreign regulatory approvals, third-party manufacturers and suppliers, our intellectual property, the potential effects of government regulation and local, regional and national and international economic conditions and events affecting our business. We cannot assure that the forward-looking statements in this presentation will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. These 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 completion of the preparation of our 2022 year-end financial statements (including all required disclosures) and our 2022 year-end audit; (ii) the ability to implement business plans, goals and forecasts, and identify and realize additional opportunities, (iii) the risk of downturns and a changing regulatory landscape in the highly competitive healthcare industry, (iv) the size and growth of the market in which we operate, and (v) our ability to pursue our new strategic direction, and exit our reproductive health and somatic tumor testing businesses. The information, opinions and forward-looking statements contained in this announcement speak only as of its date and are subject to change without notice.

Use of Non-GAAP Financial Measures

This presentation includes non-GAAP financial measures, including Adjusted Gross Margin. We define Adjusted Gross Margin as our Adjusted Gross Profit divided by our revenue. Adjusted Gross Profit is a non-GAAP financial measure that we define as revenue less cost of services, excluding stock-based compensation expense and restructuring costs. Management believes that these non-GAAP measures of financial results are useful in evaluating the GeneDx's operating performance compared to that of other companies in its industry, as this metric generally eliminates the effects of certain items that may vary from company to company for reasons unrelated to overall operating performance.

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 circumstances 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 www.sec.gov. Requests for copies of such documents should be directed to our Investor Relations department at GeneDx Holdings Corp. 333 Ludlow Street, North Tower, 8th Floor, Stamford, Connecticut, 06902. Our telephone number is 800-298-6470.

Our mission: deliver personalized and actionable health insights to inform diagnosis, direct treatment and improve drug discovery.

GeneDx

The problem: lack of genomic data and connectivity with EMR



Symptoms

Tests are ordered



More tests

But no answers



Try new doctors

But no records



Suboptimal care

Waiting for answers
that come too late



Patients miss milestones

Waiting for a proper
diagnosis



More tests

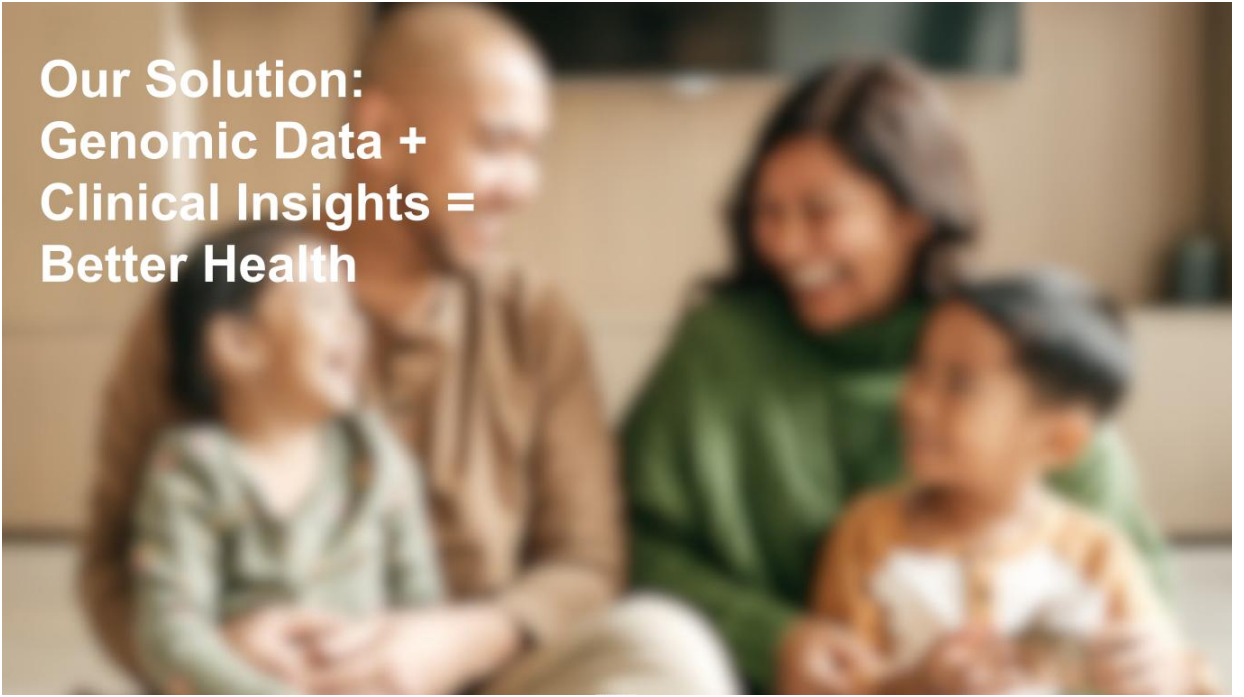
And more spending

Years of missed
diagnosis leads to:

- Inappropriate treatments
- Increased costs on the healthcare system
- Suffering for patients and families
- Stress on providers
- Missed opportunities to develop treatments and solutions

GeneDx

**Our Solution:
Genomic Data +
Clinical Insights =
Better Health**



Built by GeneDx: Genomic interpretation platform

Since our inception more than 20 years ago, we believe we offer the **most definitive genomic analysis in the industry**, borne from over a decade of constructing our proprietary data sets

>400K clinical
exomes

>2.7 million
phenotypes

> 1 million DNA
extractions

>400 gene discovery
publications

Invested in:

- Scalable genome lab and informatics
- New commercial strategy and team
- Medical affairs and managed care

GeneDx

Built by Sema4: Centrellis health insights platform

We've spent over 10 years developing the most sophisticated dataset in the industry, complete with custom algorithms and more accurate analyses

3.1 million patient health records

8 million disease diagnoses

47 million phenotypes

20 years of records abstracted from **56 million** clinical documents

- Strengthening data asset for Centrellis
- Reorganized product and technology team for scale
- Discontinued reproductive health, somatic oncology, commercial operations

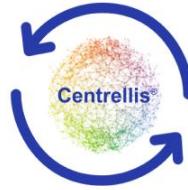
GeneDx

Best of both creates a seamless solution



Sequence once

Expand the use of and deliver best in class whole exome/genome analysis & interpretation



Combine clinical + genomic data

Match structured clinical and genomic data and supplement with disease models to drive insights



Generate genomic insights over time

Generate patient-specific and disease profiles to generate actionable reports upon presentation of symptoms

Providing actionable insights - Leveraging clinical data adds a critical layer onto what we know from structured genomic data including, phenotypic information, symptoms, family history, and longitudinal data

GeneDx

**The strategy is working:
high volume and revenue
growth, expanding gross
margins, reduced cash
burn**

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Preliminary 2022 Financial Results¹

Excluding revenues and costs from the exited business activities, we expect GeneDx to:

- Generate pro forma revenues between **\$170-173 million** in 2022, a **37-40% increase** from 2021
- Produce pro forma test result volume of **>180,000** in 2022, a **23% increase** from 2021
- Deliver pro forma adjusted gross margin between **38-41%** in 2022, a **34% increase** from 2021²

1. GeneDx has not completed the preparation of its financial statements for the year ended December 31, 2022. The preliminary, unaudited results presented in this presentation for the year ended December 31, 2022, are based on current expectations and are subject to adjustment, as the company completes the preparation of its 2022 year-end financial statements and its 2022 year-end audit. Further, the preliminary unaudited results for 2022 and the comparable results for 2021 are presented on a pro forma basis assuming GeneDx and Sema4 were combined for the entirety of 2021 and 2022 and exclude the revenues and costs from the exited reproductive health and somatic tumor testing businesses. Actual results may differ materially from those disclosed in this presentation and will include the results of the legacy GeneDx business only from the date of Sema4 Holdings Corp.'s acquisition of GeneDx on April 29, 2022, the purchase accounting associated with the acquisition of GeneDx, and will also include the financial impacts of exited Sema4 business activities for the full year.

2. Adjusted gross margin is a non-GAAP financial measure. GeneDx has not provided a reconciliation of its preliminary unaudited Adjusted Gross Margin to the most directly comparable GAAP measure because certain items excluded from GAAP cannot be reasonably calculated or predicted at this time. Accordingly, a reconciliation is not available without unreasonable effort.

GeneDx

2023 Guidance

Revenues between \$205-220 million for full year 2023

Expanded adjusted gross margin profile 2023 and beyond

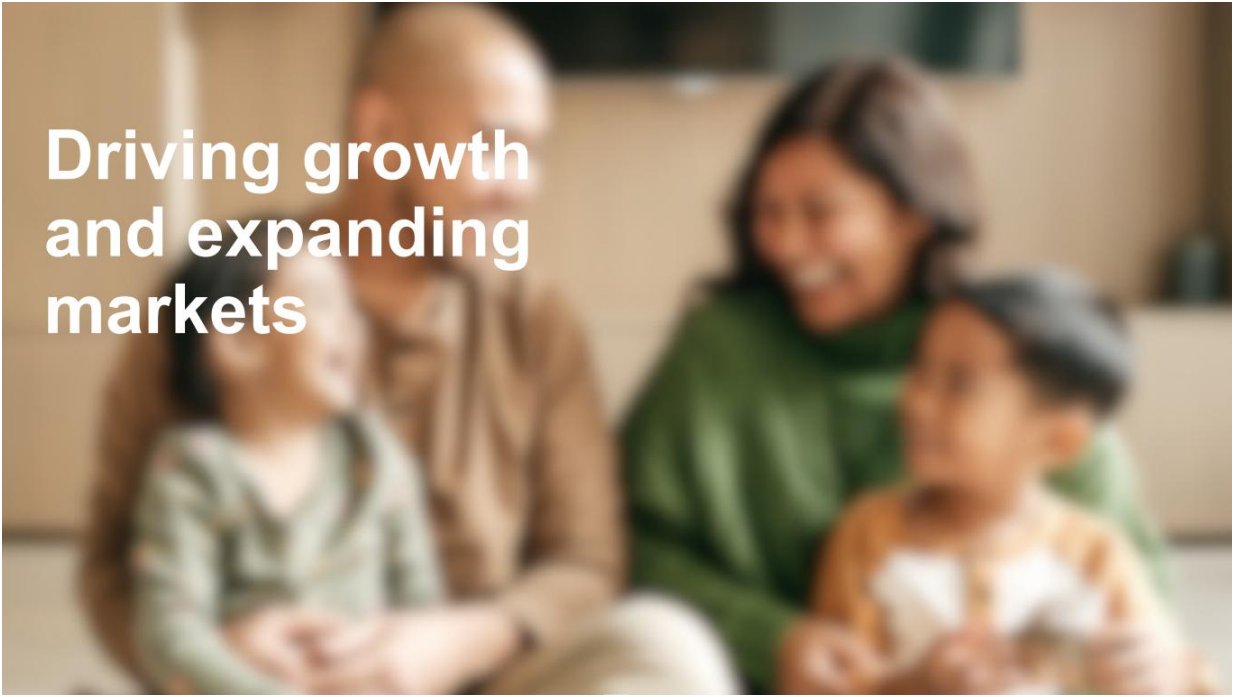
Use of net \$95-110 million in cash in 2023 for continuing operations

Inclusive of servicing obligations of the exited business activities, total cash burn in 2023 between \$130-145 million, a >50% reduction year-over-year

Turn to profitability in 2025



**Driving growth
and expanding
markets**



Quickly growing into a significant opportunity

Conservatively, our diagnostic testing total addressable market is ~\$30 billion¹



**Rare Disease
& Pediatrics: \$3B**

Rapidly growing patient
opportunity and substantial
cost savings via early screening



Adults: \$16B

Rapidly expanding into
cardio and neuro to replace status
quo panels and individual gene tests



**Newborn
Screening: \$10B**

Eventual inclusion of genetics
in screening programs

GeneDx

¹ Company Estimates supported by DefinitiveHC diagnosis data

Starting with rare disease and pediatrics



- >7000 individual diseases affecting 10% of the total population

- 400 million people worldwide

- 50% of people affected by rare diseases are children

- 700 medicines in development – same as oncology with regulatory pathway via Orphan Drug Act

GeneDx

Today's strategy expedites diagnoses, saves money per patient with rapid exome and genome sequencing
Starting with the most vulnerable patients



NICU Patient



Test ordered



Rapid results ✓



Patient retention ✓



Patients connected ✓



Healthier outcomes ✓

Faster answer → Better outcomes → Lower Costs

\$30,000¹ per case average savings
 in the NICU from reduced length of
 stay, unnecessary care (Inpatient)

\$6,800² savings per diagnosis
 when tested at first tertiary
 presentation for **Pediatric Delay**
Disorder (outpatient)

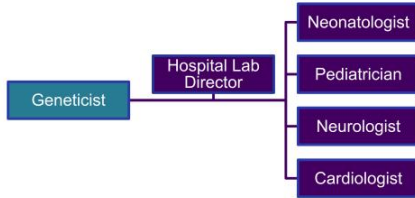


¹ScienceDaily. (2017, October 19). Rapid whole-genome sequencing of neonatal ICU patients is useful and cost-effective. ScienceDaily.
²Tan TY, Dillon OJ, Stark Z, et al. Diagnostic Impact and Cost-effectiveness of Whole-Exome Sequencing for Ambulant Children With Suspected
 Monogenic Conditions. JAMA Pediatrics. 2017;171(9):855. doi:10.1001/jamapediatrics.2017.1755

With a rapidly growing and loyal customer base

• Leveraging decades of earned trust amongst expert geneticists to expand into incremental call points and use cases

• 94% of pediatric specialists in the U.S. who order exome testing have ordered from GeneDx in the past 12 months¹.



¹Company estimates, Definitive Healthcare



+500



Emerging guidelines and medical policies underpin rapid growth

~70% of commercial payers have coverage for exome / WGS, when criteria are met and an ever growing number of commercial payers and Medicaid programs are adopting favorable coverage¹.

In January 2023, UnitedHealthcare® issues Medical Policy Update Bulletin which provides Exome/Whole Genome Sequencing coverage across their Commercial Plans, effective March 1, 2023

ACMG Practice Guideline published July 2021:

“Strong recommendation based on the available evidence to support the use of ES/GS as either a first- (or second-) line test in patients ES/ GS demonstrates clinical utility for the patients and their families with limited evidence for negative outcomes and the ever increasing emerging evidence of therapeutic benefit.”

NSGC Guideline recommended October 2022:

“Recommending Exome Sequencing as a First-Tier Genetic Test for Unexplained Epilepsies”

American Epilepsy Society recommends...Exome or genome sequencing are favored for most scenarios, as they are more likely to provide a diagnosis.

¹Company estimates, Definitive Healthcare



Transforming the standard of care



October 27, 2022

Sema4 | GeneDx Announces Results from Phase 1 of Seq First Study, Demonstrating Broad Utility of Rapid Whole Genome Sequencing for Critically Ill Newborns



October 5, 2022

Sema4 | GeneDx To Provide Whole Genome Sequencing and Interpretation Services for Landmark Genomic Newborn Screening Study



October 26, 2022

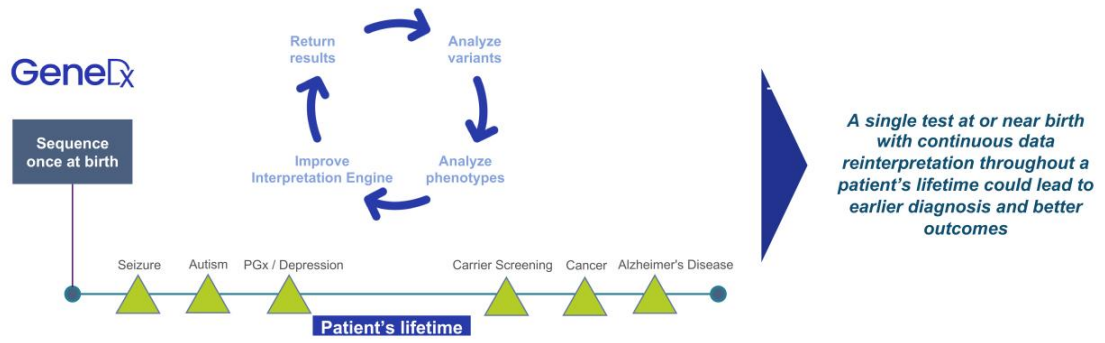
Sema4 | GeneDx collaborates on new research demonstrating genome and exome sequencing deliver more diagnostic certainty than multi-gene panels

July 2021

GeneDx one of only two labs selected to partner with UnitedHealthcare® in a NICU rapid exome sequencing program

GeneDx

Tomorrow's strategy delivers the promise of sequence once, analyze forever, deliver actionable information



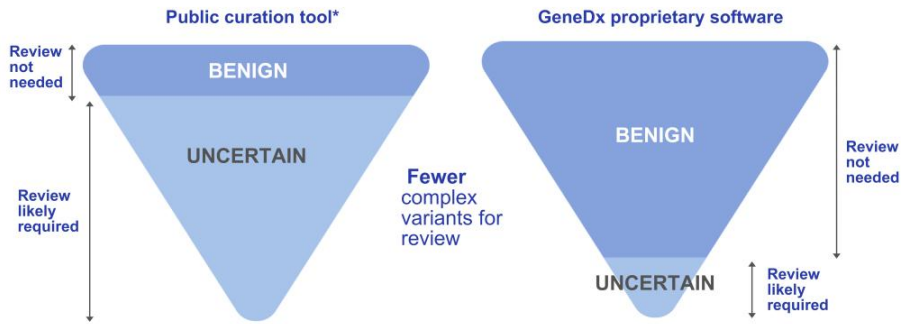
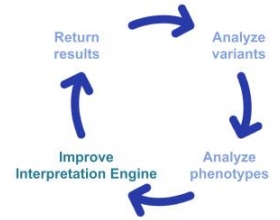
GeneDx

**Miss Less.
Discover More.**

Our unparalleled
interpretation
platform.

GeneDx

Delivering fewer uncertain findings, critical for expanding utilization



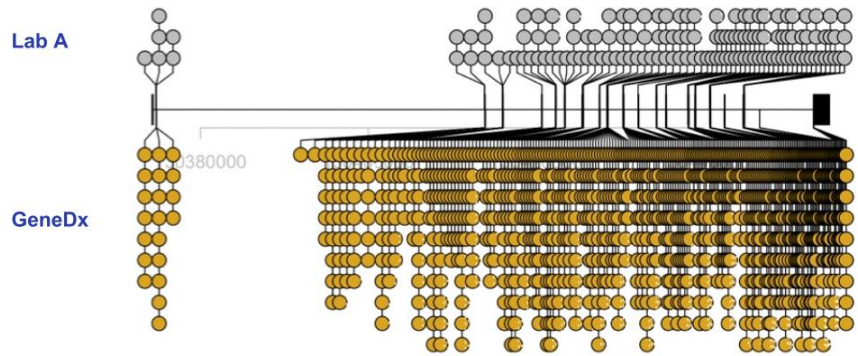
- Fewer uncertain findings lead to improved clarity for clinicians and patients
- More expertly curated disease-causing variants vs. public data sets
- Definitive diagnosis in more cases

GeneDx

*ClassifyCNV

Panels leave patients behind. Exome and genome do not.

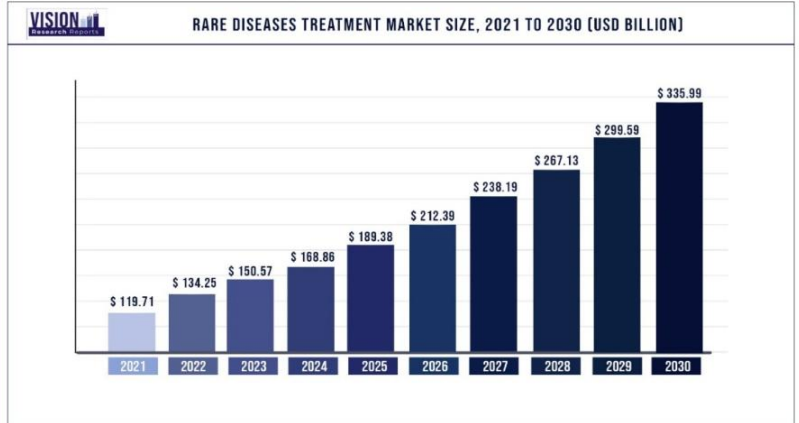
The snowball effect of accumulated GeneDx data identifies more pathogenic findings that others miss



GeneDx

Untapped partners: biopharma

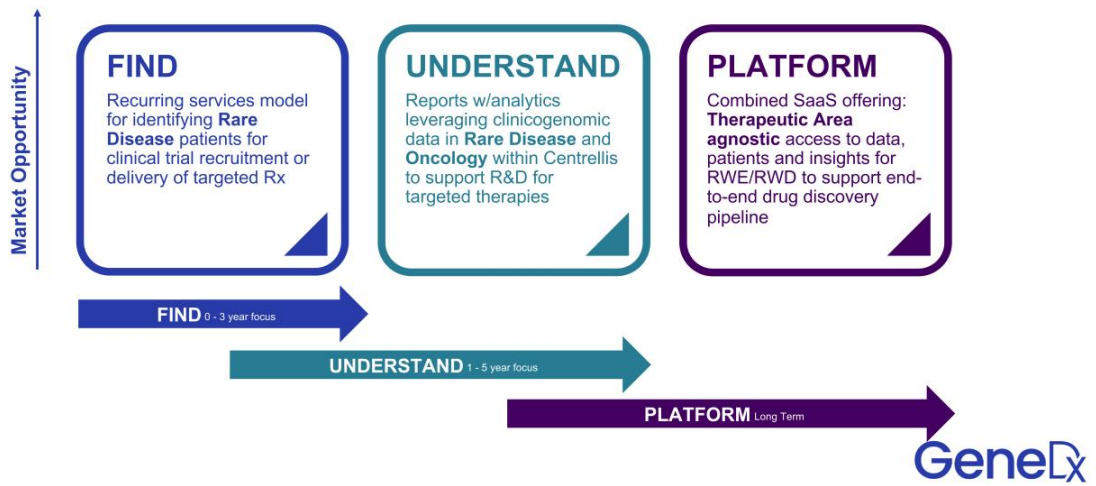
In 2020 alone, more than half (55%) of novel new drug and biological approvals were orphan drugs for rare diseases.



GeneDx

Data strategy leverages Centrellis as a solutions provider

Biopharma research offerings unlock upside as platform expands



Experienced management team with decades of leadership in genetics, data science, healthcare



Katherine Stueland
Chief Executive Officer



Jennifer Brendel
Chief Commercial Officer



Matthew Davis
Chief Technology & Product Officer



Kevin Feeley
Chief Financial Officer



Kareem Saad
Chief Transformation Officer



Gustavo Stolovitzky
Chief Science Officer



Karen White
Chief People Officer



One test. There's no one better.

GeneDx
