

# Our mission: eradicate cancer and the suffering it causes

#### **Evercore ISI HealthCONx conference**

Kevin Conroy, Chairman and CEO



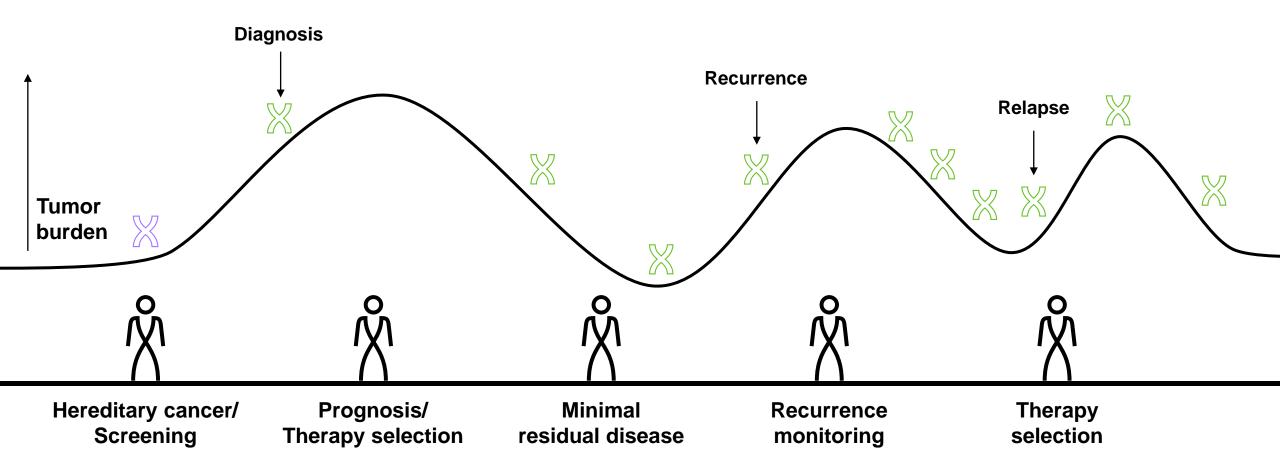
## Safe harbor statement

#### **Forward-Looking Statements**

Some of the information presented here today may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company. These statements are based on management's current expectations and the actual events or results may differ materially and adversely from these expectations. We refer you to the documents the Company files from time to time with the Securities and Exchange Commission. Specifically, the Company's most recent annual report on Form 10-K and any subsequently filed quarterly reports on Form 10-Q and current reports on Form 8-K. These documents identify important risk factors that could cause the actual results to differ materially from those contained in the Company's projections of forward-looking statements.

**EXACT SCIENCES** 

# Detecting cancer earlier at every step, starting with screening



# We plan to lead 3 of the largest impact opportunities in cancer diagnostics



multi-cancer early detection



colorectal cancer screening



minimal residual disease and recurrence monitoring





cologuard® 2.0 colon cancer blood test



**TARDIS** 

Notes: Cologuard 2.0 and colon cancer blood test have not been cleared or approved by the FDA; U.S. TAMs only Source: Exact Sciences estimates, includes U.S. markets only

# Supporting new innovative tests with rigorous scientific evidence

#### expected data readouts

	U.S. TAM	current evidence	1H 2022	2H 2022	1H 2023
Cologuard 2.0 colon blood	\$18B			X	X
multi-cancer	\$25B	X	X	X	
minimal residual disease	\$15B	X		X	



Note: these tests have not been cleared or approved by the FDA; Cologuard 2.0 and colon blood prospective data may not read out simultaneously Sources: https://www.exactsciences.com/publications





### problem

**#2** 

deadliest cancer in the U.S.

### opportunity

110<sub>M</sub>

Americans ages 45 to 85 recommended for screening

Sources: American Cancer Society Cancer Facts & Figures 2021; U.S. Census data; Exact Sciences estimates





### scientific approach

multi-marker stool test methylation + protein

lower false positive rate
improve precancer sensitivity

### planned path forward





Note: Cologuard 2.0 has not been cleared or approved by the FDA – targets presented here are goals for test performance





### problem

**57%** 

screening rate for 45 to 85 year olds

### opportunity

46M

unscreened Americans

Sources: Division of Cancer Prevention and Control, Centers for Disease Control and Prevention (2021); U.S. Census data; Exact Sciences estimates





### scientific approach

multi-marker blood test

provide another option to get screened

## planned path forward

case-control data

finish BLUE-C enrollment

2023 top-line BLUE-C readout

FDA submission

Medicare coverage

USPSTF inclusion

primary care launch

Note: colon cancer blood test has not been cleared or approved by the FDA





problem

70%

of diagnosed cancers have no standard screening test opportunity

**115**M

Americans between ages 50 and 85 who could be screened

Sources: NIH. "SEER Mortality Data, 2006-2015." <a href="https://seer.cancer.gov/data/">https://seer.cancer.gov/data/</a>; U.S. Census data; Exact Sciences estimates





#### **EXAS** case-control study

86%
sensitivity
specificity
total samples
cases
controls
257

#### **Cohen case-control study**

62%	99%	
sensitivity	specificity	
total samples	1,817	
cases	1,005	
controls	812	
types of cancer	8	

#### **Detect-A prospective study**

<b>27</b> %	<b>99</b> %
sensitivity	specificity

women tested	9,911

**no cancer** 9,815

types of cancer 10

Sources: A. M. Lennon et al., Science (2020); J. D. Cohen et al., Science (2018)

Note: EXAS case-control data are preliminary from a study of 180 cases and 257 controls; validation set was 1/3 of total samples; currently evaluating whether performance is maintained in early-stage disease across additional cancers; performance degradation is typical when moving from smaller case-control to larger prospective trials; stage breakdown: 5 stage I, 43 stage II, 65 stage IV, 11 un-staged

types of cancer





### scientific approach

multi-marker blood test and PET-CT follow up

methylation + mutation + protein + other class

#### planned path forward



marker selection & 2022 assay lock data



pivotal trial launch



early access launch to generate evidence

interim data & after readout

**FDA** submission

Medicare coverage



**USPSTF** inclusion



primary care launch



# minimal residual disease & recurrence monitoring



problem

85%

of relapses are caught too late for curative surgery

opportunity

**12**M

testing opportunities for patients in the U.S.

Sources: M. Elferink et al., Springer (2014); Exact Sciences estimates



# minimal residual disease & recurrence monitoring



#### scientific approach

#### tumor-informed:

TARDIS technology allows evaluation of up to 115 mutations

tumor-naive: multi-marker approach

#### planned path forward



2022

retrospective CRC validation data



multiple prospective studies underway

2023

& after

early access

500

interim CORRECT-MRD readout



Medicare coverage



full Precision
Oncology launch

Source: B. McDonald et al., Sci. Transl. Med. (2019)



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Q&A

