

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, 2020

EXACT SCIENCES CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35092
(Commission
File Number)

02-0478229
(I.R.S. Employer
Identification No.)

441 Charmany Drive
Madison, WI 53719
(Address of Principal Executive Offices)(Zip Code)

Registrant's telephone number, including area code: (608) 284-5700

Not Applicable
(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, \$0.01 par value per share	EXAS	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

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.

2.02. Results of Operations and Financial Conditions.

On January 12, 2020, Exact Sciences Corporation (the "Company") announced certain preliminary financial information for the quarter and full year ended December 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

7.01 Regulation FD Disclosure.

Attached hereto as Exhibit 99.2 is a PowerPoint presentation that the Company will present at the 2020 J.P. Morgan Healthcare Conference in San Francisco on January 15, 2020.

9.01. Financial Statements and Exhibits.

Exhibits

The exhibits furnished as a part of this Current Report on Form 8-K are listed in the Exhibit Index attached hereto and incorporated herein by reference.

The information furnished in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press release, dated January 12, 2020, issued by Exact Sciences Corporation, furnished herewith.
99.2	PowerPoint presentation to be used by Exact Sciences Corporation on January 15, 2020, at the J.P. Morgan Healthcare Conference, furnished herewith.

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.

EXACT SCIENCES CORPORATION

Date: January 13, 2020

By: /s/ Jeffrey T. Elliott
Jeffrey T. Elliott
Chief Financial Officer

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For Immediate Release

Exact Sciences Announces Preliminary Fourth Quarter 2019 Results

- Expected total revenue of \$294-296M, including Screening revenue of \$229-230M, an increase of 61 percent from 2018, and Precision Oncology revenue of \$65-66M for period Nov. 8, 2019 through Dec. 31, 2019
- Expected Precision Oncology proforma revenue for full fourth quarter of \$118-119M, an increase of 13 percent from 2018

MADISON, Wis., Jan. 12, 2020 — Exact Sciences Corp. (Nasdaq: EXAS) today announced that the company expects to report revenue between \$294 million and \$296 million for the fourth quarter ended Dec. 31, 2019.

"Building off a transformative 2019, Exact Sciences is uniquely positioned to change the way cancer is diagnosed and treated," said Kevin Conroy, chairman and CEO of Exact Sciences. "Following our combination with Genomic Health, we have the leading scientific minds, an experienced commercial team with deep relationships, and the global footprint necessary to support the growth of current and future cancer diagnostics. We've never been more excited about the future of Exact Sciences."

Preliminary, Unaudited Fourth-Quarter 2019 Financial Results

For the three-month period ended December 31, 2019, as compared to the same period of 2018 (where applicable):

- Expected total revenue between \$294 million and \$296 million
- Expected Screening revenue between \$229 million and \$230 million, an increase of 61 percent
- Expected Precision Oncology revenue between \$65 million and \$66 million for the period Nov. 8, 2019 through Dec. 31, 2019, following the close of the Genomic Health acquisition
- Expected Precision Oncology proforma revenue for the full fourth quarter between \$118 million and \$119 million, an increase of 13 percent, assuming Genomic Health were a standalone entity
- Cologuard® test volume was 477,000, an increase of 63 percent
- Oncotype DX® test volume was 41,000, an increase of 14 percent

Preliminary, Unaudited 2019 Financial Results

For the twelve-month period ended December 31, 2019, as compared to the same period of 2018 (where applicable):

- Expected total revenue between \$874.5 million and \$876.5 million, including Precision Oncology revenue between \$65 million and \$66 million for the period Nov. 8, 2019 through Dec. 31, 2019, following the close of the Genomic Health acquisition
- Expected Screening revenue between \$809.5 million and \$810.5 million, an increase of 78 percent
- Expected Precision Oncology proforma revenue between \$455 million and \$456 million, an increase of 16 percent, assuming Genomic Health were a standalone entity
- Cologuard test volume was 1.68 million, an increase of 80 percent
- Oncotype DX test volume was 156,000, an increase of 14 percent

For the fourth quarter and 2019, Screening includes revenue from Cologuard and Biomatrica products. Precision Oncology includes global Oncotype DX product revenue. Proforma revenue figures for Precision Oncology for the three and twelve-month periods ended Dec. 31, 2019 include results prior to the acquisition of Genomic Health by Exact Sciences which closed on Nov. 8, 2019.

Exact Sciences has not completed preparation of its financial statements for the fourth quarter or full year of 2019. The revenue ranges presented in this news release for the fourth quarter of 2019 and for the year ended Dec. 31, 2019 are preliminary and unaudited and are thus inherently uncertain and subject to change as we complete our financial results for the fourth quarter of 2019. We are in the process of completing our customary year-end close and review procedures as of and for the year ended Dec. 31, 2019, and there can be no assurance that our final results for this period will not differ from these estimates. During the course of the preparation of our consolidated financial statements and related notes as of and for the year ended Dec. 31, 2019, we or our independent registered public accountants may identify items that could cause our final reported results to be materially different from the preliminary financial estimates presented herein.

Exact Sciences plans to report 2019 financial results and provide guidance during its February 2020 earnings call.

About Cologuard

Cologuard was approved by the FDA in August 2014, and results from Exact Sciences' prospective 90-site, point-in-time, 10,000-patient pivotal trial were published in the New England Journal of Medicine in March 2014. Cologuard is included in the American Cancer Society's (2018) colorectal cancer screening guidelines and the recommendations of the U.S. Preventive Services Task Force (2016) and National Comprehensive Cancer Network (2016). Cologuard is indicated to screen adults 45 years of age and older who are at average risk for colorectal cancer by detecting certain DNA markers and blood in the stool. Do not use Cologuard if you have had precancer, have inflammatory bowel disease and certain hereditary syndromes, or have a personal or family history of colorectal cancer. Cologuard is not a replacement for colonoscopy in high risk patients. Cologuard performance in adults ages 45-49 is estimated based on a large clinical study of patients 50 and older. Cologuard performance in repeat testing has not been evaluated.

The Cologuard test result should be interpreted with caution. A positive test result does not confirm the presence of cancer. Patients with a positive test result should be referred for diagnostic colonoscopy. A negative test result does not confirm the absence of cancer. Patients with a negative test result should discuss with their doctor when they need to be tested again.

Medicare and most major insurers cover Cologuard. For more information about Cologuard, visit www.cologuardtest.com. Rx Only.

About Oncotype DX

The Oncotype DX® portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. In breast cancer, the Oncotype DX Breast Recurrence Score® test is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score® test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention, and the Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego and offered exclusively by Exact Sciences. With more than 1 million patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com, www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org.

About Exact Sciences Corp.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter solutions providing the clarity to take life-changing action, earlier. Building on the success of Cologuard and Oncotype DX, Exact Sciences is investing in its product pipeline to take on some of the deadliest cancers and improve patient care. Exact Sciences unites visionary collaborators to help advance the fight against cancer. For more information, please visit the company's website at www.exactsciences.com, follow Exact Sciences on Twitter @ExactSciences, or find Exact Sciences on Facebook.

Forward-Looking Statements

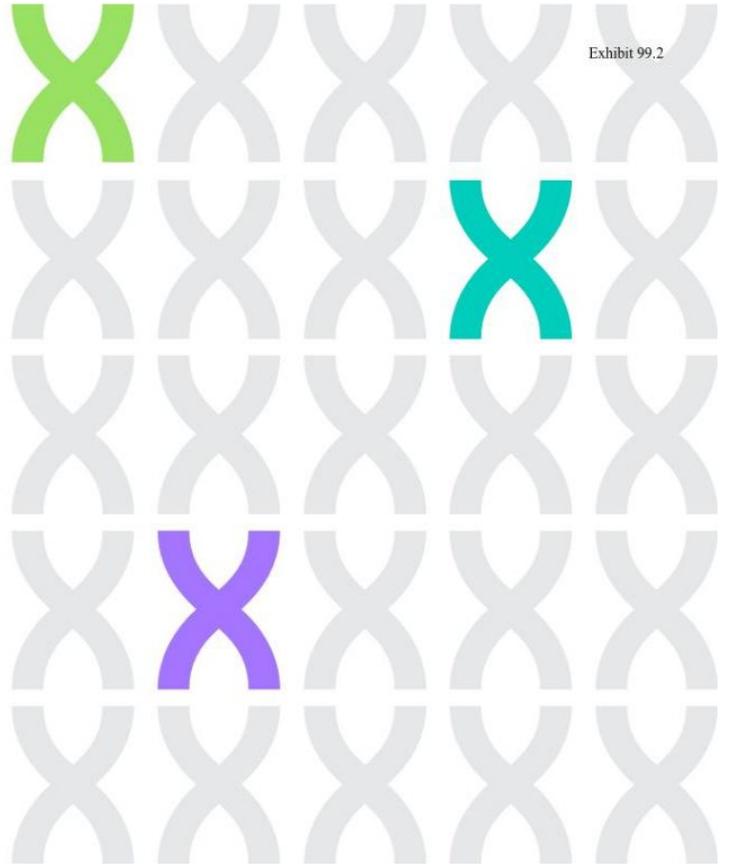
This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this news release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of

forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales, marketing and patient adherence efforts, expectations concerning payer reimbursement, the anticipated results of our product development efforts and the anticipated benefits of our acquisition of Genomic Health, including estimated synergies and other financial impacts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; the amount and nature of competition from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services and assess potential market opportunities; our ability to effectively utilize strategic partnerships, such as through our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; the possibility that the anticipated benefits from our acquisition of Genomic Health cannot be realized in full or at all or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of Genomic Health's operations will be greater than expected; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

Building the Leading Cancer Diagnostics Company

Kevin Conroy, Chairman and CEO

January 15, 2020



Safe harbor statement

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate" or other comparable terms. All statements other than statements of historical facts included in this presentation regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales, marketing and patient adherence efforts, expectations concerning payer reimbursement, the anticipated results of our product development efforts and the anticipated benefits of our acquisition of Genomic Health, including estimated synergies and other financial impacts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; the amount and nature of competition from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services and assess potential market opportunities; our ability to effectively utilize strategic partnerships, such as through our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; the possibility that the anticipated benefits from our acquisition of Genomic Health cannot be realized in full or at all or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of Genomic Health's operations will be greater than expected; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; and the other risks and uncertainties described in the Risk Factors and in Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.



EXACT SCIENCES

We strive to **change lives** through earlier detection and smarter answers for cancer patients.



2019 Screening results

Preliminary, unaudited financials

	Q4 2019	2019	
Revenue	\$229-230M	\$809.5-810.5M	78% 2019 Y/Y revenue growth
Cologuard® tests	477K	1.68M	
New Cologuard providers	12K	50K	

2019 Precision Oncology results

Preliminary, unaudited financials

	Partial Q4 2019*	Proforma Q4 2019**	Proforma 2019**	
Revenue	\$65-66M	\$118-119M	\$455-456M	16% 2019 Y/Y revenue growth
Oncotype DX® tests	23K	41K	156K	

*Revenue reported on a GAAP basis from the close of the Genomic Health combination through the end of 2019 (11/8/19-12/31/19)

**Revenue that would have been recognized for the full fourth quarter and year if Genomic Health were a standalone entity

Key 2019 accomplishments

Power the Partnership

Genomic Health combination

Cologuard tests increased 80%
Cologuard ordering providers increased 34%
Lab capacity expanded to 7M tests

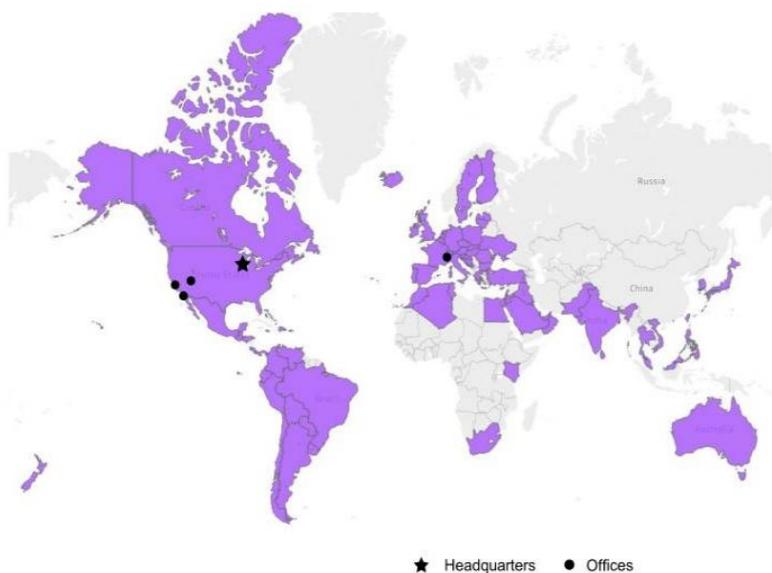
Enhance Cologuard

Cologuard 45-49 label expansion
Cologuard 2.0 data release
BLUE-C initiation

Advance Liquid Biopsy

Liver data release

Leading, global, advanced cancer diagnostics company



Exact Sciences

4,000+
employees

1,000+
commercial organization

\$1.6B+
projected 2020 revenue

Positioned for long-term success

SCREENING	PRECISION ONCOLOGY	INTERNATIONAL	PIPELINE
cologuard®	oncotypeDX®	oncotypeDX®	EXACT SCIENCES
Field teams	Field teams	Field team/presence	R&D team
500 primary care	100 oncology	40 oncology	250 people
60 gastroenterology	50 urology	90 countries	Liver
35 health system			Pancreatic
			Esophageal
			Bladder

2020 Corporate Priorities

Deliver More **Answers**

Enhance Customer **Experience**

Power New **Growth**



1

Screening

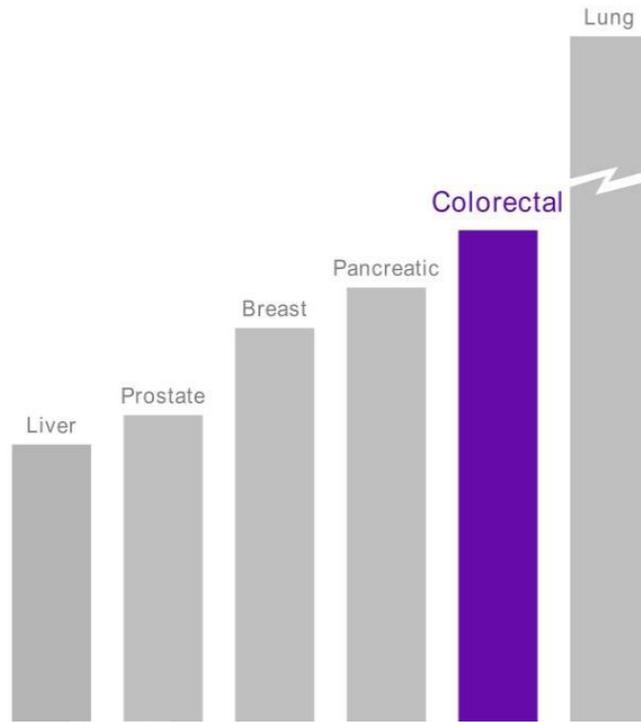
Ernst & Young

10



Colorectal cancer: America's second deadliest cancer

53,200
annual deaths

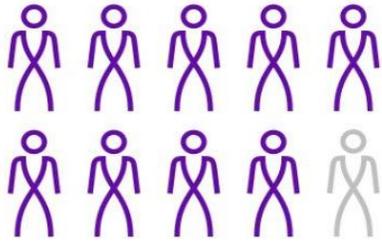


Source: American Cancer Society, Cancer Facts & Figures 2020; all figures annual

Exact Sciences

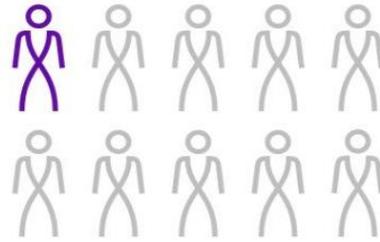
Detecting colorectal cancer earlier is critical

Diagnosed in Stages I or II



9/10 survive 5 years

Diagnosed in Stage IV



1/10 survive 5 years

Source: SEER 18 2009-2015, colorectal cancer statistics

Exact Sciences

Cologuard: addressing the colorectal cancer challenge



94%

Early-stage cancer sensitivity*

Easy to use

No preparation

No time off work

Non-invasive

No sedation

24/7 customer support

For adults 45 years or older and at average risk

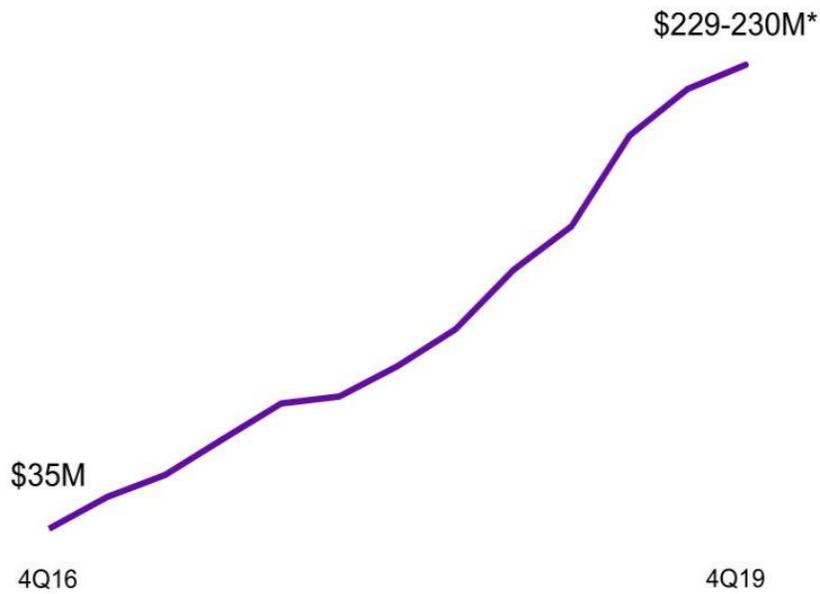
Developed with



MAYO CLINIC

*For stage I and II cancers; 92% sensitivity overall, 87% specificity
Source: Imperiale TF et al., N Engl J Med (2014)

Demand fueling strong Cologuard growth



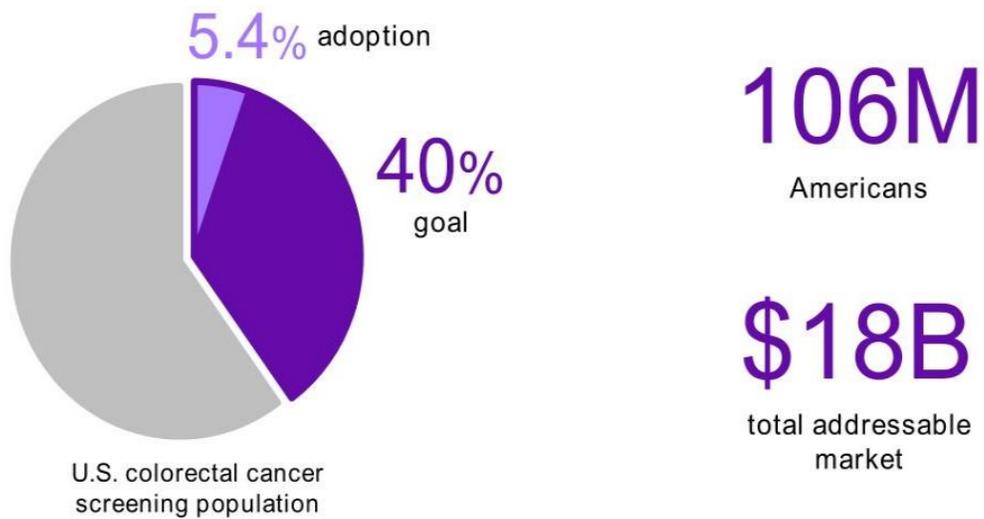
3.5M+

people screened since launch

*Preliminary, unaudited Screening business unit Q4 2019 revenue

Exact Sciences

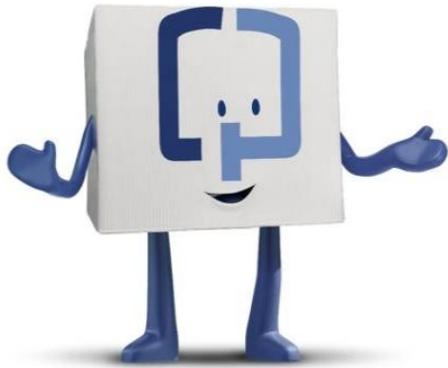
Capturing a large U.S. screening opportunity



Source: Exact Sciences estimates, assuming 106 million average-risk, asymptomatic people ages 45-85, revenue per test of \$500-\$525, and 3-year interval for Cologuard; market share = (477,000 completed tests in 4Q19 x 4 to annualize x 3 to account for interval) / 106M

Exact Sciences

Cologuard growth opportunities



Exact Sciences



Near-term
Sales team productivity



Mid-term
19M people ages 45-49



Long-term
Cologuard 2.0 enhancements

16

2

Precision Oncology

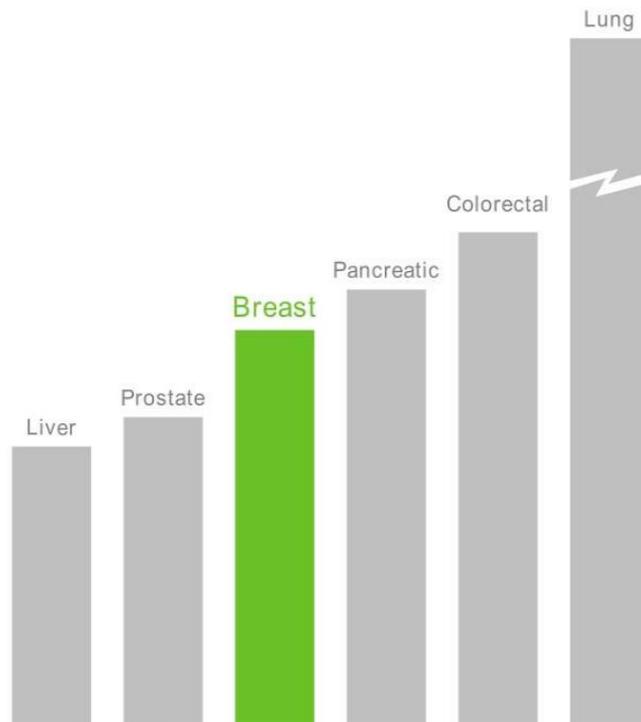
Exact Sciences

17



Breast cancer: America's fourth deadliest cancer

42,690
annual deaths



Source: American Cancer Society, Cancer Facts & Figures 2020; all figures annual

Exact Sciences

Guiding therapy for early-stage breast cancer



Prognostic and predictive

Early stage: HER2 (-) ER (+)
 Node (-) Node (+)



1. Sparano et al. N Engl J Med. 2018
2. Geyer et al. NPJ Breast Cancer. 2018

Oncotype DX: standard of care in breast cancer

1M+

patients tested

96K+

patients worldwide with published
prospective outcomes

150+

publications

ASCO®

NCCN®

ESMO

ST. GALLEN

NICE

Real-world evidence supporting Oncotype DX adoption

TAILORx

10,000 women, 9 years

Early-stage, **node-negative**
breast cancer

Published in June 2018

RxPONDER

4,000 women, up to 10 years

Early-stage, **node-positive**
breast cancer

Expected readout in 2022

Capturing a large global breast cancer opportunity

U.S. opportunity

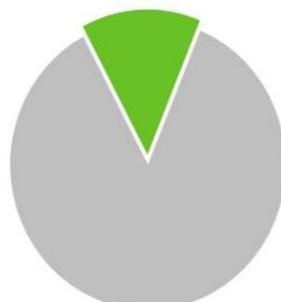
68% adoption



140K people
\$500M opportunity

International opportunity*

14% adoption



200K people
\$400M opportunity

Source: Exact Sciences estimates
*Opportunity in key strategic markets

Exact Sciences

Helping inform prostate cancer treatment recommendations

oncotypeDX[®]
Genomic Prostate Score

Predicts clinical risk and tumor aggressiveness



For low- and intermediate-risk patients



33K annual prostate cancer deaths in U.S.¹



Helps inform active surveillance vs. aggressive treatment



Changes treatment recommendation for 1/4 men²



15% adoption in \$440M U.S. opportunity³

1. American Cancer Society, Cancer Facts & Figures 2020; all figures annual

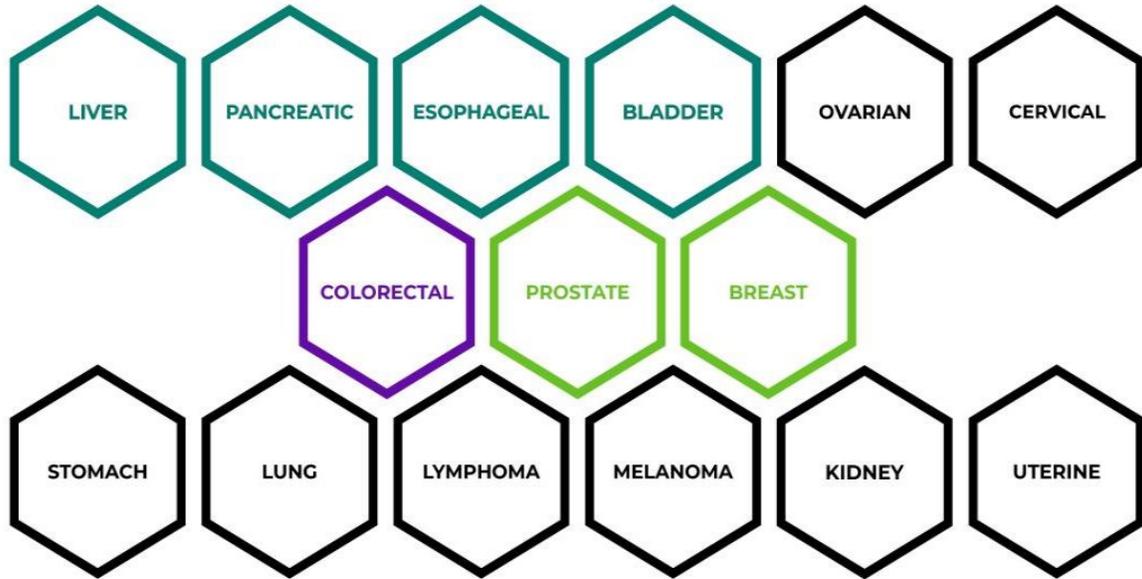
2. Badani et al. Urol Pract. 2015

3. Exact Sciences estimates

3

Pipeline





Deep R&D capabilities

Multiple classes of biomarkers

Proprietary DNA chemistry

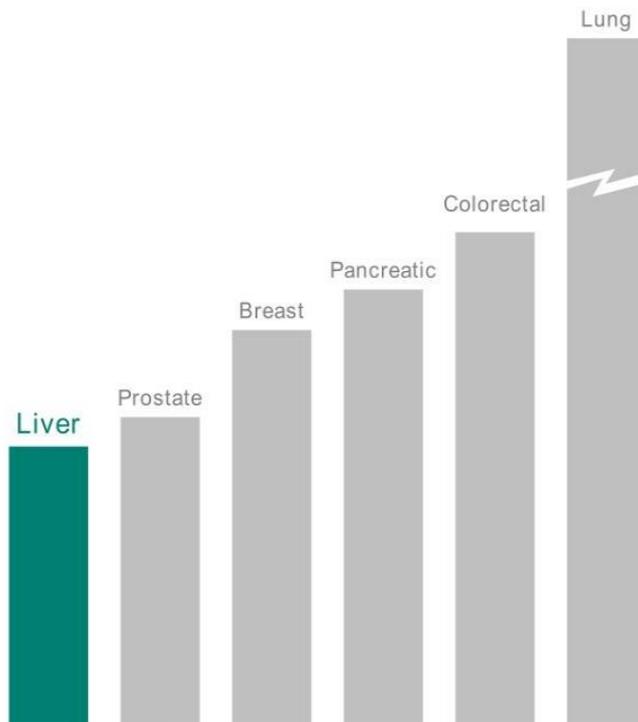
State-of-the-art labs

Flexible, automated platform



Liver cancer: America's sixth deadliest cancer

30,160
annual deaths

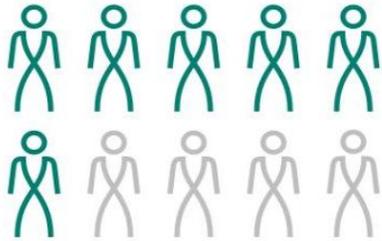


Source: American Cancer Society, Cancer Facts & Figures 2020; all figures annual

Exact Sciences

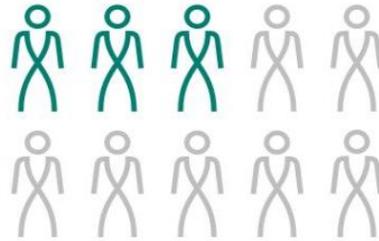
Regular liver cancer testing leads to better outcomes

Under regular testing



6/10 survive 3 years

Not under regular testing



3/10 survive 3 years

Source: Kuo, YH et al., Eur J Cancer (2010)

Exact Sciences

Next steps to capturing a large U.S. liver cancer opportunity

3M

Americans

\$1.5B

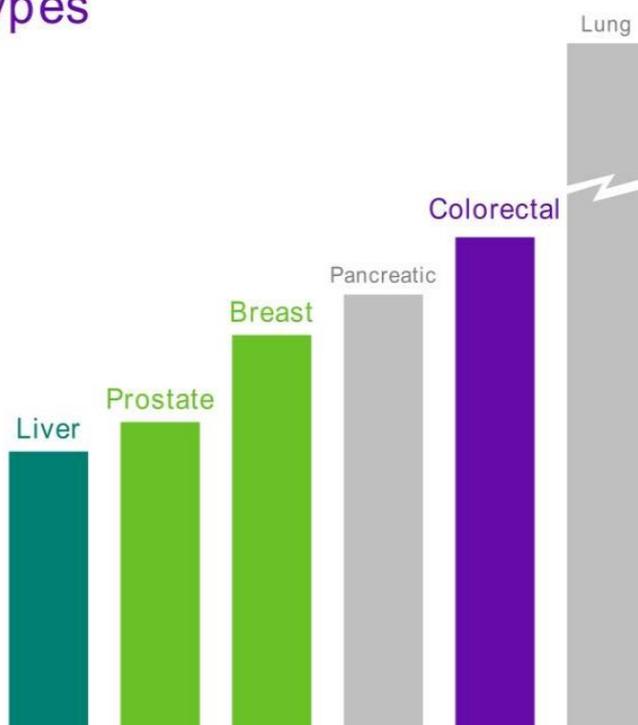
total U.S.
addressable market

Additional data in
2020

Test available in
2H20

Note: Expect additional data in 2020 and to make the liver cancer test available in 2H20
Source: Exact Sciences estimates; total addressable market assumes revenue per test of \$500 and 3M Americans tested annually

Earlier detection and smarter answers across several cancer types



Note: expect to make liver cancer test available in 2020
Source: American Cancer Society, Cancer Facts & Figures 2020; all figures annual

Exact Sciences

The leading global cancer diagnostics company

\$1.6B+

projected 2020 revenue

4.7M+

people tested to-date
and growing

\$1.2B+

projected 2020 gross profit

**EXACT
SCIENCES**

Note: 4.7M+ total people tested with Cologuard
and Oncotype DX products combined

EXACT SCIENCES

