

Exact Sciences Corporation (EXAS)

American Cancer Society Says 45 Is the New 50

Reiterate Outperform rating. Today, the American Cancer Society updated its guidelines to recommend starting colorectal cancer screening at age 45, vs. the prior recommendation of 50. While it'll likely take time to materialize (need payer updates, change in practice, FDA label expansion, other guideline inclusion, etc.), we think this update presents an exciting opportunity for EXAS/Cologuard mid/longer-term (expanding market 20%+) and note other opportunities for market expansion (like expanding Cologuard's label to include high-risk patients) also exist.

- **ACS guideline update presents exciting mid/long-term opportunity.**

- **ACS recommends starting CRC screening at 45:** Today, the American Cancer Society updated its guidelines to recommend starting colorectal cancer screening at age 45, vs. the prior recommendation of 50.

- **Expanding EXAS' addressable market:** According to the 2010 census, there were ~22.7M Americans aged 45-49 in 2010 (latest census.gov estimates show 21.0M as of July 1, 2017); we estimate ~80%+ of those would be average-risk and estimate penetration of this new age group would expand Cologuard's addressable market by ~20%+ (same census data show 94.5M Americans aged 50-85 in 2010 and 108.7M estimated as of July 2017). Note that some payers like Aetna already consider CRC screening beginning at age 45 medically necessary for African Americans.

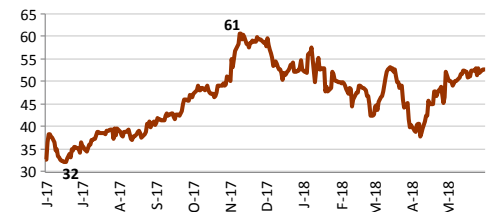
- **ACS emphasizes importance of choice:** We also found it encouraging that this guideline update puts a big emphasis on the importance of patient preference/choice of different CRC screening options. Rather than prioritizing certain tests, the new guidelines recommend providers offer patients the opportunity to select either a structural (visual) examination or a high-sensitivity stool test in order to increase adherence.

- **Steps forward from here:** EXAS is currently working on the trial design for an FDA supplement to expand the indicated age on Cologuard's label, but hasn't started the trial yet (expect more color later in the year); we note Cologuard performed better (had higher specificity) in the lower age group in DeeP-C, so we're optimistic on the outcome of such a trial. In the meantime, there are a number of states (~20-30E) that mandate coverage of ACS-recommended tests, and other payers can choose to cover off-label. Note the recommendation to begin screening at age 45 is a "qualified recommendation," while the recommendation for regular screening in adults aged 50+ is a "strong recommendation" (still a bit unclear what this means in practice, but we believe it still has clout). We believe inclusion in other guidelines like NCCN and HEDIS quality measures will also be important to change practice.

- We plan to update our model at a later date.

RESEARCH UPDATE

1-Year Price Chart



Stock Data

Rating:	Outperform
Suitability:	Speculative Risk
Price Target:	\$58
Price (5/30/18):	\$58.04
Market Cap (mil):	\$7,023
Shares Out (mil):	121.0
Average Daily Vol (mil):	2.22
Dividend Yield:	0.0%

Estimates

FY Dec	2017A	2018E	2019E
Q1	(0.32) A	(0.33) A	(0.25) E
Q2	(0.27) A	(0.38) E	(0.22) E
Q3	(0.23) A	(0.36) E	(0.15) E
Q4	(0.18) A	(0.32) E	(0.09) E
Fiscal EPS	(0.99) A	(1.38) E	(0.71) E
Fiscal P/E	NM	NM	NM

Chart/Table Sources: FactSet and Baird Data. Price chart reflects most recent closing price.

Please refer to Appendix
- Important Disclosures
and Analyst Certification

Exact Sciences is a molecular diagnostics company focused on reducing colorectal cancer-related deaths through widespread adoption of a non-invasive, proprietary, stool-based DNA screening assay.

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Investment Thesis

- **Seasoned management team.**
 - Kevin Conroy (President and CEO) and Maneesh Arora (SVP and COO) were previously the CEO and CFO, respectively, of Third Wave (Hologic acquired in 2008). We think this management team has solid molecular diagnostics experience.
- **Colorectal cancer screening is a large, unmet need.**
 - CRC is very preventable, yet in the U.S. there are about 135K new cases (60% caught late-stage) and ~50K deaths annually, and ~\$14B is spent on treatment.
 - While CRC screening is widely covered by insurance, including for all people with Medicare, screening compliance among the 80M+ Americans age 50+ is just ~65%.
- **Cologuard presents a new paradigm in CRC screening.**
 - Cancer sensitivity (92%) is superior to FIT performance, which was 74% in DeeP-C.
 - Pre-cancer sensitivity is 42% overall (FIT is 24%) and 66% for polyps \geq 2cm, which are ~5x more likely to progress to cancer.
 - Validated through ~10,000-patient study, which incorporated input from FDA, CMS, and key opinion leaders.
- **Cologuard's compliance rate is above FIT and colonoscopy.**
 - We believe Cologuard's superiority claims over FIT and patient-friendly format (at-home test, no bowel prep, only requires a small sample) appeals to both doctors/systems and patients.
 - FIT requires annual testing, while Cologuard has a three-year interval, which we think will benefit adherence over time.
 - A 2016 *American Journal of Gastroenterology* publication found that only ~14% of patients were adherent with annual FOBT testing over a three-year period, while only ~38% of patients completed a colonoscopy within the first 12 months (another 2% completed in the next two years). Since launch, Cologuard's compliance rate has ranged from 65% to 75%, with the recent tick-down due to mix shift toward commercially insured patients (compliance ~70%-75% for Medicare and ~55%-60% for commercially insured). We expect this may initially tick down further before improving over time to 70%+.
- **Valuation.** Our \$58 price target is based on a blend of EV/S (10.0x on +2-year, 9.0x on +3-year, and 6.0x on CY23E revenue, above life sciences/diagnostics peer median of ~4.4x due to relative growth profile) and DCF (~13% WACC, 4.0% terminal growth).

Risks & Caveats

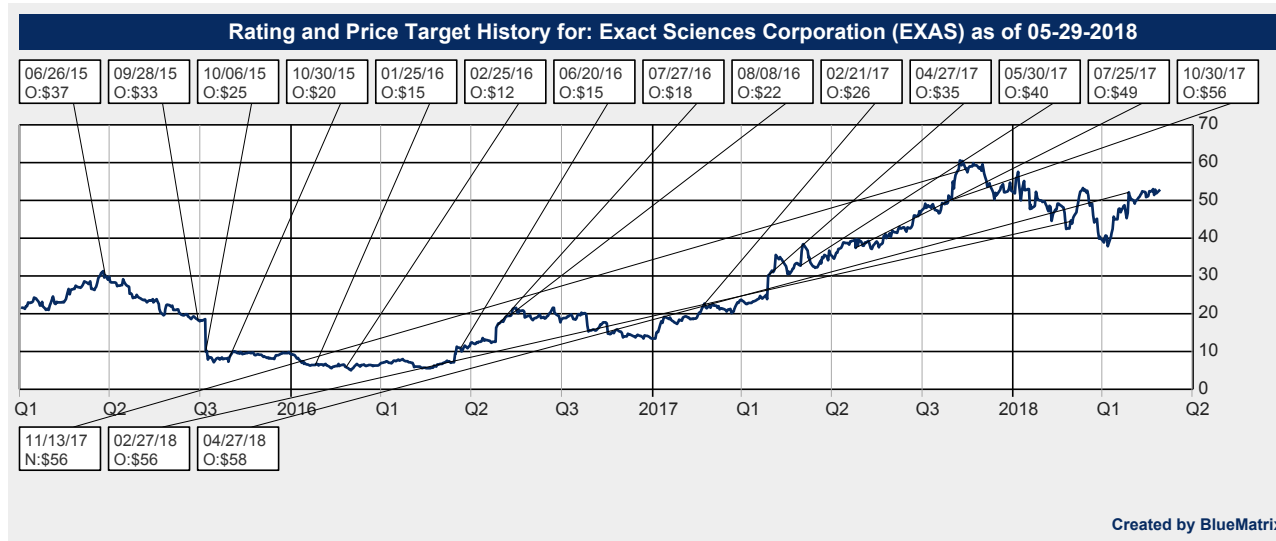
- **FDA and other governmental regulation.** Cologuard has received FDA approval and CE marking, but will require additional approvals in certain geographies (e.g., CFDA approval in China) should EXAS decide to enter those markets.
- **Reimbursement.** The company has secured ~87% U.S. coverage for Cologuard. EXAS will need to obtain reimbursement coverage at an acceptable level from private payors. Changes in reimbursement levels or timing could significantly impact EXAS' revenue, profitability, and cash flow.
- **Cash usage.** We expect EXAS to reach initial profitability during 2019. EXAS had approximately \$1.04B cash/equivalents as of 1Q18-end.
- **Intellectual property.** EXAS depends on its IP portfolio for its future growth and must successfully defend its current IP and continue to expand the portfolio, either through internal R&D or external licenses and/or acquisitions.
- **Competition.** The molecular diagnostics market is very competitive with several large, better funded companies, such as Roche. EXAS will compete with colonoscopy providers, service-based

companies, such as LabCorp, and traditional diagnostic companies that manufacture FOBTs/FITs, such as Danaher, and blood-based test manufacturers, like Epigenomics. Additional competitors may enter this space, such as GeneNews, Genomic Health, GRAIL, and VNRX.

Company Description

Exact Sciences is a molecular diagnostics company focused on commercializing Cologuard, a non-invasive, proprietary, stool-based DNA (sDNA) screening assay for the early detection and prevention of colorectal cancer (CRC). Cologuard received FDA approval in August 2014, a positive CMS national coverage decision in October 2014, and final CMS reimbursement in December 2014. The company's technology is already included in CRC screening guidelines of the American Cancer Society, U.S. Multi-Society Task Force, National Comprehensive Cancer Network, and United States Preventive Services Task Force. Through its partnership with the Mayo Clinic, Exact Sciences is also developing assays for detecting pancreatic, esophageal, lung, and other cancers.

Appendix - Important Disclosures and Analyst Certification



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