Exact Sciences Corporation (EXAS)
FDA Approves Cologuard Label Expansion for 45-49

- FDA approves Cologuard for use in patients 45 years and older.
  - FDA label expansion: This morning, EXAS announced that the FDA has approved Cologuard for use in average-risk individuals ages 45 and older, expanded from its previous label for use in individuals ages 50 and older (link to supplement approval details). Note EXAS had previously expected a decision in 1H20.
  - Details: The PMA supplement approval order statement from the FDA states the approval is, “to expand the indicated age range for Cologuard Stool DNA-Based Colorectal Cancer Screening Test from “50 years or older” to “45 years or older,”” with a decision date of September 20.
  - Market expansion: This expands Cologuard’s addressable market to include the ~19M average-risk Americans ages 45-49 (from the 87M+ ages 50-85, +21%). We note there are likely more unscreened individuals in the 45-49 age group, such that the increase in the number of people immediately available for screening is likely even higher.
  - Path forward: This approval follows the American Cancer Society’s decision to recommend screening in this age group in a May 2018 guideline update. This label expansion allows EXAS to market Cologuard for use in this age group, which we think will be important in educating physicians about the rising incidence in this age group and Cologuard’s value proposition/ability to increase screening. We note several payers (like Aetna) have already lowered the screening age to 45 and many states require payers to follow American Cancer Society guidelines. That said, we still think it will take some time for to educate physicians and for payers to more broadly cover the 45-49 age group.

Valuation Synopsis
Our $130 price target is based on a blend of EV/S (13.0x on +1-year, 10.0x on +2-year, and 10.0x on CY24E revenue, above diagnostics peer median of ~6x due to relative growth profile; plus 5.0x GHDX-related revenue, slightly below peer median) and DCF (~13% WACC, 5.0% terminal growth).

Risk Synopsis
FDA and government regulation, cash usage, competition, and reimbursement.

Please refer to Appendix - Important Disclosures and Analyst Certification

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

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