

## Life Sciences &amp; Diagnostic Tools

Thoughts on Exact Sciences & Guardant  
CRC screening clinical trial publications

Price Objective Change

## NEJM publishes ECLIPSE &amp; BLUE-C studies

After the 3/13 market close, the *New England Journal of Medicine* (NEJM) published results from two non-invasive colorectal cancer (CRC) screening studies: Exact Sciences' (EXAS) stool-based BLUE-C study for Cologuard Plus (CG+) and Guardant Health's (GH) blood-based ECLIPSE study for Shield. These publications largely confirmed what had been previously reported. In our view, these reports are incrementally positive for both companies, but more so for EXAS, as GH still has several regulatory and commercial hurdles to clear.

## EXAS: CG+ FDA approval by year-end, launch in early '25

EXAS held a conference call on 3/14 to discuss the data. CG+'s 94% CRC sensitivity, 91% specificity, and 43% advanced adenoma (AA) sensitivity were all an improvement from "Classic" CG's 92%, 87%, and 42%, respectively. The incremental information from the call included staging data (87% sensitivity in Stage I, 94% in Stage II, 97% in Stage III, and 100% in Stage IV) and discussions of an additional \$6bn market opportunity that mgmt. believes could come from expanding the eligible screening population to younger individuals and those with a limited family history of CRC. Specifically, to be ready for potential label expansion, the BLUE-C study enrolled individuals aged 40-44. Having submitted the CG+ to the Food & Drug Administration (FDA) in Dec '23, EXAS expects approval later this year and a commercial launch in early 2025. For CG Blood, mgmt. continues to expect to have a readout in mid '24. We think that EXAS is making good progress and ever-increasing the barriers to entry to the stool-based CRC screening market. We maintain our estimates and our Buy rating on EXAS given the upcoming key catalysts, strong competitive position, improving profitability, and attractive valuation.

## GH: Incremental progress, but questions remain

The ECLIPSE publication largely confirmed what GH had shared in Dec '22, including CRC sensitivity of 83%, specificity of 90%, and AA sensitivity of 13%, as well as staging data for Shield. Incremental information included 65% sensitivity for pathology-confirmed Stage I (vs 55% for clinical Stage I). As the data meet FDA thresholds, we still expect Shield to receive FDA approval in 2024. However, the publication raised several questions. For example, the interval of the test will be determined by the United States Preventive Services Taskforce (USPSTF) guidelines in 2026, which will impact uptake and reimbursement. There is also a debate about the importance of AA vs. adherence, and how this will be incorporated into the USPSTF guideline. While we expect to learn more during the FDA AdCom meeting to be held during 2Q24, given the uncertainty surrounding Shield, we think it is prudent to lower our Screening sales forecasts in the outyears (our FY24-26 ests are unchanged as we had not expected Shield to reach \$100mn in sales until 2028). As a result, we move our DCF-based PO (still 11% WACC, 3% terminal rate) down to \$28 (from \$35). This PO implies a FY25 EV/Sales multiple of ~4x, in line with GH's peer group median. That said, we reiterate our Buy rating citing attractive valuation for the core business.

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Equity  
United States  
Life Sciences & Diagnostic Tools

**Derik de Bruin**  
Research Analyst  
BofAS  
+1 646 855 3100  
[derik.de\\_bruin@bofa.com](mailto:derik.de_bruin@bofa.com)

**Michael Ryskin**  
Research Analyst  
BofAS  
+1 646 855 4373  
[michael.ryskin@bofa.com](mailto:michael.ryskin@bofa.com)

**Wolf Chanoff**  
Research Analyst  
BofAS  
+1 646 954 8482  
[wolf.chanoff@bofa.com](mailto:wolf.chanoff@bofa.com)

**John Kim**  
Research Analyst  
BofAS  
+1 646 855 3874  
[john.kim4@bofa.com](mailto:john.kim4@bofa.com)

**Avantika Dhabaria**  
Research Analyst  
BofAS  
+1 646 743 0170  
[avantika.dhabaria@bofa.com](mailto:avantika.dhabaria@bofa.com)

## Exhibit 1: PO Change Table

PO changes

Ticker	Prior PO	New PO
GH	\$35	\$28

Source: BofA Global Research

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Timestamp: 14 March 2024 05:28PM EDT

## Price objective basis & risk

### Exact Sciences (EXAS, \$58.53, C-1-9)

Our \$88 PO is based on a discounted cash flow (DCF) analysis that assumes a 3% terminal growth rate and a 11% WACC.

Upside risks to our estimates are better than expected Cologuard and Oncotype DX products ramp, higher reimbursement levels, and successful pipeline developments.

Downside risks are real or perceived slowdown in the Cologuard ramp, weakness related to COVID-19, declining compliance rates, pricing erosion, and competitive threats from liquid biopsy screening tests.

### Guardant Health (GH, \$18.37, C-1-9)

Our PO of \$28 is based on a discounted cash flow (DCF) analysis, which assumes a 3% terminal growth rate and a 11% weighted-average cost of capital (WACC). We believe that a DCF analysis better reflects the company's business given that both sales and operating expenses are expected to ramp significantly in future years.

Downside risks to our PO are regulatory approval for the company's SHIELD CRC (colorectal cancer) screening assay, inclusion of SHIELD in practice guidelines, CMS and commercial payer reimbursement for SHIELD and Guardant's other liquid-biopsy products, execution risks, market risks, competition, commercial risks, lingering headwinds from the COVID-19 pandemic, technology risks, and additional dilutive capital raises. Upside risks are faster than expected product uptake, higher reimbursement levels, successful pipeline developments, greater market penetration, and the acquisition of the company.

## Analyst Certification

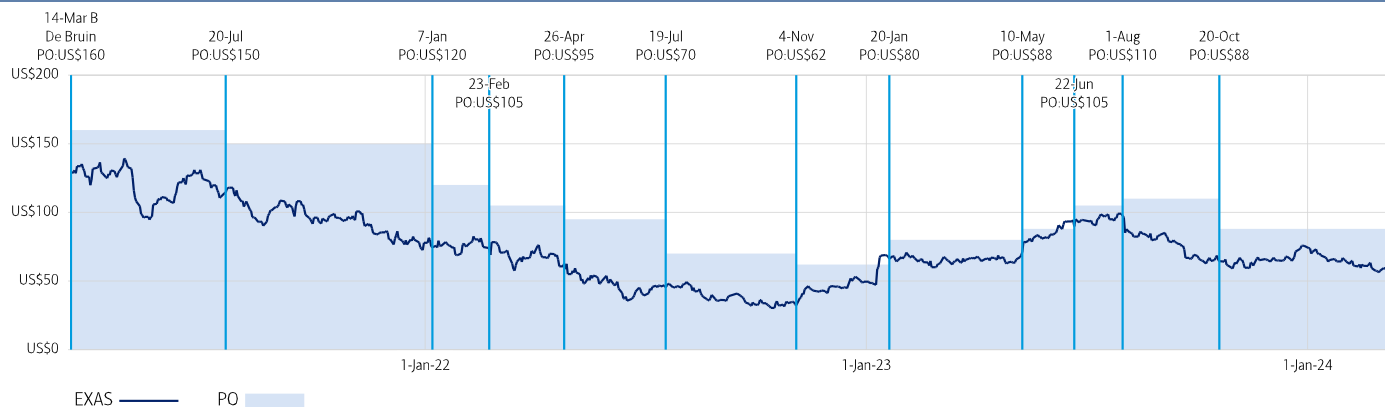
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**US - Life Science, Diagnostic Tools and Animal Health Coverage Cluster**

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
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	Bruker Corporation	BRKR	BRKR US	Michael Ryskin
	Certara	CERT	CERT US	Michael Ryskin
	Charles River Laboratories	CRL	CRL US	Michael Ryskin
	Elanco Animal Health	ELAN	ELAN US	Michael Ryskin
	Exact Sciences	EXAS	EXAS US	Derik de Bruin
	Guardant Health	GH	GH US	Derik de Bruin
	ICON plc	ICLR	ICLR US	Derik de Bruin
	IQVIA Holdings Inc	IQV	IQV US	Derik de Bruin
	LabCorp	LH	LH US	Michael Ryskin
	Maravai	MRVI	MRVI US	Michael Ryskin
	Qiagen	QGEN	QGEN US	Michael Ryskin
	Qiagen N.V.	XQGNF	QIA GY	Michael Ryskin
	Quest Diagnostics	DGX	DGX US	Michael Ryskin
	Stevanato Group S.p.A.	STVN	STVN US	Michael Ryskin
	Thermo Fisher Scientific	TMO	TMO US	Michael Ryskin
	West Pharmaceutical Services	WST	WST US	Michael Ryskin
	Zoetis Inc.	ZTS	ZTS US	Michael Ryskin
<b>NEUTRAL</b>				
	10x Genomics, Inc.	TXG	TXG US	Michael Ryskin
	Agilent Technologies	A	A US	Michael Ryskin
	Danaher Corporation	DHR	DHR US	Michael Ryskin
	Evotec SE	EVO	EVO US	Michael Ryskin
	Hologic, Inc.	HOLX	HOLX US	Derik de Bruin
	IDEXX Laboratories	IDXX	IDXX US	Michael Ryskin
	Mettler-Toledo	MTD	MTD US	Michael Ryskin
	NeoGenomics Inc.	NEO	NEO US	Derik de Bruin
	Revvity Inc	RVTY	RVTY US	Michael Ryskin
	Schrodinger, Inc.	SDGR	SDGR US	Michael Ryskin
	Waters Corp.	WAT	WAT US	Michael Ryskin
<b>UNDERPERFORM</b>				
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	Fortrea	FTRE	FTRE US	Derik de Bruin
	Ginkgo Bioworks Holdings, Inc	DNA	DNA US	Derik de Bruin
	Illumina, Inc.	ILMN	ILMN US	Michael Ryskin
	Myriad Genetics	MYGN	MYGN US	Derik de Bruin
	Phibro Animal Health	PAHC	PAHC US	Michael Ryskin

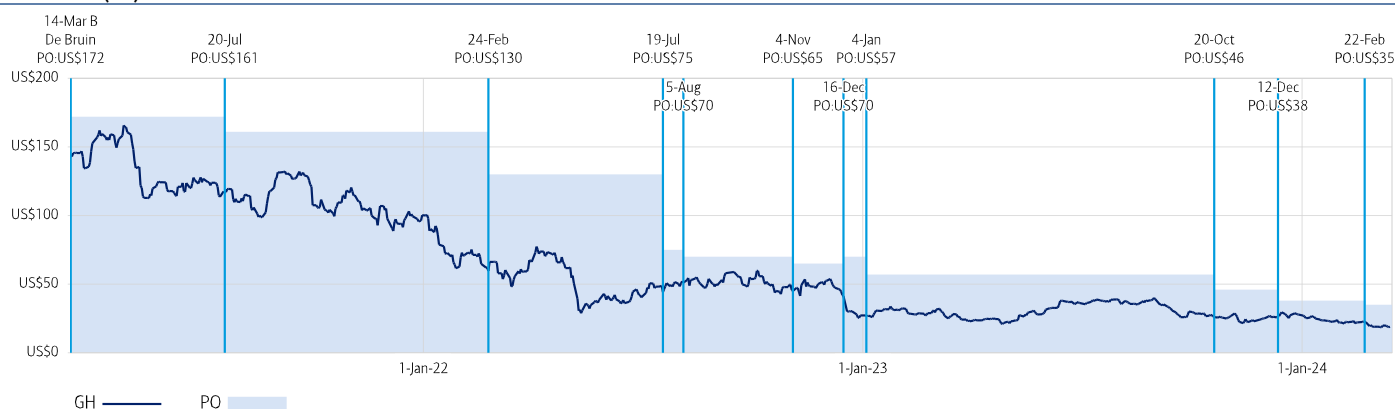
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**Exact Sciences (EXAS) Price Chart**

B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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**Guardant Health (GH) Price Chart**

B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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**Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)**

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

**Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)**

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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