

Guardant Health

Shield CRC AdCom delayed until 2Q; initial FY24 guidance looks conservative

Reiterate Rating: BUY | PO: 35.00 USD | Price: 22.27 USD

4023 sales in-line with preliminary results

Guardant Health (GH) preannounced upside 4Q23 top-line results (see <u>our earlier note for details</u>), and so there were few surprises regarding the quarterly results. As such, much of the call focused on GH's initial '24 guide and pipeline updates.

FY24 sales midpoint below Street, ahead of BofAe

The midpoint of the FY24 sales guide for \$655-670mn (+16-19% yoy) was just ahead of our \$660mn but below Street's \$670mn. Precision Oncology (PO) is expected to grow ~20% yoy (vs Street ~21%), with Clinical up at least 20% & Biopharma up low-double-digits. Developmental services revenues are expected to be flat y/y. We see this initial guide as conservative given positive pricing and test volume trends, suggesting upside potential as the year progresses. GH continues to control costs, as OpEx are expected to grow 1-3% Y/Y, inclusive of ~\$200mn spending for the Shield program. After ending FY23 with \$1.2bn in cash, mgmt. sees a modestly lower cash burn of ~\$325mn in FY24.

AdCom delayed till late 2Q24 due to FDA staffing issues

Beyond guidance, the key takeaway from the call was an update on the FDA Advisory Committee (AdCom) for GH's Shield CRC (Colorectal Cancer) screening test. Due to the timing of the recruiting of panel members, the AdCom is now expected to convene late in 2Q24 instead of 3/28 as previously communicated. As the AdCom was already a point of controversy, the delay may not sit well with investors. However, mgmt. noted that FDA approval is independent of the AdCom and that approval and CMS reimbursement are still expected in 2024. Regarding the label, GH has not had discussions with FDA, but it is not dependent on the AdCom. Our model assumes that Shield will be approved as a second-line option targeting an unscreened patient population of ~50mn persons, but we don't see >\$100mn until FY28 given the need for guideline inclusion.

Update ests & lower PO to \$35; Core business progressing

We update our forecasts, raising FY24 sales but trimming outyear estimates largely for more conservative MRD (minimal residual disease) test volumes. As a result, our DCF-based PO (still 11% WACC, 3% terminal rate) is lowered to \$35 from \$38. The AdCom and Shield approval, as well as expected competitor news, may overhang for the stock in 1H24. However, the core business is progressing (G360 is cash flow breakeven) and mgmt. seems willing to jettison Shield if it goes against them. We reiterate our Buy rating on GH given the company's leading position in the liquid biopsy market and attractive valuation for the core franchise.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(4.26)	(3.19)	(2.50)	(1.85)	(1.20)
GAAP EPS	(6.41)	(3.95)	(3.35)	(2.70)	(2.10)
EPS Change (YoY)	-91.0%	25.1%	21.6%	26.0%	35.1%
Consensus EPS (Bloomberg)			(3.10)	(2.76)	(2.27)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-11.4%	-12.0%	-12.7%	-10.0%	-7.2%
* For full definitions of <i>IQ</i> method SM measures, see page 4.					

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Refer to important disclosures on page 5 to 7. Analyst Certification on page 3. Price
Objective Basis/Risk on page 3.

Timestamp: 22 February 2024 11:38PM EST

22 February 2024

Equity

Key Changes		
(US\$)	Previous	Current
Price Obj.	38.00	35.00
2024E EPS	-2.85	-2.50
2025E EPS	-2.15	-1.85
2026E EPS	NA	-1.20
2024E EBITDA (m)	-278.1	-293.4
2025E EBITDA (m)	-193.0	-216.1
2026E EBITDA (m)	NA	-134.6

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Stock Data

Price	22.27 USD
Price Objective	35.00 USD
Date Established	22-Feb-2024
Investment Opinion	C-1-9
52-Week Range	20.67 USD - 41.06 USD
Mrkt Val (mn) / Shares Out (mn)	2,711 USD / 121.7
Free Float	95.9%
Average Daily Value (mn)	34.68 USD
BofA Ticker / Exchange	GH / NAS
Bloomberg / Reuters	GH US / GH.OQ
ROE (2024E)	NA
Net Dbt to Eqty (Dec-2023A)	4.1%
FSGMeter™	Medium

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to "BofA ESGMeter Methodology"

iQprofile[™] Guardant Health

<i>iQ</i> method [™] – Bus Performance*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Return on Capital Employed	-28.6%	-28.9%	-28.6%	-32.3%	-29.6%
Return on Equity	-123.5%	-322.0%	NM	NM	NM
Operating Margin	-121.1%	-85.3%	-66.2%	-45.3%	-29.8%
Free Cash Flow	(309)	(325)	(344)	(270)	(194
i Q method [™] – Quality of Earnings*					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash Realization Ratio	NM	NM	NM	NM	NN
Asset Replacement Ratio	0x	0x	1.3x	1.3x	1.3
Tax Rate	NM	NM	NM	NM	NN
Net Debt-to-Equity Ratio	NM	4.1%	NM	NM	NN
Interest Cover	NA	NA	NA	NA	N/
Income Statement Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Sales	450	564	663	805	990
% Change	20.3%	25.5%	17.6%	21.4%	23.0%
Gross Profit	293	337	392	479	59
% Change	16.9%	14.9%	16.3%	22.1%	23.59
EBITDA	(403)	(344)	(293)	(216)	(135
% Change	-74.3%	14.7%	14.8%	26.3%	37.7%
Net Interest & Other Income	(9)	46	40	40	40
Net Income (Adjusted)	(435)	(352)	(299)	(223)	(146
% Change	-92.7%	19.1%	15.3%	25.2%	34.5%
Free Cash Flow Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Net Income from Cont Operations (GAAP)	(555)	(436)	(400)	(325)	(256
Depreciation & Amortization	36	43	46	50	. 54
Change in Working Capital	6	34	(25)	(25)	(26
Deferred Taxation Charge	NA	NA	NA	NA	N/
Other Adjustments, Net	203	35	93	94	10
Capital Expenditure	0	0	(58)	(63)	(68
Free Cash Flow	-309	-325	-344	-270	-194
% Change	-13.7%	-5.0%	-5.8%	21.5%	28.0%
Share / Issue Repurchase	NA	NA	NA	NA	N/
Cost of Dividends Paid	0	0	0	0	(
Change in Debt	0	0	0	0	(
Balance Sheet Data (Dec)					
(US\$ Millions)	2022A	2023A	2024E	2025E	2026
Cash & Equivalents	142	1,134	695	330	38
	97	89	95	105	129
Trade Receivables			141	167	166
Other Current Assets	953	125		167	
Other Current Assets Property, Plant & Equipment	168	145	157	170	184
Other Current Assets Property, Plant & Equipment Other Non-Current Assets	168 250	145 294	157 294	170 294	184 294
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets	168 250 1,610	145 294 1,786	157 294 1,382	170 294 1,065	184 294 1,15 5
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt	168 250 1,610 0	145 294 1,786 0	157 294 1,382 0	170 294 1,065 0	18 [,] 29 [,] 1,15 !
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt Other Current Liabilities	168 250 1,610 0 193	145 294 1,786 0 206	157 294 1,382 0 204	170 294 1,065 0 213	184 294 1,15 5 (212
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt	168 250 1,610 0 193 1,137	145 294 1,786 0 206 1,140	157 294 1,382 0 204 1,140	170 294 1,065 0 213 1,141	18- 29- 1,15! (21: 1,49
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	168 250 1,610 0 193 1,137 219	145 294 1,786 0 206 1,140 282	157 294 1,382 0 204 1,140 282	170 294 1,065 0 213 1,141 282	184 294 1,15 5 (212 1,49 282
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities Total Liabilities	168 250 1,610 0 193 1,137 219 1,550	145 294 1,786 0 206 1,140 282 1,628	157 294 1,382 0 204 1,140 282 1,626	170 294 1,065 0 213 1,141 282 1,636	18 ² 29 ² 1,15 5 (21 ² 1,49 28 ² 1,98 5
Other Current Assets Property, Plant & Equipment Other Non-Current Assets Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	168 250 1,610 0 193 1,137 219	145 294 1,786 0 206 1,140 282	157 294 1,382 0 204 1,140 282	170 294 1,065 0 213 1,141 282	18 ⁴ 29 ⁴ 1,155 (21 ² 1,49 28 ² 1,985 (830

Company Sector

Healthcare Technology & Distribution

Company Description

Guardant Health (GH) is a high growth genomics-based molecular diagnostics company that develops and commercializes precision medicine tests for the study and treatment of cancer. The company is an early mover and leader in the emerging liquid biopsy-based cancer testing market. The company has one commercial clinical product, a gene panel called Guardant360, and an intriguing pipeline of potentially disruptive products. GH also has numerous biopharma R&D and companion diagnostics partnerships.

Investment Rationale

We are bullish on Guardant Health given early leadership in liquid biopsy-based testing for cancer. We estimate GH's total addressable market to be above \$35b. We see upside from higher test volumes/commercial clinical test pricing, increasing uptake of the company's cancer recurrence monitoring products, and cancer screening programs. While still facing many competitive, commercial, and regulatory risks, we believe GH's technology is differentiated.

Stock Data

Average Daily Volume

1,557,305

Quarterly Earnings Estimates

	2023	2024
Q1	-1.06A	-0.66E
Q2	-0.82A	-0.65E
Q3	-0.67A	-0.61E
Q4	-0.64A	-0.58E



Price objective basis & risk

Guardant Health (GH)

Our PO of \$35 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

I, Derik de Bruin, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

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

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Avantor, Inc.	AVTR	AVTR US	Michael Ryskin
	Bruker Corporation	BRKR	BRKR US	Derik de Bruin
	Certara	CERT	CERT US	Michael Ryskin
	Charles River Laboratories	CRL	CRL US	Derik de Bruin
	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	Derik de Bruin
	Maravai	MRVI	MRVI US	Michael Ryskin
	Qiagen	QGEN	QGEN US	Derik de Bruin
	Qiagen N.V.	XQGNF	QIA GY	Derik de Bruin
	Quest Diagnostics	DGX	DGX US	Derik de Bruin
	Stevanato Group S.p.A.	STVN	STVN US	Derik de Bruin
	Thermo Fisher Scientific	TMO	TMO US	Derik de Bruin
	West Pharmaceutical Services	WST	WST US	Derik de Bruin
	Zoetis Inc.	ZTS	ZTS US	Michael Ryskin
NEUTRAL				
	10x Genomics, Inc.	TXG	TXG US	Michael Ryskin
	Agilent Technologies	A	A US	Derik de Bruin
	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	Derik de Bruin
	NeoGenomics Inc.	NEO	NEO US	Derik de Bruin
	Revity Inc	RVTY	RVTY US	Derik de Bruin
	Schrodinger, Inc.	SDGR	SDGR US	Michael Ryskin
	Waters Corp.	WAT	WAT US	Derik de Bruin
	vaccis corp.	¥¥/11	WAIUS	Defin de Diulii
UNDERPERFORM				
	Align Technology	ALGN	ALGN US	Michael Ryskin
	Fortrea	FTRE	FTRE US	Derik de Bruin



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

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	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

IQmethod[™] Measures Definitions

Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) \times (1 $-$ Tax Rate) + Goodwill Amortization	Total Assets — Current Liabilities + ST Debt + Accumulated Goodwill Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations — Total Capex	N/A
Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt — Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense
Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations - Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt +	Sales
EV / EBITDA	Other LT Liabilities Enterprise Value	Basic EBIT + Depreciation + Amortization
LV / LDITUA	LITTEIDIBE Value	Dasic LDIT + Dedieciation + Athoritzation

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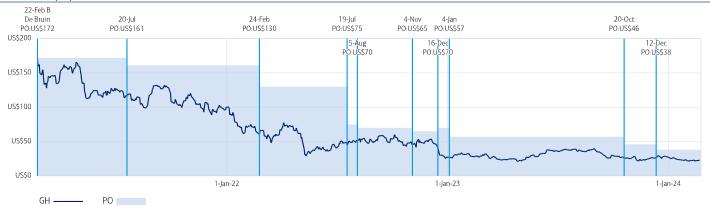
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Important Disclosures

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 R1	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 R1	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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Investment rating Total return expectation (within 12-month period of date of initial rating) Ratings dispersion guidelines for coverage cluster^{R2}

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

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