



GUARDANT HEALTH

Research on Guardant Health - 4/15/19

Description: Guardant Health, Inc. was incorporated in 2011 and is headquartered in Redwood City, California. They are a precision oncology company that provides blood tests, data sets, and analytics in the United States and internationally. The company offers liquid biopsy tests for advanced stage cancer, such as Guardant360, a molecular diagnostic test that measures various cancer-related genes; and GuardantOMNI, a broader gene panel, including genes associated with homologous recombination repair deficiency and biomarkers for immuno-oncology applications. It also provides LUNAR-1 for minimal residual disease and recurrence detection in cancer survivors. In addition, the company is developing LUNAR-2 for early detection of cancer in higher risk individuals. Further, it offers development services, including companion diagnostic development and regulatory approval, clinical trial referral, and liquid biopsy testing development and support services to biopharmaceutical companies and medical institutions.

Ticker: GH

Price: \$77.54

Market Cap: \$6.7B

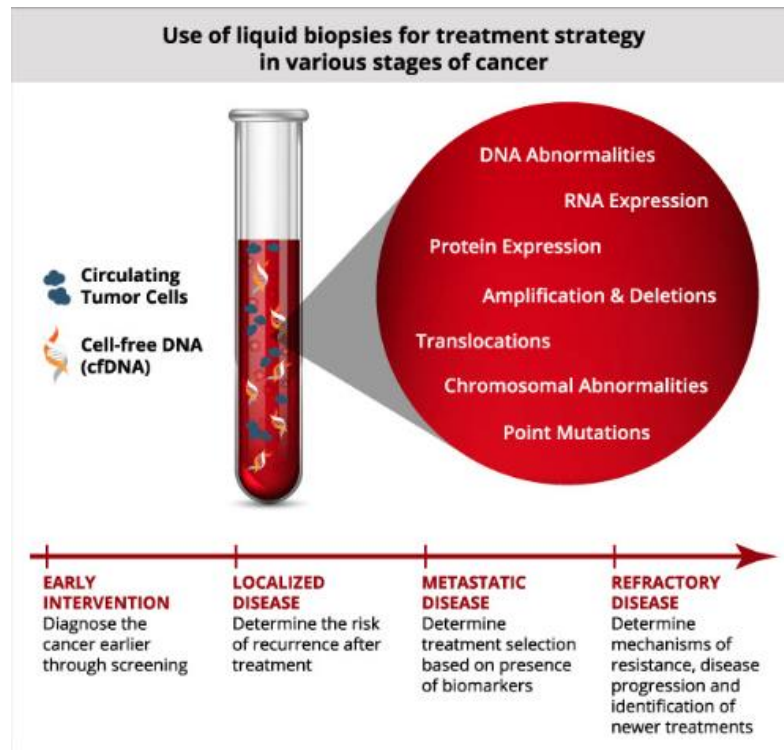
Performance: +106.3% YTD

Analysis

Guardant Health hit the public markets back in October of 2018 at \$19 per share, closed the day up 70% to \$32.20 per share, and have ran as high as \$106.58 a month ago.

GH is in a unique company as they offer liquid biopsy tests. What are these? Right now, there are two main ways for trying to catch cancer early, tissue biopsies and liquid biopsies.

As tumors increase in volume something known as cfDNA enters into the bloodstream. Physicians can use the blood drawn from a patient's arm to analyze DNA that tumors typically shed into the bloodstream. Depending on the tumor size and vascularity, the amount of cfDNA released in the circulation can vary from 0.01% to 90% of all DNA present in plasma. Therefore, liquid biopsies provide a *noninvasive* approach to tumor molecular profiling without having to obtain tumor tissue.



Advantages and benefits of Liquid Biopsies

- Non-invasive method for identification of tumor markers, either as an alternative for patients whose tissue is unable to be biopsied or as an adjunct to evaluate drug response.
- Possibly less costly than tumor biopsy and analysis.
- Provides an accurate snapshot of the genomic landscape of the tumor, bypassing issues such as intratumor heterogeneity, as it is speculated that CTCs and cfDNA carry the driver mutations causing metastases.

- Able to obtain serial samples during treatment to assess for drug resistance and tumor progression. This is not picked up with a tumor biopsy given that tumor biopsies are generally only done prior to treatment, therefore mutations indicating resistance would not be picked up as these generally arise after starting therapy.
- Unlike tissue biopsy where the tumor DNA is preserved in formalin-fixed paraffin embedded (FFPE) blocks, DNA cross linking does not occur with liquid biopsy; thereby facilitating tumor DNA sequencing.

Disadvantages and challenges of Liquid Biopsies

- Potentially miss biomarkers expressed in the tumor
- Test variability and assay sensitivity and specificity
- CTCs are rare, fragile and heterogenous
- Lack of consensus in technical approaches of choice

Most research we’ve found indicated that tissue biopsies are still the preferred method but this means the future of liquid biopsies is still young and large. For example, according to GH they believe the total market opportunity is greater than \$35B in the U.S. That includes a market Guardant is already in—using liquid biopsies in late-stage cancers (an about \$6B opportunity, by the company’s estimates)—plus two that it is working toward, the cancer recurrence detection market (about \$15B) and early cancer risk detection (about \$18B).

U.S. Patient Population	Advanced-Stage Cancer ~700 K	Cancer Survivors ~15 million	Asymptomatic, Hi-Risk ~35 million
Information	Therapy Selection GUARDANT 360, EMN1	Recurrence Monitoring LUNAR - 1	Screening & Early Detection LUNAR - 2
Intervention	Targeted & Immunology therapies 50+ biopharma companies	Neoadjuvant, Adjuvant, or Curative	Curative or Preventative
U.S. Market Size	~\$6B	~\$15B	~\$18B



As you can see, the total addressable market is huge for GH but let's now dive into each business segment of theirs: Guardant360, GuardantOMNI, Lunar-1, and Lunar-2.

Guardant360

For oncologists, Guardant360 provides comprehensive genomic results from a simple blood draw (liquid biopsy) in approximately seven days which is roughly a week quicker turnaround time than standard tissue biopsies. Since its launch in 2014, Guardant360 has been used by more than 5,000 oncologists and all 27 National Comprehensive Cancer Network Centers.

GuardantOMNI

GuardantOMNI, launched in 2017, is designed for biopharmaceutical customers to use as a comprehensive genomic profiling tool to help accelerate clinical development programs in immuno-oncology and targeted therapy. Companies who want to increase the chances of a drug's success in clinical trials use GuardantOMNI to help identify patients whose cancer has the right molecular profile for their clinical program. GuardantOMNI also helps monitor patient response to investigational drugs or combinations of drugs, and perform retrospective analyses on plasma samples in storage.

Lunar-1

Is based on recurrence detection and residual disease detection and is a new blood-based assay intended to detect early-stage cancer and recurrence of disease launched by GH in January of this year. The assay improves upon Guardant360 by accurately reporting genomic alterations down to frequencies of 0.01%, and effectively filtering out biological noise sources. Right now, the LUNAR assay is available for Research Use Only (RUO), enabling biopharma companies and academic researchers to use it to identify new drug development opportunities to serve these patients. This program's initial focus will be on lung, breast, colorectal, and ovarian cancers.

Lunar-2

LUNAR-2's research and development program is aimed towards early detection by attempting to develop an accurate, affordable blood test for widespread use among higher-risk asymptomatic individuals. They are leveraging data from tens of thousands of cancer patients to potentially develop tests with unprecedented sensitivity and specificity for the detection of cancer as early as possible.

At this moment in time, a large majority of Guardant's revenue is coming from Guardant360 and GuardantOMNI under the "precision oncology testing" revenues. The development services revenues are derived from diagnostic development and regulatory approval services, clinical trial referrals and liquid biopsy testing development and support.

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Revenue:			
Precision oncology testing	\$ 78,407	\$ 42,088	\$ 24,496
Development services	12,232	7,754	753
Total revenue	90,639	49,842	25,249
Costs and operating expenses:			
Cost of precision oncology testing ⁽¹⁾⁽²⁾	39,846	28,883	22,065
Cost of development services	3,364	2,735	59
Research and development expense ⁽¹⁾⁽²⁾	50,714	25,562	10,859
Sales and marketing expense ⁽¹⁾⁽²⁾	53,465	32,497	26,192
General and administrative expense ⁽¹⁾⁽²⁾	36,192	36,777	9,921
Total costs and operating expenses	183,581	126,454	69,096
Loss from operations	(92,942)	(76,612)	(43,847)
Interest income	5,266	2,234	733
Interest expense	(1,251)	(2,702)	(3,018)
Loss on debt extinguishment	—	(5,075)	—
Other income (expense), net	4,702	(1,059)	(1)
Loss before provision for income taxes	(84,225)	(83,214)	(46,133)
Provision for income taxes	38	7	6
Net loss	\$ (84,263)	\$ (83,221)	\$ (46,139)

(1) Amounts include stock-based compensation expense as follows:

On March 12th, GH posted their results and growth has been stellar (as we've already seen above).

The good news as you can already tell is that GH is growing fast but they are no where near profitable. This isn't necessarily a bad thing as the company is spending a ton to grow the business but the real concern is whether or not they get in the black anytime over the next

few years. Right now the company is spending a significant amount on sales & marketing, R&D, and general & admin and based on their guidance we aren't so sure positive net income or cash flow is near.

- Revenue for the year ended December 31, 2018 was \$90.6 million, an 82% increase from \$49.8 million in 2017.
- Precision oncology revenue increased 86% driven by an increase in test volume and an increase in average price driven by reimbursement from Medicare starting in the fourth quarter of 2018 and an increase in GuardantOMNI test volume.
- Tests for clinical customers increased 15% and tests for biopharmaceutical customers increased 65%. There were 29,592 clinical tests and 10,370 biopharmaceutical tests performed during 2018.
- Gross profit was \$47.4 million for the year ended December 31, 2018, an increase of \$29.2 million from \$18.2 million in 2017. Gross margin was 52.3%, as compared to 36.6% in 2017.
- Operating expenses were \$140.4 million for the year ended December 31, 2018, as compared to \$94.8 million in 2017, an increase of 48%.
- Net loss attributable to Guardant Health, Inc. common stockholders was \$85.1 million in the year ended December 31, 2018, as compared to \$89.0 million in 2017.
- Net loss per share attributable to Guardant Health, Inc. common stockholders was \$2.80 in year ended December 31, 2018, as compared to \$7.07 in 2017.
- Cash, cash equivalents and marketable securities were \$496.5 million as of December 31, 2018.

The company expects full year 2019 revenue to be in the range of \$130 million to \$135 million, representing 43% to 49% growth over full year 2018 but net loss is expected to be in the range of \$126 million to \$129 million in 2019 which would make it the greatest loss in the company's history in a fiscal year.

With roughly \$500M in cash, negative levered free cash flow of -\$66M in 2018, a stock price that has been on a tear, and their recent acquisition of Bellwether Bio for an undisclosed amount that is not included in that \$500M number, we wouldn't be surprised to see a secondary offering to raise more money.

While it may sound wrong to say we can see this happening sometime in the Summer as the lock up period for insiders expired on April 2nd and allows some insiders to let go of some shares beforehand (wouldn't be the first time). Speaking of the share price being on tear let's talk about GH's valuation. Right now, the company is currently valued at \$6.7B. With revenues set to come in at \$130-135M this year that places the price-to-sales ratio around 50x.

This is FAR from cheap but we want to highlight something because the biotech/pharma industry is a wacky one. There used to be a company very similar to GH called Foundation Medicine on the public markets and it traded under the ticker FMI. FMI screened 67,000 people to collect genetic data that helped inform cancer treatment regimens (sound familiar?) which was up 54% from 2016.

They also had revenues of \$153M in 2017, which were up 31% Y/Y, clinical test volumes accelerated 57% to nearly 22,000 tests in Q1 2018, and as a result, revenue grew 101% to \$52.8 million in Q1 2018 before getting bought out by Roche for a whopping \$5.3B.

Compare this to GH and the numbers aren't too far off. FMI also didn't have Lunar-1 and Lunar-2 type services in the works either. As we mentioned above, GH actually conducted nearly 30,000 tests vs. FMI's 22,000 and has also gather over 70,000 data samples, more than FMI's 67,000 at the time of being bought out.

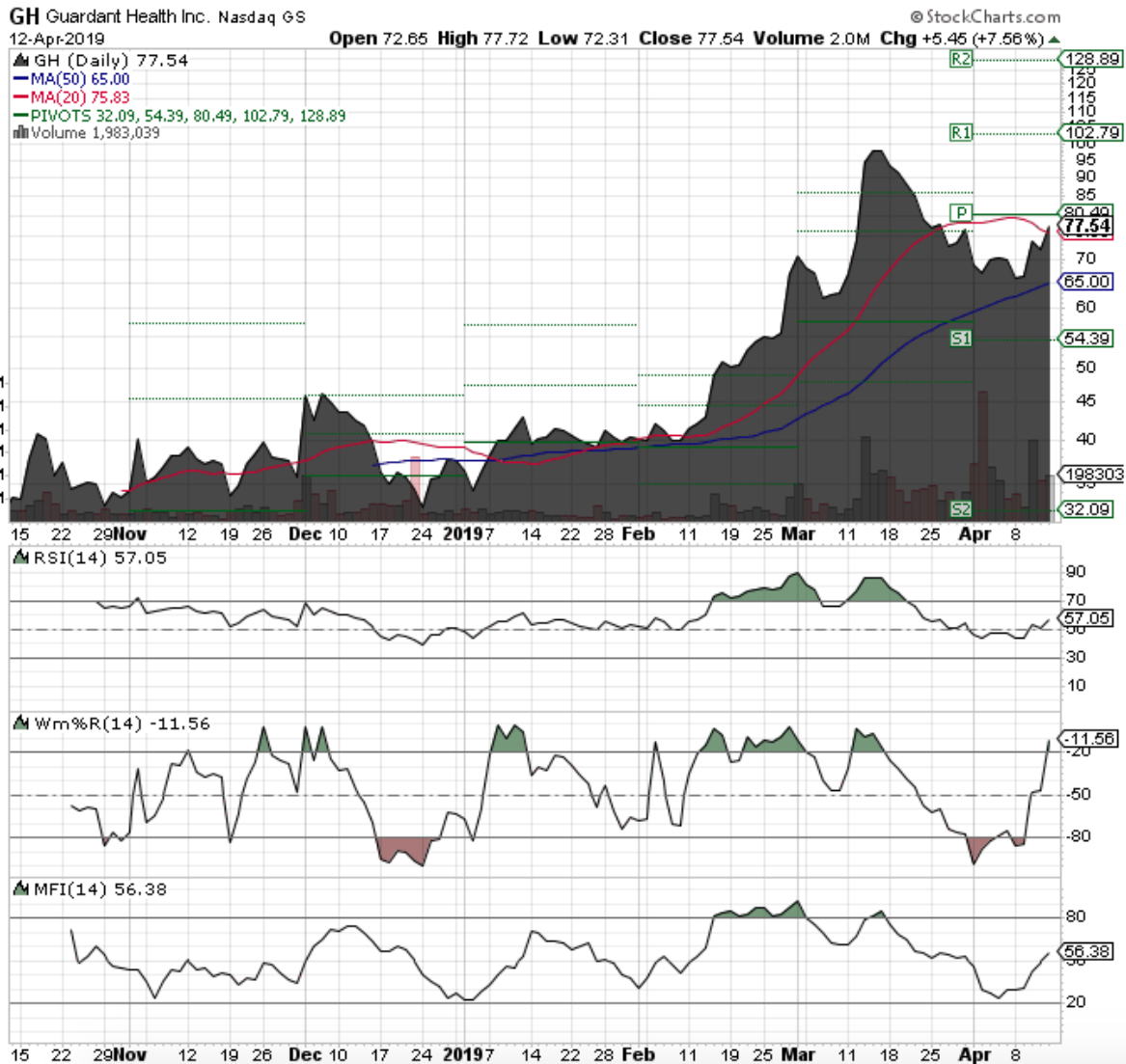
This is why it is so important to look at precedent transactions. Yes, this valuation is crazy high but pharma giants like Roche and many others don't seem to be caring too much lately as we've seen a plethora of monster deals in this space at sky high valuations.

Something that has been helping GH very recently is the latest news surrounding insurance coverage. Guardant Health's liquid biopsy, Guardant360, will now be a covered benefit for the members of the health plans associated with eviCore, a technology assessment company. The test will be considered medically necessary to assist in selecting therapy for patients with advanced lung cancer and will increase the total lung cancer coverage for Guardant360 to more than 150M Americans, including for all Medicare beneficiaries, members of Cigna, Blue Shield of California, UPMC Health Plan, BCBS FEP (Federal Employees Program), and many others.

This opens up GH to such a larger pool of potential customers now which means further opportunities for growth.

Overall, we like GH and the space they are operating in. We can actually see them being a prime takeout candidate by another large player in the industry. Given the fact that SoftBank owns a 33.4% stake and Sequoia Capital owns a 9.3% stake, revenue has been solid, the company has additional revenue opportunities via Lunar-1 and Lunar-2 along with help from medical plan coverage for their core business, we'd say long-term they are set up to continue their run.

Technically speaking, we can see continued momentum to \$80-82 off this medical coverage news, followed by a pullback to \$73-75. We'd like to see what insiders want to do now that the lock up period is over first and then go from there but right now shares have just hit overbought on Williams %R. This, alone, isn't enough for us to say its overbought though because the RSI and MFI haven't hit those levels yet but seem as though they will soon.



Wrapping our head around this valuation is still tough to do and that is why we found another company in this space that has also been performing pretty well that we'd recommend you also look into. The company is called NeoGenomics (NEO) and below is a snapshot we took from their corporate presentation. They are also in the same space as GH and consider themselves a pure-play on the industry with a \$2B valuation and larger revs than GH.

Perhaps diversifying your holdings between the two and some of the other names below is a better and more safe way of playing the growing liquid biopsy and diagnostic market.

Clinical Reference Labs (with oncology divisions)	Pure Play Oncology Reference Labs (comprehensive test menus)	Niche Oncology Players (limited test menus)
  