



Guardant Health S-1 Review

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A Closer Look at Guardant Health's Impending IPO:

Guardant Health, which filed an [S-1](#) on September 5, 2018 in anticipation of going public, is a precision oncology company that aims to improve the diagnosis and treatment of cancer through its proprietary gene sequencing technology. Founded in 2012 in the San Francisco Bay Area, Guardant has received over [\\$500 million](#) in private funding, most recently closing a [\\$360 million](#) round in May 2017 led by SoftBank's Vision Fund. The company plans to list on the [NASDAQ](#) under the ticker "GH." Timing, pricing and size of the offering are still TBA.

Guardant's sector, precision oncology, focuses on "matching cancer patients to personalized treatments based on the [underlying molecular profile](#) of their tumors." In other words, precision oncology aims to treat cancer with a scalpel instead of a sledge hammer. Traditionally, a tumor's molecular information has been collected through a tumor tissue biopsy requiring surgery. However, Guardant's technology allows for liquid biopsy-based tests, or the extraction of a tumor's molecular information via a blood test. Unlike tissue biopsies, which Guardant also argues are more invasive, time-consuming and costly, liquid biopsies can be used across all stages of cancer (including early stages) and provide a more representative molecular profile of a tumor in its entirety, improving diagnostic and treatment abilities.

Guardant Health's IPO may serve as a litmus test for more pure-play, gene sequencing oncology companies.

Notably, Guardant's competitors are mostly diversified, large, multi-billion-dollar companies with substantial operating histories. Additionally, Guardant Health's younger competitors have largely remained private, such as Adaptive Biotechnologies, or have been acquired, such as Foundation Medicine, Inc. Consequently, Guardant Health's IPO may serve as a litmus test for more pure-play, gene sequencing oncology companies.



Because of the advantages of liquid biopsies, many leading companies are entering the space and competing with Guardant Health. Guardant’s main competition comes from diagnostic companies that profile cancer’s molecular information using gene sequencing in either blood or tissue. Within the liquid biopsy sector, Guardant’s chief public competitors include Roche Holdings, Inc., Thermo Fisher Scientific Inc., Illumina, Inc., Qiagen N.V. and Sysmex Inostics. Illumina-backed GRAIL and Natera Inc. are also developing early cancer detection tests. Traditional public competitors in the broader tissue-based genomic profiling sector include Laboratory Corporation of America, Quest Diagnostics Inc., and Myriad Genetics. For reference, we have included below one-year forward Price / Sales multiples for Guardant’s closest public competitors.

Guardant Health Public Comparables (as of September 10, 2018):

Company	Ticker	P/S
Roche Holdings*	RHHBF	3.6x
Thermo Fisher Scientific	TMO	3.8x
Illumina	ILMN	13.7x
Qiagen N.V.	QGEN	5.3x
Sysmex Inostics*	SSMXF	7.0x
Natera	NTRA	4.8x
Laboratory Corp. of America	LH	1.5x
Quest Diagnostics	DGX	1.9x
Myriad Genetics	MYGN	3.4x
Mean		5.0x
Median		3.8x
Mean excl. Outliers**		4.7x
Median excl. Outliers**		4.3x

Source: YCharts data as of September 10, 2018

*Represents TTM figures

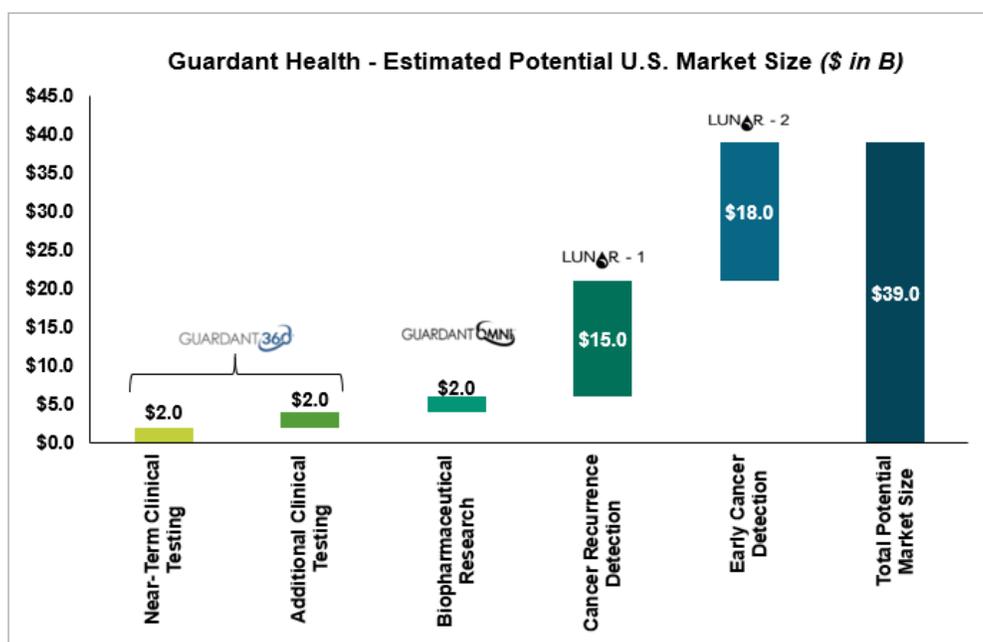
**Excludes data for Thermo Fisher Scientific, Laboratory Corp. of America and Quest Diagnostics



As you evaluate prior investment decisions or whether to buy GH in the future, please find below some of our key investment takeaways from Guardant Health's S-1 filing:

Investment Highlights:

1. Chasing a \$40 Billion Market. The company argues that its liquid biopsy technology has application in three key domestic market opportunities: (1) therapy selection in advanced cancers, (2) recurrence detection in cancer survivors and (3) early detection of cancer in higher risk individuals. Within the therapy selection market opportunity, Guardant believes there is a [\\$4 billion](#) clinical opportunity for its flagship Guardant360 liquid biopsy product and a [\\$2 billion](#) opportunity with biopharmaceutical companies that will use the GuardantOMNI product for comprehensive genomic profiling in immuno-oncology and targeted therapy research. The company is also working to develop its LUNAR-1 and LUNAR-2 products, for identifying cancer recurrence in survivors and early detection of cancer in higher risk individuals, respectively. Guardant estimates that the market for recurrence detection is roughly [\\$15 billion](#) and the market for early detection of cancer is approximately [\\$18 billion](#).

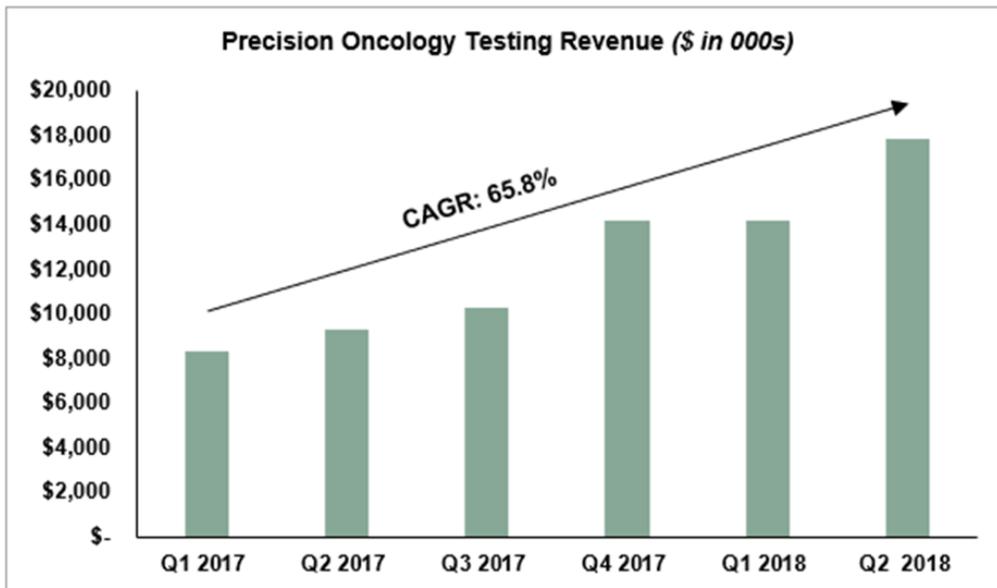


Source: Company [S-1 Filing](#)



2. Large Internationalization Opportunities. While Guardant offers tests in 38 countries outside the United States, international revenue currently represents a small fraction of overall revenue (14.3% in 2016, 4.2% in 2017 and 18.3% in 1H 2018). However, the company's business strategy contemplates significant international expansion, including through its joint venture with SoftBank. The SoftBank JV was formed to accelerate the commercialization of Guardant's products in Asia, the Middle East and Africa, with a near-term focus on Japan. As the parties evaluate international opportunities, the SoftBank JV may create direct operations, sell through a distribution model or license to a third party in any given market. Although Guardant does not quantify the global opportunity for its products, it notes that research predicts that there will be [22 million](#) new cancer cases and [13 million](#) cancer deaths by 2030.

3. Strong Commercial Adoption Thus Far. Guardant Health has enjoyed strong commercial adoption of its products by clinicians and biopharmaceutical companies, as demonstrated in the rapid growth of its precision oncology testing revenue from the provision of liquid biopsy testing services to oncologists and biopharmaceutical customers, as well as from biopharmaceutical research and development services provided to its biopharmaceutical customers. To date, Guardant's platform has been used by over [5,000](#) oncologists, who have ordered over [70,000](#) Guardant360 tests, and over [40](#) biopharmaceutical companies.



Source: Company [S-1 Filing](#)

4. Technological Advantage. Guardant argues that it has the highest-performing clinical liquid biopsy, with a turnaround time of fewer than [seven days](#) after receiving a testing sample. Moreover, the company believes that its platform is able to detect genomic alterations at sensitivity levels greater than those of its competitors. Guardant’s technological strength relies on, among other things, a proprietary tumor DNA sample preparation biochemistry, that is able to convert extracted tumor DNA into a sequencing library, thus enabling greater sensitivity to detect mutations at [“ultra-low variant frequency.”](#) The company also utilizes a proprietary bioinformatics engine that reduces tumor DNA sequencing error rates by 1000-fold vis-à-vis conventional sequencing technology. Finally, Guardant’s machine learning capabilities enable continuous sequencing performance improvement as data is incorporated from additional blood samples.

5. Key Regulatory Approvals. The company also believes that its Guardant360 product was the first comprehensive liquid biopsy approved by the New York State Department of Health. Additionally, Guardant’s biopsy laboratory is the first to become certified under the Federal Clinical Laboratory Improvement Amendments, according to the company. In January 2018, the FDA granted Guardant360 the [“Expedited Access Pathway”](#) designation,



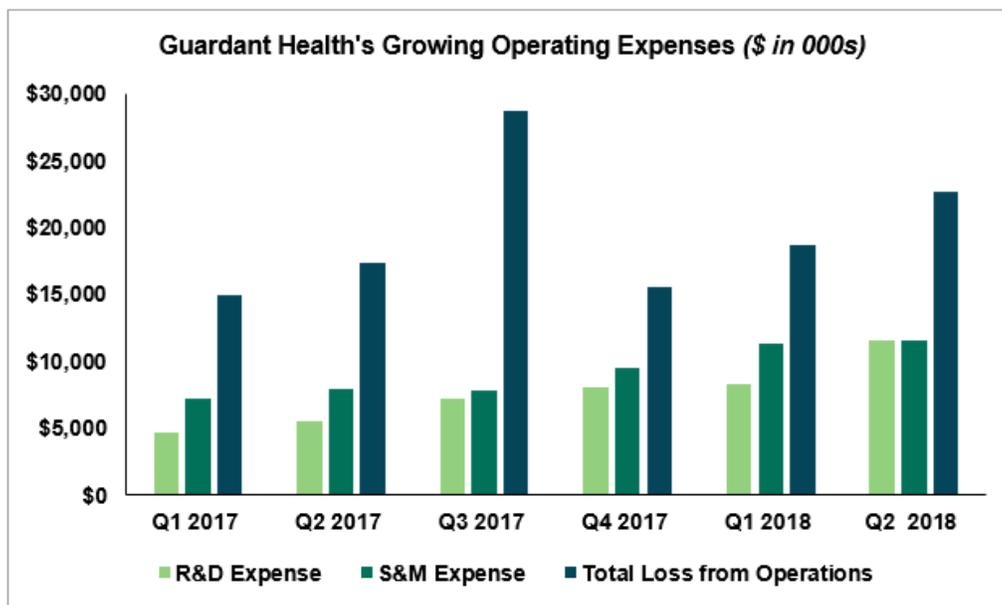
which offers faster review for “breakthrough” medical devices. With FDA approval, Guardant would have a potential path to reimbursement by Medicare and believes that FDA approval will be increasingly necessary for diagnostic tests to gain adoption, both in the United States and abroad. Guardant plans to submit a pre-market approval application for Guardant360 to the FDA in the first half of 2019.

Investment Risks & Considerations:

- 1. Stiff Competition.** Because of the benefits of liquid biopsy testing, many companies have entered the space and now compete with Guardant Health. Guardant’s competitors within the liquid biopsy space include Foundation Medicine, which was acquired by Swiss biotech giant Roche Holdings, Thermo Fischer Scientific Inc., Illumina, Inc., and Qiagen N.V., among others. Many of these companies are large, multinational corporations with substantial resources behind them to fund the research and development of liquid biopsy products. Moreover, Guardant states that certain of its customers are also developing their own liquid biopsy tests and may decide to enter the market or otherwise stop using Guardant’s products. With competition coming from various, well-funded sources, Guardant may find it difficult to maintain its purported technological edge.
- 2. Rapid Cash Burn.** Guardant Health has a strong cash position—approximately [\\$300 million](#) as of Q2 2018 and will of course raise substantial funds from its impending IPO. However, the company also burns cash at a rapid clip as it develops the LUNAR products. Over the last six quarters, the company has lost almost \$20 million per quarter on average from its operations. If Guardant ends up raising \$100 million in its IPO, this funding may only last the company 12 to 15 months, and Guardant will be forced to utilize more of its balance sheet. The cash burn is largely due to the company’s high sales and marketing and research and development expenses, which exceeded 100% of Guardant’s total loss from operations in the last three reported quarters. Guardant will have to continue its rapid revenue growth to



justify these expenses, or it may lose the faith of both its private and public investors and run out of cash before LUNAR-1 and LUNAR-2 reach commercial application.



Source: Company [S-1 Filing](#)

- 3. Healthcare Policy & Regulatory Risks.** The healthcare industry has faced substantial policy and regulatory uncertainty in recent years, and Guardant Health risks severe business damage depending on the government's regulatory actions. Currently, the FDA has a policy of enforcement discretion with respect to "laboratory-developed tests" (LDTs), pursuant to which the FDA does not enforce its regulatory requirements for such tests. This allows Guardant to market and sell its tests currently within the United States. However, the FDA has stated its intention to change its enforcement discretion policy with respect to LDTs, which may cause the company to come under widespread regulatory requirements, including additional clinical trials prior to selling existing tests or launching any other tests in the future.
- 4. Technology Development Risk.** Guardant Health estimates a potential market worth \$39 billion in the United States alone. Currently, however, the vast majority of Guardant's revenue comes from its Guardant360 product, which it released in 2014. According to the Company, the potential market for its Guardant360 product is only [\\$4 billion](#) of the \$39 billion, and tackling the remainder of Guardant's potential addressable market will require the



company to release the LUNAR-1 and LUNAR-2 products. The company admits that products from its LUNAR-1 and LUNAR-2 programs will take time and considerable resources to develop, and that the company may not be able to complete development and commercialization on a timely basis. As of now, Guardant faces concentration risk from its Guardant360 product, which faces intense and varied competition, as discussed.

5. Insurance Reimbursement Risk. Guardant's revenue depends on broad coverage and reimbursement for its tests from payers, including both commercial and government. If payers such as insurance companies do not provide coverage of or adequate reimbursement for Guardant's products, demand for the company's tests may suffer if patients are forced to pay out of pocket. Coverage and reimbursement determinations by insurance companies depend on a number of factors, including an assessment that a test is appropriate, medically necessary or cost-effective, and it is difficult to predict if Guardant will be able to convince payers with sufficient evidence of the clinical utility its tests. Additionally, all or a portion of the Affordable Care Act may be modified or repealed, which could result in lower numbers of insured individuals, adversely affecting Guardant's business. Finally, as competitors enter the markets, the availability of coverage and the reimbursement rate for Guardant's tests may decrease due to pricing pressure from increased competition.

Summary—Can Guardant Prevail Over the Giants?

In recent newsletters we highlighted the growing dominance of [large companies](#) over smaller challengers. Relatedly, despite some stumbles over the summer from the tech giants, Amazon, Apple, Google and their peers (of which there are few) continue to [outperform](#) and concentrate tech dominance within their hands. With Guardant's IPO, we see another smaller challenger to established companies, like diagnostics and biopharmaceutical giants [Illumina, Inc.](#) and [Roche Holdings](#). Hoping to avoid a similar fate faced by other prominent emerging companies, who were either [outspent](#) or [acquired](#) by larger rivals, Guardant's IPO may further illuminate whether the corporate elite's cash war chest is too great for most entrepreneurial ambitions.