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A $3 Billion Startup's Shares Gain On Hopes For A Cancer Blood Test

This bloody company is already worth $3.3 billion.

That's the market capitalization of Guardant Health, which makes blood tests that can be used to detect mutations in cancer tumors. Shares have doubled from the $19 price set in the company's October 4 initial public offering, which raised $273 million. Sell-side analysts at Cowen, Leerink Partners, J.P. Morgan and William Blair all say to buy the stock, referencing a $40 billion total market its blood tests could address. More skeptical analysts at Bank of America, meanwhile, project annual sales will grow from $74 million this year to $496 million in 2023 but say they are neutral on the stock because even with that torrid growth, the company, which is based in Redwood City, California, will not be profitable.

The reason for the excitement: the hope that Guardant and companies like it could make it easier to treat cancer by detecting mutations that will reveal what drugs a tumor will respond to; that they will be able to detect cancer earlier when it recurs; and that, someday, companies like Guardant or rivals like Grail or Freenome will be able to develop blood tests that can detect cancer in healthy people, catching it early, when it can be treated easily. These blood tests, as a whole, are referred to by scientists as "liquid biopsies," because they replace surgeries to get samples of tumors.

Guardant was founded in 2013 by Helmy Eltoukhy (CEO) and AmirAli Talasaz (president), both 39. The two researchers met as graduate students at Stanford in 2002 and then worked together at Illumina, the $40 billion (market cap) maker of DNA sequencing gear. Each owns shares in Guardant that are worth in excess of $200 million.

Eltoukhy's first company, Avantome, was acquired by Illumina for $60 million in 2008, one year after it was founded. For four years, he worked as an executive in the company's research labs.

"It was a great time, obviously, in their history," says Eltoukhy. "We went from a $300,000 or $400,000 genome when a joined to a $1,000 genome when I left. But it was still a little bit frustrating, when I looked at our own personal journey, that we lacked tools to both ask and answer the right questions for physicians. [There was] a lot of great progress on the research side, but not a lot of it was moving the needle on the clinical side."

Talasaz had studied electrical engineering in Tehran. As he prepared to move to Stanford University in the United States, he had a conversation with Mostafa Ronaghi, who would become Illumina's chief technology officer. "Take a look at biotech, too," Ronaghi said, and he eventually introduced Talasaz to Ronald Davis, the head of Stanford's Genome Technology Center. Talasaz went to Stanford in 2001, earned a Ph.D. at there in 2007, and worked in Davis' center until 2009, when he founded Auriphex Biosciences, a company that

developed new ways of isolating stray cancer cells from the blood. “I had lost my dearest friends and family to cancer,” Talasaz says. “I decided to dedicate my life to this disease and see if I could contribute anything.”

Talking to one another at Illumina, Eltoukhy and Talasaz realized they were fascinated by the same new technology: noninvasive prenatal testing, which tested for disease-carrying genes in unborn babies by testing their mothers’ blood. Couldn’t a similar technology detect cancer, they wondered?

It was a much tougher problem. The blood is full of pieces of DNA shed by cells. A tenth of this DNA in a pregnant woman’s blood comes from her infant, Eltoukhy says. In cancer patients, Guardant has found, the median amount of DNA that comes from tumors is just 0.4%. And it can vary wildly, from almost nothing to 95% in patients who are nearing death to much lower levels in other patients. Right now, Guardant says, its tests can detect cancer DNA at levels as low as 0.02% of the total amount of DNA in a patient’s blood.

Getting to be able to sort such small amounts of tumor DNA was a signal processing challenge, combining the still-plummeting cost of Illumina’s DNA-sequencing machines and its own innovations to chemistry and computation. The company raised $9.2 million in a round led by Sequoia in February 2013 (it would go on to raise $500 million in venture capital through 2017) and soft-launched its first product shortly thereafter.

Prenatal testing was DNA sequencing’s first big market. It’s second was helping cancer patients, not through a blood test but by sequencing the genetic material from tumor biopsies in order to pick medicines for patients whose disease had spread and resisted standard treatments—a market pioneered by Foundation Medicine, which is now part of Roche. Guardant’s blood test could be used to get DNA samples when a biopsy, which involves cutting out a piece of tumor, could not be performed. Guardant’s first product, Guardant360, looked at mutations in 54 genes. (The current version examines 73 genes and has a list price of $7,800.)

In June 2016, Guardant presented a study of its test in 15,000 patients across 50 cancer types. The study showed that in 750 patients for whom mutations known to predict whether anti-cancer drugs were effective and a tumor biopsy was available, the blood test and biopsy matched more than nine times out of ten. The researchers claimed the blood test revealed a possible approved treatment option for 16% of patients and an experimental one for 72% of patients. Eltoukhy says revealing the study was one of his best days at Guardant. “It’s one of those field of dreams moments,” Eltoukhy says. “If you build it, will they come?” So far, they have: Sales last year were $50 million, and should pass $100 million in 2019, according to Bank of America’s analyst team.

For Talasaz, the potential of the technology comes back to patients. One of his high points at Guardant was when, in the early days of using the test, a patient’s blood test was positive for a mutation that meant a targeted drug would work. It did, and the doctor sent Guardant the CAT scans to prove it. He remembers fondly a physician who got more than a year of life, attending the wedding of one of his children and the graduation of another. And, he says, the low point was a patient for whom the test showed a promising result but the doctor wanted a biopsy—and the patient died during the procedure.

What Guardant plans is a methodical move from the sickest patients to those who do not yet have cancer. A newer version of their test, launched in 2017, looks at 500 genes, but

this test still focuses on patients with advanced cancer. There are 700,000 in the U.S. Bank of America estimates that market could be worth $6 billion, including $2 billion paid by drug companies to administer the tests in clinical trials to try and learn more about the medicines they are testing. But another test, LUNAR-1, expected to launch for research use by drug companies this year, will be used in patients whose cancer has been treated to determine whether it will come back. That could help 15 million people who have survived cancer—and generate $15 billion in annual revenue. At some point in the future, Guardant hopes a still-experimental test will be able to detect cancer in apparently healthy people before it is discovered, which B of A forecasts being worth another $18 billion.

That will be a competitive landscape. Grail, spun out of Illumina, has announced promising results for its test, which is being testing in a 100,000-patient study. It has raised $1.6 billion, according to Pitchbook. Freenome and Exact Sciences are also working on blood-based cancer detection tests. Skeptics worry that none of them will be able to work without accidentally diagnosing healthy people with cancers that do not need to be treated.

“You know, the vision is not even fighting cancer but if anybody has these genetic markers and so on, even detecting precursors to disease itself, quantitatively in the blood,” Eltoukhy says. “But it's step by step to get there.”
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