

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report: May 7, 2019
(Date of earliest event reported)



Invitae Corporation

(Exact name of the registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36847
(Commission
File Number)

27-1701898
(I.R.S. employer
identification number)

1400 16 th Street, San Francisco, California 94103
(Address of principal executive offices, including zip code)

(415) 374-7782
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, \$0.0001 par value per share	NVTA	New York Stock Exchange



Invitae Reports 47% Growth in Quarterly Revenue and Volume Year-Over-Year

- On track to deliver more than 500,000 test samples, and more than \$220 million in revenue in 2019 --*
- Signed eight new biopharma partnerships in the quarter, expanding the breadth of the genome network --*
- Management hosting conference call and webcast today at 4:30pm Eastern/1:30pm Pacific --*

SAN FRANCISCO, May 7, 2019 – Invitae Corporation (NYSE: NVT), the leader in advanced medical genetics, today announced financial and operating results for the first quarter ended March 31, 2019 .

“We’ve seen another first quarter of foundational growth across all of our customer segments, with strong momentum putting us well on our way to exceed our 2019 guidance and in 2020 to serve more than one million patients with more than \$500 million in revenue,” said Sean George, co-founder and chief executive officer of Invitae. “Invitae is rapidly becoming the preferred provider of genetic information for clinicians and biopharma partners and increasingly the partner of choice for third-party commercial payers seeking to improve patient outcomes and lower healthcare costs. We intend to continue driving the transformation of the genetics industry as we further extend our leadership position in bringing genetics into mainstream medicine, improving patient outcomes and lowering costs for everyone.”

First Quarter 2019 Financial Results

- Accessioned more than 94,000 samples in the first quarter of 2019 , representing a 47% increase over the more than 64,000 samples in the first quarter of 2018 . Billable volume was approximately 87,000 in the first quarter of 2019
- Generated revenue of \$40.6 million in the first quarter of 2019 , representing a 47% increase over the first quarter of 2018 revenue of \$27.7 million
- Reduced the average cost per sample to \$226 in the first quarter of 2019 , representing a 19% reduction from a \$279 average cost per sample in the first quarter of 2018
- Achieved gross profit of \$19.3 million in the first quarter of 2019 which is double the \$9.6 million gross profit in the first quarter of 2018

Total operating expenses, which exclude cost of revenue, for the first quarter of 2019 were \$55.5 million compared to \$46.1 million in the first quarter of 2018 . For the first quarter of 2019 , Invitae reported a net loss of \$37.7 million , or a \$0.47 loss per share, compared to a net loss of \$36.1 million in the first quarter of 2018 , or a \$0.66 net loss per share.

In the first quarter of 2019, Invitae completed a public offering of common stock, resulting in gross proceeds of \$196.7 million and net proceeds of \$184.5 million.

As of March 31, 2019, cash, cash equivalents, restricted cash and marketable securities totaled \$287.1 million. Net increase in cash, cash equivalents and restricted cash for the quarter was \$140.2 million, with cash burn for the quarter at \$29.6 million.

“We are committed to making the investments necessary to meet our 2020 goals,” said Shelly Guyer, chief financial officer of Invitae. “To that end, we have capital totaling nearly \$300 million, which we will invest in advancing the development of our total cancer care offering, accelerating the development and commercialization of our new direct channel for patients, and continuing to invest in further engineering capabilities to reduce costs, add content and enhance the quality of our offering overall.”

Invitae's Corporate and Scientific Highlights

- Announced the availability of non-invasive prenatal screening (NIPS) using maternal cell-free DNA, rounding out Invitae's comprehensive women's health genetic testing services
 - Named as one of seven labs in UnitedHealthcare's (UHC) Preferred Lab Network designed to make it easier for providers to choose from UHC's broader network of more than 300 labs, based on a rigorous quality review process
 - Presented various studies at The American College of Medical Genetics and Genomics (ACMG) Annual Clinical Genetics Meeting generated by researchers from Invitae
 - Shared data on the limitations of a direct-to-consumer strategy testing that detects only three of the thousands of genetic variants in *BRCA1* and *BRCA2* associated with hereditary breast and ovarian cancer (HBOC) risk, showing this strategy results in a clinical false negative rate of approximately 90% of those at risk for HBOC
 - Shared data from more than 113,000 patients that support broadening genetic testing guidelines to include patients with potentially actionable germline variants that are missed when clinicians adhere to current guidelines
 - Published data in the *Journal of Clinical Oncology* by Invitae scientists in collaboration with researchers from the TME Breast Care Network showing that current guidelines for genetic testing of breast cancer patients miss as many patients with pathogenic variants as they find. The American Society of Breast Surgeons (ASBS) revised its genetic testing guidelines for hereditary breast cancer to include all patients with a personal history of breast cancer
 - Collaborated with investigators at Tulane Cancer Center on the largest study to date on the genetics of prostate cancer. The study, published in *JAMA Oncology*, found that guidelines for genetic testing of prostate cancer patients excluded a substantial number of patients with disease causing genetic variants from having genetic testing done and concluded that broader genetic testing of patients with prostate cancer is warranted
 - Extended Invitae's genome network by signing eight new biopharma partnership contracts since the beginning of the year
 - Expanded its Behind the Seizure program with BioMarin to include two additional partners, Stoke Therapeutics and Xenon Pharmaceuticals, to help speed the diagnosis of genetic epilepsy in children experiencing unprovoked seizures from birth to age five
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- Partnered with Ultragenyx Pharmaceutical on a new testing program to offer sponsored genetic testing to accurately diagnose more patients suspected of having a genetic hypophosphatemia disorder, or provide confirmatory testing for those who have been clinically diagnosed with X-linked hypophosphatemia (XLH)

Webcast and Conference Call Details

Management will host a conference call and webcast today at 4:30 p.m. Eastern / 1:30 p.m. Pacific to discuss financial results and recent developments. The dial-in numbers for the conference call are (866) 393-4306 for domestic callers and (734) 385-2616 for international callers, and the reservation number for both is 3435689. Following prepared remarks, management will respond to questions from investors and analysts, subject to time limitations.

The live webcast of the call may be accessed by visiting the investors section of the company's website at ir.invitae.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the company's website.

About Invitae

Invitae Corporation (NYSE: NVTA) is the leading advanced medical genetics company, whose mission is to bring comprehensive genetic information into mainstream medicine to improve healthcare for billions of people. Invitae's goal is to aggregate the world's genetic tests into a single service with higher quality, faster turnaround time and lower prices. For more information, visit the company's website at invitae.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the company's financial results for the quarter ended March 31, 2019; estimated guidance for 2019 and future financial performance; the timing and impact of the company's partnerships, product offerings and distribution channels; investment plans; and the company's beliefs regarding the growth of its business, its position and impact on the genetic testing industry, its success in executing on its mission and achieving its goals, and the benefits of genetic testing. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the actual results for the quarter ended March 31, 2019; the company's ability to continue to grow its business; the company's history of losses; the company's ability to compete; the company's failure to manage growth effectively; the company's need to scale its infrastructure in advance of demand for its tests and to increase demand for its tests; the risk that the company may not obtain or maintain sufficient levels of reimbursement for its tests; the company's failure to successfully integrate or fully realize the anticipated benefits of acquired businesses; the company's ability to use rapidly changing genetic data to interpret test results accurately and consistently; security breaches, loss of data and other disruptions; laws and regulations applicable to the company's business; and the other risks set forth in the company's Annual Report on Form 10-K for the year ended December 31, 2018. These forward-looking statements speak only as of the date hereof, and Invitae Corporation disclaims any obligation to update these forward-looking statements.

Non-GAAP Financial Measures

To supplement Invitae's consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP), the company monitors and considers cash burn, which is a non-GAAP financial measure. This non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and is not necessarily comparable to similarly-titled measures presented by other companies. Cash burn excludes (1) changes in marketable securities other than investments made in privately held companies, (2) cash received from equity financings, including proceeds from a public offering of common stock in March 2019, (3) cash received from loan proceeds, and (4) cash received from exercises of warrants. Management believes cash burn is a liquidity measure that provides useful information to management and investors about the amount of cash consumed by the operations of the business. A limitation of using this non-GAAP measure is that cash burn does not represent the total change in cash, cash equivalents, and restricted cash for the period because it excludes cash provided by or used for other operating, investing or financing activities. Management accounts for this limitation by providing information about its operating, investing and financing activities in the statements of cash flows in its consolidated financial statements in its most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K and by presenting net cash provided by (used in) operating, investing and financing activities as well as the net increase in cash, cash equivalents and restricted cash in its reconciliation of cash burn. In addition, other companies, including companies in the same industry, may not use cash burn, may calculate cash burn in a different manner than management or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of cash burn as a comparative measure.

Because of these limitations, cash burn should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with GAAP. Investors are encouraged to review the reconciliation of net increase in cash, cash equivalents and restricted cash to cash burn provided in the table below.

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands)
(unaudited)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 252,502	\$ 112,158
Marketable securities	28,714	13,727
Accounts receivable	23,700	26,296
Prepaid expenses and other current assets	16,569	13,258
Total current assets	321,485	165,439
Property and equipment, net	25,757	27,886
Operating lease assets	37,290	—
Restricted cash	5,871	6,006
Intangible assets, net	29,156	30,469
Goodwill	50,095	50,095
Other assets	6,845	3,064
Total assets	\$ 476,499	\$ 282,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 9,867	\$ 7,812
Accrued liabilities	25,354	26,563
Operating lease obligations	4,419	—
Finance lease obligations	1,960	1,937
Total current liabilities	41,600	36,312
Operating lease obligations, net of current portion	42,634	—
Finance lease obligations, net of current portion	875	1,375
Debt	74,828	74,477
Other long-term liabilities	150	8,956
Total liabilities	160,087	121,120
Stockholders' equity:		
Common stock	9	8
Accumulated other comprehensive income (loss)	8	(5)
Additional paid-in capital	870,784	678,548
Accumulated deficit	(554,389)	(516,712)
Total stockholders' equity	316,412	161,839
Total liabilities and stockholders' equity	\$ 476,499	\$ 282,959

INVITAE CORPORATION

Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Test revenue	\$ 39,619	\$ 27,053
Other revenue	934	618
Total revenue	40,553	27,671
Cost of revenue	21,254	18,076
Research and development	17,994	15,366
Selling and marketing	24,193	18,924
General and administrative	13,319	11,780
Loss from operations	(36,207)	(36,475)
Other income, net	638	1,647
Interest expense	(2,108)	(1,292)
Net loss	\$ (37,677)	\$ (36,120)
Net loss per share, basic and diluted	\$ (0.47)	\$ (0.66)
Shares used in computing net loss per share, basic and diluted	79,369	54,382

INVITAE CORPORATION

Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (37,677)	\$ (36,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,286	3,433
Stock-based compensation	5,223	4,393
Remeasurements of liabilities associated with business combinations	(130)	1,093
Other	388	32
Changes in operating assets and liabilities:		
Accounts receivable	2,596	(224)
Prepaid expenses and other current assets	(3,365)	(1,156)
Other assets	1,019	(2,548)
Accounts payable	(307)	(1,574)
Accrued expenses and other liabilities	601	(231)
Net cash used in operating activities	<u>(28,366)</u>	<u>(32,902)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(20,781)	(225)
Proceeds from sales of marketable securities	—	19,965
Proceeds from maturities of marketable securities	6,000	2,078
Purchases of property and equipment	(2,764)	(1,871)
Net cash provided by (used in) in investing activities	<u>(17,545)</u>	<u>19,947</u>
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs	184,490	—
Proceeds from issuance of common stock	2,107	191
Proceeds from debt financing	—	19,792
Finance lease principal payments	(477)	(638)
Net cash provided by financing activities	<u>186,120</u>	<u>19,345</u>
Net increase in cash, cash equivalents and restricted cash	140,209	6,390
Cash, cash equivalents and restricted cash at beginning of period	118,164	17,459
Cash, cash equivalents and restricted cash at end of period	\$ 258,373	\$ 23,849

INVITAE CORPORATION

Reconciliation of Net Increase in Cash, Cash Equivalents and Restricted Cash to Cash Burn
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	(28,366)	(32,902)
Net cash provided by (used in) investing activities	(17,545)	19,947
Net cash provided by financing activities	186,120	19,345
Net increase in cash, cash equivalents and restricted cash	140,209	6,390
Adjustments:		
Purchases of investments	20,781	225
Sales of investments	—	(19,965)
Maturities of investments	(6,000)	(2,078)
Purchases of investments in privately held companies	—	(225)
Proceeds from public offering of common stock, net of issuance costs	(184,490)	—
Net proceeds from issuance of debt	—	(19,792)
Proceeds from exercises of warrants	(88)	(191)
Cash burn	(29,588)	(35,636)

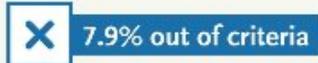
Source: Invitae Corporation

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Data supports the utility of genetic testing amongst broader patient populations

Positive rates



in breast surgery patients

Published in the *Journal of Clinical Oncology* in a collaboration with researchers from the TME Breast Care Network and Invitae

One in Six



prostate cancer cases are hereditary

Published in *JAMA Oncology* in largest study to date on the genetics of prostate cancer by Tulane University School of Medicine and Invitae



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