

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: August 6, 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 \$53.5 Million in Quarterly Revenue Driven by More Than 111,000 Samples in Quarterly Volume

-- Increased quarterly revenue by 43% and volume by 52% year-over-year --

-- Announced appointment of Sean George as chairman of the Board of Directors, retirement of Randy Scott as executive chairman, effective September 1, 2019--

-- Hosting conference call and webcast today at 4:30pm Eastern/1:30pm Pacific --

SAN FRANCISCO, August 6, 2019 – Invitae Corporation (NYSE: NVTA), a leading medical genetics company, today announced financial and operating results for the second quarter ended June 30, 2019 .

“We have now delivered our 25th quarter of impressive growth in both revenue and volume, while continuing to invest in new technologies that further our position as a leader in the rapidly evolving genetics industry,” said Sean George, co-founder and chief executive officer of Invitae. “We are beginning to stand out to our customers as the company that offers the most comprehensive menu of high-quality, affordable genetic testing to everyone who can benefit, enabling us to bring genetics more broadly into mainstream medicine. With the success we’ve had in the first half of the year, we are confident in our ability to achieve our 2019 guidance.”

Second Quarter 2019 Financial Results

- Accessioned more than 111,000 samples in the second quarter of 2019 , representing a 52% increase over the more than 73,000 samples in the second quarter of 2018 . Billable volume was nearly 111,000 in the second quarter of 2019
- Generated revenue of \$53.5 million in the second quarter of 2019 , representing a 43% increase over the second quarter of 2018 revenue of \$37.3 million
- Reported the average cost per sample at \$252 in the second quarter of 2019 , representing a 10% reduction from a \$279 average cost per sample in the second quarter of 2018
- Achieved gross profit of \$25.5 million in the second quarter of 2019 compared to \$16.9 million in gross profit in the second quarter of 2018

Total operating expenses, which exclude cost of revenue, for the second quarter of 2019 were \$77.4 million , which includes \$25.3 million in research and development, \$21.3 million in general and administrative and \$30.8 million in sales and marketing expenses for the quarter. Comparatively, total operating expenses for the second quarter of 2018 was \$46.9 million . Contributing to the increase in operating expense was acquisition-related costs.

For the second quarter of 2019, Invitae reported a net loss of \$48.7 million , or a \$0.54 loss per share, compared to a net loss of \$31.7 million in the second quarter of 2018 , or a \$0.47 net loss per share. Excluding acquisition-related expenses and income tax benefit, our non-GAAP net loss was \$46.8 million in the second quarter of 2019 , or a \$0.52 non-GAAP net loss per share.

As of June 30, 2019, cash, cash equivalents, restricted cash, and marketable securities totaled \$254.0 million. Net decrease in cash, cash equivalents and restricted cash for the quarter was \$5.1 million. Cash burn for the quarter was \$33.2 million.

Invitae's Corporate and Scientific Highlights

- Reduced patient-pay pricing for its non-invasive prenatal screening (NIPS) to \$99, increasing access to testing for women in early pregnancy
 - Announced the addition of supplemental RNA testing for variants of uncertain significance (VUS), beginning with patients undergoing cancer testing, to contribute to research and further reduce the uncertainty inherent in genetic testing results
 - Launched Invitae's direct channel to make it easier for customers to order and receive the same high-quality, medical genetic testing from Invitae that experts use and trust
 - Continued progress with payers, as Invitae was named one of seven labs in UnitedHealthcare's (UHC) Preferred Lab Network (PLN), effective as of July 1, 2019. The PLN was 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. Services accessed through the PLN are at a lower average cost than other lab providers
 - 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
 - Presented research at the American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating the importance of germline multigene panel testing in guiding therapy for expanding groups of cancer patients can impact patient outcomes and inform surgical strategy, treatments, and clinical trial eligibility
 - Continued investment in M&A to drive technologies to scale the business and improve quality
 - Acquired Singular Bio, Inc., a privately held company developing single molecule detection technology enabling lower costs and expanded use of high-quality cell-free, nucleic acid analysis, initially for application in NIPS
 - Acquired Jungla Inc., a privately held company funded by Andreessen Horowitz (a16z) that has developed a cloud-based platform that further enhances Invitae's genetic variant interpretation and ability to deliver high-quality, more affordable genetic testing
 - Extended Invitae's genome network with the addition of 12 new biopharma partnership programs in the second quarter of 2019
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- Launched ID YOUR IRD, an initiative with Spark Therapeutics, to offer genetic testing at no charge to patients suspected by their healthcare providers of having an inherited retinal disease (IRD), a group of rare, progressive eye disorders that may result in vision loss or blindness caused by inherited genetic changes
- Announced the availability of its *Detect* programs to provide no-charge genetic testing to improve diagnosis and treatment in four conditions: muscular dystrophy, hereditary prostate cancer, cardiomyopathy and arrhythmia and lysosomal storage diseases
- Announced the appointment of Sean George as the new chairman of the board of directors and the retirement of executive chairman Randy Scott, effective September 1, 2019

“During my 35 years in the biotech industry, it has been amazing to watch the genomics field emerge from the early days of the human genome project to now affecting millions of lives around the world,” said Randy Scott, executive chairman. “I couldn’t be more proud to be a part of the Invitae story, and I look forward to following the progress of a great team on a great mission to make genetic information more affordable and accessible for all. I plan to continue to support the Invitae team as a private investor and look forward to the tremendous growth that lies ahead.”

“Given the stage of growth we’re in, we are confident in our ability to scale as we bring genetics to mainstream medicine, and Randy’s leadership and vision have been central to getting us here,” said Sean George. “We’re deeply grateful to Randy for his passion for Invitae’s success and for his role as a pioneer and innovator in the genetics industry.”

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 6153749. Following prepared remarks, management will respond to questions from investors and analysts, subject to time limitations.

The live webcast of the call and slide deck may be accessed by visiting the investors section of the company’s website at ir.invitae.com. A replay of the webcast and conference call 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 June 30, 2019 ; estimated guidance for 2019 and future financial performance; the impact of the company's acquisitions, product offerings and distribution channels; the retirement plans of the company's executive chairman, appointment of a new chairman, and the timing thereof; 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 June 30, 2019 and the year ending December 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2019. 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 is providing non-GAAP research and development expense, non-GAAP general and administrative expense, non-GAAP net loss and net loss per share and cash burn, which are non-GAAP financial measures. These non-GAAP financial measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similarly-titled measures presented by other companies. Management believes these non-GAAP financial measures are useful to investors in evaluation the company's ongoing operating results and trends.

Non-GAAP research and development expense, non-GAAP general and administrative expense and non-GAAP net loss exclude acquisition-related stock-based compensation related to inducement grants, post-combination expense related to the acceleration of equity grants in connection with the company's business combinations, and acquisition-related income tax benefits. These non-GAAP financial measures are limited in value because they exclude certain items that may have a material impact on the reported financial results. Management accounts for this limitation by analyzing results on a GAAP basis as well as a non-GAAP basis and also by providing GAAP measures in the company's public disclosures.

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 the company's operating, investing and financing activities in the statements of cash flows in the consolidated financial statements in the company's 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 reconciliation of cash burn.

In addition, other companies, including companies in the same industry, may not use cash burn, non-GAAP research and development and general and administrative expense, or non-GAAP net loss or may calculate these metrics in a different manner than management or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of these non-GAAP measures as comparative measures. Because of these limitations, the company's non-GAAP financial measures 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 non-GAAP reconciliations provided in the table below.

INVITAE CORPORATION

Consolidated Balance Sheets

(in thousands)
(unaudited)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 247,000	\$ 112,158
Marketable securities	800	13,727
Accounts receivable	23,143	26,296
Prepaid expenses and other current assets	16,976	13,258
Total current assets	287,919	165,439
Property and equipment, net	29,021	27,886
Operating lease assets	40,228	—
Restricted cash	6,243	6,006
Intangible assets, net	57,832	30,469
Goodwill	76,556	50,095
Other assets	5,103	3,064
Total assets	\$ 502,902	\$ 282,959
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,255	\$ 7,812
Accrued liabilities	27,801	26,563
Operating lease obligations	5,102	—
Finance lease obligations	1,934	1,937
Total current liabilities	40,092	36,312
Operating lease obligations, net of current portion	45,694	—
Finance lease obligations, net of current portion	429	1,375
Debt	75,184	74,477
Other long-term liabilities	—	8,956
Total liabilities	161,399	121,120
Stockholders' equity:		
Common stock	9	8
Accumulated other comprehensive income (loss)	—	(5)
Additional paid-in capital	944,559	678,548
Accumulated deficit	(603,065)	(516,712)
Total stockholders' equity	341,503	161,839
Total liabilities and stockholders' equity	\$ 502,902	\$ 282,959

INVITAE CORPORATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Test revenue	\$ 52,302	\$ 36,350	\$ 91,921	\$ 63,403
Other revenue	1,173	956	2,107	1,574
Total revenue	53,475	37,306	94,028	64,977
Cost of revenue	28,006	20,447	49,260	38,523
Research and development	25,302	15,784	43,296	31,150
Selling and marketing	30,779	18,707	54,972	37,631
General and administrative	21,274	12,436	34,593	24,216
Loss from operations	(51,886)	(30,068)	(88,093)	(66,543)
Other income, net	1,381	188	2,019	1,835
Interest expense	(2,121)	(1,791)	(4,229)	(3,083)
Net loss before taxes	(52,626)	(31,671)	(90,303)	(67,791)
Income tax benefit	(3,950)	—	(3,950)	—
Net loss	\$ (48,676)	\$ (31,671)	\$ (86,353)	\$ (67,791)
Net loss per share, basic and diluted	\$ (0.54)	\$ (0.47)	\$ (1.01)	\$ (1.12)
Shares used in computing net loss per share, basic and diluted	90,863	67,807	85,148	60,775

INVITAE CORPORATION

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

	Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (86,353)	\$ (67,791)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,725	6,927
Stock-based compensation	19,540	10,505
Remeasurements of liabilities associated with business combinations	(286)	709
Benefit from income taxes	(3,950)	—
Other	1,182	462
Changes in operating assets and liabilities, net of business acquired:		
Accounts receivable	3,153	(4,037)
Prepaid expenses and other current assets	(3,825)	(512)
Other assets	2,410	(1,428)
Accounts payable	(3,954)	(3,106)
Accrued expenses and other liabilities	4,267	(396)
Net cash used in operating activities	<u>(61,091)</u>	<u>(58,667)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(20,781)	(900)
Proceeds from sales of marketable securities	—	19,965
Proceeds from maturities of marketable securities	34,000	2,078
Acquisition of business, net of cash acquired	3,193	—
Purchases of property and equipment	(8,824)	(3,084)
Net cash provided by investing activities	<u>7,588</u>	<u>18,059</u>
Cash flows from financing activities:		
Proceeds from public offerings of common stock, net of issuance costs	184,490	53,480
Proceeds from issuance of common stock	5,123	4,933
Proceeds from debt financing	—	19,781
Finance lease principal payments	(1,031)	(1,170)
Net cash provided by financing activities	<u>188,582</u>	<u>77,024</u>
Net increase in cash, cash equivalents and restricted cash	135,079	36,416
Cash, cash equivalents and restricted cash at beginning of period	118,164	17,459
Cash, cash equivalents and restricted cash at end of period	\$ <u>253,243</u>	\$ <u>53,875</u>

INVITAE CORPORATION

Reconciliation of GAAP to Non-GAAP Research and Development Expense

(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	\$ 25,302	\$ 15,784	\$ 43,296	\$ 31,150
Acquisition-related stock-based compensation	(2,586)	—	(2,586)	—
Non-GAAP research and development	<u>\$ 22,716</u>	<u>\$ 15,784</u>	<u>\$ 40,710</u>	<u>\$ 31,150</u>

Reconciliation of GAAP to Non-GAAP General and Administrative Expense

(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
General and administrative	\$ 21,274	\$ 12,436	\$ 34,593	\$ 24,216
Acquisition-related post-combination expense	(3,212)	—	(3,212)	—
Non-GAAP general and administrative	<u>\$ 18,062</u>	<u>\$ 12,436</u>	<u>\$ 31,381</u>	<u>\$ 24,216</u>

Reconciliation of Net Loss to Non-GAAP Net Loss Per Share

(in thousands, except per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	\$ (48,676)	\$ (31,671)	\$ (86,353)	\$ (67,791)
Acquisition-related stock-based compensation	2,586	—	2,586	—
Acquisition-related post-combination expense	3,212	—	3,212	—
Acquisition-related income tax benefit	(3,950)	—	(3,950)	—
Non-GAAP net loss	<u>\$ (46,828)</u>	<u>\$ (31,671)</u>	<u>\$ (84,505)</u>	<u>\$ (67,791)</u>
Non-GAAP net loss per share, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (0.47)</u>	<u>\$ (0.99)</u>	<u>\$ (1.12)</u>
Shares used in computing net loss per share, basic and diluted	<u>90,863</u>	<u>67,807</u>	<u>85,148</u>	<u>60,775</u>

INVITAE CORPORATION

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

	Three Months Ended March 31, 2019	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Net cash used in operating activities	(28,366)	(32,725)	(61,091)
Net cash provided by (used in) investing activities	(17,545)	25,133	7,588
Net cash provided by (used in) financing activities	186,120	2,462	188,582
Net increase (decrease) in cash, cash equivalents and restricted cash	140,209	(5,130)	135,079
Adjustments:			
Purchases of investments	20,781	—	20,781
Maturities of investments	(6,000)	(28,000)	(34,000)
Proceeds from public offering of common stock, net of issuance costs	(184,490)	—	(184,490)
Proceeds from exercises of warrants	(88)	(25)	(113)
Cash burn	(29,588)	(33,155)	(62,743)

Source: Invitae Corporation

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