
**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 and Exchange Act of 1934**

Date of Report: **August 8, 2016**

(Date of earliest event reported)

Invitae Corporation

(Exact name of 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)

458 Brannan Street, San Francisco, California 94107
(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 (*see* General Instruction A.2. below):

- 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))
-
-

Item 2.02 Results of Operations and Financial Condition.

On August 8, 2016, Invitae Corporation (the “Company”) issued a press release announcing financial results for its fiscal quarter ended June 30, 2016. The full text of the press release is furnished as Exhibit 99.1 to this report.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Invitae Corporation dated August 8, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: August 8, 2016

INVITAE CORPORATION

By: /s/ Lee Bendekgey
Name: Lee Bendekgey
Title: Chief Financial Officer, General Counsel and Secretary



Invitae announces second quarter 2016 financial results, secures contract with a national payer and expands its network of regional private payers

- Accelerated development of a 20,000-gene medical exome to be available in Q1:2017 –
- Nearly tripled volume with more than 12,000 test reports delivered –
- Lowered COGS to approximately \$500 –
- Signed first biopharma agreements –
- Hosting webinar/conference call at 4:45 pm ET / 1:45 pm PT –

SAN FRANCISCO, August 8, 2016 — Invitae Corporation (NYSE: NVTA), a genetic information company, today announced financial and operating results for the second quarter ended June 30, 2016. The company made substantial progress on all four of its key metrics, including securing contracts with a major national payer and adding more regional private plans. The company also announced it is accelerating the development of its medical exome, to be comprised of more than 20,000 genes, which it expects will be available in the first quarter of 2017.

“Today we are announcing that we will be ‘leapfrogging’ our year-end goal of 3,000 genes in production by jumping to approximately 20,000 genes with a ‘boosted’ exome. Combined with our large and growing panel offerings we believe we will be able to provide the full spectrum of content for virtually every current clinical need,” said Randy Scott, chairman and CEO of Invitae. “We’ve made significant progress with Medicare and a national private payer now on board and more private payers to come in the near future. We believe the reimbursement tide is turning rapidly as payers adopt our low cost platform and begin to eliminate the high gross margins that have restrained market growth and patient access to genetic testing.”

Total revenue was \$5.6 million for the second quarter of 2016, compared to \$4.0 million in the first quarter of 2016. Operating expenses, excluding the costs of tests delivered, were \$23.2 million compared to \$23.3 million for the first quarter of 2016. Costs of tests delivered were \$6.5 million for the second quarter of 2016 compared to \$6.0 million in the first quarter of 2016.

The company reported total revenue of \$5.6 million in the second quarter of 2016, compared to \$1.8 million in the second quarter of 2015. Operating expenses, excluding the costs of tests delivered, were \$23.2 million compared to \$22.1 million for the second quarter of 2015. Costs of tests delivered were \$6.5 million for more than 12,500 samples accessioned in the second quarter of 2016 compared to \$3.9 million for more than 4,600 samples accessioned in the second quarter of 2015. Net loss was \$24.8 million in the second quarter of 2016, or a \$0.77 loss per share. Operating expenses in the second quarter of 2016 included non-cash expenses of approximately \$5.2 million, including depreciation, equity compensation, and non-cash rent expense for a new production facility, which the company expects to occupy later this year.

At June 30, 2016, cash, cash equivalents, restricted cash, and marketable securities totaled approximately \$90.2 million, approximately \$18.5 million less than the comparable amount as of March 31, 2016.

Following are recent highlights:

- **Increased volume:** Increased volume by 170% year-over-year by delivering more than 12,000 billable reports and accessioning more than 12,500 samples. Also announced that the company completed the comprehensive Clinical Laboratory Evaluation Program and received its clinical laboratory permit from the state of New York, and is now offering testing for hereditary cancer, cardiology, and pediatric patients.
 - **Lowered COGS:** Reduced cost of goods sold (COGS) from approximately \$600 in the first quarter of 2016 to approximately \$500 per sample accessioned in the second quarter.
 - **Expanded content:**
 - Announced it has accelerated development of its medical exome, which will be comprised of more than 20,000 genes, including 3,000 clinically important genes with “boosted” sequence coverage, and is expected to be available in the first quarter of 2017.
 - Continued to expand its menu to strengthen its cancer offering with a seven-gene Breast Cancer STAT Panel for patients who need rapid test results to guide surgical decisions and treatment options.
 - **Improved reimbursement:** Established reimbursement with several payers, including Aetna and Medicare, bringing total lives covered to approximately 95 million:
 - Signed an agreement on July 1, 2016 to become part of Aetna’s (NYSE: AET) laboratory network, effective August 15, 2016.
 - Secured contracts with other regional Blue Cross Blue Shield affiliates, including Blue Shield of California as a preferred in-network laboratory for hereditary breast and ovarian cancer (HBOC) and Lynch syndrome testing, as well as Blue Cross Blue Shield of Illinois, Blue Cross Blue Shield of Rhode Island, Wellmark (Iowa and South Dakota), as well as other private payers.
 - Began receiving payments in April from the Centers for Medicare and Medicaid Services (CMS) for Invitae’s multi-gene tests for hereditary breast cancer-related disorders under new billing guidelines and an expanded coverage policy by Palmetto’s MolDX program. Payments are made by Noridian, CMS’s administrative contractor for California.
 - Signed additional contracts with institutional customers, increasing its total number of active institutional customers to more than 100 accounts worldwide.
 - **Improved competitive advantage with our oncology offering:** In addition to the seven-gene Breast Cancer STAT Panel for patients who need rapid test results to guide surgical decisions and treatment options, Invitae:
 - Launched CancerCHECK, a tool designed to guide and support community oncologists to more easily follow clinical guidelines on the use of hereditary cancer genetic testing.
 - Highlighted data at the 2016 American Society of Clinical Oncology Annual meetings, including:
 - Prospective registry of multiplex testing (PROMPT): A web-based platform to assess cancer risk of genetic variants (Board #341) provides an update on patients enrolled in the PROMPT registry (in which Invitae participates), including most commonly reported variants in multiple hereditary cancer genes and the corresponding incidence of diseases.
 - Variant classifications in BRCA1 and BRCA2: A systematic analysis of interlaboratory concordance (Board #415) uses ClinVar to demonstrate that variant classifications in BRCA1 and BRCA2 are highly concordant across major clinical testing laboratories in an estimated patient population of roughly 20,000, adding to the weight of evidence supporting confidence in Invitae’s clinical interpretation of patient genetic testing results.
 - Effect of patient directed input on genetic testing in the surgical setting (Abstract e13117) demonstrates the effectiveness of Invitae’s Family History Tool to improve the accuracy of patient-reported information, increasing appropriate use of genetic testing to identify abnormalities without triggering over-testing.
-

- Critical co-diagnostic or ancillary assessment: Germline testing for patients with somatic tumor profiling (Abstract e13123) found that a substantial fraction of patients with mutations detected by tumor assays in fact carry both germline and somatic mutations. This suggests that somatic testing in cancer is an important entry point for germline testing, which in turn can help guide ongoing management of patients and family members.
- Distribution of genetic variants detected via next-generation sequencing in an international private practice (Abstract e13032) demonstrated feasibility of Invitae's panel test in Singapore, a multi-ethnic society. At the same time, discrepancies in the frequency of pathogenic variants versus variants of unknown significance (VUS) between Caucasian and non-Caucasian patients observed by all labs highlight the value of expanding variant data collection to include ethnically diverse patients in order to improve the care of these patients.
- **Beginning to build genome network:** Signed contracts and began working with pharmaceutical and biotech companies, including MyoKardia, Parion Sciences, and others to provide genetic testing for clinical trial and other programs to help connect patients to potential treatments.
- **Commitment to data sharing:** Submitted information on more than 10,000 clinically observed genetic variants to the ClinVar project, an effort by the National Center for Biotechnology Information (NCBI) to aggregate all of the world's known relationships between genetic variants and disease, bringing our total submissions to more than 22,000.

"We have executed consistently on all business measures over the last seven quarters, our business model is indeed working, and we are seeing the operating leverage that we expect will soon move us to positive gross margins and subsequently drive us toward positive cash flow generation. We continued to maintain operating effectiveness as we scale through almost tripled year-over-year sample volume growth. In fact, our turnaround times continue to improve as we grow volume to the 50,000-70,000 samples we projected for the year," said Sean George, president and COO of Invitae. "Now with payers and other industry partners working with us, we are increasing our commercial leverage and can accelerate driving the change in the genetic testing landscape to an industry in which we believe we are well-positioned to be the leader."

Indicators of our Success in 2016

The four guiding indicators of success in 2016 include:

1. Reducing COGS per test
2. Increasing content
3. Increasing volume
4. Improving reimbursement and cash collections

Webinar and Conference Call Details

The dial-in numbers for the conference call are (877) 201-0168 for domestic callers and (647) 788-4901 for international callers, and the reservation number for both is 48736029.

The live webcast of the conference 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's (NYSE: NVTA) mission is to bring comprehensive genetic information into mainstream medical practice to improve the quality of healthcare for billions of people. Invitae's goal is to aggregate most of the world's genetic tests into a single service with higher quality, faster turnaround time, and lower price than many single-gene and panel tests today. The company currently provides a diagnostic service comprising hundreds of genes for a variety of genetic disorders associated with oncology, cardiology, neurology, pediatrics, and other rare disease areas. For more information, visit our website at invitae.com.

Safe Harbor Statements

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 expectations regarding its ability to obtain reimbursement; the company's beliefs regarding its positioning in the market; the company's accelerated development of its medical exome to be comprised of more than 20,000 genes and its belief that it will be available in the first quarter of 2017; the company's expectation that it will occupy its new production facility later this year; the company's expectations regarding being cash flow positive; future performance levels; and the indicators of the company's success and its expected actions with respect to those indicators. 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: risks associated with the company's ability to develop and commercialize new tests and expand into new markets; the company's ability to use rapidly changing genetic data to interpret test results accurately, consistently and quickly; the company's history of losses; 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; laws and regulations applicable to the company's business, including potential regulation by the Food and Drug Administration; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016. These forward-looking statements speak only as of the date hereof, and Invitae Corporation disclaims any obligation to update these forward-looking statements.

NOTE: Invitae and the Invitae logo are trademarks of Invitae Corporation. All other trademarks and service marks are the property of their respective owners.

Invitae Corporation
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
	(unaudited)			
Revenue	\$ 5,581	\$ 1,801	\$ 9,536	\$ 3,030
Costs and operating expenses:				
Cost of revenue	6,476	3,866	12,463	7,065
Research and development	10,713	11,837	21,373	20,292
Selling and marketing	6,843	6,189	13,886	10,929
General and administrative	5,637	4,034	11,206	7,474
Total costs and operating expenses	<u>29,669</u>	<u>25,926</u>	<u>58,928</u>	<u>45,760</u>
Loss from operations	(24,088)	(24,125)	(49,392)	(42,730)
Interest and other income (expense), net	(659)	(98)	(861)	(102)
Interest expense	(100)	(35)	(184)	(63)
Net loss	<u>\$ (24,847)</u>	<u>\$ (24,258)</u>	<u>\$ (50,437)</u>	<u>\$ (42,895)</u>
Net loss per share, basic and diluted	\$ (0.77)	\$ (0.76)	\$ (1.57)	\$ (1.75)
Shares used in computing net loss per share, basic and diluted	32,154,982	31,809,683	32,060,260	24,477,309

Invitae Corporation
Condensed Consolidated Balance Sheets
(In thousands)

	June 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,587	\$ 73,238
Marketable securities	53,699	53,780
Prepaid expenses and other current assets	11,465	4,292
Total current assets	96,751	131,310
Property and equipment, net	18,708	18,709
Restricted cash	4,872	4,831
Other assets	862	1,826
Total assets	<u>\$ 121,193</u>	<u>\$ 156,676</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,899	\$ 3,500
Accrued liabilities	4,187	4,253
Capital lease obligation, current portion	1,456	1,588
Debt, current portion	2,725	1,536
Total current liabilities	12,267	10,877
Capital lease obligation, net of current portion	913	1,576
Debt, net of current portion	8,400	5,504
Other long-term liabilities	6,920	343
Total liabilities	28,500	18,300
Stockholders' equity:		
Common stock	4	4
Accumulated other comprehensive gain (loss)	32	(15)
Additional paid-in capital	318,056	313,349
Accumulated deficit	(225,399)	(174,962)
Total stockholders' equity	92,693	138,376
Total liabilities and stockholders' equity	<u>\$ 121,193</u>	<u>\$ 156,676</u>

The condensed, consolidated balance sheet at December 31, 2015 has been derived from the audited consolidated financial statements at that date included in the company's annual report on Form 10-K for the year ended December 31, 2015.

Source: Invitae Corporation

Contact:
Laura D'Angelo
pr@invitae.com
314-920-0617