CANCER GENETICS, INC
Form 8-K
July 16, 2015

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 (Date of earliest event reported): **July 15, 2015**

CANCER GENETICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35817**	**04-3462475**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 Route 17 North 2nd Floor, Rutherford, New Jersey 07070

(Address of Principal Executive Offices) (Zip Code)

Registrant s telephone number, including area code **(201) 528-9200**

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement.

On July 15, 2015, Cancer Genetics, Inc. (the Company) entered into a Controlled Equity Offering℠ Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor Fitzgerald), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald shares of its common stock, par value $0.0001 per share.

The Company is not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market to sell shares from time to time based upon the Company s instructions, including any price, time or size limits specified by the Company. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an at-the-market offering as defined in Rule 415 under the U.S. Securities Act of 1933, as amended, or, with the Company s prior consent, any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald s obligations to sell shares under the Sales Agreement are subject to satisfaction of certain conditions, including customary closing conditions for transactions of this nature. The Company will pay Cantor Fitzgerald a commission of 3.0% of the aggregate gross proceeds from each sale of shares and has agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. The Company has also agreed to reimburse Cantor Fitzgerald for certain specified expenses.

Sales of shares of common stock under the Sales Agreement will be made pursuant to the registration statement on Form S-3 (File No. 333-196374), which was declared effective by the U.S. Securities and Exchange Commission (the SEC) on June 5, 2014, and a related prospectus supplement filed with the SEC on July 15, 2015, for an aggregate offering price of up to $20,000,000.

The foregoing summary of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Sales Agreement, which is filed herewith as Exhibit 1.1.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy any shares under the Sales Agreement, nor shall there be any sale of such shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Item 2.02. Results of Operations and Financial Condition.

The Company is currently compiling its financial results for the three months ended June 30, 2015, and such financial information is not yet available. However, management s preliminary estimate of use of cash, or cash burn, for the three months ended June 30, 2015 indicates a burn of approximately $4.8 million in the quarter. This amount is approximately $1.3 million more that the Company s average cash burn and is predominately due to the timing of the payment of premiums for the Company s annual business insurance renewal and payments of employee bonuses accrued in the year ended December 31, 2014.

The estimates above are preliminary and may change. We have not completed the preparation of our quarterly financial statements for the quarter ended June 30, 2015, we and our auditors have not completed our normal quarterly review procedures for the quarter, and there can be

no assurances that our final results for this quarter will not differ from these estimates, which changes could be material. These estimates should not be viewed as a substitute for full interim financial statements prepared in accordance with GAAP or as a measure of our performance.

Item 8.01. Other Events.

The Company s business is subject to significant regulation and is greatly dependent on our ability to protect our proprietary discoveries and technologies. The risks described below under the captions Regulatory Risks Relating to Our Business and Intellectual Property Risks Related to Our Business supplement and provide certain updates to certain of the regulatory and intellectual property related risks set forth under the captions Regulatory Risks Relating to Our Business and Intellectual Property Risks Related to Our Business, respectively, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 (the Form 10-K). The risk factor updates set forth below should be read in conjunction with the risk factors set forth in our most recent Form 10-K under the caption Item 1A. Risk Factors, as may be updated from time to time by subsequent filings under the Securities Exchange Act of 1934, as amended.

Any of these risks could have a material adverse effect on the Company s business, prospects, financial condition and results of operations. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business operations. These risks also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

RISK FACTORS

Regulatory Risks Relating to Our Business

We conduct business in a heavily regulated industry, and if we are unable to obtain regulatory clearance or approvals in the United States, if we experience delays in receiving clearance or approvals, or if we do not gain acceptance from other laboratories of any cleared or approved diagnostic tests at their facilities, our growth strategy may not be successful.

We currently offer our proprietary tests in conjunction with our comprehensive panel of laboratory services in our CLIA-certified and CAP-accredited laboratory. Because we currently offer these tests and services solely for use within our laboratory, we believe we may market the tests as laboratory developed tests (LDTs), which are tests designed, manufactured and used within a single laboratory. Although the Food and Drug Administration (FDA) has statutory authority to assure that medical devices, including LDTs, are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs. Specifically, under current FDA enforcement policies and guidance, LDTs generally do not require FDA premarket clearance or approval before commercialization, and we have marketed our LDTs on that basis (although, the FDA has recently announced that such policy may be changing). While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

In addition, an element of our long-term strategy is to place molecular diagnostic tests on-site with other laboratories to broaden access to our technology and increase demand for our tests and any future diagnostic tests that we may develop. If we were to offer our tests through third-party laboratories, these tests would most likely not be subject to the FDA s current exercise of enforcement discretion over LDTs, and would be subject to the applicable medical device regulations. For example, these tests could become subject to the FDA s requirements for premarket review. Unless an exemption applies, generally, before a new medical device or a new use for a medical device may be sold or distributed in the United States, the medical device must receive either FDA clearance of a 510(k) pre-market notification or pre-market approval. As a result, before we can market or distribute our tests in the United States for use by other clinical testing laboratories, we must first obtain pre-market clearance or pre-market approval from FDA. We have not yet applied for clearance or approval from FDA, and would need to complete additional validations before we are ready to apply. We believe it would likely take two years or more to conduct the studies and trials necessary to obtain approval from FDA to commercially launch any of our proprietary products outside of our clinical laboratory. Once we do apply, we may not receive FDA clearance or approval for the commercial use of our tests on a timely basis, or at all. If we are unable to obtain clearance or approval or if clinical diagnostic laboratories do not accept our tests, our ability to grow our business by deploying our tests could be compromised.

Recent announcements from the Federal Food and Drug Administration may impose additional regulatory obligations and costs upon our business.

On October 3, 2014 the FDA issued two draft guidance documents regarding its intent to modify its policy of enforcement discretion and increase oversight over LDTs. The two draft guidance documents are entitled Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (the Framework Guidance) and FDA Notification and Medical Device Reporting for Laboratory Developed Test (LDTs) (the Notification Guidance). According to the Framework Guidance, FDA plans to modify its policy of enforcement discretion with respect to LDTs using a phased-in, risk-based approach consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, to many LDTs that have historically been marketed without FDA premarket review and oversight. The FDA states its intention in the Framework Guidance to publish general LDT classification guidance within

18 months of the date on which the Framework Guidance is finalized. According to the Framework Guidance, devices that are already in use at the time FDA initiates enforcement of the premarket review requirements will be permitted to remain in use pending FDA s review and consideration of the premarket submission so long as a premarket submission is timely made. For the highest risk LDTs, the Framework Guidance provides that enforcement of the premarket submission requirements will begin 12 months after the guidance is finalized. For lower risk LDTs, enforcement will be phased in over the following four to nine years. Under this new risk based approach, it is possible that some level of pre-market review may be required for our LDTs either a 510(k) or PMA which may

require us to generate additional clinical data. While the FDA has proposed that devices that are already in use at the time FDA initiates enforcement of the premarket review requirements will be permitted to remain in use pending FDA s review and consideration of the premarket submission so long as a premarket submission is timely made, we may nevertheless be required to cease commercial sales of our products and conduct additional clinical testing prior to making submissions to the FDA to obtain premarket clearance or approval.

The draft guidance documents are subject to public comment. The final date for comments was February 2, 2015. We cannot tell at this time what additional costs and regulatory burdens, any final FDA guidance or FDA enforcement of its regulations may have on our business or operations.

If we and our tests become subject to FDA s enforcement of its medical device regulations pursuant to the FDA s plans to modify its policy of enforcement discretion with respect to LDTs, we may be subject to significant and onerous regulatory obligations. Even if the FDA does not finalize these Guidances, it is possible that Congress many act to impose new regulatory requirements on LDTs. See section below entitled *Risk Factors Additional Information About Regulatory Risks Relating to Our Business If the FDA regulates LDTs as proposed, then it would classify LDTs according to the current system used to regulate medical devices. Under that system, there are three different classes of medical devices, with the requirements becoming more stringent depending on the Class.*

If our laboratory facilities become damaged or inoperable, or we are required to vacate any facility, our ability to provide services and pursue our research and development efforts may be jeopardized.

We currently derive substantially all of our revenues from our laboratory testing services. We do not have any clinical reference laboratory facilities outside of our facilities in Rutherford, New Jersey, Morrisville, North Carolina and Hyderabad, India. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with collaborators, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if any of our laboratories became inoperable we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests. Even if we find a third-party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. Moreover, we believe our tests are currently subject to an exercise of enforcement discretion by the FDA because the tests are considered LDTs. If we are required to find a third-party laboratory to conduct our testing services, we believe the FDA would consider our tests to be medical devices that are no longer subject to its exercise of enforcement discretion for LDTs. In that case, we may be required to obtain premarket clearance or approval prior to offering our tests, which would be time-consuming and costly and could result in delays in our ability to sell or offer our tests.

Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to fines, penalties, liability, and adverse effects to our business and our reputation.

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual

property, and proprietary business information owned or controlled by ourselves or our customers, payors, and biopharmaceutical partners. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such improper access or disclosure, or loss of information could require us to provide notice to the affected individuals, the press, and regulatory bodies, result in legal claims or proceedings, liability, fines and penalties under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH), their implementing regulations, and similar state laws. Unauthorized access, loss, or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

The U.S. Department of Health and Human Services Office for Civil Rights (OCR) may impose penalties on a covered entity, such as us, for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity s failure to comply was due to willful neglect. These penalties include civil monetary penalties of $100 to $50,000 per violation, up to an annual, per violation cap of $1,500,000. A single breach incident can result in violations of multiple standards, resulting in possible penalties potentially in excess of $1,500,000. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one year imprisonment. The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 and up to 10 years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The U.S. Department of Justice is responsible for criminal prosecutions under HIPAA.

HIPAA authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of Protected Health Information.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities for compliance with the HIPAA privacy and security regulations. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured Protected Health Information may receive a percentage of the Civil Monetary Penalty fine paid by the violator.

HIPAA further requires covered entities to notify affected individuals without unreasonable delay and in no case later than 60 calendar days after discovery of the breach if their unsecured Protected Health Information is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, it must be reported to HHS and local media without unreasonable delay, and HHS will post the name of the breaching entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us

to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Health care policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations and cash flows.

In March 2010, U.S. President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA), which makes a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the PPACA:

- Requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax may apply to some or all of our current products and products which are in development.

- Mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the fee schedule payment amount. These changes in payments apply to some or all of the clinical laboratory test services we furnish to Medicare beneficiaries.

- Establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for services, including clinical laboratory services, beginning in 2016, and for hospital services beginning in 2020.

Although some of these provisions may negatively impact payment rates for clinical laboratory services, the PPACA also extends coverage to approximately 32 million previously uninsured people, which may result in an increase in the demand for our tests and services. The mandatory purchase of insurance has been strenuously opposed by a number of state governors, resulting in lawsuits challenging the constitutionality of certain provisions of the PPACA. On June 28, 2012, the Supreme Court upheld the constitutionality of the health care reform law, with the exception of certain provisions dealing with the expansion of Medicaid coverage under the law. While most of the law s provisions went into effect in 2013 and 2014, Congress has proposed a number of legislative initiatives, including possible repeal of the PPACA. On June 25, 2015, the Supreme Court affirmed the Fourth Circuit Court of Appeals in King v. Burwell, which allows the federal government to continue to extend tax subsidies to those individuals who purchased coverage through federal exchanges, in addition to the exchanges established by individual states. Although other federal circuit courts found that the subsidies were not permitted, the Supreme Court has now held that the tax subsidies to individuals who purchased through the federal exchanges are permitted under PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, starting in 2013. This 2% sequester was recently extended through 2024.

The full impact on our business of the PPACA and the new law is uncertain. In addition, on February 22, 2012, the President signed the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA), which, among other things, mandated an additional change in Medicare reimbursement for clinical laboratory services. This legislation requires a rebasing of the Medicare clinical laboratory fee schedule to effect a 2% reduction in payment rates otherwise determined for 2013. This will serve as a base for 2014 and subsequent years. As a result of the changes mandated by PPACA and MCTRJCA, the Centers for Medicare & Medicaid Services (CMS) projects laboratory services for 2015 will be reduced by approximately 0.25%.

Further, in 2014, Congress passed the Protecting Access to Medicare Act or PAMA which also makes significant changes in the way the Medicare will pay for laboratory services. Under PAMA, laboratories will be required to report the amount that they are paid by third party payors for each test beginning in January 2016. CMS will use this data to calculate a weighted median for each test. That new price will become effective on January 1, 2017, although any resulting reductions will be phased in over time. This data reporting process will be repeated every three years for most tests, although certain advanced diagnostic tests will have to report every year. It is possible that some of our tests may qualify as Advanced Diagnostic Laboratory Tests, which will require us to submit pricing annually. In addition, under PAMA, we will also be required to obtain new codes from CMS or any entity it designates, for our tests that do not currently have codes. If PAMA results in a significant reduction in the prices for our tests, it could have a significant impact on our revenues.

Certain of our laboratory services are paid under the Medicare Physician Fee Schedule and, under the current statutory formula, the rates for these services are updated annually. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provides a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA extended existing payment rates through June 30, 2015, with a 0.5% update for July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA requires the establishment of the Merit-Based Incentive Payment System (MIPS), beginning in 2019, under which physicians may receive performance-based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also requires the Centers for Medicare & Medicaid Services, or CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models, such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our services, which could adversely impact our revenues and results of operations.

In addition, many of the Current Procedure Terminology (CPT) procedure codes that we use to bill our tests were revised by the AMA, effective January 1, 2013. In the Final Rule, CMS announced that it has decided to keep the new molecular codes on the Clinical Laboratory Fee Schedule (CLFS), rather than move them to the Medicare Physician Fee Schedule as some stakeholders had urged. CMS also announced that for 2013 it would price the new codes using a gapfilling process by which it will refer the codes to the Medicare contractors to allow them to determine an appropriate price. Those prices were determined and became effective January 1, 2014. In addition, CMS also stated that it would not recognize certain of the new codes for Multi-Analyte Assays with Algorithmic Assays (MAAAs) because it does not believe they qualify as clinical laboratory tests. However, more recently, it has determined that the individual contractors may determine whether to pay for MAAA tests on a case by case basis. Our reimbursement could be adversely affected by CMS action in this area. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The taxes imposed by the new federal legislation and the expansion of government s role in the U.S. health care industry as well as changes to the reimbursement amounts paid by payors for our products or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these services would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

If FDA were to begin requiring approval or clearance of our tests, we could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval or we could experience decreased demand for, or reimbursement of, our tests.

Although FDA maintains that it has authority to regulate the development and use of LDTs, such as ours, as medical devices, it has not exercised its authority with respect to most LDTs as a matter of enforcement discretion. FDA does not generally extend its enforcement discretion to reagents or software provided by third parties and used to perform LDTs, and therefore these products must typically comply with FDA medical device regulations, which are wide-ranging and govern, among other things: product design and development, product testing, product labeling, product storage, pre-market clearance or approval, advertising and promotion and product sales and distribution.

We believe that our proprietary tests, as utilized in our laboratory testing, are LDTs. As a result, we believe that pursuant to FDA s current policies and guidance that FDA does not require that we obtain regulatory clearances or approvals for our LDTs. The container we provide for collection and transport of tumor samples from a pathology laboratory to our clinical reference laboratory may be a medical device subject to FDA s enforcement of its medical device regulations but we believe it is currently exempt from pre-market review by FDA. While we believe that we are currently in material compliance with applicable laws and regulations, we cannot assure you that FDA or other regulatory agencies would agree with our determination, and a determination that we have violated these laws, or a public announcement that we are being investigated for possible violations of these laws, could adversely affect our business, prospects, results of operations or financial condition.

Moreover, FDA guidance and policy pertaining to diagnostic testing is continuing to evolve and is subject to ongoing review and revision. A significant change in any of the laws, regulations or policies may require us to change our business model in order to maintain regulatory compliance. At various times since 2006, FDA has issued guidance documents or announced draft guidance regarding initiatives that may require varying levels of FDA oversight of our tests. For example, in June 2010, FDA announced a public meeting to discuss the agency s oversight of LDTs prompted by the increased complexity of LDTs and their increasingly important role in clinical decision-making and disease management, particularly in the context of personalized medicine. FDA indicated that it was considering a risk-based application of oversight to LDTs and that, following public input and discussion, it might issue separate draft guidance on the regulation of LDTs, which ultimately could require that we seek and obtain either pre-market clearance or approval of LDTs, depending upon the risk-based approach FDA adopts. The public meeting was held in July 2010 and further public comments were submitted to FDA through September 2010. Section 1143 of the Food and Drug Administration Safety and Innovation Act, signed by the U.S. President on July 9, 2012, required FDA to notify U.S. Congress at least 60 days prior to issuing a draft or final guidance regulating LDTs and provide details of the anticipated action.

On July 31, 2014, FDA notified Congress pursuant to the FDASIA that it intended to issue draft Guidances that would modify its policy of enforcement discretion with respect to LDTs and begin to enforce the applicable medical device regulations with respect to such products and tests. On October 3, 2014, the FDA issued two separate draft guidances: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (The Framework Draft Guidance) and FDA Notification and Medical Device Reporting for Laboratory Developed Tests (the Notification Draft Guidance.). In the Framework Draft Guidance, FDA states that after the Guidances are finalized, it will no longer exercise enforcement discretion with respect to LDTs and will, instead, regulate them in a risk-based manner consistent with the existing classification of medical devices. Thus, the FDA plans to begin to enforce its medical device requirements, including premarket submission requirements, on LDTs that have historically been marketed without FDA premarket review and oversight. Comments on the Draft Guidances were due on February 2 and those comments are now being considered by the FDA. It is not known when the FDA may issue final Guidances or what form those Guidances may take.

The Framework Draft Guidance states that within six months after the Guidances are finalized, all laboratories will be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. The FDA will then begin a phased review of the LDTs available, based on the risk associated with the test. For the highest risk LDTs, which the FDA classifies as Class III devices, the Framework Draft Guidance states that the FDA will begin to require premarket review within 12 months after the Guidance is finalized. Other high risk LDTs will be reviewed over the next four years and then lower risk tests, which will be classified as Class II, will be reviewed in the following four to nine years. The Framework Draft Guidance states that FDA expects to issue a separate Guidance describing the criteria for its risk-based

classification 18-24 months after the Guidances are finalized. At this time, we cannot predict how our tests would be classified.

If the FDA regulates LDTs as proposed, then it would classify LDTs according to the current system used to regulate medical devices. Under that system, there are three different classes of medical devices, with the requirements becoming more stringent depending on the Class.

If and when the Guidances are finalized, and the FDA begins to actively enforce its premarket submission regulations with respect to LDTs, we will be required to obtain premarket clearance for our tests under Section 510(k) of the FDCA or approval of a PMA, unless an exemption applies. The premarket review process may require that we conduct clinical trials in support of a 510(k) submission or PMA application. These trials generally require an effective Investigational Device Exemption, or IDE, from FDA for a specified number of patients, unless the product is exempt from IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin 30 days after the submission of the IDE application unless FDA or the appropriate institutional review boards at the clinical trial sites place the trial on clinical hold.

The process for submitting a 510(k) premarket notification and receiving FDA clearance usually takes from three to twelve months, but it can take significantly longer and clearance is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process. Despite the time, effort and expense expended, there can be no assurance that a particular test ultimately will be cleared or approved by the FDA through either the 510(k) clearance process or the PMA process on a timely basis, or at all.

Under the Guidances, we could also for the first time be subject to enforcement of other regulatory requirements applicable to medical devices. For example, our currently-marketed LDTs would also be subject to significant post-market requirements. After a device is placed on the market, regardless of the classification or pre-market pathway, it remains subject to significant regulatory requirements. Even if regulatory approval or clearance of a medical device is granted, FDA may impose limitations or restrictions on the uses and indications for which the device may be labeled and promoted. Medical devices may be marketed only for the uses and indications for which they are cleared or approved.

Device manufacturers must also comply with the FDA s registration and device listing requirements. A medical device manufacturer s manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality Systems Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA. FDA also may inspect foreign facilities that export products to the United States.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, denial of 510(k) clearance or PMA applications for new products, or challenges to or withdrawal of existing 510(k) clearances or PMA applications.

We cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for our tests, whether through additional guidance issued by FDA, new enforcement policies adopted by FDA or new legislation enacted by Congress. We believe it is possible that legislation will be enacted into law or guidance could be issued by FDA, which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. Given the attention Congress continues to give to these issues, legislation affecting this area may be enacted into law. The House Energy and Commerce Committee has recently drafted legislation, which if passed, would create a new center within the FDA to regulate LDTs. The new legislation would clarify that LDTs are not considered medical devices under applicable FDA law, but would still subject many LDTs to regulatory review to ensure their clinical validity. If enacted, such legislation could result in increased regulatory burdens on us as we continue to develop and introduce new tests.

In addition, the Secretary of the Department of Health and Human Services requested that its Advisory Committee on Genetics, Health and Society make recommendations about the oversight of genetic testing. A final report was published in April 2008. If the report s recommendations for increased oversight of genetic testing were to result in further regulatory burdens, they could negatively affect our business and delay the commercialization of tests in development.

The requirement of pre-market review could negatively affect our business until such review is completed and clearance or approval to market is obtained. FDA could require that we stop selling our tests pending pre-market clearance or approval. If FDA allows our tests to remain on the market but there is uncertainty about our tests, if they are labeled investigational by FDA or if labeling claims FDA allows us to make are very limited, orders or reimbursement may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a PMA application with FDA. If FDA requires pre-market review, our tests may not be cleared or approved on a timely basis, if at all. We may also decide voluntarily to pursue FDA pre-market review of our tests if we determine that doing so would be appropriate.

Additionally, should future regulatory actions affect any of the reagents we obtain from vendors and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform our testing.

We are subject to federal and state health care fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal Anti-kickback Statute, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, in return for or to induce either the referral of an individual for, or the purchase order or recommendation of, any item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of designated health services with whom the physician or a member of the physician s immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

- HIPAA, which established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;

- the federal civil monetary penalties law, which prohibits, among other things, offering or transferring remuneration, including waivers of co-payments and deductible amounts (or any part thereof), to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal false claims laws, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

The PPACA, among other things, also imposed new reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information timely, completely and accurately for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1.0 million per year for knowing failures). Manufacturers must submit reports by the 90th day of each calendar year. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because we manufacture our own LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that the government will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

We have adopted policies and procedures designed to comply with these laws, including policies and procedures relating to financial arrangements between us and physicians who refer patients to us. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The government alleged that we engaged in improper billing practices in the past and we may be the subject of such allegations in the future as the growth of our business and sales organization may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these laws and regulations is further increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medi-Cal or other state or federal health care programs, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

We are required to comply with laws governing the transmission, security and privacy of health information that require significant compliance costs, and any failure to comply with these laws could result in material criminal and civil penalties.

Under the administrative simplification provisions of HIPAA, the U.S. Department of Health and Human Services has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of Protected Health Information used or disclosed by health care providers and other covered entities. Three principal regulations with which we are currently required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions.

The privacy regulations cover the use and disclosure of Protected Health Information by health care providers. It also sets forth certain rights that an individual has with respect to his or her Protected Health Information maintained by a health care provider, including the right to access or amend certain records containing Protected Health Information or to request restrictions on the use or disclosure of Protected Health Information. We have implemented policies, procedures and standards in an effort to comply appropriately with the final HIPAA security

regulations, which establish requirements for safeguarding the confidentiality, integrity and availability of Protected Health Information, which is electronically transmitted or electronically stored. The HIPAA privacy and security regulations establish a uniform federal floor and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records

containing Protected Health Information. As a result, we are required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Moreover, HITECH, among other things, established certain health information security breach notification requirements. Under HIPAA, a covered entity must notify any individual without unreasonable delay and in no case later than 60 calendar days after discovery of the breach if their unsecured Protected Health Information is subject to an unauthorized access, use or disclosure. If a breach affects 500 patients or more, it must be reported to HHS and local media without unreasonable delay, and HHS will post the name of the breaching entity on its public website. If a breach affects fewer than 500 individuals, the covered entity must log it and notify HHS at least annually.

These laws contain significant fines and other penalties for wrongful use or disclosure of Protected Health Information. We have implemented practices and procedures to meet the requirements of the HIPAA privacy regulations and state privacy laws. In addition, we are in the process of taking necessary steps to comply with HIPAA s standards for electronic transactions, which establish standards for common health care transactions. Given the complexity of the HIPAA, HITECH and state privacy restrictions, the possibility that the regulations may change, and the fact that the regulations are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. To the extent that we submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied. Additionally, the costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. We could be subject to criminal penalties and civil sanctions for failing to comply with the HIPAA, HITECH and state privacy restrictions, which could result in the incurrence of significant monetary penalties. For further discussion of HIPAA and the impact on our business, see the section in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 entitled *Risk Factors Risks Related to Our Business and Strategy Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to fines, penalties, liability, and adverse effects to our business and our reputation.*

Intellectual Property Risks Related to Our Business

We may become involved in lawsuits or other proceedings to protect or enforce our patents or other intellectual property rights, which could be time-consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages.

From time to time we may face intellectual property infringement (or misappropriation) claims from third parties. Some of these claims may lead to litigation. The outcome of any such litigation can never be guaranteed, and an adverse outcome could affect us negatively. For example, were a third-party to succeed on an infringement claim against us, we may be required to pay substantial damages (including up to treble damages if such infringement were found to be willful). In addition, we could face an injunction, barring us from conducting the allegedly infringing activity. The outcome of the litigation could require us to enter into a license agreement which may not be pursuant to acceptable or commercially reasonable or practical terms or which may not be available at all. It is also possible that an adverse finding of infringement against us may require us to dedicate substantial resources and time in developing non-infringing alternatives, which may or may not be possible. In the case of diagnostic tests, we would also need to include non-infringing technologies which would require us to re-validate our tests. Any such re-validation, in addition to being costly and time consuming, may be unsuccessful.

Furthermore, we may initiate claims to assert or defend our own intellectual property against third parties. Any intellectual property litigation, irrespective of whether we are the plaintiff or the defendant, and regardless of the outcome, is expensive and time-consuming, and could divert our management s attention from our business and negatively affect our operating results or financial condition. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future collaborators.

Finally, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by

disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our technologies in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our technologies in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to maintain intellectual property protection, our competitive position could be harmed.

Our ability to compete and to achieve sustained profitability is impacted by our ability to protect our proprietary discoveries and technologies. Currently, we rely on a combination of U.S. and foreign patents and patent applications, copyrights, trademarks, confidentiality or non-disclosure agreements, material transfer agreements, licenses, work for hire agreements, and invention assignment agreements to protect our intellectual property rights. We also maintain certain company know how and technological innovations designed to provide us with a competitive advantage in the market place as trade secrets.

It is possible that our pending patent applications may not result in issued patents. Any patents that may be issued to us might be challenged by third parties as being invalid or unenforceable, or third parties may independently develop similar or competing technology that avoids our patents.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. For instance, a suit brought in the United States District Court for the Southern District of New York by multiple plaintiffs, including the American Civil Liberties Union (ACLU), against Myriad Genetics and the USPTO may have an impact on the biotechnology industry. The case involved certain of Myriad s U.S. patents related to the breast cancer susceptibility genes BRCA1 and BRCA2. Plaintiffs alleged, among other things, that gene related patents (as a whole) stifled diagnostic testing and research

that could lead to cures in the future. On June 13, 2013, the Supreme Court ruled that isolated genomic DNA is not patent-eligible under section 101 of the Patent Act, but cDNA is patentable. More recently, the U.S. Court of Appeals for the Federal Circuit ruled that a patent held by genetic testing company Sequenom Inc. on detecting fetal DNA in a pregnant woman s blood was invalid. While the decision may be appealed to the Supreme Court, at present, it is unknown exactly how this case, and the Myriad case, will impact biotech patents directed to genetic testing.

In addition, on February 5, 2010, the Secretary s Advisory Committee on Genetics, Health and Society for HHS voted to approve a report entitled Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests. That report defines patent claims on genes broadly to include claims to isolated nucleic acid molecules as well as methods of detecting particular sequences or mutations. The report also contains six recommendations, including the creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes, or for anyone using the patent-protected genes in the pursuit of research. The report also recommended that the Secretary should explore, identify, and implement mechanisms that will encourage more voluntary adherence to current guidelines that promote non-exclusive in-licensing of diagnostic genetic and genomic technologies. It is unclear whether these recommendations will be acted upon by the HHS, or if the recommendations would result in a change in law or process that could negatively impact our patent portfolio or future research and development efforts.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
1.1	Controlled Equity Offering℠ Sales Agreement, dated July 15, 2015, by and between Cancer Genetics, Inc. and Cantor Fitzgerald & Co.
5.1	Opinion of Lowenstein Sandler LLP
23.1	Consent of Lowenstein Sandler LLP (included in Exhibit 5.1)

SIGNATURES

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

CANCER GENETICS, INC.

Dated: July 15, 2015	By:	/s/ Edward J. Sitar Name: Edward J. Sitar Title: Chief Financial Officer

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