CANCER GENETICS, INC
Form 8-K
October 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): October 9, 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):

[ ] 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 2.01 Completion of Acquisition or Disposition of Assets.

On October 9, 2015, Cancer Genetics, Inc. ("Cancer Genetics", the "Company", "we" or "us") completed its acquisition of substantially all the assets and the assumption of certain liabilities of Response Genetics, Inc. ("Response Genetics") pursuant to the terms of the Acquisition Agreement (as defined below). The nature and amount of the consideration paid for such acquisition and the description of the Response Genetics business acquired by us are disclosed in Item 8.01 of this Form 8-K, which is incorporated by reference into this Item 2.01. Audited financial statements of Response Genetics, unaudited financial statements of Response Genetics and certain unaudited pro forma financial information of Cancer Genetics reflecting the acquisition of Response Genetics are attached as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, respectively, and incorporated by reference herein.

A copy of the Acquisition Agreement was previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated August 20, 2015, and is incorporated by reference herein. The description of the terms of the Acquisition Agreement contained in this report is qualified in its entirety by reference to such exhibit.

Item 8.01 Other Events.

Acquisition Agreement

On August 10, 2015, Cancer Genetics filed a quarterly report on Form 10-Q with the Securities and Exchange Commission announcing, among other things, that Cancer Genetics agreed, in principle, to act as the "stalking horse bidder" in connection with the sale of substantially all the assets and assumption of certain liabilities of Response Genetics in connection with Response Genetics' filing of a chapter 11 petition for bankruptcy in the Delaware Bankruptcy Court (the "Bankruptcy Court"). On August 21, 2015, we filed a Current Report on Form 8-K with the Securities and Exchange Commission announcing, among other things, the definitive Amended and Restated Asset Purchase Agreement (the "Acquisition Agreement"). On October 9, 2015, Cancer Genetics acquired substantially all the assets and assumed certain liabilities of Response Genetics for approximately $13,400,000, comprised of $7,000,000, in cash, and 788,584 shares of the Company's common stock, with the common stock being valued at $6,400,000.

Our Strategy

We believe this acquisition will offer many synergies that enhance our mission:

- Expand the size and geographic scope of our laboratory operations by adding Response Genetics' Los Angeles, California-based laboratory. We acquired Response Genetics' approximately 27,000 square foot, CLIA-certified and CAP-accredited laboratory located in Los Angeles, California, which has performed clinical oncology diagnostic testing for over 3,000 unique physicians, laboratories and hospital sites across the United States.

- Expand the size and geographic presence of our clinical sales force. Through this acquisition, we increased our geographic presence, particularly in the Western and Southeastern United States. We expect that our joint clinical sales force will have national reach and be among the largest oncology-focused clinical sales groups in the molecular diagnostics field.

- Acquire Response Genetics' Tissue of Origin® (TOO®) test, which we believe is the only FDA-cleared and Medicare-reimbursed test for identifying the primary site of otherwise unclassifiable malignant tumors. TOO® is a gene expression-based microarray that targets over 2,000 genetic sites to classify the originating tissue type of cancerous cells. TOO® will represent our first test with FDA clearance to commercialize outside our laboratory facilities.

- Gain expertise in solid tumor cancer types and expand our portfolio of proprietary genomic tests and services. Response Genetics is a leader in solid tumor molecular diagnostics, particularly in lung cancer, colorectal cancer and melanoma, with these tests assisting clinical decision-making based on a patient's genomic information. Solid tumors account for eight of the ten most common cancer types in the United States, impacting nearly 1.2 million patient lives annually. The acquisition provides us with the immediate opportunity to offer our existing customers an expanded test menu in solid tumors as well as the TOO® test. We expect to start marketing the combined entity's comprehensive portfolio of tests and services in the fourth quarter of 2015.

- Expand our biopharma customer base and our biopharma service offering. Through this acquisition, we expanded our biopharma customer base and contracts, including the multi-year ALCHEMIST Trial contract with the National Cancer Institute, or NCI, focused on biomarker-based treatment for lung cancer, which was awarded to Response

Genetics in 2014. Further, this acquisition provides us with an opportunity to capitalize on our expanded portfolio of oncology diagnostics through our relationships with our existing biopharma customers and to Response Genetics' existing biopharma customers.

- Expand our collaborative relationships with leading research centers and research and development of next-generation sequencing panels. Through the acquisition, we acquired the rights to offer and market a clinically actionable lung cancer next-generation sequencing panel developed by leading genomic scientists and clinicians at Knight Laboratories at Oregon Health & Science University.

Description of the Response Genetics Business

Overview

Response Genetics was formed as a Delaware corporation in September 1999. Response Genetics is a life sciences company engaged in the research and development of clinical diagnostic tests for cancer. Its mission is to provide personalized genetic information that will help guide physicians and patients in choosing the treatment from which a given patient is most likely to benefit as well as providing clinical testing services for pharmaceutical companies. Response Genetics generated revenues primarily from sales of its ResponseDX® diagnostic tests, which Response Genetics launched in 2008, and by providing clinical trial testing services to pharmaceutical companies.

Response Genetics' proprietary technologies enable it to reliably and consistently extract ribonucleic acid ("RNA") and deoxyribonucleic acid ("DNA") from tumor specimens that are stored as formalin-fixed and paraffin-embedded ("FFPE") specimens and thereby to analyze genetic information contained in these tissues. Response Genetics' technologies also enable it to use the FFPE patient biopsies for the development of diagnostic tests.

Methodologies used in Response Genetics' Testing Services

PCR

A number of Response Genetics' tests are based on the polymerase chain reaction ("PCR"), which is a sensitive, precise and reliable technology that gives numerical values that are not dependent on subjective interpretations. Response Genetics developed and extensively validated technology to perform quantitative PCR analysis of gene expressions in FFPE tumor tissues. Response Genetics has used its technological expertise in many projects for the pharmaceutical industry and for many collaborative scientific studies. The benefit of its capability for patients is that in many cases, no tissue samples other than the pre-treatment diagnostic are required for biomarker analysis.

FISH

Response Genetics' laboratory also offers Fluorescence in situ hybridization ("FISH") technology tests, which may be used to determine whether specific genes, loci or regions are present or if deletions, duplications, amplifications or other structural rearrangements have occurred.

Tech-Only FISH Service Launched

In August 2013, Response Genetics launched a partnership program with its pathology clients who wish to analyze and report the results of FISH tests. The program has as its centerpiece a state-of-the-art fluorescence slide scanning system that converts stained FISH slides into high-resolution digitized images that can be interrogated as deeply and intuitively as through traditional microscopy. The scanning system is interfaced with Response Genetics' portal that clients use to access testing status and reports for their patients. Pathologists who participate in Response Genetics'

program are able to perform the professional component ("PC") of FISH tests, provide the results of those analyses on customized reports, and bill for that service after Response Genetics provides the technical component ("TC") of each test.

The program was designed with maximum flexibility for participating pathologists to use it for the tests and/or cases of their choice, including both translocation and amplification tests. Response Genetics also continues to provide "global" (both TC and PC) FISH services, and Response Genetics' partner pathologists can select from these options as best fits their preferences. At the inception of the program in 2013, four tests were included (ALK, ROS1, HER2, MET); Response Genetics recently added RET and FGFR1, which Response Genetics believed would make its Tech-Only FISH offering the broadest in the industry for solid tumor testing.

Sequencing

Response Genetics' laboratory also offers DNA sequencing, which is the process of determining the nucleotide order of a given DNA fragment. Currently, its validated methodology uses the chain termination method (Sanger Method), which uses sequence specific termination of a DNA synthesis reaction using modified nucleotide substrates.

Proprietary Technologies

Response Genetics utilizes proprietary technologies for the extraction of RNA from FFPE tissues which enables it to reliably recover RNA suitable for a variety of applications, such as gene expression research, development of diagnostics, and microarray platforms. In addition, Response Genetics' technologies permit gene profiling analysis of current clinical trials, most of which use the paraffin embedding technique for tissue specimen storage.

Response Genetics developed extraction methodologies that allow reliable and consistent isolation of RNA and DNA from FFPE suitable for use in various types of analysis. Response Genetics validated its methodologies, which particularly address issues of recovery of RNA, accuracy, and precision. Further, Response Genetics' methodologies allow for rapid extraction of RNA with little or no DNA contamination, which makes it suitable for large-scale analysis.

•Micro-dissection of each specimen to separate tumor from non-tumor tissue. Most tumor biopsy specimens are mixtures of normal and tumor tissue. A specimen may include only a small percentage of tumor cells. The molecular biology of tumor and normal tissues may be considerably different and mixing the two may yield false results for gene expression profiling and false negative results for mutation detection due to the diluting effect of normal cells relative to tumor cells. To accurately measure gene expression and establish expression profiles of various pathologic lesions, it is important to analyze RNA from tumor cells. With the assistance of a pathologist, Response Genetics can identify the tumor cells and isolate them. Moreover, Response Genetics' procedure for tumor cell enrichment enables greater assay sensitivity relative to standard methods.

•Isolation of DNA from the same specimen used to obtain RNA. Alterations in DNA sequence that are inherited (polymorphisms) as well as acquired (mutations) are often associated with disease susceptibilities, treatment response, and survival. DNA polymorphisms and mutations may change the gene expression pattern of a cell in specific ways. Characterization of gene expression profiles associated with various DNA sequence alterations may lead to a better understanding of disease mechanisms and may suggest new and better treatments. Response Genetics' technique for isolating DNA and RNA from the same specimen facilitates such efforts because in many cases the amount of available tissue may not be sufficient for separate isolation of DNA and RNA. In addition, measuring gene expressions and DNA sequence alteration in the same cells rather than in different areas of the tissue specimen is likely to give more valid data.

Response Genetics believed these technologies may be used as a powerful tool to establish diagnostic gene sets for predicting a patient's likelihood of survival under a particular treatment regimen. Such diagnostic tests will provide the opportunity for choosing the best treatment prior to therapy and thus enable application of personalized medicine based on each person's unique genetics.

ResponseDX®

The outcome of cancer therapy is highly variable due to genetic differences among the tumors in cancer patients. Some patients respond well with tumor shrinkage and increase in life span. Other patients do not obtain benefit from the same therapy and may actually experience toxic side effects, psychological trauma and delay in effective treatment.

Until recently, most cancer treatment regimens were administered without any pre-selection of patients on the basis of the particular genetics of their tumor. However, advances in molecular technologies have enabled researchers to identify and measure genetic factors in patients' tumors that may predict the probability of success or failure of many anti-cancer agents. In order to increase the chances of a better outcome for cancer patients, Response Genetics offers and continues to expand its offering of tests for measuring predictive factors for therapy response in tumor tissue samples. Response Genetics provides these testing services for non-small cell lung cancer ("NSCLC"), colorectal cancer ("CRC"), gastric and gastroesophageal cancer ("GE"), melanoma and thyroid cancer, breast cancer and glioma through its ResponseDX: Lung®, ResponseDX: Colon®, ResponseDX: Gastric®, ResponseDX: Melanoma®, ResponseDX®: Thyroid, ResponseDX®: Breast and ResponseDX®: Glioma test suites at its laboratory located in Los Angeles, California, which is certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). These tests serve to help oncologists make optimal therapeutic decisions for cancer patients. The results from its tests may help oncologists choose among therapies to treat their cancer patients.

In August 2013, Response Genetics acquired substantially all of the assets of Pathwork Diagnostics, Inc. including its FDA-cleared Tissue of Origin cancer test. This newly acquired test was launched commercially by Response Genetics in February 2014 as the ResponseDX: Tissue of Origin® test. The ResponseDX: Tissue of Origin® test is a microarray-based gene expression test that aids in identifying challenging tumors, including metastatic, poorly differentiated, and undifferentiated cancers. The ResponseDX: Tissue of Origin® test uses a proprietary microarray platform and proprietary software to compare the expression of 2,000 genes in a patient's tumor with a panel of 15 known tumor types that represent 90% of all cancers. The test received FDA clearance in June 2010.

Response Genetics is also continuing its exclusive agreement with Knight Diagnostic Laboratories, a division of the Oregon Health and Science University Knight Cancer Institute, for a proprietary next generation sequencing panel for lung cancer.

Sales, Marketing and Client Services for ResponseDX® tests

Response Genetics offers its ResponseDX® testing services nationwide and in some instances, internationally. Response Genetics' primary sales market includes community based oncologists, pathologists, physician offices and hospitals. Selling diagnostic testing services of cancer requires a knowledgeable and skilled sales force that can help oncologists and pathologists understand the value of its testing services. Response Genetics' sales representatives and account executives generally have previous sales experience in the oncology and the pathology field, including pharmaceutical sales market, diagnostic equipment sales market, medical diagnostic services market, and/or laboratory services market and have knowledge of community-based hospitals and oncology practices. Response Genetics' sales force is compensated through a combination of salaries, commissions based upon actual sales performance and incentives from time to time, all at levels commensurate with each individual's qualifications, performance and responsibilities.

As of September 30, 2015, Response Genetics' sales team was comprised of 14 members, including its Vice President of Sales. Response Genetics' sales force is organized into three regions. The Regional Sales Director in each region trains account executives and develops sales territories while supporting the account executives in his or her region. Its sales strategy focused on expanding the ResponseDX® testing services while acquiring new customers. Response Genetics' sales approach was designed to understand its current and potential customers' needs and to provide the appropriate solutions from its expanding range of diagnostic services.

Response Genetics has developed a set of marketing materials to support its sales efforts. Response Genetics' marketing materials provide a summary of its tests along with practical information regarding how to order its tests. When creating its marketing materials Response Genetics focused on establishing a distinctive corporate brand and continuing to build upon its ResponseDX® brand.

Response Genetics competes largely on the basis of the quality of its tests, its turnaround time, the convenience of ordering its tests and the innovation of its services.

Intellectual Property

Response Genetics relies on a combination of patents, trade secret, copyright and trademark laws, license agreements, nondisclosure and other contractual provisions and technical measures to protect its intellectual property rights in its products, technology and processes. Response Genetics has proprietary rights in several areas as further described below.

First, Response Genetics exclusively licenses from USC the use of the RGI-1 extraction methodologies and related technologies, which have been patented in the United States and a number of other jurisdictions, including Australia,

Austria, Belgium, Canada, China, Denmark, France, Germany, Hong Kong, Ireland, Israel, Italy, Luxembourg, Mexico, The Netherlands, Norway, Russia, South Korea, Spain, Sweden, Switzerland and the United Kingdom. In September 2014, Response Genetics streamlined its USC licensed technologies by relinquishing its license to use the foreign jurisdiction patents which Response Genetics does not use in providing its services. Currently, Response Genetics' exclusive license from USC is for seven United States patents claiming methods related to the extraction technology. Response Genetics uses these proprietary methods when meeting its contractual obligations with various clients and when developing diagnostic tests for cancer. Response Genetics' USC licensed patents are scheduled to expire between December 2019 and March 2021.

Next, Response Genetics has identified and is in the process of identifying tumor response markers, which provide an indication of an anti-cancer drug's effectiveness or ineffectiveness based upon the level of such determinant in a particular tumor. Response Genetics has obtained patents claiming methods and products and has patent applications pending that claim methods and products related to certain tumor response markers in the United States and in a number of other jurisdictions, including Austria, Belgium, Canada, France, Germany, Hong Kong, Ireland, Italy, Japan, Korea, Liechtenstein, The Netherlands, New Zealand, Spain, Sweden,

Switzerland, the United Kingdom, Argentina, Israel, China and Mexico. Response Genetics holds issued patents relating to tumor response markers which run until 2021 to 2024, and hold pending patent applications filed in 2001, 2002 or as recently as 2012. For example, Response Genetics has patented methods related to quantifying expression of response markers from tumor tissue, which provide guidance in determining appropriate chemotherapeutic regimens for patients that are candidates for treatment with particular chemotherapies. Currently, Response Genetics has fourteen United States patents that relate to certain aspects of its proprietary technology as it applies to certain tumor markers. Such markers include thymidylate synthase (TS), dihydropyrimidine dehydrogenase (DPD), excision repair gene CC1 (ERCC1), glutathione-s transferase pi (GST-p), epidermal growth factor receptor (EGFR) and HER2/neu gene, though its patents are not directed to all aspects of expression of such markers and may not preclude competition from others concerning such markers. Response Genetics uses some of its patented methods in fulfilling certain of its contractual obligations with various clients. Response Genetics has also licensed the use of its patents related to certain markers and technology know-how to GSK.

Finally, Response Genetics has proprietary rights and know-how in the factors which assist it in utilizing the quantitative gene expression levels Response Genetics measures and computes. Response Genetics' proprietary rights related to conversion factors in quantitative gene expression levels do not include patent coverage. However, Response Genetics has obtained patents claiming methods and products related to the determination of the expression levels of certain tumor response marker genes in the United States and in a number of other jurisdictions, including Austria, Australia, Belgium, Canada, France, Germany, Hong Kong, Ireland, Italy, Japan, Korea, Liechtenstein, The Netherlands, New Zealand, Spain, Sweden, Switzerland, Taiwan, the United Kingdom, Argentina, China, Mexico and Israel. The term of these patents will run until 2021 or 2022. These patents include five United States patents that relate to certain aspects of its proprietary technology useful in determining levels of the expression of the tumor marker genes including TS, ERCC1, DPD and GST-p.

Response Genetics pursued the registration of its trademarks in the United States and internationally. Response Genetics, Response Genetics and Design, Man in Circle Design, Kras is Only Half the Equation, ResponseDX®, ResponseDX: Lung®, ResponseDX: Colon®, ResponseDX: Gastric®, ResponseDX: Tissue of Origin®, ResponseDX: TOO®, ResponseDX: Melanoma®, The Right Therapy for each Patient the First Time and Because Everyone Has a Different Response are registered trademarks in the United States. Response Genetics has pursued additional marks by filing trademark applications in the United States and abroad.

Regulations and Legal Environment

Response Genetics' business is subject to extensive laws and regulations, which are substantially the same as the regulatory framework applicable to Cancer Genetics. Certain regulations applicable to Response Genetics are summarized below.

Clinical Laboratory Regulations

Response Genetics received its CLIA certificate as a "high complexity" laboratory in 2007. To renew this certificate, Response Genetics participates in College of American Pathologist ("CAP") surveys and unannounced periodic inspections approximately every two years. Response Genetics' most recent CAP inspection took place on October 1, 2014, and resulted in continued accreditation for two years with reinspection expected prior to November 4, 2016. Loss of Response Genetics' CLIA certification, change in CLIA or CLIA regulations or in the interpretation thereof, could have a material adverse effect on Response Genetics' business.

Response Genetics' clinical operations are also subject to regulation under state laws which in some areas are more stringent than CLIA. State clinical laboratory laws generally require that laboratories and/or laboratory personnel meet certain qualifications. State clinical laboratory laws also generally require laboratories to specify certain quality

assurance metrics and to maintain certain records. For example, California requires that Response Genetics maintains a state issued license and comply with California standards for its laboratory operations, including the standards for laboratory personnel and testing processes. Certain other states, including Rhode Island, Florida, Maryland, New York and Pennsylvania, require that Response Genetics holds licenses to test specimens from patients residing in those states. Certain state regulations or standards differ from CLIA and CAP, requiring additional compliance work in order to maintain the applicable certification or license with that state. Additional states may require similar licenses in the future. Potential sanctions for violation of these state requirements include license suspension, limitation, or revocation, directed plan of action, on-site monitoring, civil monetary penalties, criminal sanctions, overpayments or recoupments of reimbursement received from testing, and cancellation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity, which could adversely affect Response Genetics' business and results of operations. Finally, Response Genetics may be subject to regulation in foreign jurisdictions, including in Europe and Asia, if it expands offering of its tests or distribution of its tests internationally.

Food and Drug Administration Regulation

Pursuant to its authority under the Federal Food, Drug and Cosmetic Act, or the FDC Act, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostic devices, or IVDs, used for clinical purposes. The FDA regulates, among other things, the research, design, development, pre-clinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices.

Laboratory Developed Tests

Although the FDA has statutory authority to regulate medical devices, the FDA has historically exercised its enforcement discretion and not enforced applicable provisions of the FDC Act and FDA regulations with respect to LDTs, which are a subset of IVDs that are intended for clinical use and developed, validated and offered within a single laboratory for use only in that laboratory. We believe that many of Response Genetics' tests fall within the definition of an LDT. As a result, we believe certain of the Response Genetics tests are not currently subject to the FDA's enforcement of its medical device regulations and the applicable FDC Act provisions. However, reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to FDA regulation.

Post-market Regulation

Response Genetics obtained clearance under section 510(k) of the FDC Act for its Tissue of Origin. After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for products; or
- criminal prosecution.

Federal and State Physician Self-Referral Prohibitions

Response Genetics is subject to the federal physician self-referral prohibitions (the "Stark Law") and restrictions under California's Physician Ownership and Referral Act ("PORA"). These restrictions prohibit Response Genetics from billing a patient or any governmental or private payer for any test when the physician ordering the test, or any member of such physician's immediate family, has a direct or indirect investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and PORA contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has stockholders' equity exceeding $75 million at the end of its most recent fiscal year or on average during the previous three fiscal years, and which satisfies certain other requirements. In addition, both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by

the physician. Response Genetics has compensation arrangements with a number of physicians for personal services, such as speaking engagements and specimen tissue preparation. Response Genetics has structured these arrangements with terms intended to comply with the requirements of the personal services exception to Stark Law and PORA.

However, Response Genetics cannot be certain that regulators would find these arrangements to be in compliance with Stark Law, PORA or similar state laws. If Response Genetics is deemed to not be in compliance by the applicable regulators, it would be required to refund any payments Response Genetics receives pursuant to a referral prohibited by these laws to the patient, the payer or the Medicare program, as applicable.

Penalties for a violation of the Stark Law include: refunds of amounts collected by an entity in violation of the Stark Law, denial of payment for the services provided in violation of the prohibition, and civil penalties of up to $15,000 per service arising out of the prohibited referral. Additionally, a person who engages in a scheme to circumvent the Stark Law's prohibition may be subject to a civil penalty of up to $100,000. A violation of PORA is a misdemeanor and could result in civil penalties and criminal fines.

Other states have self-referral restrictions with which Response Genetics has to comply that differ from those imposed by federal and California law. While Response Genetics has attempted to comply with these laws, it is possible that some of its financial arrangements with pathologist and physicians could be subject to regulatory scrutiny at some point in the future, and Response Genetics cannot provide assurance that it will be found to be in compliance with these laws following any such regulatory review.

Regulation of Reimbursement and Coverage

Revenues for clinical laboratory testing services come from a variety of sources and depend significantly on the availability of third-party reimbursement, including from Medicare and Medicaid programs, commercial insurers and managed care organizations. Response Genetics is currently a Medicare laboratory services provider. Response Genetics also receives reimbursement from third-party payers for its testing services. As is the case with health care services generally, the majority of payers pay for its testing services at varying levels that may be significantly lower or otherwise differ from its list prices. Obtaining reimbursement from third-party payers is both time consuming and expensive. Payment from third-party payers may not be sufficient to allow Response Genetics to sell its services on a profitable and competitive basis.

Response Genetics derived approximately 38% and 33.5% of its net sales of ResponseDX® testing services directly from the Medicare program in 2013 and 2014, respectively. For the six months ended June 30, 2014 and 2015, approximately 36% and 38%, respectively, of Response Genetics' revenues were derived directly from the Medicare program. Therefore, compliance with complex Medicare reimbursement rules is important to its operations. Once Medicare has determined that it will cover a particular test, or that a test will be provided as a benefit, payment is generally made under the Clinical Laboratory Fee Schedule with amounts assigned to specific procedure billing codes. Each Medicare carrier jurisdiction has a fee schedule that establishes the price for each specific laboratory billing code. This fee schedule is updated annually. As a Medicare-participating laboratory based in California, Response Genetics bills under the Medicare program's California contractors fee schedule and will have to comply with this contractor's coverage and payment policies. In recent years, both government and private sector payers have made efforts to contain or reduce health care costs, including reimbursement for clinical laboratory services. In January 2013, the initial 2013 annual Medicare fee schedule update was announced which included proposed changes to Medicare reimbursement rates that significantly reduced the reimbursement rates for certain of the testing services provided by Response Genetics. In addition, on July 8, 2013, the Centers for Medicare and Medicaid Services ("CMS") released a proposed rule for 2014 entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014" that contained a number of provisions that adversely impacted the level of reimbursement for a variety of tests for which Response Genetics receives reimbursement from Medicare. Response Genetics participated with other impacted organizations to provide guidance to the local Medicare Administrative Contractor ("MAC") that resulted in the local MAC updating certain pricing which reflected an increase in many of the tests originally priced in January 2013. On October 1, 2013, CMS issued updated payment rates for some, but not all, of the Common Procedural Terminology ("CPT") codes used by Response Genetics which reflected an increase in reimbursement amount or positive coverage determination from the January 2013 initial pricing.

In 2014, Congress passed the Protecting Access to Medicare Act of 2014, or PAMA, which will make significant changes in the way that Medicare pays for laboratory services. Under the new law, beginning in 2016, clinical laboratories will be required to report the prices that private payers, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. Medicare will then calculate a weighted average of the reported prices, which will become the new fee schedule beginning in 2017. Most laboratories will have to submit pricing information every three years, although laboratories performing certain other tests, referred to as Advanced Diagnostic Laboratory Tests, will have to report every year. On September 25, 2015, CMS published a proposed rule that proposed how CMS intends to implement the requirements of PAMA. At this time, we do not know what the impact of these proposals will be on our business.

As a result of CPT code changes and Medicare price changes, Response Genetics re-evaluated the assumptions employed in its model for estimating revenue to be recognized for ResponseDX® testing. Response Genetics views the code and price changes described above as affecting only the assumptions Response Genetics used in pricing its services. The nature of the testing services Response Genetics provides, the evidence it gathers to establish the creditworthiness of its payers and the delivery method of its services have not changed from prior periods, and there are no indicators that these assumptions require change. Response Genetics

experienced a departure from normal reimbursement from the payer community in 2013. Response Genetics experienced an increase in denial of claims for certain services it provides and an increase in denial of its appeal for payment of these denied claims. As a result, Response Genetics believed it needed to acquire new skills in collections. Consequently, Response Genetics restructured and overhauled its billing department in late 2014/early 2015. Response Genetics has already seen a significant increase in its collections related to its ResponseDX sales. Response Genetics expected to continue to see improvements throughout 2015 and beyond from these efforts. Response Genetics engaged a seasoned billing/reimbursement expert on a consulting basis to assist with this overhaul and restructuring effort.

On November 13, 2014, CMS published CMS-1612-FC, a new final rule with comment period (the "Final Rule") entitled "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015". The Final Rule which was initially proposed on July 3, 2014 contains a number of provisions including new and modified CPT codes that may adversely impact the level of reimbursement for certain tests offered by Response Genetics, including FISH tests for which Response Genetics receives reimbursement from the Medicare program. The Final Rule established lower relative value units ("RVU's") for FISH testing which lower valuation led to a 16-20% reduction in multiplex FISH reimbursement in 2015 after taking into account the NCCI changes from 2014 discussed below. Reimbursement for less frequent single-probe FISH testing was reduced by 45-50%. The Final Rule was subject to a 60 days comment period which ended on December 30, 2014. Impacted organizations similarly situated as Response Genetics have provided guidance to the local Medicare MAC. It is uncertain if the guidance provided to Medicare and the local MAC by impacted organizations will result in fee increases or additional positive coverage determinations in 2015. If, however, the current level of reduction in reimbursement rates is adopted as is, it may adversely impact its reimbursement from Medicare for FISH.

On July 8, 2015, CMS issued its proposed Physician Fee Schedule Rule for 2016. That Rule also proposed some changes to the codes that we bill frequently. At this time, we do not know whether CMS will implement these changes or what the impact will be on our revenues.

Additionally, CMS has as part of its regulatory structure developed the National Correct Coding Initiative ("NCCI") that is intended to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Medicare Part B claims. In December 2013, the NCCI Coding Policy Manual changed the billing requirements for FISH testing. The change relates to what NCCI considers "bundled" services and limits the allowable quantity of certain tests that are billed for FISH testing. This impacts Response Genetics by limiting the number of units Response Genetics may bill for certain test codes, which lowers the overall reimbursement Response Genetics receives for FISH tests. There can be no assurance that CMS will make any modifications in the existing language of the NCCI and effective on January 1, 2015, the AMA adopted all of the NCCI definitions for FISH which may adversely impact its reimbursement from commercial insurance plans going forward if adopted.

A number of proposals for legislation or regulation continue to be under discussion which could have the effect of substantially reducing Medicare reimbursements for clinical laboratories or introducing cost sharing to beneficiaries. Depending upon the nature of regulatory action, if any, which is taken and the content of legislation, if any, which is adopted, Response Genetics could experience a significant decrease in revenues from Medicare, which could have a material adverse effect on Response Genetics. Response Genetics was unable to predict, however, the extent to which such actions will be taken.

Information Technology

Response Genetics implemented a commercially available and supported system used to perform tracking, evaluation, and reporting of laboratory specimens as they are analyzed. Hardware and software used in conjunction with this

system are commercially available items that can be procured. Response Genetics also makes use of commercial software applications that allow for biostatistical analysis of data generated.

Industry standard tools and techniques are used to support business functions on Response Genetics informatics environment. This includes areas such as office applications, collaboration, electronic mail, general ledger/accounting software, internet connectivity, backup strategies, and security measures.

Specimen storage equipment consists of lockable cabinets that are catalogued for the storage of paraffin-embedded specimens for Response Genetics' clients. Response Genetics' database provides locator information in order to retrieve these archived specimens as needed. In addition, Response Genetics maintains freezers to store frozen tissue specimens. These freezers are monitored via computerized probes on a continuous basis to ensure that temperatures are maintained at levels necessary to keep these specimens frozen. Should temperatures in any of the freezers move out of range due to mechanical failure an emergency alert is sent to Response Genetics for response. These freezers are also supported by a freestanding emergency backup generator that will engage in the event of a general power outage in order to maintain freezer temperatures at necessary levels.

Competition

Response Genetics provides services in a segment of the healthcare industry that is highly fragmented and extremely competitive. Any failure to respond to technological advances and emerging industry standards could impair its ability to attract and retain clients. This industry is characterized by rapid technological change. Response Genetics' actual and potential competitors in the United States and abroad may include major clinical and pathology laboratories, such as Quest Diagnostics Inc., Laboratory Corporation of America, Clarient, Inc. (acquired by GE), and specialized laboratories such as Genoptics Inc. (acquired by Novartis Pharmaceuticals), NeoGenomics, Inc., Caris Life Sciences (acquired by Miraca), Foundation Medicine, university laboratories and other research institutions. Many of Response Genetics' potential competitors have considerably greater financial, technical, marketing, research and other resources than Response Genetics does, which may allow these competitors to discover important information and technology before Response Genetics does. Response Genetics anticipates its competition to aggressively compete for market share. Response Genetics' competitors may succeed in developing diagnostic products that circumvent its technologies or product candidates. Also, Response Genetics' competitors may succeed in developing technologies or products that are more effective than those that are developed or will be developed by Response Genetics or that would render its technology or product candidates less competitive or obsolete.

In addition, Response Genetics developed its services and product candidates to impact certain methods for treating cancer. If those methods change, it is likely that the demand for its services and product candidates could significantly decline or cease altogether. The development of new or superior competing technologies or products, or a change in the methodology of treating cancer, could affect its competitive position and harm its business. Moreover, these competitors may offer broader product lines and have greater name recognition than Response Genetics and may offer discounts as a competitive tactic.

Additionally, several development-stage companies are currently making or developing product candidates that compete with or will compete with Response Genetics' potential products. Competitors may succeed in developing, obtaining approval from the FDA or marketing technologies or products that are more effective or commercially attractive than its potential products or that render its technologies and current or potential products obsolete. Competitors may also develop proprietary positions that may prevent Response Genetics from commercializing product candidates.

Employees

As of September 30, 2015, Response Genetics had 90 employees, comprising 87 full-time and 3 part-time employees. Response Genetics' employees are not represented by any collective bargaining organizations and Response Genetics considers its relations with its employees to be good.

Risks Related to the Response Genetics Acquisition

In light of the history of losses and ultimate bankruptcy of Response Genetics and our own history of losses, we anticipate that we will need additional financing in the future to continue our operations and to continue the operations of the combined company.

We incurred losses of $9.3 million, $16.6 million, and $12.4 million for the first six months of fiscal 2015, and for the fiscal years ended December 31, 2014 and 2013, respectively. From our inception in April 1999 through June 30, 2015, we had an accumulated deficit of $87.2 million.

Response Genetics incurred losses of $8.9 million, $13.7 million, and $8.0 million for the first six months of fiscal 2015, and for the fiscal years ended December 31, 2014 and 2013, respectively. From its inception in September 1999 through June 30, 2015, it had an accumulated deficit of $87.8 million. As a result of its history of losses, Response

Genetics was required to seek the protection of the bankruptcy courts by filing a bankruptcy petition in the United States Bankruptcy Court for the District of Delaware on August 9, 2015.

We expect our losses to continue principally as a result of ongoing research and development expenses and increased sales and marketing costs. The combined company's research and development expenses will increase with the addition of the ongoing activities of the Response Genetics business, particularly as their genetic tests largely relate to a different set of cancers than the cancers for which we have expertise. We also anticipate additional costs being incurred for integration of the two businesses, including integration of our sales forces. Our losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development and commercialization efforts, as well as the risks inherent in any acquisition and particularly in the acquisition of a company in bankruptcy, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve

profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

We would likely seek such funding through public or private financings or some combination of the two. We may also seek funding through collaborative arrangements if we determine them to be necessary or appropriate. Additional funding may not be available to us on acceptable terms, or at all. If we obtain capital through collaborative arrangements, these arrangements could require us to relinquish rights to the combined company's technology or product candidates and could result in our receiving only a portion of the revenues associated with the partnered test or product. If we raise capital through the sale of equity, or securities convertible into equity, it would result in dilution to our then existing stockholders. Issuances of our securities in connection with any future capital raise may additionally cause anti-dilution adjustments to certain of our outstanding warrants. If we raise additional capital through the incurrence of indebtedness, the documents governing the terms of such debt would likely contain terms restricting our business activities, and holders of debt instruments would have rights and privileges senior to those of our equity investors. In addition, servicing the interest and principal repayment obligations under debt facilities could divert funds that would otherwise be available to support research and development, clinical or commercialization activities.

Additional financing may not be available when needed or may not be available on terms acceptable to us. The combined company's inability to obtain necessary capital or financing to fund these needs could adversely affect the combined company's business, results of operations and financial condition.

Any acquisition exposes a company to additional risks.

Acquisitions may entail numerous risks for Cancer Genetics, including:

- competing claims for capital resources;
- ability to retain and grow relationships with Response Genetics' key customers;
- difficulties in assimilating acquired operations, technologies or products; and
- diversion of management's attention from our core business.

Our management has limited experience in purchasing and integrating new businesses. Our failure to successfully complete the integration of Response Genetics could have a material adverse effect on our business, financial condition and operating results.

Failure of the Response Genetics acquisition to achieve potential benefits could harm the business and operating results of the combined company.

We expect that the acquisition of the Response Genetics businesses will result in potential benefits for the combined company, including the expansion of the number and geographic coverage or our marketing team, the expansion of our menu of genetic tests offered to cover 8 of the 10 most common solid tumor types, the expansion of the geographic coverage of our laboratories and introductions to additional potential biopharmaceutical partners for our testing services. No assurance can be given that we will achieve any or all of these potential benefits. Even if we are able to achieve any of these potential benefits, we cannot predict with certainty when the benefits will occur, or to the extent to which they actually will be achieved. For example, the benefits from the acquisition may be offset by costs incurred in integrating the businesses and investments to improve and modernize the facilities. The failure to achieve anticipated benefits could harm the business, financial condition and operating results of the combined company.

If the market for the combined company's tests and services does not experience significant growth or if the combined company's tests and services do not achieve broad acceptance, the combined company's operations will suffer.

Cancer Genetics cannot accurately predict the future growth rate or the size of the market for the combined company's tests and services. The expansion of this market depends on a number of factors, such as:

- the results of clinical trials;

- the cost, performance and reliability of the combined company's tests and services, and the tests and services offered by competitors;

- customers' perceptions regarding the benefits of the combined company's tests and services;

- customers' satisfaction with our tests and services; and

- marketing efforts and publicity regarding our tests and services.

If the combined company is unable to manage growth in its business, its prospects may be limited and its future results of operations may be adversely affected.

The combined company intends to expand its research and development activities, its sales and marketing programs and other activities as needed to meet future demand. Any significant expansion may strain the combined company's managerial, financial and other resources. If the combined company is unable to manage its growth, its business, operating results and financial condition could be adversely affected. The combined company will need to improve continually its operations, financial and other internal systems to manage its growth effectively, and any failure to do so may lead to inefficiencies and redundancies, and result in reduced growth prospects and diminished operational results.

If the Response Genetics tests that we acquired do not continue to perform as expected, or if we cannot continue to improve those tests to keep pace with rapid advances in technology, medicine and science, our operating results, reputation and business could suffer.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers are likely to be particularly sensitive to test defects and errors. As a result, the failure of the tests or services we acquired from Response Genetics to perform as expected could significantly impair the reputation and the public image of the tests and services of the combined company as a whole, and we may be subject to legal claims arising from any defects or errors. We have not previously marketed a FDA-cleared test, such as the TOO® test which we acquired. In addition to the difficulties of capturing market share with this test, we will have to comply with FDA inspections and regulations related to a cleared test, which we do not have previous experience. Further, in recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer and in methods used to analyze very large amounts of genomic information. We must continuously develop new tests and enhance our existing tests to keep pace with evolving standards of care. The tests we acquired from Response Genetics could become obsolete unless we continually innovate to incorporate the latest science of and expand them to demonstrate benefit in patients treated with new therapies. If we cannot adequately update our tests to incorporate the latest advances in genetic information and demonstrate the applicability of our tests to new treatments, sales of our tests and services could decline, which would have a material adverse effect on our business, financial condition and results of operations.

The unaudited pro forma financial information included in this report may not necessarily reflect our operating results and financial condition following the Response Genetics acquisition.

The unaudited pro forma financial information included in this Current Report on Form 8-K is derived from our and Response Genetics' separate historical consolidated financial statements. The unaudited pro forma financial information is presented for informational purposes. The preparation of the unaudited pro forma financial information is based upon available information and certain assumptions and estimates that we and Response Genetics currently believe are reasonable. These assumptions and estimates may not prove to be accurate, and the unaudited pro forma financial information does not necessarily reflect what our results of operations and financial position would have been had the Response Genetics acquisition been completed if these assumptions were accurate, or occurred during the period presented, or what our results of operations or financial position will be in the future. The unaudited pro forma financial information does not reflect future events that may occur after the Response Genetics acquisition, including the potential realization of operating cost savings (synergies) or restructuring activities or other costs related to planned integration of Response Genetics, and does not consider potential impacts of current market conditions on revenues or expenses.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired

1. The audited consolidated balance sheets as of December 31, 2014 and 2013 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows of Response Genetics for each of the two years in the period ended December 31, 2014, together with the related notes to the consolidated financial statements and the accompanying Report of Independent Registered Public Accounting Firm are set forth in Exhibit 99.1 to this Current Report on Form 8-K.

2. The unaudited consolidated balance sheets as of June 30, 2015 and December 31, 2014 and unaudited statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows of Response

Genetics for the three and six months ended June 30, 2015 and 2014, together with the related notes to the consolidated financial statements are set forth in Exhibit 99.2 to this Current Report on Form 8-K.

(b) Pro Forma Financial Information

1. The unaudited pro forma consolidated financial information related to the acquisition of Response Genetics is attached as Exhibit 99.3 to this Current Report on Form 8-K.

(d) Exhibits

23.1 Consent of BDO USA, LLP

99.1 Audited consolidated balance sheets as of December 31, 2014 and 2013 and the related statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows of Response Genetics for each of the two years in the period ended December 31, 2014, together with the related notes to the consolidated financial statements and the accompanying Report of Independent Registered Public Accounting Firm

99.2 Unaudited consolidated balance sheets as of June 30, 2015 and December 31, 2014 and unaudited statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows of Response Genetics for the three and six months ended June 30, 2015 and 2014, together with the related notes to the consolidated financial statements

99.3 Unaudited pro forma consolidated financial statements and explanatory notes for the year ended December 31, 2014, the six months ended June 30, 2015 and as of June 30, 2015

SIGNATURE

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.

CANCER GENETICS, INC.

By: /s/ Edward J. Sitar
Name: Edward J. Sitar
Title: Chief Financial Officer

Date: October 16, 2015