CANCER GENETICS, INC
Form 10-Q
November 09, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015
Or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to
Commission file number 001-35817

CANCER GENETICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-3462475
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

201 Route 17 North 2nd Floor
Rutherford, NJ 07070
(201) 528-9200
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ¨ No ý

As of November 1, 2015, there were 10,651,924 shares of common stock, par value $0.0001 of Cancer Genetics, Inc. outstanding.

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PART I — FINANCIAL INFORMATION
Item 1. Financial Statements (Unaudited)
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Consolidated Balance Sheets (Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$19,917,926	$25,554,064
Accounts receivable, net of allowance for doubtful accounts	5,165,093	5,028,620
Other current assets	1,540,501	1,172,750
Total current assets	26,623,520	31,755,434
FIXED ASSETS, net of accumulated depreciation	3,778,605	4,310,126
OTHER ASSETS		
Restricted cash	300,000	6,300,000
Patents	585,259	502,767
Investment in joint venture	300,225	1,047,744
Goodwill	3,187,495	3,187,495
Deposit for acquisition	880,000	—
Other	324,641	1,564
Total other assets	5,577,620	11,039,570
Total Assets	$35,979,745	$47,105,130
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$4,437,373	$3,762,567
Obligations under capital leases, current portion	61,079	58,950
Deferred revenue	1,173,128	544,446
Bank term note, current portion	833,333	—
Total current liabilities	6,504,913	4,365,963
Obligations under capital leases	254,021	300,385
Deferred rent payable and other	289,319	347,840
Line of credit	—	6,000,000
Warrant liability	34,000	52,000
Acquisition note payable	657,744	560,341
Deferred revenue, long-term	782,818	924,850
Bank term note	5,138,783	—
Total liabilities	13,661,598	12,551,379
STOCKHOLDERS' EQUITY		
Preferred stock, authorized 9,764,000 shares, $0.0001 par value, none issued	—	—
Common stock, authorized 100,000,000 shares, $0.0001 par value, 9,861,340 and 9,821,169 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	986	982
Additional paid-in capital	114,754,824	112,520,268
Accumulated (deficit)	(92,437,663)	(77,967,499)
Total Stockholders' Equity	22,318,147	34,553,751
Total Liabilities and Stockholders' Equity	$35,979,745	$47,105,130

See Notes to Unaudited Consolidated Financial Statements.

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Cancer Genetics, Inc. and Subsidiaries
Consolidated Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$4,000,332	$3,221,850	$12,555,806	$6,163,895
Cost of revenues	3,103,227	2,565,715	9,342,399	5,358,872
Gross profit	897,105	656,135	3,213,407	805,023
Operating expenses:				
Research and development	1,801,813	1,390,189	4,335,235	3,092,733
General and administrative	3,487,242	3,104,100	9,535,723	8,230,966
Sales and marketing	1,242,803	1,070,531	3,543,047	2,737,967
Total operating expenses	6,531,858	5,564,820	17,414,005	14,061,666
Loss from operations	(5,634,753)	(4,908,685)	(14,200,598)	(13,256,643)
Other income (expense):				
Interest expense	(111,620)	(36,166)	(227,140)	(408,087)
Interest income	4,906	18,789	30,288	57,130
Change in fair value of acquisition note payable	315,453	—	(90,714)	—
Change in fair value of warrant liability	214,000	129,000	18,000	324,000
Total other income (expense)	422,739	111,623	(269,566)	(26,957)
Loss before income taxes	(5,212,014)	(4,797,062)	(14,470,164)	(13,283,600)
Income tax provision (benefit)	—	—	—	(1,813,941)
Net (loss)	$(5,212,014)	$(4,797,062)	$(14,470,164)	$(11,469,659)
Basic net (loss) per share	$(0.54)	$(0.50)	$(1.49)	$(1.22)
Diluted net (loss) per share	$(0.56)	$(0.51)	$(1.49)	$(1.25)
Basic Weighted-Average Shares Outstanding	9,726,067	9,575,789	9,714,824	9,386,613
Diluted Weighted-Average Shares Outstanding	9,727,597	9,575,789	9,716,214	9,403,245

See Notes to Unaudited Consolidated Financial Statements.

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Cancer Genetics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Unaudited)

	Nine Months Ended September 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss)	$(14,470,164)	$(11,469,659)
Adjustments to reconcile net (loss) to net cash (used in) operating activities:		
Depreciation	971,192	487,656
Amortization	26,177	20,146
Provision for bad debts	212,914	—
Equity-based consulting and compensation expenses	2,177,554	2,129,880
Change in fair value of acquisition note payable	90,714	—
Change in fair value of Gentris contingent consideration	(162,000)	—
Change in fair value of warrant liability	(18,000)	(324,000)
Amortization of loan guarantee fees, financing fees and debt issuance costs	4,960	310,500
Loss in equity method investment	747,519	659,426
Changes in:		
Accounts receivable	(349,387)	(521,429)
Other current assets	(367,751)	(169,940)
Other non-current assets	(85,856)	—
Accounts payable, accrued expenses and deferred revenue	1,330,145	985,644
Deferred rent and other	(58,521)	(18,050)
Net cash (used in) operating activities	(9,950,504)	(7,909,826)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of fixed assets	(439,671)	(944,423)
Decrease (increase) in restricted cash	6,000,000	(6,000,000)
Patent costs	(108,669)	(95,408)
Investment in JV	—	(1,000,000)
Deposit for acquisition of Response Genetics	(880,000)	—
Cash used in acquisition of Gentris, net of cash received	—	(3,180,930)
Cash from acquisition of BioServe	—	311,264
Net cash provided by (used in) investing activities	4,571,660	(10,909,497)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principal payments on capital lease obligations	(44,235)	(21,554)
Payments for deferred equity offering costs	(237,221)	—
Proceeds from warrant exercises	—	178,102
Proceeds from option exercises	23,480	79,018
Proceeds from offering of common stock, net of offering costs	33,526	—
Principal payments on notes payable	—	(127,532)
Payment of debt issuance costs	(32,844)	—
Net cash provided by (used in) financing activities	(257,294)	108,034
Net (decrease) in cash and cash equivalents	(5,636,138)	(18,711,289)
CASH AND CASH EQUIVALENTS		
Beginning	25,554,064	49,459,564
Ending	$19,917,926	$30,748,275
SUPPLEMENTAL CASH FLOW DISCLOSURE		
Cash paid for interest	$157,603	$92,692

SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES		
Fixed assets acquired through capital lease arrangements	$—	40,922
Cashless exercise of derivative warrants	—	125,000
Value of shares issued as partial consideration of Gentris and BioServe	—	1,515,992
Net tangible assets acquired via acquisition	—	1,255,084

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See Notes to Unaudited Consolidated Financial Statements.

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Notes to Unaudited Consolidated Financial Statements

Note 1. Organization, Description of Business, Basis of Presentation and Acquisitions

We are an oncology diagnostics company focused on developing, commercializing and providing DNA-based tests and services to improve the personalization of cancer treatment and to better inform biopharmaceutical companies of genomic factors influencing subject responses to therapeutics. Our vision is to become the oncology diagnostics partner for companies and clinicians by participating in the entire care continuum from bench to bedside. We believe the diagnostic industry is undergoing a metamorphosis in its approach to oncology testing, embracing individualized medicine as a means to drive higher standards of patient treatment and disease management. Similarly, biopharmaceutical companies are increasingly engaging companies such as ours to provide information on clinical trial participants' DNA profiles in order to identify genomic variations that may be responsible for differing responses to pharmaceuticals, and particularly to oncology drugs, thereby increasing the efficiency of trials while lowering related costs. We believe tailored therapeutics can revolutionize oncology medicine through DNA-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique. We have created a unique position in the industry by providing targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' DNA as we attempt to reach the next milestone in personalized medicine.

We were incorporated in the State of Delaware on April 8, 1999 and have offices and state-of-the-art laboratories located in New Jersey, North Carolina, Shanghai (China), and Hyderabad (India). Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, NY State and NABL (India).We have two advisory boards to counsel our scientific and clinical direction. Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. Our Clinical Advisory Board is comprised of clinicians and scientists focused on clinical implementation of our proprietary tests and services and mapping those tests and services to patient needs. Our services are built on a foundation of world-class scientific knowledge and intellectual property in solid and blood-borne cancers, as well as strong academic relationships with major cancer centers such as Memorial Sloan-Kettering, Mayo Clinic, and the National Cancer Institute.

Basis of Presentation

The accompanying unaudited condensed financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions for interim reporting as prescribed by the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary to make the financial statements not misleading have been included. As such, the information included in this quarterly report on Form 10-Q should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2014, filed with the Securities and Exchange Commission on March 16, 2015. The consolidated balance sheet as of December 31, 2014, included herein was derived from the audited financial statements as of that date, but does not include all disclosures including notes required by GAAP. Interim financial results are not necessarily indicative of the results that may be expected for any future interim period or for the year ending December 31, 2015.

In the second quarter of 2015, we adopted ASU No. 2015-03, "Simplifying the Presentation of Debt Issuance Costs". Previously, debt issuance costs were recorded as assets on the balance sheet. This update requires that debt issuance costs related to a debt liability be presented on the balance sheet as a direct deduction from the carrying amount of the debt liability, consistent with debt discounts. This update does not change the recognition and

measurement of debt issuance costs and requires retrospective adoption. We did not have debt issuance costs in the December 31, 2014 Consolidated Balance Sheet.

2014 Acquisitions

On July 16, 2014, we purchased substantially all of the assets of Gentris Corporation, ("Gentris"), with its principal place of business in North Carolina, for approximately $4.8 million. There were no changes in the preliminary purchase price allocation or goodwill impairment for Gentris during the nine months ended September 30, 2015.

On August 18, 2014, we acquired BioServe Biotechnologies (India) Private Limited, an Indian corporation ("BioServe") for an aggregate purchase price of approximately $1.1 million. During the nine months ended September 30, 2015, there was no goodwill impairment for BioServe, and the preliminary allocation of the purchase price was retrospectively adjusted for a measurement period adjustment to increase goodwill by approximately $193,000, reduce fixed assets by approximately

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$136,000, reduce other assets by approximately $38,000 and reduce other current assets by approximately $19,000. The fair value of the assets acquired and liabilities assumed as of August 18, 2014 are now as follows:

	Amount
Accounts receivable	$151,002
Other current assets	102,064
Fixed assets	488,481
Other assets	378,440
Goodwill	734,925
Current liabilities	(758,614)
Other liabilities	(22,049)
Total Purchase Price	$1,074,249

The results of operations for the three and nine months ended September 30, 2015 include the operations of Gentris and BioServe and include combined revenues of $1,728,238 and $5,357,382, respectively, and a combined net loss of $1,043,224 and $2,202,254, respectively. The following table provides certain pro forma financial information for the Company as if the acquisitions of Gentris and BioServe discussed above occurred on January 1, 2014:

	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2014
Revenue	$3,493,345	$10,329,910
Net loss	(6,039,858)	(13,325,068)
Basic net loss per share	$(0.63)	$(1.40)
Diluted net loss per share	(0.64)	(1.43)

Acquisition of Response Genetics, Inc.

On October 9, 2015, we acquired substantially all the assets and assumed certain liabilities of Response Genetics, Inc. (“Response Genetics”), with its principal place of business in California, in a transaction valued at approximately $13.4 million, comprised of $7 million in cash and 788,584 shares of the Company’s common stock, with the common stock being valued at $6.4 million.

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.

The transaction is being accounted for using the acquisition method of accounting for business combinations in accordance with GAAP. Under this method, the total consideration transferred to consummate the acquisition is being allocated to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values as of the closing date of the acquisition. The acquisition method of accounting requires extensive use of estimates and judgments to allocate the consideration transferred to the identifiable tangible and intangible assets acquired and liabilities assumed. Accordingly, the allocation of the consideration transferred is preliminary and will be adjusted upon completion of the final valuation of the assets acquired and liabilities assumed. The final valuation is expected to be completed as soon as practicable but no later than 12 months after the closing date of the acquisition.

The consolidated financial statements for the three and nine months ended September 30, 2015 and 2014 do not include the operations of Response Genetics. The results of operations for Response Genetics will be included in the Company’s consolidated financial statements beginning on October 9, 2015.

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The preliminary allocation of the purchase price of the fair value of the assets acquired and liabilities assumed as of October 9, 2015 are as follows:

	Amount
Accounts receivable	$350,000
Prepaid expenses and other current assets	500,000
Property and equipment	1,000,000
Intangible assets	550,000
Goodwill	11,550,000
Accrued expenses	(425,000)
Obligations under capital leases	(125,000)
Total Purchase Price	$13,400,000

The following table provides certain pro forma financial information for the Company as if the acquisition of Response Genetics discussed above occurred on January 1, 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$6,879,587	$7,686,841	$23,043,458	$18,805,055
Net loss	(10,353,822)	(8,181,903)	(27,522,585)	(21,450,482)
Basic net loss per share	$(0.98)	$(0.79)	$(2.62)	$(2.11)
Diluted net loss per share	(1.00)	(0.80)	(2.62)	(2.14)

The pro forma numbers above are derived from historical numbers of the Company and Response Genetics. Over time the operations of Response Genetics will be integrated into the operations of the Company. This integration may change how certain tests are coded and submitted to payers (including Medicare) and, consequently, may result in differences in the future in which revenues and bad debt expenses are recorded when compared with the historical methods of Response Genetics. At the current time, we do not have enough information to prepare a reliable estimate of any possible changes.

Note 2. Revenue and Accounts Receivable

Revenue by service type for the three and nine months ended September 30, 2015 and 2014 is comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Biopharma Services	$2,608,427	$1,930,799	8,614,441	$2,830,687
Clinical Services	1,149,241	1,237,831	3,273,585	3,279,988
Discovery Services	242,664	53,220	667,780	53,220
	$4,000,332	$3,221,850	$12,555,806	$6,163,895

Accounts receivable by service type at September 30, 2015 and December 31, 2014 consists of the following:

	September 30, 2015	December 31, 2014
Biopharma Services	$2,879,064	$3,203,335
Clinical Services	2,401,775	1,925,176
Discovery Services	348,344	151,285
Allowance for doubtful accounts	(464,090)	(251,176)

$5,165,093	$5,028,620

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Allowance for Doubtful Accounts	
Balance, December 31, 2014	$251,176
Bad debt provision	212,914
Balance, September 30, 2015	$464,090

Biopharma Services provide companies customized solutions for patient stratification and treatment selection through an extensive suite of DNA-based testing services. Clinical Services provide information on diagnosis, prognosis and theranosis of cancers to guide patient management. These tests can be billed to Medicare, another third party insurer or the referring community hospital or other healthcare facility. Discovery Services provide the tools and testing methods for companies and researchers seeking to identify new DNA-based biomarkers for disease.

We have historically derived a significant portion of our revenue from a limited number of test ordering sites. Test ordering sites account for all of our Clinical Services revenue along with a portion of our Biopharma Services revenue. Our test ordering sites are hospitals, cancer centers, reference laboratories, physician offices and biopharmaceutical companies. The top five test ordering sites during the three months ended September 30, 2015 and 2014 accounted for 59% and 59% respectively, of our testing volumes, with 27% and 45%, respectively, of the volume coming from community hospitals. During the three months ended September 30, 2015, there were two biopharmaceutical companies which accounted for approximately 15% and 11% of our total revenue. During the three months ended September 30, 2014, there were two biopharmaceutical companies which accounted for approximately 17% and 12% of our total revenue, respectively.

The top five test ordering sites during the nine months ended September 30, 2015 and 2014 accounted for 80% and 58% respectively, of our testing volumes, with 31% and 40%, respectively, of the volume coming from community hospitals. During the nine months ended September 30, 2015, there were two biopharmaceutical companies which accounted for approximately 23% and 11% of our total revenue, respectively. During the nine months ended September 30, 2014, there was one biopharmaceutical company which accounted for approximately 22% of our total revenue.

While we have agreements with our Biopharma clients, volumes from these clients are subject to the progression and continuation of the trials which can impact testing volume. We generally do not have formal written agreements with other testing sites and, as a result, we may lose these significant test ordering sites at any time.

The breakdown of our Clinical Services revenue (as a percent of total revenue) is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Medicare	12%	9%	8%	13%
Other insurers	7%	14%	7%	21%
Other healthcare facilities	9%	15%	8%	19%
	28%	38%	23%	53%

Note 3. Earnings Per Share

For purposes of this calculation, stock warrants, outstanding stock options and unvested restricted shares are considered common stock equivalents using the treasury stock method, and are the only such equivalents outstanding.

Basic net loss and diluted net loss per share data were computed as follows:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net (loss) for basic earnings per share	$(5,212,014)	$(4,797,062)	$(14,470,164)	$(11,469,659)
Change in fair value of warrant liability	214,000	129,000	18,000	324,000
Net (loss) for diluted earnings per share	$(5,426,014)	$(4,926,062)	$(14,488,164)	$(11,793,659)
Denominator:				
Weighted-average basic common shares outstanding	9,726,067	9,575,789	9,714,824	9,386,613
Assumed conversion of dilutive securities:				
Common stock purchase warrants	1,530	—	1,390	16,632
Potentially dilutive common shares	1,530	—	1,390	16,632
Denominator for diluted earnings per share – adjusted weighted-average shares	9,727,597	9,575,789	9,716,214	9,403,245
Basic net (loss) per share	$(0.54)	$(0.50)	$(1.49)	$(1.22)
Diluted net (loss) per share	$(0.56)	$(0.51)	$(1.49)	$(1.25)

The following table summarizes equivalent units outstanding that were excluded from the earnings per share calculation because their effects were anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Common stock purchase warrants	1,041,725	1,531,696	1,041,725	1,531,696
Stock options	2,008,466	1,461,724	2,008,466	1,461,724
Restricted shares of common stock	132,167	105,833	132,167	105,833
	3,182,358	3,099,253	3,182,358	3,099,253

Note 4. Bank Term Note and Line of Credit

On May 7, 2015, we entered into a new debt financing facility with Silicon Valley Bank (“SVB”) to refinance the Company’s cash collateralized loan from Wells Fargo and to provide an additional working capital line of credit. The SVB credit facility provides for a $6.0 million term note (“Term Note”) and a revolving line of credit (“Line of Credit”) for an amount not to exceed the lesser of (i) $4.0 million or (ii) an amount equal to 80% of eligible accounts receivable. The Term Note requires interest-only payments through April 30, 2016 and beginning May 1, 2016, monthly principal payments of approximately $167,000 will be required plus interest through maturity on April 1, 2019. The interest rate of the Term Note is the Wall Street Journal prime rate plus 2%, with a floor of 5.25% and an additional deferred interest payment of $180,000 will be due upon maturity. The Line of Credit requires monthly interest-only payments of the Wall Street Journal prime rate plus 1.5% and matures on May 7, 2017. The new loan agreement requires maintenance of certain financial ratios and grants SVB a first security interest in substantially all Company assets (other than our intellectual property). Pursuant to the new loan agreement, the Company is no longer required to maintain restricted cash accounts. At September 30, 2015 the principal balance of the Term Note was $6,000,000 and the principal balance of the Line of Credit was $0.

The following is a summary of long-term debt as of September 30, 2015:

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	September 30, 2015
Term Note, principal balance	$6,000,000
Less unamortized debt issuance costs	27,884
Term Note, net	5,972,116
Less current maturities	833,333
Long-term portion	$5,138,783

Principal maturities of the Term Note as of September 30, 2015 are as follows: 2016 - $1,333,333; 2017 - $2,000,000; 2018 - $2,000,000; 2019 - $666,667.

Note 5. Sale of Net Operating Losses

In January 2014, we executed a sale of $22,301,643 of gross state NOL carryforwards resulting in the receipt of $1,813,941. The Company transferred the NOL carryforwards through the Technology Business Tax Certificate Transfer Program sponsored by the New Jersey Economic Development Authority.

Note 6. Equity Incentive Plans

We have two equity incentive plans: the 2008 Stock Option Plan (the “2008 Plan”) and the 2011 Equity Incentive Plan (the “2011 Plan”, and together with the 2008 Plan, the “Stock Option Plans”). The Stock Option Plans are meant to provide additional incentive to officers, employees and consultants to remain in our employment. Options granted are generally exercisable for up to 10 years. On May 14, 2015, the stockholders voted to increase the number of shares reserved by the 2011 Plan to 2,650,000 shares of common stock.

At September 30, 2015, 825,100 shares remain available for future awards under the 2011 Plan and 93,616 shares remain available for future awards under the 2008 Plan. As of September 30, 2015, no stock appreciation rights and 270,500 shares of restricted stock have been awarded under the Stock Option Plans.

A summary of employee and non-employee stock option activity for the nine months ended September 30, 2015 is as follows:

	Options Outstanding			
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding January 1, 2015	1,839,458	$10.58	8.49	$618,250
Granted	292,150	9.91		
Exercised	(4,371)	5.37		
Canceled or expired	(118,771)	9.63		
Outstanding September 30, 2015	2,008,466	$10.55	7.93	$1,313,377
Exercisable September 30, 2015	881,027	$9.89	6.66	$862,492

Aggregate intrinsic value represents the difference between the estimated fair value of our common stock and the exercise price of outstanding, in-the-money options. The fair value of our common stock was $7.82 at September 30, 2015 and $6.68 at December 31, 2014, based on the closing price on the NASDAQ Capital Market. During the three and nine months ended September 30, 2015, we received approximately $1,000 and $24,000, respectively, from the

exercise of options. The options exercised during the three and nine months ended September 30, 2015 had a total intrinsic value of approximately $1,000 and $25,000, respectively.

As of September 30, 2015, total unrecognized compensation cost related to non-vested stock options granted to employees was $5,536,069 which we expect to recognize over the next 3.32 years.

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As of September 30, 2015, total unrecognized compensation cost related to non-vested stock options granted to non-employees was $536,138 which we expect to recognize over the next 2.25 years. The estimate of unrecognized non-employee compensation is based on the fair value of the non-vested options as of September 30, 2015.

The fair value of options granted to employees is estimated on the grant date using the Black-Scholes option valuation model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation, including the expected term (the period of time that the options granted are expected to be outstanding), the volatility of our common stock, a risk-free interest rate, and expected dividends. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period estimates are revised. No compensation cost is recorded for options that do not vest. We use the simplified calculation of expected life described in the SEC's Staff Accounting Bulletin No. 107, Share-Based Payment, and volatility is based on an average of the historical volatilities of the common stock of three entities with characteristics similar to those of the Company. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. We use an expected dividend yield of zero, as we do not anticipate paying any dividends in the foreseeable future. Expected forfeitures are assumed to be zero due to the small number of plan participants and the plan design which has monthly vesting after an initial cliff vesting period.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted to employees during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Volatility	55.71 %	75.02 %	61.16 %	75.04 %
Risk free interest rate	1.63 %	2.02 %	1.65 %	1.84 %
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Term (years)	6.16	6.29	6.15	6.10
Weighted-average fair value of options granted during the period	5.41	6.13	5.65	6.86

In May 2014, we issued 200,000 options to our Director, Raju Chaganti, with an exercise price of $15.89. See Note 11 for additional information. The following table presents the weighted-average assumptions used to estimate the fair value of options reaching their measurement date for non-employees during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Volatility	69.56 %	71.30 %	69.97 %	71.87 %
Risk free interest rate	2.02 %	2.43 %	2.11 %	2.53 %
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %
Term (years)	8.58	9.58	8.84	9.79

Restricted stock awards have been granted to employees, directors and consultants as compensation for services. At September 30, 2015, there was $838,146 of unrecognized compensation cost related to non-vested restricted stock granted to employees; we expect to recognize the cost over 2.64 years. At September 30, 2015, there was $536 of unrecognized compensation cost related to non-vested restricted stock granted to non-employees; we expect to recognize the cost over 0.03 years.

The following table summarizes the activities for our non-vested restricted stock awards for the nine months ended September 30, 2015:

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	Non-vested Restricted Stock Awards	
	Number of Shares	Weighted-Average Grant Date Fair Value
Non-vested at January 1, 2015	132,500	$ 8.14
Granted	43,000	9.70
Vested	(33,333)	9.27
Canceled	(10,000)	$ 8.42
Non-vested at September 30, 2015	132,167	$ 8.36

The following table presents the effects of stock-based compensation related to stock option and restricted stock awards to employees and non-employees on our Statement of Operations during the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenues	$59,081	$26,200	$163,006	$67,109
Research and development	92,726	188,633	316,306	345,803
General and administrative	530,301	593,715	1,585,869	1,615,359
Sales and marketing	41,820	27,551	112,373	101,609
Total stock-based compensation	$723,928	$836,099	$2,177,554	$2,129,880

Note 7. Warrants

We have issued certain warrants which contain an exercise price adjustment feature in the event we issue additional equity instruments at a price lower than the exercise price of the warrant. The warrants are described herein as derivative warrants. For all derivative warrants, in the event equity instruments are issued at a price lower than the exercise price of the warrant, the exercise price is adjusted to the price of the new equity instruments issued (price adjustment feature). For certain of these warrants, the number of shares underlying the warrant is also adjusted to an amount computed by dividing the proceeds of the warrant under its original terms by the revised exercise price (share adjustment feature). As of September 30, 2015 all warrants with a share adjustment feature have either expired or have been exercised. The derivative warrants are initially recorded as a warrant liability at fair value with a corresponding entry to the loan guarantee fee asset, debt discount, additional paid-in capital or expense dependent upon the service provided in exchange for the warrant grant.

The following table summarizes the warrant activity for the nine months ended September 30, 2015:

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Issued With / For	Exercise Price		Warrants Outstanding January 1, 2015	2015 Warrants Expired	Warrants Outstanding September 30, 2015
Non-Derivative Warrants:					
Financing	$10.00		243,334	—	243,334
Financing	15.00		436,079	—	436,079
Debt guarantee	15.00		352,312	—	352,312
Consulting	10.00		29,138	(19,138)	10,000
Total non-derivative warrants	$13.78	B	1,060,863	(19,138)	1,041,725
Derivative Warrants:					
Financing	$10.00	A	60,000	—	60,000
Series B pref. stock	10.00	A	15,015	—	15,015
Consulting	10.00	A	200	—	200
Total derivative warrants	10.00	B	75,215	—	75,215
Total	$13.53	B	1,136,078	(19,138)	1,116,940

These warrants are subject to fair value accounting and contain an exercise price adjustment feature. See Note 8.

A Assuming the offering described in Note 14 closes, the exercise price of these warrants will adjust to $4.00 on November 12, 2015.

B Weighted-average exercise prices are as of September 30, 2015.

Note 8. Fair Value of Warrants

The following table summarizes the derivative warrant activity subject to fair value accounting for the nine months ended September 30, 2015:

Issued with/for	Fair value of warrants outstanding as of December 31, 2014	Change in fair value of warrants	Fair value of warrants outstanding as of September 30, 2015
Series B preferred stock	$8,000	$(6,000)	$2,000
Financing	44,000	(12,000)	32,000
	$52,000	$(18,000)	$34,000

The following tables summarize the assumptions used in computing the fair value of derivative warrants subject to fair value accounting at the date of issue or exercise during the nine months ended September 30, 2015 and 2014, and at September 30, 2015 and December 31, 2014.

Issued with Debt Guarantee	Exercised During the Nine Months Ended September 30, 2014	
Exercise price	$10.00	
Expected life (years)	0.60	
Expected volatility	49.01	%
Risk-free interest rate	0.08	%
Expected dividend yield	—	%

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Issued with Series B Preferred Shares	As of September 30, 2015	As of December 31, 2014	Exercised During the Nine Months Ended September 30, 2014
Exercise price	$ 10.00	$ 10.00	$ 10.00
Expected life (years)	0.13	0.88	1.72
Expected volatility	57.27 %	49.95 %	46.60 %
Risk-free interest rate	— %	0.25 %	0.33 %
Expected dividend yield	— %	— %	— %

Issued for Consulting	As of September 30, 2015	As of December 31, 2014
Exercise price	$ 10.00	$ 10.00
Expected life (years)	0.39	1.14
Expected volatility	49.38 %	49.25 %
Risk-free interest rate	0.08 %	0.25 %
Expected dividend yield	— %	— %

Issued with Financing	As of September 30, 2015	As of December 31, 2014	Exercised During the Nine Months Ended September 30, 2014
Exercise price	$ 10.00	$ 10.00	$ 13.34
Expected life (years)	0.48	1.23	9.78
Expected volatility	49.99 %	50.23 %	74.70 %
Risk-free interest rate	0.08 %	0.25 %	1.95 %
Expected dividend yield	— %	— %	— %

The assumed Company stock price used in computing the fair value of warrants exercised during the nine months ended September 30, 2014 was $15.20 – $19.86. In determining the fair value of warrants outstanding at each reporting date, the Company stock price was $7.82 at September 30, 2015 and $6.68 at December 31, 2014 based on the closing price on the NASDAQ Capital Market.

Note 9. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Fair Value Measurements and Disclosures Topic of the FASB Accounting Standards Codification requires the use of valuation techniques that are consistent with the market approach, the income approach and/or the cost approach. Inputs to valuation techniques refer to the assumptions that market participants would use in pricing the asset or liability. Inputs may be observable, meaning those that reflect the assumptions market participants would use in pricing the asset or liability developed based on market data obtained from independent sources, or unobservable, meaning those that reflect our own assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. In that regard, the Topic establishes a fair value hierarchy for valuation inputs that give the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets that we have the ability to access as of the measurement date.

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

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Level 3: Significant unobservable inputs that reflect our own assumptions about the assumptions that market participants would use in pricing an asset or liability.

The following table summarizes the financial liabilities measured at fair value on a recurring basis segregated by the level of valuation inputs within the fair value hierarchy utilized to measure fair value:

	September 30, 2015			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	$34,000	$—	$—	$34,000
Gentris contingent consideration	45,000	—	—	45,000
Note payable to VenturEast	626,101	—	—	626,101
	$705,101	$—	$—	$705,101

	December 31, 2014			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant liability	$52,000	$—	$—	$52,000
Gentris contingent consideration	293,400	—	—	293,400
Note payable to VenturEast	534,828	—	—	534,828
	$880,228	$—	$—	$880,228

The warrant liability consists of stock warrants we issued that contain an exercise price adjustment feature. In accordance with derivative accounting for warrants, we calculated the fair value of warrants and the assumptions used are described in Note 8, “Fair Value of Warrants”. Realized and unrealized gains and losses related to the change in fair value of the warrant liability are included in Other income (expense) on the Statement of Operations.

The value of the Gentris consideration was determined using a discounted cash flow of the expected payments required by the purchase agreement. During the nine months ended September 30, 2015, we recognized a gain of approximately $162,000 due to the decrease in probability of paying the contingent consideration.

The ultimate payment to VenturEast will be the value of 84,278 shares of common stock at the time of payment. The value of the note payable to VenturEast was determined using the fair value of our common stock less a discount for credit risk. During the three and nine months ended September 30, 2015, we recognized a gain (loss) of approximately $315,000 and $(91,000), respectively, due to the change in value of the note.

Realized and unrealized gains and losses related to the change in fair value of the Gentris contingent consideration are included in general and administrative expense, while realized and unrealized gains and losses related to the VenturEast note are included in other income (expense) on the Consolidated Statement of Operations.

A table summarizing the activity for the derivative warranty liability which is measured at fair value using Level 3 inputs is presented in Note 8. The following table summarizes the activity of the notes payable to VenturEast and Gentris consideration which were measured at fair value using Level 3 inputs:

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	Note Payable to VenturEast	Gentris Contingent Consideration
Fair value at December 31, 2014	$534,828	$293,400
Change in fair value	91,273	(162,000)
Partial settlement of liability	$—	(86,400)
Fair value at September 30, 2015	$626,101	$45,000

Note 10. Joint Venture Agreement

In November 2011, we entered into an affiliation agreement with the Mayo Foundation for Medical Education and Research ("Mayo"), subsequently amended. Under the agreement, we formed a joint venture with Mayo in May 2013 to focus on developing oncology diagnostic services and tests utilizing next generation sequencing. The joint venture is a limited liability company, with each party initially holding fifty percent of the issued and outstanding membership interests of the new entity (the "JV"). In exchange for our membership interest in the JV, we made an initial capital contribution of $1.0 million in October 2013. In addition, we issued 10,000 shares of our common stock to Mayo pursuant to our affiliation agreement and recorded an expense of approximately $175,000. We also recorded additional expense of approximately $231,000 during the fourth quarter of 2013 related to shares issued to Mayo in November 2011 as the JV achieved certain performance milestones. In the third quarter of 2014, we made an additional $1.0 million capital contribution.

The agreement also requires aggregate total capital contributions by us of up to an additional $4.0 million. We currently anticipate that we will make capital contributions of $1.0 million in the first quarter of 2016. The timing of the remaining installments is subject to the JV's achievement of certain operational milestones agreed upon by the board of governors of the JV. In exchange for its membership interest, Mayo's capital contribution will take the form of cash, staff, services, hardware and software resources, laboratory space and instrumentation, the fair market value of which will be approximately equal to $6.0 million. Mayo's continued contribution will also be conditioned upon the JV's achievement of certain milestones.

Our share of the JV's net loss was approximately $343,000 and $349,000 for the three months ended September 30, 2015 and 2014, respectively, and $748,000 and $659,000 for the nine months ended September 30, 2015 and 2014, respectively, and is included in research and development expense on the Consolidated Statement of Operations. We have a net receivable due from the JV of approximately $0 and $10,000 at September 30, 2015 and December 31, 2014, respectively, which is included in other current assets in the Consolidated Balance Sheets.

The joint venture is considered a variable interest entity under ASC 810-10, but we are not the primary beneficiary as we do not have the power to direct the activities of the JV that most significantly impact its performance. Our evaluation of ability to impact performance is based on our equal board membership and voting rights and day-to-day management functions which are performed by the Mayo personnel.

Note 11. Related Party Transactions

John Pappajohn, a member of the Board of Directors and stockholder, had personally guaranteed our revolving line of credit with Wells Fargo Bank through March 31, 2014. As consideration for his guarantee, as well as each of the eight extensions of this facility through March 31, 2014, Mr. Pappajohn received warrants to purchase an aggregate of 1,051,506 shares of common stock of which Mr. Pappajohn assigned warrants to purchase 284,000 shares of common stock to certain third parties. Warrants to purchase 440,113 shares of common stock have been exercised by Mr. Pappajohn through September 30, 2015. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of these warrants outstanding retained by Mr. Pappajohn was 352,312 at $15.00 per share.

In addition, John Pappajohn also had loaned us an aggregate of $6,750,000 (all of which was converted into 675,000 shares of common stock at the IPO price of $10.00 per share). In connection with these loans, Mr. Pappajohn received warrants to purchase an aggregate of 202,630 shares of common stock. After adjustment pursuant to the terms of the warrants in conjunction with our IPO, the number of warrants outstanding was 436,079 at $15.00 per share at September 30, 2015.

Effective January 6, 2014, the Board of Directors appointed John Pappajohn to serve as the Chairman of the Board. As compensation for serving as the Chairman of the Board, the Company will pay Mr. Pappajohn $100,000 per year and granted to Mr. Pappajohn 25,000 restricted shares of the Company’s common stock, and options to purchase an aggregate of 100,000 shares of the Company's common stock. The options have a term of ten years from the date on which they were granted. The

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restricted stock and the options each vest in two equal installments on the one-year anniversary and the two-year anniversary of the date on which Mr. Pappajohn became the Chairman of the Board.

On October 14, 2015 the Board of Directors granted John Pappajohn 2,500 restricted shares of the Company's common stock and options to purchase an aggregate of 10,000 shares of the Company's common stock as compensation for serving on the Board of Directors. The restricted stock vests on the one-year anniversary date of the grant and the stock options vest in two equal installments on the one-year anniversary and the two-year anniversary date of the grant.

In August 2010, we entered into a consulting agreement with Equity Dynamics, Inc. ("EDI"), an entity controlled by John Pappajohn, pursuant to which EDI received a monthly fee of $10,000. The consulting agreement was terminated effective March 31, 2014. Subsequently, the Company entered into a new consulting agreement with EDI effective April 1, 2014 pursuant to which it will receive a monthly fee of $10,000. Total expenses for the three months ended September 30, 2015 and 2014 were $30,000, and for the nine months ended September 30, 2015 and 2014, total expenses were $90,000. As of September 30, 2015, we owed EDI $0.

On September 15, 2010, we entered into a three-year consulting agreement with Dr. Chaganti which was subsequently renewed through December 31, 2016 pursuant to which Dr. Chaganti receives $5,000 per month for providing consulting and technical support services. Total expenses for each of the three months ended September 30, 2015 and 2014 were $15,000. Total expenses for each of the nine months ended September 30, 2015 and 2014 were $45,000. Pursuant to the terms of the renewed consulting agreement, Dr. Chaganti received an option to purchase 200,000 shares of our common stock at a purchase price of $15.89 per share vesting over a period of four years. Total non-cash stock-based compensation recognized under the consulting agreement for each of the three months ended September 30, 2015 and 2014 was $59,500 and $76,375, respectively. Total non-cash stock-based compensation recognized under the consulting agreement for each of the nine months ended September 30, 2015 and 2014 was $220,625 and $288,500, respectively. Also pursuant to the consulting agreement, Dr. Chaganti assigned to us all rights to any inventions which he may invent during the course of rendering consulting services to us. In exchange for this assignment, if the USPTO issues a patent for an invention on which Dr. Chaganti is listed as an inventor, we are required to pay Dr. Chaganti (i) a one-time payment of $50,000 and (ii) 1% of any net revenues we receive from any licensed sales of the invention. In 2015, we paid Dr. Chaganti $150,000 which was recognized as an expense in fiscal 2014 when three patents were issued.

On October 14, 2015 the Board of Directors granted Dr. Chaganti 2,500 restricted shares of the Company's common stock and options to purchase an aggregate of 10,000 shares of the Company's common stock as compensation for serving on the Board of Directors. The restricted stock vests on the one-year anniversary date of the grant and the stock options vest in two equal installments on the one-year anniversary and the two-year anniversary date of the grant.

Note 12. Contingencies

In the normal course of business, the Company may become involved in various claims and legal proceedings. In the opinion of management, the ultimate liability or disposition thereof is not expected to have a material adverse effect on our financial condition, results of operations, or liquidity.

Note 13. Cantor Sales Agreement

On July 15, 2015, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., ("Cantor") as sales agent, pursuant to which the Company may offer from time to time through Cantor, shares of our common stock having an aggregate offering price of up to $20.0 million. Subject to the

terms and conditions of the Sales Agreement, Cantor 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 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. The Company may instruct Cantor not to sell shares if the sales cannot be effected at or above the price designated by the Company from time to time. The Company is not obligated to make any sales of the shares under the Sales Agreement. The offering of shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. Cantor will receive a commission rate of 3.0% of the aggregate gross proceeds from each sale of shares and the Company has agreed to provide Cantor with customary indemnification and contribution rights. The Company will also reimburse Cantor for certain specified expenses in connection with entering into the Sales Agreement. During the three months ended September 30, 2015, the Company sold 2,800 shares of its common stock that

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resulted in net proceeds to the Company of approximately $34,000. In July 2015, we temporarily suspended selling shares of common stock using the Sales Agreement. Furthermore, under the terms of our lock up agreement with Joseph Gunnar and Feltl, we may not resume selling our common stock under the Sales Agreement until 90 days after the public offering is consummated. See Note 14 for additional information regarding the public offering.

Note 14. Subsequent Events

On November 6, 2015, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Joseph Gunnar & Co., LLC and Feltl and Company, Inc., as representatives of the several underwriters named in Schedule A to the Underwriting Agreement (the "Underwriters"). Pursuant to the terms and conditions of the Underwriting Agreement, the Company agreed to sell to the Underwriters 3,000,000 shares of its common stock, par value $0.0001 per share (the "Common Stock") and warrants on terms described below (the "Warrants") to purchase up to an aggregate of 3,000,000 shares of Common Stock, at a combined price of $4.00 per share and accompanying Warrant, less underwriting discounts and commissions and has granted the Underwriters an option to purchase up to an additional 450,000 shares of Common Stock and/or Warrants within 45 days after the date of the Underwriting Agreement. The Company also agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering as well as legal fees up to $60,000; however, an allowance shall not be paid in connection with the over-allotment option if the over-allotment option is exercised. The sale to the Underwriters is expected to close on November 12, 2015, subject to customary closing conditions.

The Underwriting Agreement provides that the obligations of the Underwriters are subject to certain conditions precedent and that the Underwriters have agreed, severally and not jointly, to purchase all of the shares and Warrants being sold under the Underwriting Agreement if any such securities are purchased (other than the securities subject to the Underwriters' option). Additionally, the Underwriting Agreement contains customary representations, warranties, and covenants by the Company and customary indemnification obligations of each of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended. In addition, subject to certain exceptions, each director and executive officer of the Company has entered into an agreement with the Underwriters not to sell, transfer or otherwise dispose of securities of the Company during the 90-day period following the offering. The Company is also restricted in its ability to sell securities during such 90-day period.

The Company estimates that the net proceeds to the Company from the offering (exclusive of proceeds from the sale of shares and/or Warrants pursuant to any exercise of the Underwriters' option described above and exclusive of proceeds, if any, from the exercise of the Warrants issued pursuant to the offering) will be approximately $10.5 million after deducting the underwriting discounts and commissions, and estimated offering expenses payable by the Company. The Company expects to use the net proceeds from the offering for contributions to its JV with Mayo, expansion of its sales and marketing capabilities, further research and development activities, expansion of business, strategic transactions and working capital and other general corporate purposes. No assurances can be given that all closing conditions will be satisfied and that the offering consummated on these terms, or at all.

Each warrant will have an exercise price of $5.00 per share (subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders), will be exercisable upon issuance and will expire five years from the date of issuance (expected to be November 12, 2015).

The foregoing description of the Underwriting Agreement and the Warrant does not purport to be complete and is qualified in its entirety by reference to the full text of the Underwriting Agreement and the Warrant, copies of which are filed herewith as Exhibits 10.2 and 4.1. The provisions of the Underwriting Agreement, including the representations and warranties contained therein, are not for the benefit of any party other than the parties to such

agreement and are not intended as a document for stockholders and the public to obtain factual information about the current state of affairs of the Company. Rather, stockholders and the public should look to other disclosures contained in the Company's filings with the Commission.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

As used herein, the "Company," "we," "us," "our" or similar terms, refer to Cancer Genetics, Inc. and its wholly owned subsidiaries: Cancer Genetics Italia, S.r.l., Gentris, LLC and BioServe Biotechnologies (India) Private Limited, except as expressly indicated or unless the context otherwise requires. The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help facilitate an understanding of our financial condition and our historical results of operations for the periods presented. This MD&A should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Reporting on Form 10-K filed with the SEC on

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March 16, 2015. This MD&A may contain forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements" below.

Overview

We are an oncology diagnostics company focused on developing, commercializing and providing DNA-based tests and services to improve the personalization of cancer treatment and to better inform biopharmaceutical companies of genomic factors influencing subject responses to therapeutics. Our vision is to become the oncology diagnostics partner for companies and clinicians by participating in the entire care continuum from bench to bedside. We believe the diagnostic industry is undergoing a metamorphosis in its approach to oncology testing, embracing individualized medicine as a means to drive higher standards of patient treatment and disease management. Similarly, biopharmaceutical companies are increasingly engaging companies such as ours to provide information on clinical trial participants' DNA profiles in order to identify genomic variations that may be responsible for differing responses to pharmaceuticals, and particularly to oncology drugs, thereby increasing the efficiency of trials while lowering related costs. We believe tailored therapeutics can revolutionize oncology medicine through DNA-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique. We have created a unique position in the industry by providing targeted somatic analysis of tumor sample cells alongside germline analysis of an individual's non-cancerous cells' DNA as we attempt to reach the next milestone in personalized medicine.

Our services are performed at our state-of-the-art laboratories located in New Jersey, North Carolina, Shanghai (China), and Hyderabad (India). Our laboratories comply with the highest regulatory standards as appropriate for the services they deliver including CLIA, CAP, NY State and NABL (India).We have two advisory boards to counsel our scientific and clinical direction. Our Scientific Advisory Board is comprised of preeminent scientists and physicians from the fields of cancer biology, cancer pathology, cancer medicine and molecular genetics. Our Clinical Advisory Board is comprised of clinicians and scientists focused on clinical implementation of our proprietary tests and services and mapping those tests and services to patient needs. Our services are built on a foundation of world-class scientific knowledge and intellectual property in solid and blood-borne cancers, as well as strong academic relationships with major cancer centers such as Memorial Sloan-Kettering, Mayo Clinic, and the National Cancer Institute.

Our clinical offerings include our portfolio of proprietary tests targeting hematological, urogenital and HPV-associated cancers, in conjunction with ancillary non-proprietary tests. Our proprietary tests target cancers that are difficult to prognose and predict treatment outcomes through currently available mainstream techniques. We provide our proprietary tests and services, along with a comprehensive range of non-proprietary oncology-focused tests and laboratory services, to oncologists and pathologists at hospitals, cancer centers, and physician offices. Our proprietary tests are based principally on our expertise in specific cancer types, test development methodologies and proprietary algorithms correlating genetic events with disease specific information. Our portfolio primarily includes comparative genomic hybridization (CGH) microarrays and next generation sequencing (NGS) panels, and DNA fluorescent in situ hybridization (FISH) probes.
The non-proprietary testing services we offer are focused in part on specific oncology categories where we are developing our proprietary tests. We believe that there is significant synergy in developing and marketing a complete set of tests and services that are disease focused and delivering those tests and services in a comprehensive manner to help with treatment decisions. The insight that we develop in delivering the non-proprietary services are often leveraged in the development of our proprietary programs and now increasingly in the validation of our proprietary programs, such as MatBA and Focus::NGS.

We expect to continue to incur significant losses for the near future. We incurred losses of $16.6 million and $12.4 million for fiscal years ended December 31, 2014 and 2013, respectively, and $14.5 million for the nine months ended September 30, 2015.

As of September 30, 2015, we had an accumulated deficit of $92.4 million.

Acquisitions

On July 16, 2014, we purchased substantially all of the assets of Gentris Corporation, a Delaware corporation ("Gentris"), with its principal place of business in North Carolina, for aggregate consideration of approximately $4.8 million.

On August 18, 2014, we acquired BioServe Biotechnologies (India) Private Limited, an Indian corporation ("BioServe") for an aggregate purchase price of approximately $1.1 million.

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On October 9, 2015, we acquired substantially all of the assets of Response Genetics, Inc. (“Response Genetics”) with its principal place of business in California, for aggregate consideration of approximately $13.4 million.

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.

We believe the acquisition of Response Genetics will enhance our business for the following reasons:

- Enable us to have a West Coast facility by adding Response Genetics' Los Angeles, California-based laboratory. We assumed the lease of 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 added 9 salespeople and 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.

- 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 immediately.

- 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 by upselling to our and 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 lung cancer next-generation sequencing panel developed by leading genomic scientists and clinicians at Knight Laboratories at Oregon Health & Science University.

Response Genetics is expected to contribute an additional $10 to $12 million to our revenue through September 30, 2016. Response Genetics incurred losses of $13.7 million and $8.0 million for the fiscal years ended December 31, 2014 and 2013, respectively. 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. Although, we expect to realize some cost efficiencies and savings as a result of integrating Response Genetics' operations into our operations, we cannot predict the impact of any such cost efficiencies and savings and we expect losses for the combined company to continue principally as a result of ongoing research and development expenses and increased sales and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets and stockholders' equity.

We expect that the acquisition of the Response Genetics businesses will result in potential benefits for the combined company, including revenue growth, 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

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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. The failure to achieve anticipated benefits could harm the business, financial condition and operating results of the combined company.

Key Factors Affecting our Results of Operations and Financial Condition

Our overall long-term growth plan is predicated on our ability to develop and commercialize our proprietary tests, penetrate the Biopharma community to achieve more revenue supporting clinical trials and develop and penetrate the Indian market. In 2014, we acquired Gentris to increase our penetration in the Biopharma space. Our proprietary tests include CGH microarrays, NGS panels, and DNA FISH probes.We continue to develop additional proprietary tests. To facilitate market adoption of our proprietary tests, we anticipate having to successfully complete additional studies with clinical samples and publish our results in peer-reviewed scientific journals. Our ability to complete such studies is dependent upon our ability to leverage our collaborative relationships with leading institutions to facilitate our research and obtain data for our quality assurance and test validation efforts.

We believe that the factors discussed in the following paragraphs have had and are expected to continue to have a material impact on our results of operations and financial condition.

Revenues

Our revenue is primarily generated through our Clinical Services and Biopharma Services. Clinical Services can be billed to Medicare, another third party insurer or the referring community hospital or other healthcare facility in accordance with state and federal law. Biopharma Services are billed to the customer directly. While we have agreements with our Biopharma clients, volumes from these clients are subject to the progression and continuation of the trials which can impact testing volume. We also derive limited revenue from Discovery Services, which are services provided in the development of new testing assays and methods. Discovery Services are billed directly to the customer.

We have historically derived a significant portion of our revenue from a limited number of test ordering sites, although the test ordering sites that generate a significant portion of our revenue have changed from period to period. Test ordering sites account for all of our Clinical Services revenue along with a portion of the Biopharma Services revenue. Our test ordering sites are hospitals, cancer centers, reference laboratories, physician offices and biopharmaceutical companies. Oncologists and pathologists at these sites order the tests on behalf of the needs of their oncology patients or as part of a clinical trial sponsored by a biopharmaceutical company in which the patient is being enrolled.

The top five test ordering clients during the three months ended September 30, 2015 and 2014 accounted for 59% and 59%, respectively, of our testing volumes, with 27% and 45%, respectively, of the test volume coming from community hospitals. During the three months ended September 30, 2015, two Biopharma clients accounted for approximately 15% and 11% of our revenue. During the three months ended September 30, 2014, two Biopharma clients accounted for approximately 17% and 12% of our revenue, respectively.

The top five test ordering clients during the nine months ended September 30, 2015 and 2014 accounted for 80% and 58%, respectively, of our testing volumes, with 31% and 40%, respectively, of the test volume coming from community hospitals. During the nine months ended September 30, 2015, two Biopharma clients accounted for approximately 23% and 11%, respectively, of our revenue. During the nine months ended September 30, 2014, one Biopharma client accounted for approximately 22% of our revenue. The loss of our largest client would materially

adversely affect our results of operations; however, the loss of any other test ordering client would not materially adversely affect our results of operations.

We receive revenue for our Clinical Services from Medicare, other insurance carriers and other healthcare facilities. Some of our customers choose, generally at the beginning of our relationship, to pay for laboratory services directly as opposed to having patients (or their insurers) pay for those services and providing us with the patients' insurance information. A hospital may elect to be a direct bill customer and pay our bills directly, or may provide us with patient information so that their patients pay our bills, in which case we generally expect payment from their private insurance carrier or Medicare. In a few instances, we have arrangements where a hospital may have two accounts with us, so that certain tests are billed directly to the hospital, and certain tests are billed to and paid by a patient's insurer. The billing arrangements generally are dictated by our customers and in accordance with state and federal law.

For the three months ended September 30, 2015, Medicare accounted for approximately 12% of our total revenue, other insurance accounted for approximately 7% of our total revenue and other healthcare facilities accounted for 9% of our total

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revenue. For the nine months ended September 30, 2015, Medicare accounted for approximately 8% of our total revenue, other insurance accounted for approximately 7% of our total revenue and other healthcare facilities accounted for 8% of our total revenue. As we expand our portfolio of tests and services and our sales activities, we expect the percentage of revenue from other healthcare facilities may decrease over the long term. However, the addition of new customers, particularly a community hospital or other large volume client, could offset this trend seen in prior years. On average, we generate less revenue per test from other healthcare facilities billed directly, than from other insurance payors. However, we have reduced sales cost associated with direct bill clients as well as significantly reduced collections risk. Typically, we negotiate discounts with directly billed healthcare facilities depending on the volume of business. With the acquisition of Response Genetics and its anticipated mix of revenues, we expect that Medicare, other insurance and other healthcare facilities will account for a higher percentage of our revenue in future quarters.

Cost of Revenues

Our cost of revenues consists principally of internal personnel costs, including stock-based compensation, laboratory consumables, shipping costs, overhead and other direct expenses, such as specimen procurement and third party validation studies. We are pursuing various strategies to reduce and control our cost of revenues, including automating our processes through more efficient technology and attempting to negotiate improved terms with our suppliers. We completed two acquisitions in 2014; Gentris in North Carolina and BioServe in India. With these two acquisitions, we intend to integrate our resources and services in an effort to reduce costs. We will continue to assess how geographic advantage can help us improve our cost structure.

Operating Expenses

We classify our operating expenses into three categories: research and development, sales and marketing, and general and administrative. Our operating expenses principally consist of personnel costs, including stock-based compensation, outside services, laboratory consumables and overhead, development costs, marketing program costs and legal and accounting fees.

Research and Development Expenses.We incur research and development expenses principally in connection with our efforts to develop our proprietary tests. Our primary research and development expenses consist of direct personnel costs, laboratory equipment and consumables and overhead expenses. We anticipate that research and development expenses will increase in the near-term, principally as a result of hiring additional personnel to develop and validate tests in our pipeline and to perform work associated with our research collaborations. In addition, we expect that our costs related to collaborations with research and academic institutions will increase. For example, in 2013, we entered into a joint venture with the Mayo Foundation for Medical Education and Research, with a focus on developing oncology diagnostic services and tests utilizing next generation sequencing. All research and development expenses are charged to operations in the periods they are incurred.

Sales and Marketing Expenses. Our sales and marketing expenses consist principally of personnel and related overhead costs for our sales team and their support personnel, travel and entertainment expenses, and other selling costs including sales collaterals and trade shows. We have started to increase our sales and marketing and clinical efforts since our IPO and we expect our sales and marketing expenses to increase significantly as we expand into new geographies and add new clinical tests and services.

General and Administrative Expenses. General and administrative expenses consist principally of personnel-related expenses, professional fees, such as legal, accounting and business consultants, occupancy costs, bad debt and other general expenses. We have incurred increases in our general and administrative expenses and anticipate further increases as we expand our business operations.

Seasonality

Our business experiences decreased demand during spring vacation season, summer months and the December holiday season when patients are less likely to visit their health care providers. We expect this trend in seasonality to continue for the foreseeable future.

Results of Operations

Three Months Ended September 30, 2015 and 2014

The following table sets forth certain information concerning our results of operations for the periods shown:

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	Three Months Ended September 30,		Change		
(dollars in thousands)	2015	2014	$	%	
Revenue	$4,000	$3,222	$778	24	%
Cost of revenues	3,103	2,566	537	21	%
Research and development expenses	1,802	1,390	412	30	%
General and administrative expenses	3,487	3,104	383	12	%
Sales and marketing expenses	1,243	1,071	172	16	%
Loss from operations	(5,635)	(4,909)	(726)	15	%
Interest income (expense)	(106)	(17)	(89)	524	%
Change in fair value of acquisition note payable	315	—	315	100	%
Change in fair value of warrant liability	214	129	85	66	%
Loss before income taxes	(5,212)	(4,797)	(415)	9	%
Income tax provision (benefit)	—	—	—	—	%
Net (loss)	$(5,212)	$(4,797)	$(415)	9	%

Revenue

The breakdown of our revenue is as follows:

	Three Months Ended September 30,					Change		
	2015			2014				
(dollars in thousands)	$	%		$	%	$	%	
Biopharma Services	$2,608	65	%	$1,931	60	%	$677	35	%
Clinical Services	1,149	29	%	1,238	38	%	(89)	(7)	%
Discovery Services	243	6	%	53	2	%	190	358	%
Total Revenue	$4,000	100	%	$3,222	100	%	$778	24	%

Revenue increased 24%, or $0.8 million, to $4.0 million for the three months ended September 30, 2015, from $3.2 million for the three months ended September 30, 2014, principally due to our Select One business, which accounted for $0.5 million of the increase, partially offset by our Clinical Services business, which saw a $0.1 million decrease, and the acquisitions of Gentris and BioServe, whose revenue accounted for $0.3 million of the increase. Our average revenue (excluding grant revenue and probe revenue) per test increased to $612 per test for the three months ended September 30, 2015 from $585 per test for the three months ended September 30, 2014, principally due to an increase in the average revenue per test from one of our Biopharma customers. Test volume increased by 19% from 3,079 tests for the three months ended September 30, 2014 to 3,676 tests for the three months ended September 30, 2015.

Revenue from Biopharma Services increased 35%, or $0.7 million, to $2.6 million for the three months ended September 30, 2015, from $1.9 million for the three months ended September 30, 2014, due to our Select One business, which accounted for $0.5 million of the increase, and the acquisition of Gentris whose revenue accounted for $0.2 million of the $0.7 million increase in Biopharma Services. Revenue from Clinical Services customers decreased modestly by $0.1 million, or 7%, due to a combination of slightly lower test volumes (3%) and a small change in our average bill price (4%). Revenue from Discovery Services, our new line of business, increased 358% to $0.2 million for the three months ended September 30, 2015, from $0.1 million for the three months ended September 30, 2014.

Cost of Revenues

Cost of revenues increased 21%, or $0.5 million, for the three months ended September 30, 2015, principally due to the following: increased costs of revenue from the acquired businesses of $0.6 million, partially offset by a reduction of outsourcing services of $0.1 million as a result of bringing outsourcing talent in-house. Gross margin improved during the three months ended September 30, 2015 due to better utilization of costs in our New Jersey laboratory along with the margin contributed from our acquired businesses.

Operating Expenses

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Research and development expenses increased 30%, or $0.4 million, to $1.8 million for the three months ended September 30, 2015, from $1.4 million for the three months ended September 30, 2014, principally due to the following: compensation costs increased by $0.1 million as a result of building up our R&D team, supplies costs increased by $0.2 million as a result of conducting more R&D projects, and collaboration costs increased by $0.3 million as we continue to build relations with other medical institutions; offset by a decrease of $0.1 million in stock based compensation. Our share of the loss from Oncospire, our joint venture with Mayo Clinic was flat.

Sales and marketing expenses increased 16%, or $0.2 million, to $1.2 million for the three months ended September 30, 2015, from $1.1 million for the three months ended September 30, 2014, principally due to increased costs from the acquired businesses of $0.1 million and compensation costs increased by $0.1 million.

General and administrative expenses increased 12%, or $0.4 million, to $3.5 million for the three months ended September 30, 2015, from $3.1 million for the three months ended September 30, 2014, principally due to increased costs from the acquired businesses of $0.1 million and compensation costs increasing by $0.2 million as a result of our increased headcount.

Interest Income (Expense)

Net interest expense increased 524%, or $0.1 million, principally due to the higher interest rate related to the debt we refinanced in May 2015.

Change in Fair Value of Acquisition Note Payable

The change in fair value of note payable resulted in $0.3 million in non-cash income for the three months ended September 30, 2015. The fair value of the note representing part of the purchase price for BioServe decreased as a consequence of a decrease in our stock price.

Change in Fair Value of Warrant Liability

The change in the fair market value of our warrant liability resulted in $0.2 million in non-cash income for the three months ended September 30, 2015, as compared to non-cash income of $0.1 million for the three months ended September 30, 2014. The fair market value of these common stock warrants decreased during the three months ended September 30, 2015 and 2014 due to a decrease in our stock price.

Nine Months Ended September 30, 2015 and 2014

The following table sets forth certain information concerning our results of operations for the periods shown:

	Nine Months Ended September 30,		Change		
(dollars in thousands)	2015	2014	$	%	
Revenue	$12,556	$6,164	$6,392	104	%
Cost of revenues	9,342	5,359	3,983	74	%
Research and development expenses	4,335	3,093	1,242	40	%
General and administrative expenses	9,536	8,231	1,305	16	%
Sales and marketing expenses	3,543	2,738	805	29	%
Loss from operations	(14,200)	(13,257)	(943)	7	%
Interest income (expense)	(197)	(351)	154	(44)	)%
Change in fair value of acquisition note payable	(91)	—	(91)	100	%
Change in fair value of warrant liability	18	324	(306)	(94)	)%

Loss before income taxes	(14,470)	(13,284)	(1,186)	9%
Income tax provision (benefit)	—	(1,814)	1,814	(100)%
Net (loss)	$(14,470)	$(11,470)	$(3,000)	26%

Revenue

The breakdown of our revenue is as follows:

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	Nine Months Ended September 30,						Change		
	2015			2014					
(dollars in thousands)	$	%		$	%		$	%	
Biopharma Services	$8,614	69	%	$2,831	46	%	$5,783	204	%
Clinical Services	3,274	26	%	3,280	53	%	(6)	—	%
Discovery Services	668	5	%	53	1	%	615	1,160	%
Total Revenue	$12,556	100	%	$6,164	100	%	$6,392	104	%

Revenue increased 104%, or $6.4 million, to $12.6 million for the nine months ended September 30, 2015, from $6.2 million for the nine months ended September 30, 2014, due to our Select One business, which accounted for $2.4 million of the increase, and the acquisitions of Gentris and BioServe, whose revenue accounted for $4.0 million of the increase. Our average revenue (excluding grant revenue and probe revenue) per test increased to $600 per test for the nine months ended September 30, 2015 from $546 per test for the nine months ended September 30, 2014, principally due to an increase in the test volume from one of our Biopharma customers. Test volume increased by 34% from 8,514 tests for the nine months ended September 30, 2014 to 11,378 tests for the nine months ended September 30, 2015.

Revenue from Biopharma Services increased 204%, or $5.8 million, to $8.6 million for the nine months ended September 30, 2015, from $2.8 million for the nine months ended September 30, 2014, due to our Select One business, which accounted for $2.4 million of the increase, and the acquisition of Gentris whose revenue accounted for $3.4 million of the $5.8 million increase in Biopharma Services. Revenue from Clinical Services customers remained the same at $3.3 million for the nine months ended September 30, 2015 and 2014. Revenue from Discovery Services, our new line of business, increased 1,160% to $0.7 million for the nine months ended September 30, 2015, from $0.1 million for the nine months ended September 30, 2014.

Cost of Revenues

Cost of revenues increased 74%, or $4.0 million, for the nine months ended September 30, 2015, principally due to the following: costs of revenue from the acquired businesses of $3.0 million; lab supplies expenses increased by $0.4 million as a result of higher test volumes; shipping costs increased by $0.1 million as a result of increased test volume; outsourced costs increased by $0.2 million as a result of providing services for tests not performed in our labs; and compensation costs increased by $0.2 million as a result of our increased headcount. Gross margin improved during the nine months ended September 30, 2015 due to better utilization of costs in our New Jersey laboratory along with the margin contributed from our acquired businesses.

Operating Expenses

Research and development expenses increased 40%, or $1.2 million, to $4.3 million for the nine months ended September 30, 2015, from $3.1 million for the nine months ended September 30, 2014, due to the following: our share of the loss from Oncospire, our joint venture with Mayo Clinic, increased $0.1 million, as it incurred three full quarters of research expenses related to the pursuit of developing new clinical tests. (In 2014, the costs associated with our joint venture started in late March); compensation costs increased by $0.4 million as a result of us building up our R&D team; supplies costs increased by $0.3 million as a result of the development of our proprietary tests; other collaboration costs increased by $0.3 million as we improve our proprietary tests; and costs associated with the acquired businesses increased by $0.1 million.

Sales and marketing expenses increased 29%, or $0.8 million, to $3.5 million for the nine months ended September 30, 2015, from $2.7 million for the nine months ended September 30, 2014, due to the following: increased costs from the acquired businesses of $0.6 million, consulting costs increased by $0.2 million as a result of us building and

developing our team, compensation costs increaed by $0.1 million as a result of increased commissions driven by increased sales; partially offset by a decrease of $0.1 million in marketing costs.

General and administrative expenses increased 16%, or $1.3 million, to $9.5 million for the nine months ended September 30, 2015, from $8.2 million for the nine months ended September 30, 2014, principally due to the following: increased costs from the acquired businesses of $1.3 million; an increase to our allowance for doubtful accounts of $0.2 million; an increase in consulting costs of $0.2 million for acquisition related services; offset by reductions in legal fees of $0.3 million due to acquisition-related costs in 2014 not present in 2015, and the Gentris contingent consideration gain of $0.2 million.

Interest Income (Expense)

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Net interest expense decreased 44%, or $0.2 million, principally due to the amortization of loan guarantee and financing fees during the nine months ended September 30, 2014.

Change in Fair Value of Acquisition Note Payable

The change in fair value of note payable resulted in $0.1 million in non-cash expense for the nine months ended September 30, 2015. The fair value of the note representing part of the purchase price for BioServe increased as a consequence of an increase in our stock price.

Change in Fair Value of Warrant Liability

The change in the fair market value of our warrant liability resulted in $18,000 in non-cash income for the nine months ended September 30, 2015, as compared to non-cash income of $0.3 million for the nine months ended September 30, 2014. The fair market value of these common stock warrants decreased during the nine months ended September 30, 2014 due to a decrease in our stock price.

Income Taxes

During the nine months ended September 30, 2014, we received $1.8 million from sales of state NOL’s. No such sales occurred in the first three quarters of 2015.

Liquidity and Capital Resources

Sources of Liquidity

Our primary sources of liquidity have been funds generated from our debt financings and equity financings. In addition, we have generated funds from cash collections from customers and cash received from sales of state NOL's. During January 2014, we received $1.8 million in cash from sales of state NOL’s.

In general, our primary uses of cash are providing for operating expenses, working capital purposes and servicing debt. As of September 30, 2015, we have up to $4.0 million available on our revolving line of credit. Our largest source of operating cash flow is cash collections from our customers.

Cash Flows

Our net cash flow from operating, investing and financing activities for the periods below were as follows:

	Nine Months Ended September 30,	
(in thousands)	2015	2014
Cash provided by (used in):		
Operating activities	$(9,951)	$(7,910)
Investing activities	4,572	(10,909)
Financing activities	(257)	108
Net (decrease) in cash and cash equivalents	$(5,636)	$(18,711)

We had cash and cash equivalents of $19.9 million at September 30, 2015, and $25.6 million at December 31, 2014.

The $5.6 million decrease in cash and cash equivalents for the nine months ended September 30, 2015, principally resulted from $10.0 million of net cash used in operations and a $0.9 million deposit paid to acquire Response

Genetics offset by a $6 million decrease in restricted cash related to our new debt financing facility with Silicon Valley Bank that does not require us to maintain restricted cash accounts.

The $18.7 million decrease in cash and cash equivalents for the nine months ended September 30, 2014, principally resulted from an increase in our restricted cash of $6.0 million related to the collateralization of our line of credit with Wells Fargo and$7.9 million of net cash used in operations, $3.0 million used in the acquisition of Gentris and an additional investment of $1.0 million in our joint venture with the Mayo Foundation.

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At September 30, 2015, we had total indebtedness of $6.6 million, excluding capital lease obligations.

Cash Used in Operating Activities

Net cash used in operating activities was $10.0 million for the nine months ended September 30, 2015. We used $10.4 million in net cash to fund our core operations, which included $0.2 million in cash paid for interest. We incurred additional uses of cash when adjusting for working capital items as follows: a net increase in accounts receivable of $0.3 million; an increase in other current assets of $0.4 million which includes prepayments for our insurance policies; an increase in other non-current assets of $0.1 million, a net increase in accounts payable, accrued expenses and deferred revenue of $1.3 million; and a net decrease in deferred rent and other of $0.1 million.

For the nine months ended September 30, 2014, we used $7.9 million in operating activities. We used $10.0 million in net cash to fund our core operations, which included $0.1 million in cash paid for interest. We incurred additional uses of cash when adjusting for working capital items as follows: a net increase in accounts receivable of $0.5 million; an increase in other current assets of $0.2 million which includes prepayments for our insurance policies; and a net decrease in accounts payable, accrued expenses (including the payout of 2013 accrued performance bonuses) and deferred revenue of $1.0 million. All of these uses of cash were partially offset by the receipt of $1.8 million from the sale of certain state NOL carryforwards in January 2014.

Cash Provided by/Used in Investing Activities

Net cash provided by investing activities was $4.6 million for the nine months ended September 30, 2015 and principally resulted from a $6 million decrease in restricted cash related to our new debt financing facility with Silicon Valley Bank that does not require us to maintain restricted cash accounts offset by a $0.9 million deposit paid to acquire Response Genetics.

Net cash used in investing activities was $10.9 million for the nine months ended September 30, 2014 and principally resulted from an increase in our restricted cash of $6.0 million related to the collateralization of our line of credit with Wells Fargo and $3.0 million used in the acquisition of Gentris, $1.0 million in our Joint Venture with the Mayo Foundation and the purchase of fixed assets of $0.9 million.

Cash Provided by/Used in Financing Activities

Net cash used in financing activities was $0.3 million for the nine months ended September 30, 2015, and principally resulted from payments for deferred equity offering costs of $0.2 million related to our July 2015 sales agreement with Cantor described below.

Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2014, and principally resulted from proceeds received from warrant and option exercises of $0.3 million offset by payments made on notes payable and capital leases of $0.1 million.

Capital Resources and Expenditure Requirements

We expect to continue to incur substantial operating losses in the future. It may take several years, if ever, to achieve positive operational cash flow. Until we can generate a sufficient amount of revenue to finance our cash requirements, which we may never do, we may need to continue to raise additional capital to fund our operations.

We also expect to use significant cash to fund acquisitions. On July 16, 2014, we purchased substantially all of the assets of Gentris, with its principal place of business in North Carolina for approximately $4.8 million. On August 18,

2014, we acquired BioServe, an Indian corporation, for an aggregate purchase price of approximately $1.1 million. On October 9, 2015, we acquired substantially all of the assets of Response Genetics, Inc. for aggregate consideration of approximately $13.4 million consisting of $7 million in cash and our common stock valued at approximately $6.4 million.

We recently improved our liquidity by entering into a line of credit with Silicon Valley Bank. See Note 4 of Notes to Unaudited Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

On July 15, 2015, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (“Sales Agreement”) with Cantor Fitzgerald & Co., (“Cantor”) as sales agent, pursuant to which the Company may offer from time to time through Cantor, shares of our common stock having an aggregate offering price of up to $20.0 million. During the three months ended September 30, 2015, the Company sold 2,800 shares of its common stock that resulted in net proceeds to the Company of approximately $34,000. In July 2015, we announced that we temporarily suspended sales under the Sales Agreement.

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Furthermore, under the terms of our lock up agreement with Joseph Gunnar and Feltl, we may not resume selling our common stock under the Sales Agreement until 90 days after the public offering is consummated.

On November 6, 2015, we entered into an underwriting agreement (the "Underwriting Agreement") with Joseph Gunnar & Co., LLC and Feltl and Company, Inc., as representatives of the several underwriters named in the Underwriting Agreement (the "Underwriters"). Pursuant to the terms and conditions of the Underwriting Agreement, we agreed to sell to the Underwriters 3,000,000 shares of our common stock, par value $0.0001 per share (the "Common Stock") and warrants (the "Warrants") to purchase up to an aggregate of 3,000,000 shares of Common Stock, at a combined price of $4.00 per share and accompanying Warrant, less underwriting discounts and commissions, and has granted the Underwriters an option to purchase up to an additional 450,000 shares of Common Stock and/or Warrants within 45 days after the date of the Underwriting Agreement. We also agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering as well as legal fees up to $60,000; however, an allowance shall not be paid in connection with the over-allotment option if the over-allotment option is exercised. Each warrant will have an exercise price of $5.00 per share (subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders), will be exercisable upon issuance and will expire five years from the date of issuance.
The sale to the Underwriters is expected to close on November 12, 2015, subject to customary closing conditions. We estimate that the net proceeds to us from the offering (exclusive of proceeds from the sale of shares and/or Warrants pursuant to any exercise of the Underwriters' option described above and exclusive of proceeds, if any, from the exercise of the Warrants issued pursuant to the offering) will be approximately $10.5 million after deducting the underwriting discounts and commissions, and estimated offering expenses payable by us.

We believe that our current cash, together with the anticipated net proceeds from this offering, will support our operations for at least the next 24 months. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all, when needed. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

We expect our operating expenses, particularly those relating to sales and marketing, to increase as we hire additional sales and marketing personnel and increase sales and marketing activities.

Our forecast of the period of time through which our current financial resources will be adequate to support our operations and our expected operating expenses are forward-looking statements and involve risks and uncertainties. Actual results could vary materially and negatively as a result of a number of factors, including:

- our ability to consummate the public offering on the terms set forth in the Underwriting Agreement, or at all;
- our ability to achieve revenue growth and profitability;
- the costs for funding the operations we recently acquired, including Response Genetics, and our ability to successfully integrate those operations with and into our own;
- our ability to obtain approvals for our new diagnostic tests;
- our ability to execute on our marketing and sales strategy for our genomic tests and gain acceptance of our tests in the market;

- our ability to obtain adequate reimbursement from governmental and other third-party payors for our tests and services;
- the costs, scope, progress, results, timing and outcomes of the clinical trials of our diagnostic tests;
- the costs of operating and enhancing our laboratory facilities;
- the costs of additional general and administrative personnel;
- the timing of and the costs involved in regulatory compliance, particularly if the regulations change;

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- the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities;
- our ability to manage the costs of manufacturing our NGS panels, microarrays and FHACT® probe;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- the effect of competing technological and market developments;
- costs related to expansion;
- our ability to secure financing and the amount thereof; and
- other risks and uncertainties discussed in our annual report on Form 10-K for the year ended December 31, 2014, as updated in our quarterly reports on Form 10-Q, current reports on Form 8-K and other reports, as applicable, we file with the Securities and Exchange Commission.

We expect that our operating expenses and capital expenditures will increase in the future as we expand our business and integrate our recent acquisitions. We plan to increase our sales and marketing headcount to promote our new clinical tests and services and to expand into new geographies and to increase our research and development headcount to develop and validate the proprietary tests currently in our pipeline, to expand our pipeline and to perform work associated with our research collaborations.

Even with the anticipated proceeds from the public offering, we may raise additional capital to fund our current operations, to repay certain outstanding indebtedness and to fund expansion of our business to meet our long-term business objectives through public or private equity offerings, debt financings, borrowings or strategic partnerships coupled with an investment in our Company or a combination thereof. If we raise additional funds through the issuance of convertible debt securities, or other debt securities, these securities could be secured and could have rights senior to those of our common stock. In addition, any new debt incurred by the Company could impose covenants that restrict our operations and increase our interest expense. The issuance of any new equity securities will also dilute the interest of our current stockholders. Given the risks associated with our business, including our unprofitable operating history and our ability to develop additional proprietary tests, additional capital may not be available when needed on acceptable terms, or at all. If adequate funds are not available, we will need to curb our expansion plans or limit our research and development activities, which would have a material adverse impact on our business prospects and results of operations.

Income Taxes

Over the past several years, we have generated operating losses in all jurisdictions in which we may be subject to income taxes. As a result, we have accumulated significant net operating losses and other deferred tax assets. Because of our history of losses and the uncertainty as to the realization of those deferred tax assets, a full valuation allowance has been recognized. We do not expect to report a benefit related to the deferred tax assets until we have a history of earnings, if ever, that would support the realization of our deferred tax assets.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Significant Judgment and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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Section 107 of the JOBS Act provides that an "emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

The notes to our audited consolidated financial statements contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

- Revenue recognition;
- Accounts receivable and bad debts;
- Stock-based compensation; and
- Warrant liability.

Cautionary Note Regarding Forward-Looking Statements

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995

This report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential," or th those terms, and similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events. There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to consummate the public offering on the terms set forth in the Underwriting Agreement, or at all;
- our ability to achieve profitability by increasing sales of our laboratory tests and services and to continually develop and commercialize novel and innovative genomic-based diagnostic tests and services for cancer patients;
- our ability to successfully fund and integrate our recently acquired operations;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to clinically validate our pipeline of genomic microarray tests currently in development;
- our ability to execute on our marketing and sales strategy for our genomic tests and gain acceptance of our tests in the market;
- our ability to keep pace with rapidly advancing market and scientific developments;

- our ability to satisfy U.S. (including FDA) and international regulatory requirements with respect to our tests and services, many of which are new and still evolving;

- our ability to obtain reimbursement from governmental and other third-party payors for our tests and services;

- competition from clinical laboratory services companies, genomic-based diagnostic tests currently available or new tests that may emerge;

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- our ability to maintain our clinical collaborations and enter into new collaboration agreements with highly regarded organizations in the cancer field so that, among other things, we have access to thought leaders in the field and to a robust number of samples to validate our genomic tests;

- our ability to maintain our present customer base and obtain new customers;

- potential product liability or intellectual property infringement claims;

- our dependency on third-party manufacturers to supply or manufacture our products;

- our ability to manage significant fluctuations in our quarterly operating results, which may occur as a result of the timing, size and duration of our contracts with biopharmaceutical companies and clinical research organizations;

- our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel with extensive experience in oncology, who are in short supply;

- our ability to obtain or maintain patents or other appropriate protection for the intellectual property in our proprietary tests and services;

- our dependency on the intellectual property licensed to us or possessed by third parties;

- our ability to expand internationally and launch our tests in emerging markets, such as India and Brazil;

- our ability to adequately support future growth; and

- the risk factors discussed in our annual report on Form 10-K for the year ended December 31, 2014, as updated in our quarterly reports on Form 10-Q, current reports on Form 8-K and other reports, as applicable, that we file with the Securities and Exchange Commission.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this quarterly report on Form 10-Q and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this quarterly report on Form 10-Q. You should read this quarterly report on Form 10-Q and the documents referenced herein and filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We have exposure to financial market risks, including changes in foreign currency exchange rates and interest rates.

Foreign Exchange Risk

We conduct business in foreign markets through our subsidiary in India (BioServe Biotechnologies (India) Private Limited) and in Italy through our subsidiary (Cancer Genetics Italia, S.r.l.). For the three months ended September 30, 2015 and 2014, approximately 7% and 3%, respectively, of our revenues were earned outside the United States and collected in local currency. Approximately 6% and 3% of our revenues were earned outside the United States and collected in local currency for the nine months ended September 30, 2015 and 2014, respectively. We are subject to risk for exchange rate fluctuations between such local currencies and the United States dollar and the subsequent

translation of the Indian Rupee or Euro to United States dollars. We currently do not hedge currency risk. The translation adjustments for the three and nine months ended September 30, 2015 and 2014, were not significant.

Interest Rate Risk

At September 30, 2015, we had interest rate risk primarily related to borrowings of $6 million on the term note with Silicon Valley Bank (“Silicon Valley Line”). Borrowings under the Silicon Valley term note bear interest at the Wall Street Journal prime rate plus 2%, with a floor of 5.25% (5.25% at September 30, 2015). If interest rates increased by 1.0%, interest expense in the remainder of 2015 on our current borrowings would increase by approximately $15,000.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We evaluated, under the supervision and with the participation of the Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 ("Exchange Act"), as amended, as of September 30, 2015, the end of the period covered by this report on Form 10-Q. Based on this evaluation, our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal accounting and financial officer) have concluded that our disclosure controls and procedures were effective at the reasonable assurance level at September 30, 2015.

Disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Due to the inherent limitations of control systems, not all misstatements may be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Controls and procedures can only provide reasonable, not absolute, assurance that the above objectives have been met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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PART II — OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in Part 1, Item 1A, of our annual report on Form 10-K for the year ended December 31, 2014, except for the updated Risk Factors set forth in our Current Report on Form 8-K under Item 8.01 Other Events, filed on July 16, 2015 and the Risks Related to Response Genetics Acquisition set forth in our Current Report on Form 8-K under Item 8.01 Other Events, filed on October 16, 2015 which Risk Factors and Risks Related to Response Genetics Acquisition are incorporated herein by reference as if set forth in full. We also updated our risk factors in our prospectus supplement dated November 6, 2015. The risk factors with material updates are set forth below.

We are an early stage company with a history of net losses; we expect to incur net losses in the future, and we may never achieve sustained profitability.

We have historically incurred substantial net losses. We incurred losses of $9.3 million for the six months ended June 30, 2015 and $16.6 million, $12.4 million and $6.7 million for fiscal years ended December 31, 2014, 2013 and 2012, 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, Response Genetics had an accumulated deficit of $87.8 million. We expect losses for the combined company to continue principally as a result of ongoing research and development expenses and increased sales and marketing costs. These 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, 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.

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 or in obtaining or attempting to obtain regulatory or court approvals for the acquisition. The failure to achieve anticipated benefits could harm the business, financial condition and operating results of the combined company.

Any acquisition exposes a company to additional risks.

Acquisitions may entail numerous risks for us, 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.

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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.

We 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. 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.

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.

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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. See section entitled "Risk Factors-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, Hyderabad, India and Los Angeles, California. 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.

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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.

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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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Recently, 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.

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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. On September 25, 2015, CMS issued a proposed rule that sets out how CMS proposes to implement PAMA. 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. On September 25, 2015, CMS released its Preliminary Determinations for new CPT codes effective in 2016, including

several new MAAA CPT codes. CMS has proposed "crosswalking" these codes to an unrelated test, resulting in a significant cut in their reimbursement. If CMS finalizes these rates, it could eventually adversely affect our reimbursement 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.

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We depend on Medicare and a limited number of private payors for a significant portion of our revenues and if these or other payors stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenues could decline.

For the year ended December 31, 2014, we derived approximately 16% of our total revenue from private insurance, including managed care organizations and other health care insurance providers, 11% from Medicare and 16% from other health care facilities billed directly. For the year ended December 31, 2014, Response Genetics derived approximately 38% of its revenue from the Medicare program. Medicare and other third-party payors may withdraw their coverage policies or cancel their contracts with us at any time, review and adjust the rate of reimbursement or stop paying for our tests altogether, which would reduce our total revenues.

Payors have increased their efforts to control the cost, utilization and delivery of health care services. In the past, measures have been undertaken to reduce payment rates for and decrease utilization of the clinical laboratory industry generally. Because of the cost-trimming trends, third-party payors that currently cover and provide reimbursement for our tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

In addition, we are currently considered a "non-contracting provider" by a number of private third-party payors because we have not entered into a specific contract to provide our specialized diagnostic services to their insured patients at specified rates of reimbursement. If we were to become a contracting provider in the future, the amount of overall reimbursement we receive is likely to decrease because we will be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenues. Further, we typically are unable to collect payments from patients beyond that which is paid by their insurance and will continue to experience lost revenue as a result.

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 be subject to the above pre-market requirements, as well as 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

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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 and may result in increased regulatory burdens on us as we continue to offer our tests and 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;

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- 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,

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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 entitled "Risk Factors-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."

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

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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.

Our stockholders may be diluted by exercises of outstanding options and warrants.

As of September 30, 2015, we had outstanding options to purchase an aggregate of 2,008,466 shares of our common stock at a weighted-average exercise price of $10.55 per share and warrants to purchase an aggregate of 1,116,940 shares of our common stock at a weighted-average exercise price of $13.53 per share. As a result of the public offering that is expected to be consummated on November 12, 2015, we will have outstanding warrants to purchase an aggregate of 4,116,940 shares of common stock at a weighted-average exercise price of $7.20 (assuming the underwriters do not exercise their option to purchase additional shares and warrants). The exercise of such outstanding options and warrants will result in dilution of the value of our shares.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds from Sales of Registered Securities

Not applicable.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

See the Index to Exhibits following the signature page hereto, which Index to Exhibits is incorporated herein by reference.

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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 thereunto duly authorized.

Cancer Genetics, Inc.
(Registrant)

Date: November 9, 2015

/s/ Panna L. Sharma
Panna L. Sharma
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2015

/s/ Edward J. Sitar
Edward J. Sitar
Chief Financial Officer
(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

Exhibit No.	Description
4.1	Form of Warrant Agreement of Cancer Genetics, Inc. (corrected) *
10.1	Amended and Restated Asset Purchase Agreement By and Between Response Genetics, Inc. a Delaware Corporation, and Cancer Genetics., a Delaware Corporation, dated as of August 14, 2015 (incorporated by reference to the Company's current report on Form 8-K filed on August 21, 2015)
10.2	Underwriting Agreement dated November 6, 2015 by and between Cancer Genetics, Inc., and Joseph Gunnar & Co., LLC and Feltl and Company Inc. (incorporated by reference to the Company's current report on Form 8-K filed on November 6, 2015)
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under The Securities Exchange Act of 1934, as amended *
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under The Securities Exchange Act of 1934, as amended *
32.1	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002 **
32.2	Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002 **
101	The following materials from the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheet at September 30, 2015 (unaudited) and December 31, 2014, (ii) Consolidated Statements of Operations for the three and nine month periods ended September 30, 2015 and 2014, (iii) Consolidated Statements of Cash Flows for the nine month periods ended September 30, 2015 and 2014 (unaudited) and (iv) Notes to Consolidated Financial Statements (unaudited)

* Filed herewith.
** Furnished herewith.