UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 [X]

For the fiscal year ended December 31, 2017

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: 000-24249**

Interpace Diagnostics Group, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

Morris Corporate Center 1, Building C

300 Interpace Parkway, Parsippany, NJ 07054

(Address of principal executive offices and zip code)

(855) 776-6419

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered Common Stock, par value \$0.01 per share The Nasdaq Stock Market LLC Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [] No [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [] No [X]

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 [X] 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 during the preceding 12 months (or for such short period that the registrant was required to submit and post such files). Yes [X] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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 definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer []

Accelerated filer []

Non-accelerated filer [] (Do not check if a smaller reporting company)

Smaller reporting company [X]

Emerging growth company []

(I.R.S. Employer

22-2919486

Identification No.)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. []

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

The aggregate market value of the registrant's common stock, \$0.01 par value per share, held by non-affiliates of the registrant on June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was \$17,851,762 (based on the closing sales price of the registrant's common stock on that date). Shares of the registrant's common stock held by each officer and director and each person who owns 10% or more of the outstanding common stock of the registrant have been excluded because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 12, 2018, 27,869,275 shares of the registrant's common stock, \$0.01 par value per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2018 Annual Meeting of Stockholders, or the Proxy Statement, to be filed within 120 days of the end of the fiscal year ended December 31, 2017, are incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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* The information required under this item is to be contained in the Proxy Statement for the registrant's annual meeting of stockholders, and is incorporated herein by reference. It is anticipated that the Proxy Statement will be filed with the Securities and Exchange Commission by April 30, 2018.

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FORWARD LOOKING STATEMENT INFORMATION

This Form 10-K, and the documents incorporated by reference in this document, our press releases and oral statements made from time to time by us or on our behalf, may contain "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended (or "the Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (or "the Exchange Act"). In this context, forward-looking statements are not historical facts and include statements about our plans, objectives, beliefs and expectations. Forward-looking statements include statements preceded by, followed by, or that include the words "believes," "expects," "anticipates," "seeks," "plans," "estimates," "intends," "projects," "targets," "should," "could," "may," "will," "can," "can have," "likely," the negatives thereof or similar words and expressions. These forward-looking statements are contained throughout this Form 10-K, including, but not limited to, statements found in Part I – Item 1 – "Business" and Part II – Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Forward-looking statements are only predictions and are not guarantees of future performance. These statements are based on current expectations and assumptions involving judgments about, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond our control. These predictions are also affected by known and unknown risks, uncertainties and other factors that may cause our actual results to be materially different from those expressed or implied by any forward-looking statement. Many of these factors are beyond our ability to control or predict. Our actual results could differ materially from the results contemplated by these forward-looking statements due to a number of factors. Such factors include, but are not limited to, the following:

- our ability to profitably grow our business, including our ability to finance our business on acceptable terms and successfully compete in the market;
- our ability to obtain broad adoption of and reimbursement for our molecular diagnostic tests in a changing reimbursement environment;
- whether we are able to successfully utilize our operating experience to sell our molecular diagnostic tests;
- our limited operating history as a molecular diagnostics company;
- our dependence on a concentrated selection of payers for our molecular diagnostic tests;
- the demand for our molecular diagnostic tests from physicians and patients;
- our reliance on our internal sales forces for business expansion;
- our dependence on third parties for the supply of some of the materials used in our molecular diagnostic tests;
- our ability to scale our operations, testing capacity and processing technology;
- our ability to continue to secure sufficient levels of reimbursement to continue to progress our business;
- our ability to compete successfully with companies with greater financial resources;
- our ability to obtain sufficient data and samples to cost effectively and timely perform sufficient clinical trials in order to support our current and future products;
- product liability claims against us;
- patent infringement claims against us;
- our involvement in current and future litigation against us;
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- the effect of potential adverse findings resulting from regulatory audits of our billing practices and the impact such results could have on our business;
- our exposure to environmental liabilities as a result of our business;
- the susceptibility of our information systems to security breaches, loss of data and other disruptions;
- our ability to enter into effective electronic data interchange arrangements with our customers and third-party payers;
- our billing practices and our ability to collect on claims for the sale of our molecular diagnostic tests;
- Our dependence on a third-party medical billing provider to operate effectively without delays, data loss, or other disruptions;
- our ability to attract and retain qualified sales representatives and other key employees and management personnel;
- competition in the segment of the molecular diagnostics industry in which we operate or expect to operate;
- our ability to obtain additional funds in order to implement our business models and strategies;
- the results of any future impairment testing for other intangible assets;
- our ability to successfully identify, complete and integrate any future acquisitions and the effects of any such items on our revenues, profitability and ongoing business;
- our compliance with our license agreements and our ability to protect and defend our intellectual property rights;
- our ability to maintain our listing with The Nasdaq Capital Market ("NASDAQ");
- the effect of adverse weather conditions such as hurricanes on our business;
- failure of third-party service providers to perform their obligations to us;
- the volatility of our stock price and fluctuations in our quarterly and annual revenues and earnings;
- our ability to obtain and maintain sufficient laboratory space to meet our processing needs;
- our ability to commercially leverage our bioinformatics data with pharmaceutical and other potential partners in new revenue lines;
- the ability to obtain or maintain supportive "guidelines" from trade and/or therapeutic related organizations focused on the clinical efficacy and utility of molecular diagnostics in our areas of focus; and
- determination that our Advanced Diagnostic Laboratory Tests (ADLTs) have become affected by the pricing provisions of the Processing Access to Medicare Act of 2014 ("PAMA") which could result in an across the board reduction in our reimbursement rates.

Please see Part I - Item 1A - "Risk Factors" of this Form 10-K, as well as other documents we file with the U.S. Securities and Exchange Commission, or the SEC, from time-to-time, for other important factors that could cause our actual results to differ materially from our current expectations and from the forward-looking statements discussed herein. Because of these and other risks, uncertainties and assumptions, you should not place undue reliance on these forward-looking statements. In addition, these statements speak only as of the date of this Form 10-K and, except as may be required by law, we undertake no obligation to revise or update publicly any forward-looking statements for any reason.

In this Form 10-K, references to "we," "our," "us," "Interpace" and the "Company" refer to Interpace Diagnostics Group, Inc., including consolidated subsidiaries as of December 31, 2017 ("fiscal 2017").

PART I

ITEM 1. BUSINESS

Company Overview

We are a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services. We develop and commercialize molecular diagnostic tests and related first line assays principally focused on early detection of patients at high risk of cancer and leveraging the latest technology to improve patient outcomes. We currently have four commercialized molecular diagnostic assays in the marketplace for which we are reimbursed by Medicare and multiple private payers: PancraGEN[®], which is a pancreatic cyst and pancreaticobiliary solid lesion molecular test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform; ThyGenX[®], which is a oncogenic mutation panel that helps identify malignant thyroid nodules; and ThyraMIR[®], which is a proprietary microRNA gene expression assay that helps to classify risk of cancer in thyroid nodules. We also launched in September 2017 RespriDXTM, which is a molecular test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of a newly formed primary lung cancer. RespriDXTM also utilizes our PathFinderTG[®], an esophageal cancer risk classifier for Barrett's Esophagus, while we gather additional market data. BarreGen[®] also utilizes our PathFinderTG[®] platform.

Our mission is to provide personalized medicine through molecular diagnostics and innovation to advance patient care based on rigorous science. We are leveraging our Clinical Laboratory Improvement Amendments ("CLIA") licensed, College of American Pathologists ("CAP"), and New York State ("NYS") accredited laboratories to develop and commercialize our assays and products. We aim to provide physicians and patients with diagnostic options for detecting genomic and other molecular alterations that are associated with gastrointestinal, endocrine, and lung cancers. Our customers consist primarily of physicians, hospitals and clinics.

The global molecular diagnostics market is estimated to be \$6.45 billion and is a segment within the approximately \$60 billion in vitro diagnostics market according to statistics from Kalorama Information, publisher of *the Worldwide Market for In Vitro Diagnostic Tests*. We believe that the molecular diagnostics market offers significant growth and strong patient value given the substantial opportunity it affords to lower healthcare costs by helping to reduce unnecessary surgeries and ensuring the appropriate frequency of monitoring. We are keenly focused on growing our test volumes, securing additional coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our four commercialized innovative tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products, like BarreGEN® in our markets.

Additional Reimbursement Coverage During 2017 and 2018 (to-date)

Reimbursement progress is key for any molecular diagnostic company. We were successful in expanding the reimbursement of our products in 2017. Specifically the most significant progress we have made regarding payers in 2017 is as follows:

• In April 2017, we announced that UnitedHealthcare, the largest health plan in the United States, has agreed to cover our ThyraMIR® test used in assessing indeterminate thyroid nodule fine needle aspirate ("FNA") biopsies. The coverage is now in effect and is subject to members' specific benefit plan design.



- In June 2017, we announced that we signed a new national contract with Aetna for our ThyGenX® and ThyraMIR® molecular tests for indeterminate thyroid nodules. The agreement covers many of Aetna's products, including commercial and Medicare Advantage plans. The agreement is our first national provider contract with a national health plan and means that we will now be part of Aetna's laboratory network for these services. The agreement went into effect August 15, 2017.
- In July 2017, we announced that Cigna, one of the largest national health plans in the United States, has agreed to cover Interpace's ThyGenX[®] test for Cigna's 15 million members nationwide, with coverage effective immediately. Cigna's coverage when combined with Aetna, UnitedHealthcare, Medicare and other payers brings the total number of covered lives for ThyGenX[®] to approximately 275 million patients nationwide.
- In August 2017, we announced that Oxford Health Plans began to cover our ThyraMIR[®] test. Oxford offers health care benefits to employers primarily in New York, New Jersey, and Connecticut making it one of the largest health plans in the heavily populated tri-state Region.
- In September 2017, we announced that the American Medical Association (AMA) assigned a new, discreet Current Procedural Terminology ("CPT") code to facilitate reimbursement of ThyraMIR[®]. simplifying and expediting the process for us in submitting claims and securing reimbursement.
- In October 2017, we announced that Medicare reimbursement for our ThyGenX[®] molecular test for indeterminate thyroid nodules will increase by 40% starting January 1, 2018. Medicare represents approximately 40% of our volume for the ThyGenX[®] test.
- In February 2018, we announced that Horizon Blue Cross Blue Shield of New Jersey, the oldest and largest health plan in New Jersey, covering 3.8 million patients living in the Northeastern United States, has agreed to cover ThyGenX[®] and ThyraMIR[®] for its members effective January 9, 2018.
- In March 2018, we announced coverage of ThyGenX[®] and ThyraMIR[®] by four new Blue Cross Blue Shield Plans, Blue Cross Blue Shield of Arizona; Blue Cross Blue Shield of South Carolina; Wellmark Blue Cross Blue Shield of Iowa; and Wellmark Blue Cross Blue Shield of South Dakota. These four plans combined represent over 5 million members.

Corporate Information

We were originally incorporated in New Jersey in 1986 and began commercial operations as a contract sales organization or "CSO" in 1987, which provided the personal promotion of pharmaceutical customers' products through outsourced sales teams. In connection with our initial public offering, we reincorporated in Delaware in 1998. Having disposed of substantially all of the assets of our CSO business in 2015, we currently operate under one operating segment, which is our molecular diagnostic business. We conduct our business through our wholly-owned subsidiaries, Interpace LLC, which was formed in Delaware in 2013, and Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007. Our executive offices are located at Morris Corporate Center 1, Building C, 300 Interpace Parkway, Parsippany, New Jersey 07054. Our telephone number is (855) 776-6419.

Strategy

Our primary goal is to build a leading oncology diagnostics and bioinformatics business focused on gastrointestinal, endocrine and lung cancer markets. We seek to grow our molecular diagnostics business both organically as well as by selective partnering, which could potentially include acquisitions or a merger. The key elements of our strategy to achieve this goal include:

- Leveraging our commercial products, including PancraGEN[®], ThyGenX[®], ThyraMIR[®], and growing our newly-launched, metastatic versus primary lung cancer test, RespriDX[™], while focusing on personalized medicine and early intervention related to cancer risk;
- Expanding our soft launch of BarreGEN[®], our esophageal cancer risk classifier for Barrett's Esophagus that utilizes our PathFinderTG[®] platform, to continue to gather data and seek key reimbursement support while seeking larger partners to collaborate with us and speed up full market introduction;
- Targeting synergistic product and service opportunities to distribute through our commercial structure;
- Developing and commercializing other related first-line assays and service offerings such as PanDNA, AccuCEA Insights and adding the TERT marker of aggressiveness to our thyroid markers;
- Expanding our sales staff rationally, while supporting our products with high quality data and studies and seeking dependable and appropriate reimbursement rates;
- Expanding our bioinformatics data collected (currently from over 45,000 patients), utilizing registries to improve our assays and leveraging data with potential collaborators;

- Continuing to strengthen our balance sheet and improve our liquidity, and
- Improving our awareness and opportunities in the public markets.

Recent Business Developments

Commercial Expansion

In August 2017, we announced the renewal and expansion of our agreement with Lab Corp, a NYSE listed company which provides leading-edge medical laboratory tests and services through a national network of primary clinical laboratories and specialty testing laboratories, to now co-market ThyraMIR® along with ThyGenX®.

On December 18, 2017, we announced that we had entered into a Laboratory Services Agreement with ARUP Laboratories, Inc. (ARUP), of Salt Lake City, Utah, whereby ARUP is utilizing us as a laboratory services provider for its menu of molecular testing services. ARUP is a national reference laboratory with one of the broadest test menus in the industry. ARUP offers comprehensive diagnostic laboratory testing to a wide array of customers including hospitals, hospital groups, commercial laboratories, GPO's, and large clinics among others, expanding our reach to providers nationwide.

Clinical Evidence

In May 2017, we announced the data presented in six posters at the Digestive Disease Week (DDW) meeting held May 6th-9th at the McCormick Center in Chicago, Illinois:

- The results presented in three of the posters support the clinical utility of PancraGEN® in assessing long-term risk of malignancy in pancreatic cystic lesions and stress the importance of using DNA analysis to better understand the risk of cancer cysts with indeterminate profiles
- The results presented in the additional three posters support the clinical utility of PancraGEN as an ancillary test for solid lesions of the pancreas and bile duct using our unique method for testing free-DNA obtained from bile duct brushings and fine needle aspirates.

In October 2017 we announced the presentation of new data based on actual clinical results for 3,471 patients tested with our ThyGenX/ThyraMIR molecular tests at the annual meeting of The American Thyroid Association (ATA) held in Victoria, British Columbia. Over 5,000 endocrinologists, endocrine surgeons, and numerous other providers who focus on endocrinology attended this annual event.

In October 2017, we reported two publications presented at the WCOG American College of Gastroenterology (ACG) 2017 Conference held in Orlando, Florida:

- The "Long-Term Risk of Surgery and Cancer in Patients Meeting AGA 2015 and Fukuoka 2012 Management Criteria for Pancreatic Cystic Lesions."
- "Regenerated Squamous Epithelium Following Radiofrequency Ablation Manifests Molecular Alterations Present in the Pretreated Barrett's Mucosa."

In November 2017, we announced that the New York State Department of Health has reviewed and approved for marketing our TERT service offering, which can be ordered in conjunction with our ThyGenX[®] molecular panel or on a stand-alone basis. While we currently market both ThyGenX[®] and ThyraMIR[®] in New York State, until now the TERT offering has been awaiting New York State approval. We believe that the TERT marker is a strong molecular predictor of the aggressiveness of thyroid cancer and adds additional insights into a patient's molecular profile.

In October 2017 we also announced that G2 Intelligence, the official publication of the Laboratory Industry Report and sponsor of the G2 War College, selected us as the "Company of the Month for September 2017".

In January 2018, we announced that CIO Applications magazine designated us as one of the top 20 Companies in 2017 for providing bioinformatics solutions to their customers through our extensive data base.

In February 2018, we announced the acceptance of five abstracts being presented at the US and Canadian Academy of Pathology (USCAP) in Vancouver, British Columbia.

Reporting Segments

We currently operate under one operating segment, which is our molecular diagnostic business. Until December 22, 2015 prior to the sale of the CSO business, we operated under two reporting segments: Commercial Services and Interpace Diagnostics. The former CSO business is reported as discontinued operations for the periods ended December 31, 2017 and 2016.

Our Business

In August 2014, we acquired certain assets from Asuragen Inc., or Asuragen, in the endocrine and thyroid cancer sectors, and in October 2014, we acquired our pancreatic and gastrointestinal assets from RedPath Integrated Technologies Inc., or RedPath. In December 2015, we sold substantially all of the assets of our CSO business and became a dedicated molecular diagnostics, bioinformatics and related first line assay company.

We are a molecular diagnostics and bioinformatics company that is focused on improving patient care by resolving diagnostic uncertainty with evidence that is trustworthy and actionable. Our products and services uniquely combine genomic technology, clinical science and pathological review to provide answers that give physicians and patients a clear path forward and help avoid risky, costly surgeries that are often unnecessary.

Our goal is to drive shareholder value by improving patient outcomes and reducing the cost of healthcare.

The role of molecular diagnostic and bioinformatics information in medical practice is evolving rapidly. The diagnosis of complex diseases as well as the role of molecular diagnostics and bioinformatics in treatment decisions continues to expand to complement the evaluation performed by pathologists. Information at the molecular level and registries of such data enable one to understand more fully the makeup and specific subtype of disease to improve diagnosis. In many cases, the molecular diagnostic and bioinformatics information derived can ultimately help guide treatment decisions as part of the standard of care.

We deploy biomarker analysis combined with microRNA expression to improve diagnostic clarity for cancer. In our thyroid and pancreatic cancer indications, cytopathological diagnosis can be ambiguous and can lead to indeterminate first line assessments and uncertainty among physicians regarding how to effectively treat patients. According to ATA, approximately 15%-35% of the early stage thyroid biopsies are initially indeterminate. Accordingly, physicians may often select surgery due to lack of confirmation of disease progression. Our thyroid tests are designed to provide clarity of diagnosis that can in turn guide treatment decisions often, eliminating costly, risky surgeries and other unnecessary medical procedures, improving the lives of patients and saving the healthcare system money.

Patients typically access our tests through their physician during the diagnostic process. All of our testing services are made available through our clinical reference laboratories located in Pittsburgh, Pennsylvania and New Haven, Connecticut, which are each CLIA certified and CAP accredited.

The published evidence supporting our tests demonstrates what we believe is the robustness of our science and clinical studies. Patients and physicians can access our full list of publications on our website. We continue to build upon our extensive library of bioinformatic data and clinical evidence. We also expect to continue expanding our offerings in gastrointestinal, endocrinology and lung cancers, as well as other cancer indications that we believe will benefit from our technology and approach.

We believe our focus on developing clinically useful tests that improve patient care while addressing the cost of healthcare is enabling the company to continue to expand in this marketplace. Our thyroid assays, ThyGenX[®] and ThyraMIR[®], are covered by our local Medicare Administrative Contractor (MAC), Novitas Solutions, and are now covered for more than 275 million people in the U.S. for use in thyroid cancer diagnosis. We announced the coverage of ThyGenX[®] and ThyraMIR[®] by numerous commercial payers during 2017 including United Healthcare and Cigna, as well as our national contract with Aetna and the renewal of our joint marketing program with LabCorp. Our pancreas assay, PancraGEN[®], for pancreatic cancer is also covered by Novitas Solutions and is now covered for more than 97 million people in the US.

Our newly launched lung assay, RespriDXTM for use in differentiating between metastatic versus primary cancer is covered by the majority of private payers, including their Medicare Advantage Plans, and an assessment for coverage is underway by Novitas for the traditional Medicare population. BarreGEN[®] for assessing Barrett's Esophagus is currently not reimbursed by our MAC nor is it covered by any major private payers.

Background

The molecular diagnostics and bioinformatics segment is highly fragmented with numerous science-based companies that have developed clinical tests or data solutions that are on the market or ready or near ready to be marketed. A vast majority of these companies have limited experience bringing a test to market and many of them do not have sufficient capital to build an infrastructure to effectively commercialize their products or tests. Due to their complexity, most molecular diagnostic tests and bioinformatics databases require a specialized go-to-market strategy that includes messaging to physicians, hospitals and potentially patients and managed care organizations as well as to pharma companies that are developing therapeutically relevant products. Additionally, robust data and clinical studies are often necessary to demonstrate to physicians, managed care organizations, guideline developers and other potential customers the benefit and utility of the assays and services offered. We believe that developing and delivering these kinds of messages is one of our core strengths.

Oncology, which represents the third largest segment after infectious disease and blood screening, is one of the fastest growing segments of the molecular diagnostics and bioinformatics market. The Centers for Medicare and Medicaid Services, or CMS, of the Department of Health and Human Services estimated in June 2014 that there were more than 5,900 independent clinical reference laboratories and specialty clinics, and more than 8,900 hospital-based laboratories, in the United States.

Our Molecular Diagnostic Tests

We are developing and commercializing molecular diagnostic tests to detect genetic alterations that are associated with gastrointestinal, endocrine and lung cancer risk, which are principally focused on early detection and identification of high potential progressors to cancer. Our tests assist healthcare providers in distinguishing between patients at risk for progression to cancer versus non-progressors. Thus, as part of a comprehensive diagnostic and treatment plan, our tests allow healthcare providers to determine whether surgery or active surveillance is most appropriate. We believe that our tests can help avoid unnecessary surgeries in those at low risk, thereby reducing healthcare costs and potential risks associated with surgery.

We offer PancraGEN[®], a molecular diagnostic test designed for determining risk of malignancy in pancreatic cysts and solid pancreaticobiliary lesions, ThyGenX[®], a next-generation sequencing test in combination with ThyraMIR[®], a novel microRNA gene expression classifier, designed to assist physicians in distinguishing between benign and malignant genotypes in indeterminate thyroid nodules, and RespriDXTM our recently-launched, metastatic versus primary platform and lung cancer test. Additionally we have also developed BarreGEN[®], a risk classifier assay for evaluating Barrett's Esophagus as a precursor to esophageal cancer, which we distribute today to limited customers via our Clinical Evaluation Program or CEP, while we gather additional data, perform clinical studies and seek reimbursement.

Gastrointestinal Cancer Products

Our current gastrointestinal cancer risk diagnostic assay, PancraGEN[®] is based on our PathFinderTG[®] platform, or PathFinderTG[®]. PathFinderTG[®] is designed to use advanced clinical algorithms to accurately stratify patients according to risk of cancer by assessing panels of DNA abnormalities in patients who have pancreaticobiliary lesions (cysts or solid masses) with potential for cancer. PathFinderTG[®] is supported by our state of the art CLIA certified, and CAP accredited laboratory in Pittsburgh, Pennsylvania. Our Pittsburgh laboratory is our major commercial-scale and development Center of Excellence where we process the majority of our current and future oncology related commercial tests, and we support our gastrointestinal development activities through this laboratory.

Accurate detection of pancreatic cancer risk is crucial. Pancreatic cancer is now the third leading cause of cancer deaths in the U.S. with an average 5 year survival rate of 8.2% according to The Centers for Disease Control and Prevention (the "CDC"s) SEER database. PancraGEN® is designed to determine the risk of malignancy in pancreatic cysts and pancreaticobiliary solid lesions. We believe that PancraGEN[®] is the leading integrated molecular diagnostic test for determining risk of pancreaticobiliary malignancy currently available on the market. We currently estimate that the immediate addressable market for PancraGEN® is approximately 130,000 indeterminate pancreaticobiliary lesions annually or approximately \$350 million annually based on the current size of the patient population and current and anticipated reimbursement rates. To date, PancraGEN[®] has been used in about 30,000 clinical cases. The National Pancreatic Cyst Registry study published in Endoscopy in 2015 demonstrated the clinical validity of PancraGEN[®] in that it more accurately determined the malignant potential of pancreatic cysts than the Sendai 2012 EUS criteria for detection of malignant pancreatic cystic lesions to help ensure that surgery is reserved for the most appropriate patients. When molecular analysis is not performed, the vast majority of all surgeries for pancreatic cysts are for benign disease. The American Gastroenterological Association 2015 Guidelines support the basic principle that too many pancreatic surgeries are being performed unnecessarily on benign lesions. In addition, the 2016 guidelines published by the American Society of Gastroenterology Endoscopy (ASGE) in Gastrointestinal Endoscopy included a specific recommendation for use of molecular testing in specific circumstances where other types of testing and analysis have not provided sufficient data on which to determine the best course of action for patient treatment. Accordingly, we believe that PancraGEN® provides a highly reliable diagnostic option for distinguishing between patients with pancreatic cysts who are at risk for developing pancreatic cancer.

We have also developed a cancer risk classifier assay, BarreGEN[®], which is designed to evaluate patients with Barrett's esophagus, an upper gastrointestinal condition that can progress into esophageal cancer. BarreGEN[®], which is also run on our PathFinderTG[®] platform, is distributed today on a limited basis through our CEP Program allowing us to gather additional data, perform clinical studies and seek initial reimbursement. We preliminarily estimate that the total market is approximately \$1.5 to \$2 billion annually based on the current size of the patient population and anticipated reimbursement rates comparable to those received currently for PancraGEN[®] for pancreatic cysts. While we anticipate the launch of BarreGEN[®] in 2018, we believe that BarreGEN[®] can also be an excellent product to partner in this potentially large market.

Endocrine Cancer Products

We currently market and sell a dual platform endocrine cancer risk diagnostic assay. The incidence of thyroid nodules is on the rise. ThyGenX[®] is a next generation DNA and RNA sequencing oncogene panel and when applied to indeterminate FNA, provides a highly specific "rule-in" test with over 80% positive predictive value in predicting whether a patient's thyroid nodule is cancerous. ThyGenX[®] works synergistically with our second endocrine cancer diagnostic test ThyraMir[®], which is based on measuring the expression level of 10 distinct microRNAs and is designed to provide a highly sensitive "rule-out" test to accurately categorize a mutation negative indeterminate FNA as being benign or malignant. Our testing is performed in our state of the art CLIA certified, CAP accredited laboratories in Pittsburgh, Pennsylvania and New Haven, Connecticut. We estimate the total market for our endocrine cancer assays is approximately \$350 million annually based on the current size of the patient population, estimated numbers of indeterminate FNAs and current and anticipated reimbursement rates. ThyGenX[®] is used by some customers as a base line oncogene panel assessment and approximately 80% of such users will reflex to also using ThyraMIR[®] as a more specific evaluation.

Endocrinologists evaluate thyroid nodules for possible cancer by collecting cells through FNA biopsies that are then analyzed by cytopathologists to determine whether or not a thyroid nodule is cancerous. It is estimated that up to 35% or up to approximately 100,000 of FNAs analyzed annually yield indeterminate results, meaning they cannot be diagnosed as definitely being malignant or benign by cytopathology alone. Traditionally, guidelines recommended that some patients with indeterminate cytopathology results undergo surgery to remove all or part of their thyroid to obtain an accurate diagnosis by looking directly at the thyroid tissue. Historically, according to a study published by Wang, et al. in 2011, in approximately 77% of these cases, the thyroid nodule proves to be benign. In addition to exposing a patient to unnecessary surgical risk and incurring costs, surgery can lead to a lifetime of thyroid hormone replacement therapy. Our ThyGenX[®] and ThyraMir[®] assays, are aimed at significantly improving the ability of physicians to determine an accurate diagnosis of an indeterminate FNA result.

Lung Cancer Product

RespriDX[™] Test and Metastatic versus Primary Platform

RespriDxTM compares the mutational fingerprint of two or more sites of cancer to determine whether the neoplastic deposits are representative of a recurrence (metastasis) of lung cancer or a new primary or independent tumor. The test defines the presence or absence of cancer in atypical cytology by comparing the mutational profile with that of known previous cancer. Microdissection is used to obtain areas of cellular atypia, followed by PCR –based analysis for loss of heterozygosity (LOH) using a panel of markers in proximity to 16 tumor suppressor genes including P16, PTEN, TP 53, and others. RespriDxTM assists physicians in determining the most appropriate course of treatment, whether chemotherapy, surgery, or other modalities.

Research and Development

We conduct most of our research and development activities at our CLIA certified and CAP accredited laboratories in Pittsburgh, Pennsylvania and New Haven, Connecticut. Our research and development efforts primarily focus on providing data and analyses necessary to support and improve our existing products on the market. Additionally, our research and development activities provide product line extension of our existing products as well as new product opportunities utilizing our proprietary platforms and extensive bioinformatics repositories and data bases.

We focus most of our research and development efforts on enhancing existing molecular diagnostic tests. We may enter into collaborative relationships with research and academic institutions for the development of additional or enhanced molecular diagnostic tests to further increase the depth and breadth of our molecular diagnostic test offerings. Where appropriate, we may also enter into licensing agreements with our collaborative partners to both license intellectual property for use in our molecular diagnostic test panels as well as licensing such intellectual property out, as appropriate.

Our research and development costs were approximately \$1.5 million and \$1.6 million in 2017 and 2016, respectively.

Customers

Our customers consist primarily of physicians, hospitals and clinics. Our revenue channels include reimbursement by Medicare, Medicare Advantage, Medicaid, and direct client billings (for example, hospitals and clinics), and commercial payers such as Blue Cross Blue Shield, Aetna, Cigna, United Healthcare and others.

Marketing

Our commercialization efforts are currently focused in cancers in endocrinology, gastroenterology and lung. Communication of our molecular diagnostic marketing messaging and value proposition are done principally through our two field-based sales teams of approximately 24 representatives and managers. Additionally, we communicate through print, digital advertising, a web presence, peer-reviewed publications, and trade show exhibits. We believe that our molecular diagnostic assays provide value to payers, physicians and patients by improving patient care and lowering healthcare costs through avoidance of unnecessary surgeries, reducing the morbidity associated with unnecessary surgeries for patients, and providing better diagnostic and prognostic insights to physicians. We support the value propositions of our molecular diagnostic tests through rigorous science and the accumulation of bioinformatics data that demonstrate clinical and analytical validity as well as clinical utility, and how they actually impact physicians' decisions. Our repository of bioinformatics data accumulated in over 37,000 cases using PancraGEN and over 20,000 cases using our thyroid assays is currently a valuable tool in developing our analytics and potentially an even more valuable tool in the future.

We also communicate to payers, integrated delivery systems and hospital systems about our molecular diagnostic tests' value through highly trained professionals who are experienced in reimbursement and business to business selling and through face to face meetings, phone calls, digital communications and advisory boards. We develop health economic analyses and budget impact models and incorporate these along with our clinical validation studies, and clinical utility studies to demonstrate our molecular diagnostic tests' value to this distinct and important constituency.

Intellectual Property

Patents, trademarks and other proprietary rights are important to us. We generate our own intellectual property portfolio and hold numerous patents and patent applications covering our existing and future products and technologies. As of December 31, 2017, we owned two issued United States Patents. The U.S. patents are directed to methods of treating a patient that has pancreatic ductal adenocarcinoma (PDAC) using the expression pattern of certain microRNAs to identify the patient as having PDAC and treating the identified patient and to methods of measuring carcinoembryonic antigen in a biological sample. As of December 31, 2017, we owned seven issued patents, two in Australia, Europe (validated in certain European countries), and Japan, and one in Canada, and ten pending patent applications in the United States patents expires in either 2032 or 2034 and our foreign patents expire in 2027 or 2031, and our pending patent applications, if issued, are expected to expire between 2027 and 2032, absent any disclaimers, adjustments or extensions. On March 29, 2017 we were notified by the European Patent Office that our EP patent # 2772550 for diagnosing thyroid cancer from a sample based upon at least MIR-375 was issued (validated in Spain, France, United Kingdom, Ireland, Italy, Belgium, Switzerland, Germany, and the Netherlands) and, provided all maintenance fees and annuities are paid, expires in 2031. On January 16, 2018, we were notified that an Opposition had been filed against EP patent # 2772550 alleging that the patent is invalid. We believe that the patent is valid and intend to defend the validity of the patent in the Opposition proceedings. Our patents are directed to certain of the technologies relating to detecting, diagnosing, and classifying thyroid tumors, pancreatic cysts and other forms of gastrointestinal disorders, such as Barrett's esophagus.

We also rely on a combination of trade secrets and proprietary processes to protect our intellectual property. We enter into nondisclosure agreements with certain vendors and suppliers to attempt to ensure the confidentiality of our intellectual property. We also enter into non-disclosure agreements with our customers. In addition, we require that all our employees sign confidentiality and intellectual property assignment agreements.

In addition to our own molecular diagnostic test development efforts, we are currently using, and intend to use in the future, certain tests and biomarkers that have been developed by third parties or by us in collaboration with third parties. While a significant amount of intellectual property in the field of molecular diagnostic tests is already in the public domain, ThyraMIR[®], ThyGenX[®], PancraGEN[®], RespriDXTM and some of the future tests developed by us, or by third parties on our behalf for use in our tests, may require, that we license the right to use certain intellectual property from third parties and pay customary royalties or make one time payments.

On August 13, 2014, we consummated an agreement to acquire certain fully developed thyroid and other tests in development for thyroid cancer, associated intellectual property and a biobank with more than 5,000 patient tissue samples, or the Acquired Property Asuragen, pursuant to an asset purchase agreement, or the Agreement. We paid \$8.0 million at closing and paid an additional \$0.5 million to Asuragen for certain integral transition service obligations set forth in a transition services agreement, entered into concurrently with the Agreement. We also entered into two license agreements with Asuragen (the Asuragen License Agreement and the CPRIT License Agreement) relating to our ability to sell the fully developed diagnostic tests and other tests in development for thyroid cancer. Under the Asuragen License Agreement, we owed a \$500,000 milestone payment, all of which was paid in installments throughout 2016 and paid in full as of January 13, 2017. We are further obligated to pay royalties on the future net sales of the miR*Inform*[®] thyroid platform through August 13, 2024 and on certain other thyroid diagnostics tests for a period of ten years following a qualifying sale, on the surage of the years following sale.

In October 2014, we acquired our pancreatic and gastrointestinal assets from RedPath. Additionally, we have a broad and growing trademark portfolio. We have secured trademark registrations for the marks $PancraGEN^{\ensuremath{\mathbb{R}}}$, $BarreGEN^{\ensuremath{\mathbb{R}}}$ and $miRInform^{\ensuremath{\mathbb{R}}}$ in the United States, and $miRInform^{\ensuremath{\mathbb{R}}}$ with the World Intellectual Property Organization. We also have pending trademark applications for our other molecular diagnostic tests in the United States.

Competition

We compete on the basis of such factors as reputation, service quality, management experience, performance record, customer satisfaction, ability to respond to specific customer needs, integration skills, product portfolio, and price. Increased competition and/or a decrease in demand for our services or molecular diagnostic tests may also lead to other forms of competition. We believe that our business has a variety of competitive advantages that allow us to compete successfully in the marketplace. While we believe we compete effectively with respect to each of these factors, certain of our competitors are substantially larger than us and have greater capital, personnel and other resources than we have. Many of our competitors also offer broader product lines outside of the molecular diagnostic testing market, and many have greater brand recognition than we do. Moreover, our competitors may make rapid technological developments that may result in our technologies and products becoming obsolete before we recover the expenses incurred to develop them or before they generate significant revenue. Increased competition may lead to pricing pressures and competitive practices that could have a material adverse effect on our market share and our ability to attract new business opportunities as well as our business, financial condition and results of operations.

We also compete with physicians and the medical community who use traditional methods to diagnose gastrointestinal and endocrine cancers. In many cases, practice guidelines in the United States have recommended therapies, surveillance or surgery to determine if a patient's condition is malignant or benign. As a result, we believe that we will need to continue to educate physicians and the medical community on the value and benefits of our molecular diagnostic tests in order to change clinical practices and continue to support the use of molecular diagnostic tests in clinical guidelines.

Specifically, in regard to our thyroid diagnostic tests, Veracyte, Inc., or Veracyte, has a molecular thyroid nodule cancer diagnostic test (Afirma) that is the current market leader and competes with our ThyGenX[®] and ThyraMir[®] tests. Quest Diagnostics Incorporated, or Quest, currently offers a diagnostic test similar to the earlier version of our ThyGenX test and recently announced an agreement to distribute the Afirma test in partnership with Veracyte. CBLPath, Inc., or CBL, is offering a diagnostic test that analyzes genetic alterations using next-generation sequencing and in 2016 Rosetta Genomics introduced a thyroid cancer micro RNA assay Rosetta Reveal GX. In addition, other thyroid based endocrine competitors include Accelerate Diagnostics, Inc., Cancer Genetics, Inc., Genomic Health Inc., NeoGenomics Inc. and Trovagene, Inc.

We are currently not aware of any direct competitors to PancraGEN[®] that integrate clinical, imaging, cytology, and molecular information to stratify patients' risk for malignancy and inform physicians on the best course of action, i.e. surgery or surveillance and surveillance interval length. Recently, University of Pittsburgh Medical Center began offering PancreaSeq, a Next Generation Sequencing "gene only" panel that focuses on the analysis of mutations in four oncogenes and three tumor suppressor genes, most of which may help establish the type of pancreatic cyst present and some of which may help establish the presence of malignancy. All but three of these related genomic regions are included in PancraGEN[®]. This laboratory test however does not integrate any additional information to fully characterize a patient's risk for pancreatic cancer. Importantly, there has been no long-term clinical validation or utility studies completed on any gene panel for pancreatic cyst fluid other than that associated with PancraGEN[®]. PancraGEN[®] has been validated in multiple studies and peer reviewed publications and has been used in over 30,000 patients. Notably, the Company validated and launched during 2017 a DNA only version of PancraGEN[®], known as PanDNATM.

It is also possible that we face future competition from laboratory-developed tests, or Laboratory Developed Tests (LDTs), developed by commercial laboratories such as Quest and other diagnostic companies developing new tests or technologies. Furthermore, we may be subject to competition as a result of new, unforeseen technologies that may be developed by our competitors in the gastrointestinal and endocrine cancer molecular diagnostic tests space.

We are aware of companies that are in the process of developing assays and LDTs for Barrett's esophagus, such as Cernostics Inc. In addition, NeoGenomics, Inc. is marketing a Barrett's assay, so it appears likely that this space will also be competitive in the future.

Government Regulations and Industry Guidelines

The healthcare industry, and thus our business, is subject to extensive Federal, State, local and foreign regulation. Both Federal and State governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business and most frequently cited in enforcement actions.

Regulations over Our Clinical Laboratories

The conduct and provision of our molecular diagnostic tests are regulated under CLIA. CLIA requires us to maintain Federal certification. CLIA imposes requirements relating to test processes, personnel qualifications, facilities and equipment, recordkeeping, quality assurance and participation in proficiency testing. CLIA compliance and certification are also a condition for participation by clinical laboratories in the Medicare Program and for eligibility to bill for services provided to governmental healthcare program beneficiaries. As a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is conducted by CMS, a CMS agent (typically a State agency), or, if the laboratory is accredited, a CMS-approved accreditation organization. Sanctions for failure to meet these certification, accreditation and licensure requirements include suspension, revocation or limitation of a laboratory's CLIA certification, accreditation or license, which is necessary to conduct business, cancellation or suspension of the laboratory's ability to receive Medicare or Medicaid reimbursement, as well as imposition of plans to correct deficiencies, injunctive actions and civil monetary and criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could harm our business. In addition to CLIA requirements, we participate in the oversight program of the CAP. Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA. CLIA does not preempt State laws that are more stringent than Federal law. State laws may require additional personnel quality control, record maintenance and/or proficiency testing.

In addition to CLIA certification, we are required to maintain State licenses to conduct testing in our Pittsburgh and New Haven laboratories. Pennsylvania, New York and Connecticut laws require that we maintain a license and establish standards for the day-to-day operation of our clinical reference laboratories in Pittsburgh and New Haven. In addition, our clinical reference laboratory is required to be licensed on a test-specific basis by California, Florida, Maryland, New York and Rhode Island. California, Florida, Maryland, New York and Rhode Island laws also mandate proficiency testing for laboratories licensed under the laws of each respective State regardless of whether such laboratories are located in California, Florida, Maryland, New York or Rhode Island. On September 26, 2016 we received approval for our ThyGenX[®] test in New York. We are currently approved to perform ThyGenX[®], ThyraMIR[®], PancraGEN[®] RespriDXTM and BarreGEN[®] in all states including the state of New York. If we were to lose our CAP Accreditation, CLIA certificate or State licenses for our laboratories, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our molecular diagnostic tests, which would eliminate a source of revenue; this could have a material adverse effect on our business, financial condition and results of operations.

Our Pittsburgh and New Haven laboratories are also subject to licensing and regulation under Federal, State and local laws relating to hazard communication and employee right-to-know regulations, and the safety and health of laboratory employees. Additionally, our Pittsburgh and New Haven laboratories are subject to applicable Federal and State laws and regulations and licensing requirements relating to the handling, storage and disposal of hazardous waste, and laboratory specimens, including the regulations of the Environmental Protection Agency, the Department of Transportation, and the National Fire Protection Agency. The regulations of the United States Department of Transportation, Public Health Service and Postal Service apply to the surface and air transportation of laboratory specimens.

In addition to its comprehensive regulation of safety in the workplace, the United States Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers whose workers may be exposed to blood-borne pathogens such as HIV and the hepatitis B virus, by preventing or minimizing any exposure through needle stick or similar penetrating injuries. Although we believe that we are currently in compliance in all material respects with such Federal, State and local laws, failure to comply with such laws could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

Further, laboratories that analyze human blood or other biological samples for the diagnosis and treatment of clinical trial subjects must comply with CLIA, as well as requirements established by Federal law, various States laws and local regulations. In addition, we are also subject to such laws relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical and biological agents and compounds. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste. The failure to meet these requirements may result in civil penalties and suspension or revocation of our CLIA certifications at our New Haven and Pittsburgh laboratories.

Potential U.S. Food and Drug Administration Regulation of Diagnostics Tests

Both United States Federal and State governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. As indicated by work plans and reports issued by these agencies, the Federal government will continue to scrutinize, among other things, the marketing, labeling, promotion, manufacturing and export of molecular diagnostic tests. While subject to oversight by CMS through its enforcement of CLIA, the FDA has claimed regulatory authority over all laboratories that produce LDTs, a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory. The FDA has regulatory responsibility over, among other areas, instruments, test kits, reagents and other devices used in clinical laboratories to perform diagnostic testing in the United States.

The FDA has generally exercised enforcement discretion over all LDTs. However, in October 2014, the FDA issued two draft guidance documents: "Framework for Regulatory Oversight of Laboratory Developed Tests," which provided an overview of how the FDA would regulate LDTs through a risk-based approach, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests," which provided guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be subject to medical device registration, listing, and adverse event reporting requirements. LDT manufacturers would be required to either submit a pre-market application and receive the FDA's approval before an LDT may be marketed, or submit a pre-market notification in advance of marketing. The Framework for Regulatory Oversight draft guidance states that within six months after the guidance documents are finalized, all laboratories will be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered. If the FDA were to regulate LDTs as proposed under the 2014 draft guidance documents, then it would classify LDTs into one of three classes according to the current system used to regulate medical devices. Class I devices are those for which reasonable assurance of the safety and effectiveness can be provided by adherence to the FDA's general regulatory controls for medical devices. Class II devices are subject to the FDA's general controls, and any other special controls as deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the devices. Class III devices are those devices which are deemed by the FDA to pose the greatest risk, such as life-sustaining, lifesupporting or implantable devices, have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device. Under the guidance documents, LDTs would also be subject to significant post-market requirements as well.

On November 18, 2016, however, the FDA announced that it would not release the final guidance at this time and instead would continue to work with stakeholders, the new administration and Congress to determine the right approach. On January 13, 2017, the FDA released a discussion paper on LDTs outlining a possible risk-based approach for FDA and CMS oversight of LDTs. According to the 2017 discussion paper, previously marketed LDTs would not be expected to comply with most or all FDA oversight requirements (grandfathering), except for adverse event and malfunction reporting. In addition, certain new and significantly modified LDTs would not be expected to comply with pre-market review unless the agency determines certain tests could lead to patient harm. Since LDTs currently on the market would be grandfathered in, pre-market review of new and significantly modified LDTs could be phased-in over a four-year period, as opposed to the nine years proposed in the Framework for Regulatory Oversight draft guidance. In addition, tests introduced after the effective date, but before their phase-in date, could continue to be offered during pre-market review.

The discussion paper notes that FDA will focus on analytical and clinical validity as the basis for marketing authorization. The FDA anticipates laboratories that already conduct proper validation should not be expected to experience new costs for validating their tests to support marketing authorization and laboratories that conduct appropriate evaluations would not have to collect additional data to demonstrate analytical validity for FDA clearance or approval. The evidence of the analytical and clinical validity of all LDTs will be made publically available. LDTs are encouraged to submit prospective change protocols in their pre-market submission that outline specific types of anticipated changes, the procedures that will be followed to implement them and the criteria that will be met prior to implementation.

Despite the FDA decision to not release the guidance at this time, it can choose to regulate LDTs at any time. Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions. There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and LDTs. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time. We are monitoring developments and anticipate that our products will be able to comply with requirements if ultimately imposed by the FDA. In the meantime, we maintain our CLIA certification of accreditation, which permits the use of LDTs for diagnostics purposes.

Healthcare, Fraud, Abuse and Anti-Kickback Laws

The Anti-Kickback Statute makes it a felony for a person or entity, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any Federal healthcare program. A violation of the Anti-Kickback Statute may result in imprisonment of up to five years and fines of up to \$250,000 for each offense in the case of individuals and \$500,000 for each offense in the case of organizations. Convictions under the Anti-Kickback Statute result in mandatory exclusion from federal healthcare programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other federal healthcare programs. Actions, which violate the Anti-Kickback Statute, also incur liability under the Federal False Claims Act, discussed in more detail below, which prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the U.S. Government.

Although the Anti-Kickback Statute applies only to federal healthcare programs, a number of states have passed statutes substantially similar to the Anti-Kickback Statute, which prohibits similar conduct toward all other health plans and third-party payers. Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between healthcare providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-Kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal healthcare programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are ambiguous and subject to varying interpretations. Further, the Federal False Claims Act, discussed in more detail below, prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in fines, imprisonment or both, and possible exclusion from Medicare or Medicaid programs.



We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law. These restrictions generally prohibit us from billing a patient or any governmental or private payer for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Persons or entities found to violate the Stark Law are required to refund any payments received pursuant to a referral prohibited by these laws to the patient, the payer or the Medicare program, as applicable. Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to \$15,000 for each service arising out of the prohibited referral;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to \$100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.

These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act.

We do retain healthcare practitioners as key opinion leaders providing consultation in various aspects of the business. These arrangements as any arrangement that includes compensation to a healthcare provider may trigger Federal or State anti-kickback and Stark Law liability. Our arrangements are designed to meet available safe harbors and exceptions provided in the anti-kickback laws and Stark laws, respectively. There is no guarantee that the government will find that these arrangements are designed properly or that they do not trigger liability. Under existing laws, all arrangements must have a legitimate purpose and compensation must be fair market value. These terms require some subjective analysis and there is limited available case law or guidance for the application of these laws to the CLIA Laboratory industry. Safe harbors in the anti-kickback laws do not necessarily equate to exceptions in the Stark Law; and there is no guarantee that the government will not have issue with the relationships between the laboratories and the healthcare providers.

HIPAA, Fraud and Privacy Regulations

The Federal government's efforts to combat fraud in the healthcare setting were consolidated and strengthened under Public Law 104-191, the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA established a comprehensive program to combat fraud committed against all health plans, both public and private by, among other things creating two new Federal offenses: healthcare fraud (18 U.S. Code § 1347) and false statements relating to healthcare matters (18 U.S. Code § 1035). These provisions prohibit: (1) the knowing and willful execution, or attempted execution, of a scheme or artifice (a) to defraud any healthcare benefit program (including private payers), or (b) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, in connection with the delivery of or payment for healthcare benefits, items, or services; and (2) the knowing and willful (a) falsification, concealment or covering up of a material fact by any trick, scheme or device, or (b) making of any materially false, fictitious or fraudulent statement or representation, or making or using any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items or services. A violation of these provisions is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs.



HIPAA, along with the Health Information Technology for Economic and Clinical Health Act and the various regulations promulgated thereunder, also establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities." The regulations promulgated under HIPAA govern: the Privacy of Individually Identifiable Health Information, restricting the use and disclosure of certain individually identifiable health information (45 C.F.R. §§ 164.500, et seq.); Administrative Requirements for electronic transactions, establishing standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures (45 C.F.R. §§ 162.100, et seq.); Security Standards for the Protection of Electronic Protected Health Information, requiring covered entities to implement and maintain certain security measures to safeguard certain electronic health information (45 C.F.R. §§ 164.302, et seq.); and Breach Notification, requiring covered entities and their business associates to provide notification following a breach of unsecured protected health information (45 C.F.R. §§ 164.400, et seq.). As a covered entity, and also in our capacity as a business associate to certain of our customers, we are subject to these standards. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards entails significant costs for us, and our failure to comply could lead to enforcement action that could have an adverse effect on our business. If we or our operations are found to be in violation of HIPAA or its implementing regulations, we may be subject to potentially significant penalties, including civil and criminal penaltie

In addition to Federal regulations issued under HIPAA, many States and foreign jurisdictions have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent laws. If we fail to comply with applicable State laws and regulations, we could be subject to additional sanctions.

Third Party Coverage and Reimbursement

Our customers' bills are paid by many different payer groups. The majority of reimbursement dollars for traditional laboratory services are provided by traditional commercial insurance products, most notably preferred provider organizations, or PPOs, and other managed care plans, as well as government healthcare programs, such as Medicare and Medicaid. PPOs, HMOs and other managed care plans typically contract with a limited number of laboratories and then designate the laboratory or laboratories to be used for tests ordered by participating physicians. We are currently an out-of-network provider with most payers, which means we do not have a contract with payers to pay a specific rate for our tests. We did announce during 2017 a new national agreement with Aetna through which the Company is now an in-network provider for Aetna's members. We are subject to applicable State laws regarding who should be billed, how they should be billed, how business should be conducted, and how patient obligations regarding cost sharing should be handled. In addition, if we become an "in-network" provider for certain payers in the future, we will also be subject to the terms of contracts (which could include reduced reimbursement rates) and may be subject to discipline, breach of contract actions, non-renewal or other contractually provided remedies for non-compliance with the contract's requirements and/or applicable laws.

We generally bill third-party payers and individual patients for testing services on a test-by-test basis. Third-party payers include Medicare, private insurance companies, institutional direct clients and Medicaid, each of which has different billing requirements. Medicare reimbursement programs are complex and often ambiguous, and are continuously being evaluated and modified by CMS. Our ability to receive timely reimbursements from third-party payers is dependent on our ability to submit accurate and complete billing statements, and/or correct and complete missing and incorrect billing information. Missing and incorrect information on reimbursement submissions slows down the billing process and increases the aging of accounts receivable. We must bill Medicare directly for tests performed for Medicare patients and must accept Medicare's fee schedule for the covered tests as payment in full. State Medicaid programs are generally prohibited from paying more than the Medicare fee schedule. Our Pittsburgh and New Haven laboratories have contracted with a healthcare billing services management company to work with our in-house staff and help manage our third-party billing.

Some billing arrangements require us to bill multiple payers, and there are several other factors that complicate billing (e.g., disparity in coverage and information requirements among various payers; and incomplete or inaccurate billing information provided by ordering physicians). In 2017 several private payers implemented pre-authorization requirements for molecular and genetic testing, including Anthem Blue Cross Blue Shield and United Healthcare. In addition, more commercial payers are contracting with and delegating risk for lab services costs to Lab Benefits Management companies (e.g. Evicore, AIM Specialty Health, LBS/Beacon). This requires us to go through their technology assessment process to secure coverage and obtain a contract as an in-network lab provider for our services. We incur additional costs as a result of our participation in Medicare and Medicaid programs because diagnostic testing services are subject to complex, stringent and frequently ambiguous federal and state laws and regulations, including those relating to coverage, billing and reimbursement. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further cost and complexity to the billing process. Further, our billing systems require significant technology investment and, as a result of marketplace demands, we need to continually invest in our billing systems. Changes in laws and regulations could further complicate our billing and increase our billing expense. CMS establishes procedures and continuously evaluates and implements changes to the reimbursement process and requirements for coverage.

As an integral part of our billing compliance program, we investigate reported failures or suspected failures to comply with Federal and State healthcare reimbursement requirements. Any Medicare or Medicaid overpayments are reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments, reimbursed the payers for overpayments and taken appropriate corrective action.

Historically, due to the nature of our business, we have performed requested testing and have reported test results regardless of collectability or form of reimbursement. We submit claims for reimbursement on a best efforts basis including the use of a third-party revenue cycle management firm. If at times the billing information is incorrect or incomplete, we subsequently attempt to contact the healthcare provider or patient to obtain any missing information and to rectify incorrect billing information. Missing or incorrect information on requisitions complicates and slows down the billing process and may also impact revenue recognition. The increased use of electronic ordering reduces the incidence of missing or incorrect information, and we are seeking to electronically integrate with more and more payers and clients. During 2017 we successfully implemented numerous electronic interfaces with providers to expedite the ordering and reporting process and increased the number of clients interacting with us via our customer portal.

There are a number of factors that influence coverage and reimbursement for molecular diagnostic tests. In the United States, the American Medical Association assigns specific CPT codes, which are necessary for reimbursement of molecular diagnostic tests. Once the CPT code is established, CMS establishes reimbursement payment levels and coverage rules under Medicaid and Medicare, and private payers establish rates and coverage rules independently. However, the availability of a CPT code is not a guarantee of coverage or adequate reimbursement levels, and the revenues generated from our tests will depend, in part, on the extent to which third-party payers provide coverage and establish adequate reimbursement levels.

United States and other government regulations governing coverage and reimbursement for molecular diagnostic testing may affect, directly or indirectly, the design of our tests and the potential market for their use. The availability of third-party reimbursement for our tests and services may be limited or uncertain. Third-party payers may deny coverage if they determine that the tests or service has not received appropriate FDA or other government regulatory clearances, is not used in accordance with cost-effective treatment methods as determined by the payer, or is deemed by the third-party payer to be experimental, unnecessary or inappropriate. Furthermore, third-party payers, including Federal and State healthcare programs, government authorities, private managed care providers, private health insurers and other organizations, frequently challenge the prices, medical necessity, and cost-effectiveness of healthcare products and services, including laboratory tests. Such payers may limit coverage of our tests to specific, limited circumstances, may not provide coverage at all, or may not provide adequate reimbursement rates, if covered. Further, one payer's determination to provide coverage does not assure that other payers will also provide coverage for the test. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to maintain our revenue and growth. Coverage policies and third-party reimbursement rates may change at any time.



Government payers, such as Medicare and Medicaid, have taken steps and are expected to continue to take steps to control the cost, utilization and delivery of healthcare services, including clinical test services. For example, Medicare has adopted policies under which it does not pay for many commonly ordered clinical tests unless the ordering physician has provided an appropriate diagnosis code supporting the medical necessity of the test. Physicians are required by law to provide diagnostic information when they order clinical tests for Medicare and Medicaid patients.

Currently, Medicare does not require the beneficiary to pay a co-payment for diagnostic information services reimbursed under the Clinical Laboratory Fee Schedule. Certain Medicaid programs require Medicaid recipients to pay co-payment amounts for diagnostic information services.

The Medicare Part B program contains fee schedule payment methodologies for clinical testing services performed for covered patients, including a national ceiling on the amount that carriers could pay under their local Medicare clinical testing fee schedules. Historically, the Medicare Clinical Laboratory Fee Schedule, or CLFS, has been subject to change. In April 2014, the President signed the Protecting Access to Medicare Act of 2014, or PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. PAMA removed CMS's authority to adjust the CLFS based and established a new method for setting CLFS rates. Implementation of this new method for setting CLFS rates began in 2017. Under PAMA, laboratories that have more than \$12,500 in Medicare revenues from laboratory services and that receive more than 50 percent of their Medicare revenues from laboratory services would report private payer data from January 1, 2016 through June 30, 2016, to CMS between January 1, 2017 and March 31, 2017. CMS posted the new Medicare CLFS rates (based on weighted median private paver rates) in November 2017 and the new rates became effective on January 1, 2018. The result of the PAMA calculations was an increase in our reimbursement rate for ThyGenX of approximately 40% for our Medicare volume. Any reductions to payment rates resulting from the new methodology are limited to 10% per test per year in each of the years 2017 through 2019 and to 15% per test per year in each of the years 2020 through 2022. CMS has issued draft regulations regarding these changes. Further rule-making from CMS will define the time period and data elements evaluated on an annual basis to set reimbursement rates. Other than our chemistry testing services, our products are defined as Advanced Diagnostic Laboratory Tests (ADLTs) and therefore, we believe the pricing provisions of PAMA do not affect our marketed molecular diagnostic tests. The only testing for which we bill that is included in the CLFS is our carcinoembryonic antigen (CEA) and Amylase chemistry testing services. For these services, we provided CMS with the median pricing received from all payers in compliance with PAMA regulations.

Penalties for violations of laws relating to billing government healthcare programs and for violations of federal and state fraud and abuse laws include: (1) exclusion from participation in Medicare/Medicaid programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business. Civil monetary penalties for a wide range of violations may be assessed on a per violation basis. A parallel civil remedy under the federal False Claims Act provides for penalties on a per violation basis, plus damages of up to three times the amount claimed.

Historically, most Medicare and Medicaid beneficiaries were covered under the traditional Medicare and Medicaid programs administered by the federal government. Reimbursement from traditional Medicare and Medicaid programs represented approximately 38% of our consolidated net revenues during 2017. Over the last several years, the federal government has continued to expand its contracts with private health insurance plans for Medicare beneficiaries and has encouraged such beneficiaries to switch from the traditional programs to the private programs, called "Medicare Advantage" programs. There has been growth of health insurance providers offering Medicare Advantage programs and of beneficiary enrollment in these programs. Commercial health plans that might not cover one or all of our tests for their commercially insured members are required to follow the Novitas LCD coverage policy for their Medicare Advantage members. To the extent we maintain the LCD coverage policies with Novitas for our products, any shift of members from traditional Medicare to Medicare Advantage plans doesn't represent a risk of lost revenue. In recent years, in an effort to control costs, states also have mandated that Medicaid beneficiaries enroll in private managed care arrangements.

The current position of the laboratories is that they do not meet the definition of an "Applicable Manufacturer" under Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act) and therefore are not subject to the disclosure or tax requirements contained in PPACA. However, as new regulations are implemented and diagnostic tests reclassified, this may change and the laboratory business may be subject to PPACA as are other companies. There is no guarantee that our interpretation of the law is now or will be in the future consistent with government guidance and interpretation.

Employees

As of February 28, 2018, we had approximately 75 full time employees. We are not party to a collective bargaining agreement with any labor union.

Corporate History

We were originally incorporated in New Jersey in 1986 and began commercial operations as a CSO in 1987. In connection with our initial public offering, we reincorporated in Delaware in 1998. Having disposed of substantially all of our CSO assets in 2015, we currently operate under one operating segment, which is our molecular diagnostic business. We conduct our business through our wholly-owned subsidiaries, Interpace LLC, which was formed in Delaware in 2013, and Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007. Our executive offices are located at Morris Corporate Center 1, Building C, 300 Interpace Parkway, Parsippany, New Jersey 07054. Our telephone number is (855) 776-6419.

Available Information

We maintain an internet website at www.interpacediagnostics.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q,

current reports on Form 8-K, and amendments to those reports are available free of charge through the "Investor Relations" portion of our website, as soon as reasonably practicable after they are filed with the SEC. The content contained in, or that can be accessed through, our website is not incorporated into this Form 10-K.

ITEM 1A. RISK FACTORS

In addition to the other information provided in this Annual Report on Form 10-K, including our financial statements and the related notes in Part II - Item 8, you should carefully consider the following factors in evaluating our business, operations and financial condition. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or that are similar to those faced by other companies in our industry or businesses in general, such as competitive conditions, may also impair our business operations. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations or cash flows.

RISKS RELATING TO OUR BUSINESS

Our molecular diagnostics business has limited revenue, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.

In 2014, we acquired RedPath and certain assets from Asuragen. As a result, we now offer four products commercially; PancraGEN[®], ThyGenX[®], ThyraMIR[®] and RespriDXTM and to a limited extent via our CEP Program, BarreGEN[®]. The revenue generated from our molecular diagnostics and bioinformatics business was \$15.9 million for the fiscal year ended December 31, 2017. For the fiscal year ended December 31, 2017, we had an operating loss of approximately \$6.3 million. Although we expect our revenue to grow in the future, there can be no assurance that we will achieve revenue sufficient to offset expenses. Over the next several years, we expect to continue to devote resources to increase adoption of, and reimbursement for, our molecular diagnostic tests and to use our bioinformatics data and to develop and acquire additional products and services. However, our business may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could have a material adverse effect on our business, financial condition and results of operations.

Our profitability will be impaired by our obligations to make royalty and milestone payments to Asuragen and other licensors.

In connection with our acquisition of certain assets of Asuragen in 2014, we are obligated to make certain royalty and milestone payments to Asuragen and other licensors. Under the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of the miR*Inform*[®] thyroid platform (i.e. ThyGenX[®]) through August 13, 2024 and on certain other thyroid diagnostics tests (i.e. ThyraMIR[®]) for a period of ten years following a qualifying sale. A similar obligation exists for the same periods, if we elect to launch any molecular tests from the miR*Inform*[®] pancreas platform.

Even if we are able to successfully launch the above referenced diagnostic tests, our profitability will be impaired by our obligations to make royalty payments to Asuragen. Although we believe, under such circumstances, that the increase in revenue will exceed the corresponding royalty payments, our obligations to Asuragen and other licensors could have a material adverse effect on our business, financial condition and results of operations if we are unable to manage our operating costs and expenses at profitable levels.

Our inability to finance our business on acceptable terms in the future may limit our ability to develop and commercialize new molecular diagnostic solutions and technologies and grow our business.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure and commercial operations. As of December 31, 2017, we had cash and cash equivalents of \$15.2 million, net accounts receivable of \$3.4 million, total current assets of \$19.8 million and total current liabilities of \$8.1 million. For the year ended December 31, 2017, we had a net loss of \$12.2 million and cash used in operating activities was \$15.3 million, including non-recurring charges. Additionally, during 2017, we raised net equity capital of approximately \$29.9 million. While our overall cash position has improved, our business is not currently cash flow breakeven or positive, and as a result, we may need to finance our business in the future through collaborations, equity offerings, debt financings, licensing arrangements or other dilutive or non-dilutive means. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing additional equity securities, dilution to our stockholders could result. In addition, we granted each institutional investor who participated in the registered direct offering completed on January 6, 2017, the right, for a period of 15 months following January 6, 2017, or until April 6, 2018, to participate in any public or private offering by us of equity securities, subject to certain exceptions, up to such investor's pro rata portion of 50% of the securities being offered, or the Participation Right. If we fail to comply with the applicable provisions of the Participation Right or do not receive waivers from such investors, we may not be able to raise funds through another equity offering, but only through the period ending April 6, 2018. In other instances, the incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business.

Our financial results currently depend solely on sales of our molecular diagnostic tests, and we will need to generate sufficient revenue from these and other molecular diagnostic products and/or solutions that we develop or acquire to grow our business.

The majority of our revenue currently is derived from the sale of our molecular diagnostic tests, which we initially launched commercially in the second half of 2014. We have several additional molecular diagnostics tests and complimentary service extensions that we have recently launched or are in late stage development, but there can be no assurance that we will be able to successfully commercialize or sufficiently grow those tests. If we are unable to increase sales of our molecular diagnostic tests, expand reimbursement for these tests, or successfully develop and commercialize other molecular diagnostic tests, our revenue and our ability to achieve and sustain profitability would be impaired, and this could have a material adverse effect on our business, financial condition and results of operations.

We have a limited operating history as a molecular diagnostics company, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were originally incorporated in New Jersey in 1986 and began commercial operations in 1987. In connection with our initial public offering, we re-incorporated in Delaware in 1998. From 1987 until 2015, our operations focused primarily on our CSO business, which provided the personal promotion of pharmaceutical customers' products through outsourced sales teams. We now conduct our molecular diagnostics and bioinformatics business through our wholly owned subsidiaries, Interpace LLC, which was formed in Delaware in 2013, and Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007. We began our own commercial sales of our molecular diagnostic tests in late 2014. Consequently, any evaluations about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history.

The loss of members of our senior management team or our inability to attract and retain key personnel could adversely affect our business.

As a small company with 75 employees, the success of our business depends largely on the skills, experience and performance of members of our senior management team and others in key management positions. The efforts of these persons will be critical to us as we continue to grow our molecular diagnostics business and develop and/or acquire additional molecular diagnostic tests. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. In addition, our commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel, and we may have to pay higher salaries to attract and retain qualified personnel. We may also be at a disadvantage in recruiting and retaining key personnel as our small size, limited resources, limited liquidity and changes in the last two years in our senior management team may be viewed as providing a less stable environment, with fewer opportunities than would be the case at one of our larger competitors. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our clinical laboratory and commercialization.



We depend on a few payers for a significant portion of our revenue, and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our molecular diagnostic tests, our revenue could decline.

Revenue for tests performed on patients covered by Medicare was approximately 38% of our revenue for the fiscal year ended December 31, 2017. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue increases, as additional payers provide reimbursement for our molecular diagnostic tests or if one or more payers were to stop reimbursing for our molecular diagnostic tests or changed their reimbursed amounts.

Novitas Solutions has been the regional MAC that handles claims processing for Medicare services with jurisdiction for PancraGEN[®], ThyGenX[®], ThyraMIR[®], BarreGEN[®] and RespriDXTM On a five-year rotational basis, Medicare requests bids for its regional MAC services. Any future changes in the MAC processing or coding for Medicare claims for our molecular diagnostic tests could result in a change in the coverage or reimbursement rates for such molecular diagnostic tests, or the loss of coverage.

Our PancraGEN[®] and ThyGenX[®] tests are reimbursed by Medicare based on applicable CPT codes. PancraGEN[®] is currently reimbursed by Medicare at \$3,038 per test, ThyGenX[®], previously reimbursed at \$1,054 per test, is currently reimbursed by Medicare at \$1,515 per test, effective January 1, 2018, and ThyraMIR[®] is currently reimbursed by Medicare at \$2,195 per test. RespriDXTM is currently only covered by the Medicare Advantage program and our BarreGEN[®] assay is not reimbursed at all. Any future reduction from the current rate would have a material adverse effect on business and results of operations.

Although we have entered into contracts with certain third-party payers which establish in-network allowable rates of reimbursement for our molecular diagnostic tests, payers may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to us. Any such actions could have a negative effect on our revenue.

If payers do not provide reimbursement, rescind or modify their reimbursement policies or delay payments for our tests, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.

Physicians may generally not order our tests unless payers reimburse a substantial portion of the test price. There is uncertainty concerning third-party reimbursement of any test incorporating new molecular diagnostic technology. Reimbursement by a payer may depend on a number of factors, including a payer's determination that tests such as our molecular diagnostic tests are: (a) not experimental or investigational; (b) pre-authorized and appropriate for the patient; (c) cost-effective; (d) supported by peer-reviewed publications; and (e) included in clinical practice guidelines. Since each payer generally makes its own decision as to whether to establish a policy or enter into a contract to reimburse our tests, seeking these approvals is a time-consuming and costly process. Although we have contracted rates of reimbursement with certain payers, which establishes in-network allowable rates of reimbursement for our PancraGEN[®], ThyGenX[®], ThyraMIR[®] and RespriDXTM assays, payers may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to us. Any such actions could have a negative effect on our revenue.

We have contracted rates of reimbursement with select payers for our PancraGEN[®], ThyGenX[®] and ThyraMIR[®] and to a limited extent, RespriDXTM. Without a contracted rate for reimbursement, claims may be denied upon submission, and we may need to appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. We expect to continue to focus resources on increasing adoption of and coverage and reimbursement for our molecular diagnostic tests. We cannot, however, predict whether, under what circumstances, or at what payment levels payers will reimburse us for our molecular diagnostic tests, if at all. In addition to our current commercial products on the market and in our pipeline, the launch of any new molecular diagnostic tests in the future may require that we expend substantial time and resources in order to obtain and retain reimbursement. Also, payer consolidation can create uncertainty as to whether coverage and contracts with existing payers will even remain in effect. Finally, commercial payers may tie their allowable rates to Medicare rates, and should Medicare reduce their rates, we may be negatively impacted. If we fail to establish broad adoption of and reimbursement for our assays, or if we are unable to maintain existing reimbursement from payers, our ability to generate revenue could be harmed and this could have a material adverse effect on our business, financial condition and results of operations.



We may experience limits on our revenue if physicians decide not to order our molecular diagnostic tests.

If we are unable to create or maintain demand for our molecular diagnostic tests in sufficient volume or if we are unable to expand our product offerings, we may not become profitable. To generate demand, we will need to continue to educate physicians and the medical community on the value and benefits of our molecular diagnostic tests in order to change clinical practices through published papers, presentations at scientific conferences and one-on-one education by our internal sales force. In addition, our ability to obtain and maintain adequate reimbursement from third-party payers will be critical to generating revenue.

In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. Accordingly, physicians may be reluctant to order a diagnostic test that may suggest surgery is unnecessary. In addition, our assays are performed at our laboratories rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support our tests. In addition, guidelines for the diagnosis and treatment of thyroid nodules may change to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use our molecular diagnostic tests. These facts may make physicians reluctant to convert to using our assays, which could limit our ability to generate revenue and achieve profitability, which could have a material adverse effect on our business, financial condition and results of operations.

We may experience limits on our revenue if patients decide not to use our molecular diagnostic tests.

Some patients may decide not to use our molecular diagnostic tests due to price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. Many insurers seek to shift more of the cost of healthcare to patients in the form of higher deductibles, co-payments, or premiums. In addition, the economic environment in the United States may result in the loss of healthcare coverage. Implementation of provisions of PPACA (also known as the Affordable Care Act) provided coverage for patients, particularly in the individual market, who were previously either uninsured or faced high premiums. However, premiums for the plans participating in the exchanges established as part of this legislation have increased and some health plans have chosen to drop out of these networks in specific markers or the program altogether. These events may result in patients dropping coverage and therefore delaying or forgoing medical checkups or treatment due to their inability to pay for our test, which could have an adverse effect on our revenue. In addition, the President of the United States has announced that he favors repealing PPACA in 2017, and leaders of the Republican-controlled federal legislature also have expressed a desire to repeal PPACA. The scope and timing of any legislation to repeal, amend, replace, or reform PPACA is uncertain, but if such legislation were to become law, it could have a significant impact on the U.S. healthcare system and our revenues. We do have a Patient Assistance Program that allows eligible patients to apply for assistance in covering a portion of their out of pocket obligation or all costs for claims denied as non-covered if they meet the criteria for participation; however, there is no guarantee that this Program will be sufficient to influence patients to agree to have their physician order our molecular tests on their behalf.

If our products do not perform as expected, we may not be able to achieve widespread market adoption among physicians, which would cause our operating results, reputation, and business to suffer.

Our success depends on the market's confidence that we can provide reliable, high-quality molecular information products. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue, particularly for clinical samples, as our test volume increases. We believe that our customers are likely to be particularly sensitive to product defects and errors, including if our products fail to detect genomic alterations with high accuracy from clinical specimens or if we fail to list, or inaccurately include, certain treatment options and available clinical trials in our product reports. As a result, the failure of our products to perform as expected would significantly impair our operating results and our reputation. We may be subject to legal claims arising from any defects or errors.

If we lose the support of key thought leaders, it may be difficult to establish products enabled by our molecular information platform as a standard of care for patients with cancer, which may limit our revenue growth and ability to achieve profitability.

We have established relationships with leading oncology thought leaders at premier cancer institutions and oncology networks. If these key thought leaders determine that our molecular information platform, our existing products or other products that we develop are not clinically effective, that alternative technologies are more effective, or if they elect to use internally developed products, we would encounter significant difficulty validating our testing platform, driving adoption, or establishing our molecular information platform and tests as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our product development could be delayed.

We have limited experience in marketing and selling our products, and if we are unable to expand our direct sales and marketing force to adequately address our customer's needs, our business may be adversely affected.

Although we have been selling commercial products since 2014, genomic diagnostics is a new area of science, and we continue to focus and refine our efforts to sell, market and receive reimbursement for our products. We may not be able to market, sell, or distribute our existing products or other products we may develop effectively enough to support our planned growth.

Our future sales will depend in large part on our ability to develop, and substantially expand, our sales force and to increase the scope of our marketing efforts. Our target market of physicians is a large and diverse market. As a result, we believe it is necessary to develop a sales force that includes sales representatives with specific technical backgrounds. We will also need to attract and develop marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability.

Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance and our ability to commercialize our products and to compete effectively will depend in part on our ability to manage this potential future growth effectively, without compromising quality.

If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenues could be diminished. In addition, we have limited history selling our molecular diagnostics tests on a direct basis and our limited history makes forecasting difficult.

If our internal sales force is not successful, or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our molecular diagnostic tests. If we fail to establish our molecular diagnostic tests in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics products. Our ability to produce product quantities that meet customer demand is dependent upon our ability to forecast accurately and plan production accordingly.



Due to how we recognize revenue, our quarterly operating results are likely to fluctuate.

During 2017 and 2016 we recognized a significant portion of our revenue when the following four revenue recognition criteria are met: persuasive evidence of an arrangement exists; services have been rendered; the selling price is fixed or determinable; and collectability is reasonably assured. We have little visibility as to when we will receive payment for our molecular diagnostic tests, and we must appeal negative payment decisions, which delays collections. For molecular diagnostic tests performed where we have an agreed upon reimbursement rate or we are able to make a reasonable estimate of reimbursement at the time delivery is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to collect. We determined the amount we expect to collect based on a per payer, per contract or agreement basis. In situations where we are not able to make a reasonable estimate of receipt of third-party notification of payment or when cash is received. Upon ultimate collection, the amount received from Medicare and other payers where reimbursement was estimated is compared to previous estimates and the contractual allowance is adjusted accordingly.

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" (or "ASC 606"), and beginning January 1, 2018 and going forward, under this new accounting revenue standard, most revenues will be recognized on the accrual basis, for the most part based upon actual collection histories for our tests and respective payers or payer groups, where a commonality exists. These measurements will likely initially result in fluctuations in our quarterly revenue. As we recognize revenue from payers on an accrual basis and later determine the judgments underlying estimated reimbursement in fact change, or were incorrect at the time we accrued such revenue, our financial results could be negatively impacted in future quarters. As a result, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. In addition, these fluctuations in revenue may make it difficult in the near term for us, research analysts and investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below consensus expectations, the price of our common stock would likely decline.

We rely on sole suppliers for some of the materials used in our molecular diagnostic tests, and we may not be able to find replacements or transition to alternative suppliers in a timely manner.

We often rely on sole suppliers for certain materials that we use to perform our molecular diagnostic tests, including Asuragen for our endocrine cancer diagnostic tests pursuant to our supply agreement with them. We also purchase reagents used in our molecular diagnostic tests from sole-source suppliers. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available in a timely manner. If these suppliers can no longer provide us with the materials we need to perform our molecular diagnostic tests, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in molecular diagnostic test processing could occur. Any such interruption may directly impact our revenue and cause us to incur higher costs.

We may experience problems in scaling our operations, or delays or reagent and supply shortages that could limit the growth of our revenue.

If we encounter difficulties in scaling our operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, we will likely experience reduced sales of our molecular diagnostic tests, increased repair or re-engineering costs, and defects and increased expenses due to switching to alternate suppliers, any of which would reduce our revenues and gross margins.

Although we attempt to match our capabilities to estimates of marketplace demand, to the extent demand materially varies from our estimates, we may experience constraints in our operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Should our need for raw materials and reagents used in our molecular diagnostic tests fluctuate, we could incur additional costs associated with either expediting or postponing delivery of those materials or reagents.



If we are unable to support demand for our molecular diagnostic tests or any of our future tests or solutions, our business could suffer.

As demand for our molecular diagnostic tests grows, we will also need to continue to scale up our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our molecular diagnostic tests. We cannot assure you that increases in scale, related improvements and quality assurance will be implemented successfully or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations will not negatively affect the quality of test results. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer, causing a material adverse effect on our business, financial condition and results of operations.

If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

We compete with physicians and the medical community who use traditional methods to diagnose gastrointestinal, endocrine and lung cancers. In many cases, practice guidelines in the United States have recommended therapies or surgery to determine if a patient's condition is malignant or benign. As a result, we believe that we will need to continue to educate physicians and the medical community on the value and benefits of our tests in order to impact clinical practices. In addition, we face competition from other companies that offer diagnostic tests. Specifically, in regard to our thyroid diagnostic tests, Veracyte has thyroid nodule cancer diagnostic tests that compete with our ThyGenX[®] and ThyraMIR[®] tests, which are currently on the market. Quest currently offers a diagnostic test similar to the earlier version of our ThyGenX[®] test, and CBL is offering a diagnostic test that analyzes genetic alterations using next-generation sequencing. Other competitors for our thyroid assays include Rosetta Genomics, Accelerate Diagnostics, Inc., Cancer Genetics, Inc., Genomic Health Inc., NeoGenomics Inc. and Trovagene, Inc. While we do not believe we currently have significant direct competition for PancraGEN[®] in the gastrointestinal market, there is the potential for indirect competition as well as significant direct competition due to the limited penetration we currently have of this market.

It is also possible that we face future competition from LDTs developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, we may be subject to competition as a result of the new, unforeseen technologies that can be developed by our competitors in the gastrointestinal and endocrine cancer molecular diagnostic tests space.

To compete successfully, we must be able to demonstrate, among other things, that our test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our tests. Since our molecular diagnostics business began in 2014, many of our potential competitors have stronger brand recognition and greater financial capabilities than we do. Others may develop a test with a lower price than ours that could be viewed by physicians and payers as functionally equivalent to our molecular diagnostic tests or offer a test at prices designed to promote market penetration, which could force us to lower the price of our molecular diagnostic tests and affect our ability to achieve and maintain profitability. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance of our molecular diagnostic tests and overall sales, which could prevent us from increasing our revenue or achieving profitability and cause the market price of our common stock to decline. As we add new molecular diagnostic tests and other products and services, we will likely face many of these same competitive risks that we do currently.

Developing new molecular diagnostic tests and related services and solutions involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other assays under development.

Developing new molecular diagnostic tests and related services and solutions will require us to devote considerable resources to research and development. We may face challenges obtaining sufficient numbers of samples to validate a newly acquired or developed molecular diagnostic test. In order to develop and commercialize new molecular diagnostic tests, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale our laboratory processes to accommodate new molecular diagnostic tests; and
- build the commercial infrastructure to market and sell new molecular diagnostic tests.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a molecular diagnostic test or related services or solutions or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating revenue from such test. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity, we might choose to abandon the development of the molecular diagnostic test, which could harm our business. In addition, competitors may develop and commercialize new competing molecular diagnostic tests faster than us or at a lower cost, which could have a material adverse effect on our business, financial condition and results of operations.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of revenue and affect the margins on our solutions. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

Unfavorable results of legal proceedings could have a material adverse effect on our business, financial condition and results of operations.

We are and may become subject to various legal proceedings and claims that arise in or outside the ordinary course of business. The results of legal proceedings cannot be predicted with certainty. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that could have a material adverse effect on our business, financial condition and results of operations. In addition, there can be no assurance that our assumption of the liability for the Settlement Agreement with the Department of Justice entered into by the former owners of Redpath may not lead to greater exposure than we anticipated.



If we are unable to develop or acquire molecular diagnostic tests to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be affected.

Recently, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require us to continuously develop our technology and to work to develop new solutions to keep pace with evolving standards of care. Our solutions could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to develop or acquire new molecular diagnostic tests or to demonstrate the applicability of our molecular diagnostic tests for other diseases, our sales could decline and our competitive position could be harmed.

If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaboration with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Moreover, it may take longer to obtain the samples we need which could delay our trials, publications, and product launches and reimbursement. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for our diagnostic tests, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from them.

If a catastrophe strikes either of our laboratories or if either of our laboratories becomes inoperable for any other reason, we will be unable to perform our testing services and our business will be harmed.

The laboratories and equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. Either of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform our tests for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we maintain insurance for damage to our property and the disruption of our business, 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.

If the U.S. Food and Drug Administration were to begin to enforce regulation of our molecular diagnostic tests, we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

Clinical laboratory tests like our molecular diagnostic tests are regulated under CLIA as well as by applicable State laws. LDTs are currently subject to enforcement discretion by the FDA, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to other regulation. In October 2014, the FDA issued two draft guidance documents: "Framework for Regulatory Oversight of Laboratory Developed Tests," which provides an overview of how the FDA would regulate LDTs through a risk-based approach, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests", which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers will be subject to medical device registration, listing, and adverse event reporting requirements. LDT manufacturers will be required to either submit a pre-market application and receive the FDA's approval before an LDT may be marketed or submit a pre-market notification in advance of marketing. The Framework for Regulatory Oversight draft guidance states that within six months after the guidance documents are finalized, all laboratories will be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered.



On November 18, 2016, however, the FDA announced that it would not release final versions of these guidance documents and would instead continue to work with stakeholders, the new administration and Congress to determine the right approach. On January 13, 2017, the FDA released a discussion paper on LDTs outlining a possible risk-based approach for FDA and CMS oversight of LDTs. According to the 2017 discussion paper, previously marketed LDTs would not be expected to comply with most or all FDA oversight requirements (grandfathering), except for adverse event and malfunction reporting. In addition, certain new and significantly modified LDTs would not be expected to comply with pre-market review unless the agency determines certain tests could lead to patient harm. Since LDTs currently on the market would be grandfathered in, pre-market review of new and significantly modified LDTs could be phased-in over a four-year period, as opposed to the nine years proposed in the Framework for Regulatory Oversight draft guidance. In addition, tests introduced after the effective date, but before their phase-in date, could continue to be offered during pre-market review.

The discussion paper notes that FDA will focus on analytical and clinical validity as the basis for marketing authorization. The FDA anticipates laboratories that already conduct proper validation should not be expected to experience new costs for validating their tests to support marketing authorization and laboratories that conduct appropriate evaluations would not have to collect additional data to demonstrate analytical validity for FDA clearance or approval. The evidence of the analytical and clinical validity of all LDTs will be made publically available. LDTs are encouraged to submit prospective change protocols in their pre-market submission that outline specific types of anticipated changes, the procedures that will be followed to implement them and the criteria that will be met prior to implementation.

Despite the FDA decision not release the guidance at this time, it can choose to release the guidance at any time in the future. If the guidance is released and pre-market review is required, our business could be negatively impacted as a result of commercial delay that may be caused by the new requirements. The cost of conducting clinical trials and otherwise developing data and information to support premarket applications may be significant. If we are required to submit applications for our currently-marketed tests, we may be required to conduct additional studies, which may be time-consuming and costly and could result in our currently-marketed tests being withdrawn from the market. Continued compliance with the FDA's regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions. There are other regulatory and legislative proposals that would increase general FDA oversight of clinical laboratories and LDTs. The outcome and ultimate impact of such proposals on the business is difficult to predict at this time. We are monitoring developments and anticipate that our products will be able to comply with requirements that are ultimately imposed by the FDA. In the meantime, we maintain our CLIA accreditation, which permits the use of LDTs for diagnostics purposes.

If we fail to comply with Federal, State and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA regulations, a Federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific personnel qualifications, facilities administration, quality systems, inspections and proficiency testing. CLIA certification is also required in order for us to be eligible to bill Federal and State healthcare programs, as well as many private third-party payers, for our molecular diagnostic tests. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. We are also required to maintain State licenses to conduct testing in our New Haven, Connecticut and Pittsburgh, Pennsylvania laboratories. Connecticut and Pennsylvania laws require that we maintain a license, and establish standards for the day-to-day operation of our clinical reference laboratory in New Haven, Connecticut and Pittsburgh, Pennsylvania. In addition, our Pittsburgh and New Haven laboratories are required to be licensed on a test-specific basis by California, Florida, Maryland, New York and Rhode Island. California, Florida, Maryland, New York and Rhode Island laws also mandate proficiency testing for laboratories licensed under the laws of each respective State regardless of whether such laboratories are located in California, Florida, Maryland, New York or Rhode Island. In 2016, we received final approval for our ThyGenX[®] and ThyraMIR[®] assays in New York State. If we were unable to obtain or lose our CLIA certificate for our laboratories, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our current molecular diagnostic tests, which could have a material adverse effect on our business, financial condition and results of operations. If we were to lose our licenses issued by New York or by other States where we are required to hold licenses, we would not be able to test specimens from those States. New molecular diagnostic tests we may develop may be subject to new approvals by governmental bodies such as New York State, and we may not be able to offer our new molecular diagnostic tests to patients in such jurisdictions until such approvals are received.



Recent legislation reforming the U.S. healthcare system may have a material adverse effect on our financial condition and operations.

PPACA made changes that significantly affected the pharmaceutical, medical device and clinical laboratory industries. Since 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. The FDA's final guidance on LDTs may require our molecular diagnostic tests to be regulated as medical devices. However, consistent with the FDA's policy of exercising enforcement discretion for LDTs, our molecular diagnostic tests are not currently listed as medical devices with the FDA. In December 2015, the Consolidated Appropriations Act was adopted, which included a two-year moratorium on the medical device excise tax. The moratorium will end on January 1, 2020, and we cannot assure that the tax will not be extended to services such as ours in the future if our tests were to be regulated as devices.

Other significant measures contained in PPACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative effect on payment rates for services. The IPAB proposals could have affected payments for clinical laboratory services beginning in 2016 and may affect those for hospital services beginning in 2020. We are monitoring the effect of PPACA to determine the trends and any potential changes that may be necessitated by the legislation, any of which may potentially affect our business.

PPACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. At the same time, there have been significant ongoing efforts to modify or eliminate the PPACA. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the PPACA remain possible. It is unknown what form any such changes or any law proposed to replace the PPACA would take, and how or whether it may affect our business in the future.

Following the 2016 U.S. general election, a single party now leads the executive branch and holds majorities in both the U.S. Senate and House of Representatives. The President of the United States has announced that he favors repealing PPACA, and leaders of the Republication-controlled federal legislature also have expressed a desire to repeal PPACA. The scope and timing of any legislation to repeal, amend, replace, or reform PPACA is uncertain, but if such legislation were to become law, it could have a significant impact on the U.S. healthcare system.

On January 20, 2017, the new administration signed an executive order directing federal agencies to exercise existing authorities to reduce burdens associated with PPACA pending further action by Congress. On the same day, the White House issued a regulatory freeze memo under which rules and guidance published but not yet effective must be frozen for 60 days pending review; rules and guidance submitted for publication but not yet published must be withdrawn; and rules and guidance not yet submitted for publication must not be submitted without further direction from the Administration. Since then, further executive orders and statements from the White House and Congress have addressed potential regulatory changes that could affect us and our customers. Changes to, or repeal of, PPACA may continue to affect coverage, reimbursement, and utilization of laboratory services, as well as administrative requirements, in ways that are currently unpredictable.

In addition to PPACA, the effect of which cannot presently be fully quantified, various healthcare reform proposals have periodically emerged from Federal and State governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012, which reduced the clinical laboratory payment rates on the Medicare CLFS by 2% in 2013. In addition, a further reduction of 2% was implemented under the Budget Control Act of 2011, which is to be in effect for dates of service on or after April 1, 2013 until fiscal year 2024. Reductions resulting from the Congressional sequester are applied to total claim payments made; however, they do not currently result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates.

State legislation on reimbursement applies to Medicaid reimbursement and Managed Medicaid reimbursement rates within that State. Some States have passed or proposed legislation that would revise reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. For example, California's Department of Health Care Services implemented a new rate methodology for clinical laboratory services, effective July 2015, that involves the use of a range of rates that fell between zero and 80% of the calculated California Medicare rate and the calculation of a weighted average (based on units billed) of such rates.

We cannot predict whether future healthcare initiatives will be implemented at the Federal or State level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by Federal legislation, cost reduction measures and the expansion in the role of the U.S. government in the healthcare industry may result in decreased revenue, lower reimbursement by payers for our tests or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Ongoing calls for deficit reduction at the Federal government level and reforms to programs such as the Medicare program to pay for such reductions may affect the pharmaceutical, medical device and clinical laboratory industries. In particular, recommendations by the Simpson-Bowles Commission called for the combination of Medicare Part A (hospital insurance) and Part B (physician and ancillary service insurance) into a single co-insurance and co-payment structure. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Combining Parts A and B may require clinical laboratories to collect co-payments from patients, which may increase our costs and reduce the amount ultimately collected.

In 2013, CMS announced plans to bundle payments for clinical laboratory tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS exempted molecular diagnostic tests from this packaging provision at that time. It is possible that this exemption could be removed by CMS in future rule making, which might result in lower reimbursement for tests performed in this setting.

PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Laboratories that receive a majority of their Medicare revenues from payments made under the CLFS and the Physician Fee Schedule must report on triennial bases (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer rates and volumes for their tests with specific CPT codes based on final payments made during a set period of data collection (the first of which was January 1 through June 30, 2016).

In April 2014, the President signed PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. PAMA removed CMS's authority to adjust the CLFS based and established a new method for setting CLFS rates. Implementation of this new method for setting CLFS rates began in 2016. Under PAMA, laboratories that have more than \$12,500 in Medicare revenues from laboratory services and that receive more than 50 percent of their Medicare revenues from laboratory services would report private payer data from January 1, 2016 through June 30, 2016, to CMS between January 1, 2017 and March 31, 2017. CMS posted the new Medicare CLFS rates (based on weighted median private payer rates) in November 2017 and the new rates became effective beginning on January 1, 2018. Any reductions to payment rates resulting from the new methodology are limited to 10 % per test per year in each of the years 2020 through 2022. CMS has issued draft regulations regarding these changes. Further rule-making from CMS will define the time period and data elements evaluated on an annual basis to set reimbursement rates for tests like ours. Under the revised Medicare Clinical Laboratory Fee Schedule, reimbursement for clinical laboratory testing is scheduled to be reduced in 2018, 2019 and 2020, though the result of the 2018 calculations was an increase in our reimbursement rate for ThyGenX of approximately 40% for our Medicare volume. PAMA calls for further revisions of the Medicare Clinical Laboratory Fee Schedule for years after 2020, based on future surveys of market rates; further reductions in reimbursement may result from such revisions.

There have also been recent and substantial changes to the payment structure for physicians, including changes passed under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was signed into law on April 16, 2015. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-Based Modifier program and the Electronic Health Record Meaningful Use program), and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

In December 2016, Congress passed the 21st Century Cures Act, which, among other things, revised the process for Local Coverage Determinations (LCDs). CMS and the Medicare Administrative Contractors (MACs) are in the process of implementing these revisions and we cannot predict whether these revisions will delay coverage for our test products, which could have a material negative impact on revenue.

Complying with numerous statutes and regulations pertaining to our molecular diagnostics and bioinformatics business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are subject to regulation by both the Federal government and the governments of the states in which we conduct our molecular diagnostics and bioinformatics business, including:

- The Food, Drug and Cosmetic Act, as supplemented by various other statutes;
- The Prescription Drug Marketing Act of 1987, the amendments thereto, and the regulations promulgated thereunder and contained in 21 C.F.R. Parts 203 and 205;
- CLIA and State licensing requirements;
- Manufacturing and promotion laws;
- Medicare billing and payment regulations applicable to clinical laboratories;
- The Federal Anti-Kickback Statute (and state equivalents), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a Federal healthcare program;
- The Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health
 information and requirements for the use of certain standardized electronic transactions, and amendments made in
 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and
 expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement
 authority to state attorneys general, and impose requirements for breach notification;

- The Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- The Federal False Claims Act (and state equivalents), which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- Other Federal and State fraud and abuse laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;
- The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- The Protecting Access to Medicare Act of 2014, which requires us to report private payer rates and test volumes for specific CPT codes on a triennial basis and imposes penalties for failures to report, omissions, or misrepresentations;
- The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier; and
- State laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a State Medicaid program at a price that is higher than what is charged to other payers.

In recent years U.S. Attorneys' Offices have increased scrutiny of the healthcare industry, as have Congress, the Department of Justice, the Department of Health and Human Services' Office of the Inspector General and the Department of Defense. These bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies based on financial arrangements with health care providers, regulatory compliance, product promotional practices and documentation, and coding and billing practices. Whistleblowers have filed numerous qui tam lawsuits against healthcare companies under the federal and state False Claims Acts in recent years, in part because the whistleblower can receive a portion of the government's recovery under such suits.

We have implemented policies and procedures designed to comply with applicable laws and regulations. We periodically conduct internal reviews of our compliance with these laws. Our compliance with some of these laws and regulations is also subject to governmental review. The growth of our business may increase the potential of violating these laws, regulations or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Violations of Federal or State regulations may incur investigation or enforcement action by the FDA, Department of Justice, State agencies, or other legal authorities, and may result in substantial civil, criminal, or other sanctions. Any action brought against us for violation of these or other laws and 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 civil and criminal penalties, damages and fines, we could be required to refund payments received by us, we could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs and we could even be required to cease our operations. Any of the foregoing consequences could have a material adverse effect on our business, financial condition and results of operations.



A failure to comply with Federal and State laws and regulations pertaining to our payment practices could result in substantial penalties.

We retain healthcare practitioners as key opinion leaders providing consultation in various aspects of our business. These arrangements, like any arrangement that includes compensation to a healthcare provider, may trigger Federal or State anti-kickback and Stark Law liability. Our arrangements are designed to meet available safe harbors and exceptions provided in the anti-kickback laws and Stark Laws, respectively. However, there are no guarantees that the Federal or State governments will find that these arrangements are designed properly or that they do not trigger liability under Federal and State laws. Under existing laws, all arrangements must have a legitimate purpose and compensation must be fair market value. These terms require some subjective analysis and there is limited available case law or guidance for the application of these laws to the CLIA laboratory industry. Safe harbors in the anti-kickback laws do not necessarily equate to exceptions in the Stark Law, and there is no guarantee that the government will agree with our payment practices with respect to the relationships between our laboratories and the healthcare providers. A failure to comply with Federal and State laws and regulations pertaining to our payment practices could result in substantial penalties and adversely affect our business, financial condition and results of operations.

International expansion of our business exposes us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

We currently have no international operations, but our business strategy may in the future include plans for international expansion. Doing business internationally involves a number of risks, including:

- multiple, conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent);
- testing of genetic material and reporting the results of such testing and other governmental approvals, permits, and licenses, or government delays in issuing such approvals, permits, and licenses;
- failure by us to obtain regulatory approvals for the manufacture, sale, and use of our products in various countries;
- additional, potentially relevant third-party intellectual property rights;
- complexities and difficulties in obtaining protection for and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with obtaining reimbursement from and managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- logistics and regulations associated with preparing, shipping, importing and exporting tissue samples, including infrastructure conditions, transportation delays, and customs;
- limits in our ability to penetrate international markets if we are not able to perform our molecular tests locally;
- financial risks, such as the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, including its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. The difference in regulations under U.S. law and the laws of foreign countries may be significant and, in order to comply with the laws of foreign countries, we may have to implement global changes to our products or business practices. Such changes may result in additional expense to us and either reduce or delay product development, commercialization or sales. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations countries.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our products, as well as by inter-governmental disputes. Any of these changes could adversely affect our business.

Our success internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.

These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws, any changes in these laws, or the interpretation.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

The TCJA reduces the U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the TCJA, we revalued deferred tax assets, net as of December 31, 2017. The tax impact of revaluation of the deferred tax assets, net was \$22,768,303, which was wholly offset by a corresponding reduction in our valuation allowance of \$22,768,303 resulting in a no net impact to our income tax expense.

The TCJA provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits. The Company did not have consolidated accumulated earnings and profits attributable to it foreign subsidiaries, accordingly, the Company did not record any income tax expense related to the transition tax.

Due to the timing of the new tax law and the substantial changes it brings, the staff of the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

U. S. generally accepted accounting principles ("GAAP") is subject to interpretation by the FASB, the Securities and Exchange Commission ("SEC"), and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, the FASB and the International Accounting Standards Board are working to converge certain accounting principles and facilitate more comparable financial reporting between companies that are required to follow U.S. GAAP and those that are required to follow International Financial Reporting Standards, or IFRS. In connection with these initiatives, the FASB issued new accounting standards for revenue recognition that replace most existing revenue recognition guidance. We have completed our assessment of the new accounting position or results of operations. The impact of the convergence of U.S. GAAP and IFRS, if any, on our financial statements is uncertain and may not be known until additional rules are proposed and adopted, which may or may not occur. Our financial statements are subject to change and if our estimates or judgments relating to our critical accounting policies prove to be incorrect, our operating results could be adversely affected.

If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.

We are subject to Federal, State and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could have a significant impact on our operating results.

Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

Our business requires that we and our third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about patients, credit card information, and our proprietary business and financial information. We face a number of risks relative to our protection of, and our service providers' protection of, this critical information, including loss of access, fraudulent modifications, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information are 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 may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. If such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, modified without our knowledge, lost or stolen. Unauthorized access, loss, modification or dissemination could disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our solution 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. In addition, the interpretation and application of consumer, health-related and data protection laws in the United States 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. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of our molecular diagnostic tests could lead to product liability claims if someone were to allege that the molecular diagnostic test failed to perform as it was designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot be certain that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

We may need to increase the size of our organization, and we may experience difficulties in managing this growth.

We are a small company with approximately 75 employees. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress and growth of our business. Our future financial performance and our ability to sell our existing molecular diagnostic tests and develop and commercialize new molecular diagnostic tests and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our clinical studies effectively;
- integrate additional management, administrative, manufacturing and regulatory personnel;
- · maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results. We may need to reduce the size of our organization in order to become profitable and we may experience difficulties in managing these reductions.

Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid for our molecular diagnostic tests.

Billing for clinical laboratory testing services is complex, time consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, including Medicare, insurance companies and patients, all of which have different billing requirements. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including write-offs of doubtful accounts and long collection cycles, which could have a material adverse effect on our business, results of operations and financial condition. Among others, the following factors make the billing process complex:

- differences between the list price for our molecular diagnostic tests and the reimbursement rates of payers;
- compliance with complex Federal and State regulations related to billing Medicare;
- disputes among payers as to which party is responsible for payment;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As we grow and introduce new tests and other services, we will likely need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our revenue and cash flow. Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees or contractors, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. These billing complexities, and the related uncertainty in obtaining payment for our diagnostic solution, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on a third-party to process and transmit claims to payers, and any delay in either could have an adverse effect on our revenue.

We rely on Quadax, Inc., a third-party provider to provide overall processing of claims and to transmit the actual claims to payers based on the specific payer billing format. If claims for our molecular diagnostic tests are not submitted to payers on a timely basis, or if we are required to switch to a different provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payers, which could have a material adverse effect on our business, financial condition and results of operations.

Enacted healthcare reform legislation may increase our costs, impair our ability to adjust our pricing to match any such increased costs, and therefore could materially and adversely affect our business, financial condition and results of operations.

Our current position is that we do not meet the definition of an "Applicable Manufacturer" under the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act) and are therefore not subject to the disclosure or tax requirements contained in PPACA. If the government were to reach a different conclusion, our failure to disclose could result in significant monetary penalties and potential claims from certain third parties.

PPACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products. At the same time, there have been significant ongoing efforts to modify or eliminate the PPACA. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017 repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. The Joint Committee on Taxation estimates that the repeal will result in over 13 million Americans losing their health insurance coverage over the next ten years and is likely to lead to increases in insurance premiums. Further legislative changes to and regulatory changes under the PPACA remain possible. It is unknown what form any such changes or any law proposed to replace the PPACA would take, and how or whether it may affect our business in the future.

Changes in governmental regulation could negatively impact our business operations and increase our costs.

The pharmaceutical, biotechnology and healthcare industries are subject to a high degree of governmental regulation. Significant changes in these regulations affecting our business could result in the imposition of additional restrictions on our business, additional costs to us in providing our molecular diagnostic tests to our customers or otherwise negatively impact our business operations. Changes in governmental regulations mandating price controls and limitations on patient access to our products could also reduce, eliminate or otherwise negatively impact our sales.

If we do not increase our revenues and successfully manage the size of our operations, our business, financial condition and results of operations could be materially and adversely affected.

The majority of our operating expenses are personnel-related costs such as employee compensation and benefits, reagents and disposable supplies as well as the cost of infrastructure to support our operations, including facility space and equipment. We continuously review our personnel to determine whether we are fully utilizing their services. If we believe we are not in a position to fully utilize our personnel, we may make reductions to our workforce. If we are unable to achieve revenue growth in the future or fail to adjust our cost infrastructure to the appropriate level to support our revenues, our business, financial condition and results of operations could be materially and adversely affected.



We may acquire businesses or assets or make investments in other companies or molecular diagnostic technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our strategy, we may pursue acquisitions of synergistic businesses or other related assets. If we make any further acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisition by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results and financial condition. Integration of an acquired company or business will also likely require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition. To finance any acquisitions or investments, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. If these funds are raised through the sale of equity or convertible debt securities, dilution to our stockholders could result. Consummating an acquisition poses a number of risks including:

- we may not be able to accurately estimate the financial impact of an acquisition on our overall business;
- an acquisition may require us to incur debt or other obligations, incur large and immediate write-offs, issue capital stock potentially dilutive to our stockholders or spend significant cash, or may negatively affect our operating results and financial condition;
- if we spend significant funds or incur additional debt or other obligations, our ability to obtain financing for working capital or other purposes could decline;
- worse than expected performance of an acquired business may result in the impairment of intangible assets;
- we may be unable to realize the anticipated benefits and synergies from acquisitions as a result of inherent risks and uncertainties, including difficulties integrating acquired businesses or retaining key personnel, partners, customers or other key relationships, and risks that acquired entities may not operate profitably or that acquisitions may not result in improved operating performance;
- we may fail to successfully manage relationships with customers, distributors and suppliers;
- our customers may not accept new molecular diagnostic tests from our acquired businesses;
- we may fail to effectively coordinate sales and marketing efforts of our acquired businesses;
- we may fail to combine product offerings and product lines of our acquired businesses timely and efficiently;
- an acquisition may involve unexpected costs or liabilities, including as a result of pending and future shareholder lawsuits relating to acquisitions or exercise by stockholders of their statutory appraisal rights, or the effects of purchase accounting may be different from our expectations;
- an acquisition may involve significant contingent payments that may adversely affect our future liquidity or capital resources;
- accounting for contingent payments requires significant judgment and changes to the assumptions used in determining the fair value of our contingent payments could lead to significant volatility in earnings;
- acquisitions and subsequent integration of these companies may disrupt our business and distract our management from other responsibilities; and
- the costs of an unsuccessful acquisition may adversely affect our financial performance.

Additional risks of integration of an acquired business include:

- differing information technology, internal control, financial reporting and record-keeping systems;
- differences in accounting policies and procedures;
- unanticipated additional transaction and integration-related costs;
- facilities or operations of acquired businesses in remote locations and the inherent risks of operating in unfamiliar legal and regulatory environments; and
- new products, including the risk that any underlying intellectual property associated with such products may not have been adequately protected or that such products may infringe on the proprietary rights of others.

If our information technology and communications systems fail or we experience a significant interruption in their operation, our reputation, business and results of operations could be materially and adversely affected.

The efficient operation of our business is dependent on our information technology and communications systems. Increasingly, we are also dependent upon our ability to electronically interface with our customers. The failure of these systems to operate as anticipated could disrupt our business and result in decreased revenue and increased overhead costs. In addition, we do not have complete redundancy for all of our systems and our disaster recovery planning cannot account for all eventualities. Our information technology and communications systems, including the information technology systems and services that are maintained by third party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, malicious attacks by computer viruses or hackers, power loss or failure of computer systems, Internet, telecommunications or data networks. In 2017, the Company discovered malware installed on certain servers. The Company believes that the malware was intended to steal processing power and was not intended to obtain Company data. The Company does not believe that any data on the affected servers was accessed or comprised. The Company removed the malware, and has enhanced its cybersecurity procedures. Additionally, our core business is largely dependent on our partially internally developed and

Company does not believe that any data on the affected servers was accessed or comprised. The Company removed the malware, and has enhanced its cybersecurity procedures. Additionally, our core business is largely dependent on our partially internally developed and partially purchased Laboratory Information Management System of LIMS. If these systems or services become unavailable or suffer a security breach, or are uneconomical or impossible to update and modify, we may expend significant resources to address these problems, and our reputation, business and results of operations could be materially and adversely affected.

We have and may continue to experience intangible asset impairment charges.

We are required to evaluate the carrying value of intangibles at least annually, and between annual tests if events or circumstances warrant such a test. We review the recoverability of long-lived assets and finite-lived intangible assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized by reducing the recorded value of the asset to its fair value measured by future discounted cash flows. This analysis requires estimates of the amount and timing of projected cash flows and, where applicable, judgments associated with, among other factors, the appropriate discount rate. Such estimates are critical in determining whether any impairment charge should be recorded and the amount of such charge if an impairment loss is deemed to be necessary. Writing down or reserving for other intangible assets or impairments would have a negative and unexpected impact on our net worth and could, among other things, affect our ability to maintain our NASDAQ listing on a longer term basis.

RISKS RELATING TO THE ASSET SALE

The Asset Purchase Agreement relating to the sale of our CSO business exposes us to contingent liabilities that could have a material adverse effect on our financial condition.

We have agreed to indemnify Publicis, the purchaser of assets of our CSO business, for damages resulting from or arising out of any inaccuracy or breach of any representation, warranty or covenant of ours in the Asset Purchase Agreement against any and all liabilities of ours not assumed by Publicis in the Asset Sale and for certain other matters. Significant indemnification claims by Publicis could have a material adverse effect on our financial condition. We will not be obligated to indemnify Publicis for any breach of certain of the representations and warranties by us under the Asset Purchase Agreement until the aggregate amount of claims for indemnification exceed \$250,000. In the event that claims for indemnification exceed this threshold, we will be obligated to indemnify Publicis to us. Claims for indemnification for breaches of covenants made by us under the Asset Purchase Agreement and for breaches of representations and warranties classified as fundamental representations or any provision of the Asset Purchase Agreement relating to taxes will not be subject to the deductible or aggregate liability cap described above. The Asset Purchase Agreement also allows Publicis to withhold monies due against an earn-out payment if indemnification claims are asserted. In addition, under the Asset Purchase Agreement, we will retain all of our debts and liabilities not assumed by Publicis.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

If we breach the Asuragen License Agreement or the CPRIT License Agreement, it could have a material adverse effect on our sales and commercialization efforts for miR*Inform*® thyroid and pancreas cancer diagnostic tests and other tests in development for thyroid cancer, and the sale of diagnostic devices and the performance of certain services relating to thyroid cancer.

We currently license certain patents and know-how from Asuragen relating to (i) miR Inform[®] thyroid and pancreas cancer diagnostic tests and other tests in development for thyroid cancer, or the Asuragen License Agreement, and (ii) the sale of diagnostic devices and the performance of certain services relating to thyroid cancer, or the CPRIT License Agreement. Under the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of the miRInform[®] pancreas platform for a period of ten years following a qualifying sale, on the future net sales of the miRInform[®] thyroid platform through August 13, 2024 and on certain other thyroid diagnostics tests for a period of ten years following a qualifying sale. Under the CPRIT License Agreement, we are obligated to pay 5% of net sales on sales of certain diagnostic devices and the performance of services relating to thyroid cancer that incorporate technology developed and funded under an agreement between Asuragen and the Cancer Prevention and Research Institute of Texas, subject to a maximum deduction of 1.5% for royalties paid to third parties. Both of the Asuragen License Agreement and the CPRIT License Agreement continue until terminated by (i) mutual agreement of the parties or (ii) either party in the event of a material breach of the respective agreement by the other party. If we materially breach or fail to perform any provision under the CPRIT License Agreement, Asuragen will have the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed patent rights would end. To the extent such licensed patent rights relate to our molecular diagnostic tests currently on the market, we would expect to exercise all rights and remedies available to us, including attempting to cure any breach by us, and otherwise seek to preserve our rights under the patent rights and other technology licensed to us, but we may not be able to do so in a timely manner, at an acceptable cost to us or at all. Any uncured, material breach under these license agreements could result in our loss of rights to practice the patent rights licensed to us under these license agreements, and to the extent such patent rights and other technology relate to our molecular diagnostic tests currently on the market, it could have a material adverse effect on our sales and commercialization efforts for miRInform® thyroid and pancreas cancer molecular diagnostic tests and other tests in development for thyroid cancer, and the sale of molecular diagnostic tests and the performance of certain services relating to thyroid cancer.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technology. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. While we apply for patents on important products and technologies and uses thereof, we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in relevant jurisdictions. Others could seek to design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent is invalid. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, competitors could willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that arguably fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business and the results of our operations. To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our overall business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.



Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our molecular diagnostic tests.

As is the case with other molecular diagnostics companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents of molecular diagnostics tests, like our molecular diagnostic tests in our PancraGEN[®] and miR*Inform*[®] platforms, involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. From time-to-time the U.S. Supreme Court, other Federal courts, the U.S. Congress or the United States Patent and Trademark Office, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. The U.S. Supreme Court later reversed that decision in Bilski v. Kappos, finding that the "machine-or-transformation" test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. On March 30, 2012, in the case Mavo Collaborative Services v. Prometheus Laboratories, Inc., the U.S. Supreme Court reversed the Federal Circuit's application of Bilski and invalidated a patent focused on a process for identifying a proper dosage for an existing therapeutic because the patent claim embodied a law of nature. On July 30, 2012, the USPTO released a memorandum entitled "2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature," with guidelines for determining patentability of diagnostic or other processes in line with the Mayo decision. On June 13, 2013, in Association for Molecular Pathology v. Myriad Genetics, the Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. The Supreme Court did not address the patentability of any innovative method claims involving the manipulation of isolated genes. On March 4, 2014, the USPTO released a memorandum entitled "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products." This memorandum provides guidelines for the USPTO's new examination procedure for subject matter eligibility under 35 U.S.C. §101 for claims embracing natural products or natural principles. On June 12, 2015, the Federal Circuit issued a decision in Ariosa v. Sequenom holding that a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female were unpatentable as directed to a naturally occurring phenomenon. On July 30, 2015, the USPTO released a Federal Register Notice entitled, "July 2015 Update on Subject Matter Eligibility," This Notice updated the USPTO guidelines for the USPTO's procedure for subject matter eligibility under 35 U.S.C. §101 for claims embracing natural products or natural principles phenomenon. On May 4, 2016, the USPTO released life science examples that were intended to be used in conjunction with the USPTO guidance on subject matter eligibility. Although the guidelines and examples do not have the force of law, patent examiners have been instructed to follow them. What constitutes a law of nature and a sufficient inventive concept remains uncertain, and it is possible that certain aspects of molecular diagnostics tests would be considered natural laws and, therefore, ineligible for patent protection. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending or issued claims will be patentable or upheld as valid as a result of such evolving standards. In addition, patents we own or license that issued before these recent cases may be subject to challenge in court or before the USPTO in view of these current legal standards. Accordingly, the evolving interpretation and application of patent laws in the United States governing the eligibility of diagnostics for patent protection may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. Changes in either the patent laws or in interpretations and application of patent laws may also diminish the value of our existing intellectual property or intellectual property that we continue to develop. We cannot predict the breadth of claims that may be allowed or enforceable in our patents or in third-party patents.



We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time and some of these claims may lead to litigation. We cannot assume that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. No assurance can be given that other patent applications will not have priority over our patent applications. If third parties bring these proceedings against our patents, we could incur significant costs and experience management distraction. Litigation may be necessary for us to enforce our patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, financial condition and operating results.

In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling our products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could have a material adverse effect on our business, financial condition, and results of operations.

RISKS RELATED TO BEING A PUBLIC COMPANY

We will continue to incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we will continue to incur significant legal, accounting, consulting and other expenses, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC, and The NASDAQ Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, these rules and regulations have and will continue to increase our legal, accounting and financial compliance costs and make some activities more complex, time-consuming and costly. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance.

RISKS RELATING TO OUR CORPORATE STRUCTURE AND OUR COMMON STOCK

If we do not meet certain of NASDAQ continued listing requirements and therefore, we risk delisting, which may decrease our stock price and make it harder for our stockholders to trade our stock.

Our common stock is currently listed for trading on NASDAQ under the symbol "IDXG." NASDAQ has adopted a number of listing standards that are applicable to our common stock for continued listing on NASDAQ. If we do not meet certain NASDAQ continued listing requirements we risk the possibility of delisting of our securities. Delisting would have an adverse effect on the price of our common stock and likely also on our business. Additionally, our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock was delisted from NASDAQ or if we are unable to transfer our listing to another U.S. national securities exchange. In order to retain our listing on NASDAQ, we are required by NASDAQ to maintain a minimum bid price of \$1.00 per share. In the event that our stock closes below the minimum bid price of \$1.00 per share for any 30 consecutive business days, we would not be incompliance with NASDAQ's continued listing requirements and our stock could be delisted from NASDAQ.



In the event our stock is delisted there can be no assurance that we will be able to regain or maintain compliance with the NASDAQ continued listing requirements, or that our common stock will not be delisted from NASDAQ in the future. If our common stock is delisted by NASDAQ, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

If our common stock is delisted by NASDAQ in the future, our common stock may be eligible to trade on the OTC Bulletin Board, OTC QB or another over-the-counter market. Any such alternative would likely result in it being more difficult for us to raise additional capital through the public or private sale of equity securities and for investors to dispose of or obtain accurate quotations as to the market value of, our common stock. In addition, there can be no assurance that our common stock would be eligible for trading on any such alternative exchange or markets. For these reasons and others, delisting could adversely affect the price of our securities and our business, financial condition and results of operations.

We have a substantial number of authorized common and preferred shares available for future issuance that could cause dilution of our stockholders' interest, adversely impact the rights of holders of our common stock and cause our stock price to decline.

We have a total of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock authorized for issuance. As of March 1, 2018 we had 72,122,006 shares of common stock and 5,000,000 shares of preferred stock available for issuance and we have reserved 1,629,077 shares of our common stock for issuance upon the exercise of outstanding awards under our stock incentive plan, 2,976,438 additional shares available for future grants of awards under our stock incentive plan as well as warrants for 13,542,148 shares of our common stock outstanding at prices ranging from a \$1.25 to \$4.69 per warrant share. We may seek financing that could result in the issuance of additional shares of our capital stock and/or rights to acquire additional shares of our capital stock. We may also make acquisitions that result in issuances of additional shares of our capital stock. Those additional issuances of capital stock could result in substantial dilution of our existing stockholders. Furthermore, the book value per share of our common stock may be reduced. This reduction would occur if the exercise price of any issued warrants, the conversion price of any convertible notes or the conversion ratio of any issued preferred stock is lower than the book value per share of our common stock at the time of such exercise or conversion. Additionally, new investors in any subsequent issuances of our securities could gain rights, preferences and privileges senior to those of holders of common stock.

Any weakness in our disclosure controls and procedures and our internal controls could have a material adverse effect on us

During 2016, management identified material weaknesses in our disclosure controls and procedures, which were subsequently remedied in 2017; however, we cannot assure you that additional material weaknesses will not be identified in the future. Any such failure could adversely affect our ability to report financial results on a timely and accurate basis, which could have other material effects on our business, reputation, results of operations, financial condition or liquidity. Potential material weaknesses in internal controls over financial reporting or disclosure controls and procedures could also cause investors to lose confidence in our reported financial information which could have an adverse effect on the trading price of our securities.



We have anti-takeover defenses that could delay or prevent an acquisition and could adversely affect the price of our common stock.

Our certificate of incorporation, as amended, and amended and restated bylaws include provisions, such as providing for three classes of directors, which may make it more difficult to remove our directors and management and may adversely affect the price of our common stock. In addition, our certificate of incorporation, as amended, authorizes the issuance of "blank check" preferred stock, which allows our Board to create one or more classes of preferred stock with rights and preferences greater than those afforded to the holders of our common stock. This provision could have the effect of delaying, deterring or preventing a future takeover or a change in control, unless the takeover or change in control is approved by our Board. We are also subject to laws that may have a similar effect. For example, Section 203 of the General Corporation Law of the State of Delaware prohibits us from engaging in a business combination with an interested stockholder for a period of three years from the date the person became an interested stockholder unless certain conditions are met. As a result of the foregoing, it will be difficult for another company to acquire us and, therefore, could limit the price that possible investors might be willing to pay in the future for shares of our common stock. In addition, the rights of our common stockholders will be subject to, and may be adversely affected by, the rights of holders of any class or series of preferred stock that may be issued in the future and in this offering.

We have not declared any cash dividends on our capital stock and do not intend to declare or pay any cash dividends in the foreseeable future. Future earnings, if any, will be used to finance the future operation and growth of our business. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on our capital stock. We do not currently anticipate paying cash dividends on our common stock in the foreseeable future and we may not have sufficient funds legally available to pay dividends. Even if the funds are legally available for distribution, we may nevertheless decide not to pay any dividends. We presently intend to retain all earnings for our operations. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our quarterly and annual revenues and operating results may vary, which may cause the price of our common stock to fluctuate.

Our quarterly and annual operating results may vary as a result of a number of factors, including:

- the commencement, delay, cancellation or completion of sales and marketing programs;
- regulatory developments;
- uncertainty about the realizable value of sales of our tests;
- timing and amount of expenses for implementing new programs and accuracy of estimates of resources required for ongoing programs;
- adoption of and coverage and reimbursement for our tests;
- timing and integration of any acquisitions; and
- changes in regulations related to diagnostics, pharmaceutical, biotechnology and healthcare companies.

We believe that quarterly, and in certain instances annual, comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of future performance especially with our adoption of ASC 606 effective beginning January 1, 2018 related to how we accrue revenues going forward. Fluctuations in quarterly and annual results could materially and adversely affect the market price of our common stock in a manner unrelated to our long-term operating performance.

Our stock price is volatile and could be further affected by events not within our control, and an investment in our common stock could suffer a decline in value.

During 2017, our common stock traded at a low of \$0.72 and a high of \$14.25. During 2016, our common stock traded at a low of \$0.70 and a high of \$19.80. The trading price of our common stock has been and could continue to be subject to:

- general volatility in the trading markets;
- significant fluctuations in our quarterly operating results;
- significant changes in our cash and cash equivalent reserves;
- announcements regarding our business or the business of our competitors;
- announcements regarding our equity offerings;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- industry and/or regulatory developments;
- changes in revenue mix;
- changes in revenue and revenue growth rates for us and for the industries in which we operate;
- changes in accounting standards, policies, guidance, interpretations or principles; and
- statements or changes in opinions, ratings or earnings estimates made by brokerage firms or industry analysts relating to the markets in which we operate or expect to operate.

The prices of our common stock listed above have been adjusted to reflect a one-for-ten reverse split on our issued and outstanding shares of common stock effected on December 28, 2016.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

The indemnification rights provided to our directors, officers and employees may result in substantial expenditures by us and may discourage lawsuits against its directors, officers, and employees.

Our certificate of incorporation, as amended, contains provisions permitting us to enter into indemnification agreements with our directors, officers, and employees. The foregoing indemnification obligations could result in us incurring substantial expenditures to cover the cost of settlement or damage awards against directors and officers, which we may be unable to recoup. These provisions and resultant costs may also discourage us from bringing a lawsuit against our directors and officers for breaches of their fiduciary duties and may similarly discourage the filing of derivative litigation by our stockholders against our directors and officers even though such actions, if successful, might otherwise benefit us and our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Parsippany, New Jersey where we lease approximately 6,000 square feet. The lease runs through September 2022. Our laboratory facilities are located in Pittsburgh, Pennsylvania and New Haven, Connecticut, where we lease a total of approximately 21,400 square feet combined. On March 15, 2018 we agreed to an extension of our Pittsburgh, Pennsylvania lease for an additional five years through June 30, 2023. Our New Haven, Connecticut lease is month-to-month.

Accordingly, we believe that our current facilities are adequate for our current and foreseeable operations and that suitable additional space will be available if needed.

ITEM 3. LEGAL PROCEEDINGS

General

We are currently a party to legal proceedings that are incidental to our business. As required, we have accrued our estimate of the probable costs for the resolution of these claims. While management currently believes that the ultimate outcome of these proceedings, individually and in the aggregate, will not have a material adverse effect on our business, financial condition, results of operations or cash flow, litigation is subject to inherent uncertainties. Were we to settle a proceeding for a material amount or were an unfavorable ruling to occur, there exists the possibility of a material adverse impact on our business, financial condition, results of operations or cash flows. To the extent there is a reasonable possibility that the losses could exceed the amounts already accrued, we will, as applicable, adjust the accrual in the period the determination is made, disclose an estimate of the additional loss or range of loss, indicate that the estimate is immaterial with respect to its financial statements as a whole or, if the amount of such adjustment cannot be reasonably estimated, disclose that an estimate cannot be made. As of December 31, 2017, our accrual for litigation and threatened litigation was not material to the consolidated financial statements. Legal fees are expensed as incurred.

Prolias Technologies, Inc. v. PDI, Inc.

On April 8, 2015, Prolias Technologies, Inc. ("Prolias") filed a complaint (the "Complaint") against the Company with the Superior Court of New Jersey (Morris County) (the "Court") in a matter entitled Prolias Technologies, Inc. v. PDI, Inc. (Docket No. MRS-L-899-15). In the Complaint, Prolias alleged that it and the Company entered into an August 19, 2013 Collaboration Agreement and a First Amendment thereto (collectively, the "Agreement") whereby Prolias and the Company agreed to work in good faith to commercialize a diagnostic test known as "Thymira." Prolias alleged in the Complaint that the Company wrongfully terminated the Agreement; breached obligations owed to it and committed torts. On March 9, 2017, the Court entered a final judgment in the Company's favor against Prolias for the sum of \$636,053 plus ten percent interest continuing to accrue on the principal balance of \$500,000 (per diem \$136.99) unless and until paid. Final judgment was also entered in the Company's favor, and against Prolias, declaring Prolias is deemed to have executed and delivered to the Company a promissory note in the amount of \$1,000,000 and Prolias is obligated to repay the Company the principal amount and all interest in accordance with the terms of the promissory note and Article 10.2(a) of the Collaboration Agreement by and between Prolias and the Company. On April 3, 2017, the final judgment against Prolias was recorded as a statewide lien. No assurance, however, can be given that the Company will ever be able to recover on the judgment against Prolias.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR OUR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on NASDAQ under the ticker symbol "IDXG." On December 28, 2016, we effected a one-for-ten reverse split of our issued and outstanding shares of our common stock. At the effective time of the reverse split, every 10 shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock, without any change in the par value per share. Our common stock began trading on NASDAQ on a reverse stock split-adjusted basis on December 29, 2016. There was no change in our ticker symbol as a result of the reverse stock split.

The price range per share of common stock presented below represents the high and low trading price for our common stock on NASDAQ for the last two years by quarter. The market prices below give retroactive effect to the one-for-ten reverse split of our issued and outstanding shares of common stock effected on December 28, 2016.

	 2017			2016			
	 HIGH		LOW		HIGH		LOW
First quarter	\$ 14.25	\$	2.10	\$	4.80	\$	1.90
Second quarter	\$ 4.45	\$	0.80	\$	6.40	\$	2.20
Third quarter	\$ 1.77	\$	0.72	\$	5.10	\$	1.50
Fourth quarter	\$ 1.80	\$	0.90	\$	19.80	\$	0.70

Holders of Record

We had 175 stockholders of record as of February 28, 2018. Not reflected in the number of stockholders of record are persons who beneficially own shares of common stock held in nominee or street name.

Dividends

We have not declared any cash dividends and do not intend to declare or pay any cash dividends in the foreseeable future. Future earnings, if any, will be used to finance the future operation and growth of our businesses.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a "smaller reporting company" for purposes of the disclosure requirements of Item 301 of Regulation S-K and, therefore, we are not required to provide this information.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. *This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the Risk Factors section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements. See Cautionary Note Regarding Forward-Looking Information at the beginning of this Form 10-K.*

COMPANY OVERVIEW

We are a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services. We develop and commercialize molecular diagnostic tests and related first line assays principally focused on early detection of patients at high risk of cancer and leverage the latest technology and personalized medicine for improved patient diagnosis and management. We currently have four commercialized molecular diagnostic assays in the marketplace for which we are reimbursed by Medicare and multiple private payers: PancraGEN[®], which is a pancreatic cyst and pancreaticobiliary solid lesion molecular test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform; ThyGenX[®], which is an oncogenic mutation panel that helps identify malignant thyroid nodules; and ThyraMIR[®], which assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay. We also launched in September 2017 RespriDXTM for assessing metastatic versus primary lung cancer tumors. RespriDXTM utilizes our PathFinderTG[®] platform and compares the genetic fingerprint of two or more sites of lung cancer to determine whether the neoplastic deposits are representative of a recurrence of cancer or a new primary (independent) cancer. We are also in the process of "soft launching" while we gather additional market data, BarreGEN[®], an esophageal cancer risk classifier for Barrett's Esophagus that also utilizes our PathFinderTG[®] platform.

Our mission is to provide personalized information through molecular diagnostics and innovation to advance patient care based on rigorous science. We are leveraging our Clinical Laboratory Improvement Amendments ("CLIA") and College of American Pathologists ("CAP"), accredited laboratories to develop and commercialize our assays and products. We aim to provide physicians and patients with diagnostic options for detecting genetic and other molecular mutations that are associated with gastrointestinal and endocrine cancer. Our customers consist primarily of physicians, hospitals and clinics.

The global molecular diagnostics market is estimated to be \$6.45 billion and is a segment within the approximately \$60 billion in vitro diagnostics market according to statistics from Kalorama Information, publisher of the *Worldwide Market for In Vitro Diagnostic Tests*. We believe that the molecular diagnostics market offers significant growth and strong patient value given the substantial opportunity it affords to lower healthcare costs by helping to reduce unnecessary surgeries and ensuring the appropriate frequency of monitoring. We are keenly focused on growing our test volumes, securing additional coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our four commercialized innovative tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products, like BarreGEN[®] in our markets.

Additional Reimbursement Coverage During 2017 and 2018 (to-date)

Reimbursement progress is key for any molecular diagnostic company. We were successful in expanding the reimbursement of our products in 2017. Specifically the most significant progress we have made regarding payers in 2017 is as follows:

- In April 2017, we announced that UnitedHealthcare, the largest health plan in the United States, has agreed to cover our ThyraMIR[®] test used in assessing indeterminate thyroid nodule fine needle aspirate ("FNA") biopsies. The coverage is now in effect and is subject to members' specific benefit plan design.
- In June 2017, we announced that we signed a new national contract with Aetna for our ThyGenX[®] and ThyraMIR[®] molecular tests for indeterminate thyroid nodules. The agreement covers many of Aetna's products, including commercial and Medicare Advantage plans. The agreement is our first national provider contract with a national health plan and means that we will now be part of Aetna's laboratory network for these services. The agreement went into effect August 15, 2017.
- In July 2017, we announced that Cigna, one of the largest national health plans in the United States, has agreed to cover Interpace's ThyGenX[®] test for Cigna's 15 million members nationwide, with coverage effective immediately. Cigna's coverage when combined with Aetna, UnitedHealthcare, Medicare and other payers brings the total number of covered lives for ThyGenX[®] to approximately 275 million patients nationwide.

- In August 2017 we announced that Oxford Health Plans began to cover our ThyraMIR[®] test. Oxford offers health care benefits to employers primarily in New York, New Jersey, and Connecticut making it one of the largest health plans in the heavily populated tri-state Region.
- In September 2017 we announced that the American Medical Association (AMA) assigned a new, discreet CPT code to facilitate reimbursement of ThyraMIR[®], simplifying and expediting the process for us in submitting claims and securing reimbursement.
- In October 2017, we announced that Medicare reimbursement for our ThyGenX[®] molecular test for indeterminate thyroid nodules will increase by 40% starting January 1, 2018. Medicare represents approximately 40% of our volume for the ThyGenX[®] test.
- In November 2017, we announced that the New York State Department of Health has reviewed and approved for marketing our TERT service offering, which can be ordered in conjunction with our ThyGenX[®] molecular panel or on a stand-alone basis. While we currently market both ThyGenX[®] and ThyraMIR[®] in New York State, until now the TERT offering has been awaiting New York State approval. We believe that the TERT marker is a strong molecular predictor of the aggressiveness of thyroid cancer and adds additional insights into a patient's molecular profile.
- In February 2018, we announced that Horizon Blue Cross Blue Shield of New Jersey, the oldest and largest health plan in New Jersey, covering 3.8 million patients living in the Northeastern United States, has agreed to cover ThyGenX[®] and ThyraMIR[®] for its members effective January 9, 2018.
- In March 2018, we announced coverage of ThyGenX[®] and ThyraMIR[®] by four new Blue Cross Blue Shield Plans, Blue Cross Blue Shield of Arizona; Blue Cross Blue Shield of South Carolina; Wellmark Blue Cross Blue Shield of Iowa; and Wellmark Blue Cross Blue Shield of South Dakota. These four plans combined represent over 5 million members.

Recent Equity Financings

During 2017, we completed several public offerings of common stock and a private placement of warrants, which resulted in aggregate net proceeds to us of approximately \$29.9 million. A description of the financings is as follows:

- On January 6, 2017, we completed a registered direct public offering, or the First Registered Direct Offering, to sell 630,000 shares of our common stock at a price of \$6.81 per share to certain institutional investors which resulted in gross proceeds to us of approximately \$4.2 million. We used the net proceeds from the First Registered Direct Offering for working capital, repayment of indebtedness and general corporate purposes. In addition, we granted each institutional investor who participated in the First Registered Direct Offering the right, for a period of 15 months following January 6, 2017, or until April 6, 2018, to participate in any public or private offering by us of equity securities, subject to certain exceptions, up to such investor's pro rata portion of 50% of the securities being offered.
- On January 25, 2017, we completed a registered direct public offering, or the Second Registered Direct Offering, to sell 855,000 shares of our common stock and a concurrent private placement of warrants to purchase 855,000 shares of our common stock, or the Warrants, to the same investors participating in the Second Registered Direct Offering, (the "Private Placement"). The Warrants and the shares of our common stock issuable upon the exercise of the Warrants were not registered under the Securities Act and were sold pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) of Regulation D promulgated thereunder. The shares of common stock sold in the Second Registered Direct Offering and the Warrants issued in the concurrent Private Placement were issued separately but sold together at a combined purchase price of \$4.69 per share of common stock and accompanying Warrant. The Second Registered Direct Offering and the Private Placement together resulted in gross proceeds to us of approximately \$4 million. We used the net proceeds from the Second Registered Direct Offering for working capital, repayment of indebtedness and general corporate purposes and also used approximately \$1.0 million to satisfy the severance obligations due to five former senior executives.



- On February 8, 2017, we completed an underwritten, confidentially marketed public offering, or the CMPO, to sell 1,200,000 shares of our common stock at a price of \$3.00 per share. In addition, we granted the underwriters an option to purchase up to an additional 9% of the total number of shares of common stock sold by us in the CMPO, solely for the purpose of covering over-allotments, if any. The underwriters exercised the over-allotment option in full. The CMPO resulted in gross proceeds to us of approximately \$3.9 million. We used the proceeds from the CMPO for working capital, repayment of indebtedness and liabilities and for general corporate purposes.
- On June 21, 2017 we completed a public offering for 9,900,000 shares of common stock together with an equal number of common warrants (the "Base Warrants"), to purchase shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the common warrants) for \$1.10 per share. Each Base Warrant upon exercise at a price of \$1.25 will result in the issuance of one share of common stock to the holder. A public trading market for the Base Warrants was established on July 5, 2017 on the OTC market under the trading symbol IDGGW. As part of the offering (the "Offering"), which closed on June 21, 2017, the related underwriters purchased the full over-allotment of 1,875,000 Base Warrants available to them for the specified \$.01 per warrant. 2,600,000 of Pre-Funded Warrants were also sold at the specified \$1.09 per warrant (the "Pre-Funded Warrants"). The combined gross proceeds of the Offering totaled \$13.7 million with approximately \$12.3 million of net funds available to us after deducting underwriting discounts and other stock issuance expenses. As of July 7, 2017, all of the 2,600,000 Pre-Funded Warrants were exercised for the \$.01 per warrant exercise price and all 2,600,000 common shares related to the warrants have been issued. On July 31, 2017, we and the underwriters closed on the exercise of the underwriters' over-allotment option to purchase an additional 875,000 shares of common stock at a price of \$1.09 per share for gross proceeds of \$0.960 million. During September 2017 we received approximately \$0.9 million from the exercise of 747,800 Base Warrants. We are using the proceeds for general working capital purposes.
- On October 12, 2017, we entered into warrant exercise agreements (each a "Warrant Exercise Agreement") with certain holders (collectively, the "Warrant Holders" and each, a "Warrant Holder") of our warrants (the "Warrants") issued in June 2017. The Warrants were issued pursuant to that certain warrant agency agreement, dated as of June 21, 2017 (the "Warrant Agency Agreement"), by and between us and American Stock Transfer & Trust Company, as warrant agent (the "Warrant Agent"). Pursuant to the Warrant Exercise Agreement, the Warrant Holders agreed to exercise Warrants for an aggregate of 4,000,000 shares of common stock in exchange for additional warrants to the Warrant Holders for the number of shares of common stock that is equal to eighty percent of the number of shares exercised by such Warrant Holder, or 3,200,000 warrants (the "Additional Warrant Shares"), at an exercise price of \$1.80 per share. We received aggregate gross proceeds of \$5,000,000 from the exercise of the Warrants, which we are using for general working capital purposes. The Warrants and Exercised Shares were registered pursuant to our Registration Statement on Form S-1 (File No. 333-218140).

Recent Notices of NASDAQ Listing Compliance

- On October 6, 2016, NASDAQ notified us that we did not comply with the audit committee requirements for continued listing on NASDAQ set forth in Listing Rule 5605(2) (the "Rule"). We were granted time to regain compliance until no later than our next annual meeting, which occurred on September 14, 2017. Based on the information regarding the appointment of Dr. Felice Schnoll-Sussman to the Company's Board of Directors and audit committee, as detailed in our Form 8-K dated September 13, 2017, NASDAQ has notified us that we now comply with the Rule and this matter is now closed.
- On July 31, 2017, NASDAQ notified us that our common stock failed to maintain a minimum bid price of \$1.00 over the previous 30 consecutive business days as required by the Listing Rules of The Nasdaq Stock Market. On August 30, 2017 NASDAQ determined that the closing bid price of our common stock had been at \$1.00 per share or greater for the 10 consecutive business days from August 15 to 28, 2017. Accordingly, NASDAQ has notified us that we had regained compliance with Listing Rule 5550(a)(2) and this matter is now closed.



DESCRIPTION OF REPORTING SEGMENTS

We currently operate under one operating segment, which is our molecular diagnostic business. Until December 22, 2015 prior to the sale of the CSO business, we operated under two reporting segments: Commercial Services and Interpace Diagnostics. The CSO business is reported as discontinued operations in all periods presented.

CRITICAL ACCOUNTING POLICIES

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or ("GAAP"). The preparation of financial statements and related disclosures in conformity with GAAP requires management to make judgments, estimates and assumptions at a specific point in time that affect the amounts reported in our consolidated financial statements and disclosed in the accompanying notes. These assumptions and estimates are inherently uncertain. Outlined below are accounting policies, which are important to our financial position and results of operations and require our management to make significant judgments in their application. Some of those judgments can be subjective and complex. Management's estimates are based on historical experience, information from third-party professionals, facts and circumstances available at the time and various other assumptions that are believed to be reasonable. Actual results could differ from those estimates. Additionally, changes in estimates could have a material impact on our consolidated results of operations in any one period. For a summary of all of our significant accounting policies, including the accounting policies discussed below, see Note 1, Nature of Business and Significant Account Policies, to our consolidated financial statements included in this Annual Report on Form 10-K.

Revenue and Cost of Revenue

Under ASC 605 through December 31, 2017, we recognized revenue from services rendered when the following four revenue recognition criteria were met: persuasive evidence of an arrangement exists; services have been rendered; the selling price is fixed or determinable; and collectability is reasonably assured.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." The standard, including subsequently issued amendments, will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The key focus of the new standard is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this key focus, there is a five-step approach outlined in the standard. Entities are permitted to apply the new standard under the full retrospective method, subject to certain practical expedients, or the modified retrospective method that requires the application of the guidance only to contracts that are uncompleted on the date of initial application. We will adopt the new revenue standard and subsequently issued amendments as of January 1, 2018 using the modified retrospective method.

Our revenue is generated using our proprietary tests. Our performance obligation is fulfilled upon the completion, review and release of test results. In conjunction with fulfilling these services, we bill the third-party payer or hospital. We recognize our revenue related to billings for Medicare, Medicare Advantage, and hospitals on an accrual basis, net of contractual adjustment, when a contract is in place, a reliable pattern of collectability exists and collectability is reasonably assured. Contractual adjustments represent the difference between the list prices and the reimbursement rate set by Medicare and Medicare Advantage, the contractual rate or the amounts agreed to with hospitals.

Until a contract has been negotiated with a commercial insurance carrier or governmental program, the services may or may not be covered by these entities existing reimbursement policies. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment, the related revenue is only recognized upon the earlier of payment notification or cash receipt. Accordingly, we recognize revenue from commercial insurance carriers, government programs, and direct-bill healthcare providers without contracts when payment is received.

Persuasive evidence of an arrangement exists and delivery is deemed to have occurred upon completion, review, and release of the test results at which time we will bill the third-party payer or hospital. The assessment of the fixed or determinable nature of the fees charged for diagnostic testing performed, and the collectability of those fees, requires significant judgment by our management. Our management believes that these two criteria have been met when there is contracted reimbursement coverage or a predictable pattern of collectability with individual third-party payers or hospitals and accordingly, recognizes revenue upon delivery of the test results. In the absence of contracted reimbursement coverage or a predictable pattern of collectability, we believe that the fee is fixed or determinable and collectability is reasonably assured only upon request of third-party payer notification of payment or when cash is received, and we recognize revenue at that time.



Cost of services consists primarily of the costs associated with operating our laboratories and other costs directly related to our tests. Personnel costs, which constitute the largest portion of cost of services, include all labor related costs, such as salaries, bonuses, fringe benefits and payroll taxes for laboratory personnel. Other direct costs include, but are not limited to, laboratory supplies, certain consulting expenses, and facility expenses.

Long-Lived Assets, including Finite-Lived Intangible Assets

We review the recoverability of long-lived assets and finite-lived intangible assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized by reducing the recorded value of the asset to its fair value measured by future discounted cash flows. This analysis requires estimates of the amount and timing of projected cash flows and, where applicable, judgments associated with, among other factors, the appropriate discount rate. Such estimates are critical in determining whether any impairment charge should be recorded and the amount of such charge if an impairment loss is deemed to be necessary. In 2016, we recorded \$3.4 million of impairment charges relating to the impairment of our certain intangible assets pertaining to the Asuragen acquisition in August 2014.

Contingencies

In the normal course of business, we are subject to various contingencies. Contingencies are recorded in the consolidated financial statements when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated, or otherwise disclosed, in accordance with ASC 450, Contingencies. Significant judgment is required in both the determination of probability and the determination as to whether a loss is reasonably estimable. In the event we determine that a loss is not probable, but is reasonably possible, and it becomes possible to develop what we believe to be a reasonable range of possible loss, then we will include disclosures related to such matter as appropriate and in compliance with ASC 450. To the extent there is a reasonable possibility that the losses could exceed the amounts already accrued, we will, when applicable, adjust the accrual in the period the determination is made, disclose an estimate of the additional loss or range of loss, indicate that the estimate is immaterial with respect to its financial statements as a whole or, if the amount of such adjustment cannot be reasonably estimated, disclose that an estimate cannot be made. We are currently a party to legal proceedings that are incidental to our business. As required, we have accrued our estimate of the probable costs for the resolution of these claims. These estimates are developed in consultation with outside counsel and are based upon an analysis of potential results, assuming a combination of litigation and settlement strategies. Predicting the outcome of claims and litigation, and estimating related costs and exposures, involves substantial uncertainties that could cause actual costs to vary materially from estimates. As of December 31, 2017, our accrual for litigation and threatened litigation was not material to the consolidated financial statements.

Income Taxes

Income taxes are based on income for financial reporting purposes calculated using our expected annual effective rate and reflect a current tax liability or asset for the estimated taxes payable or recoverable on the current year tax return and expected annual changes in deferred taxes.

We account for income taxes using the asset and liability method. This method requires recognition of deferred tax assets and liabilities for expected future tax consequences of temporary differences that currently exist between tax bases and financial reporting bases of our assets and liabilities based on enacted tax laws and rates. Deferred tax expense (benefit) is the result of changes in the deferred tax asset and liability. A valuation allowance is established, when necessary, to reduce the deferred income tax assets when it is more likely than not that all or a portion of a deferred tax asset will not be realized.

We operate in multiple tax jurisdictions and provide taxes in each jurisdiction where we conduct business and are subject to taxation. The breadth of our operations and the complexity of the various tax laws require assessments of uncertainties and judgments in estimating the ultimate taxes we will pay. The final taxes paid are dependent upon many factors, including negotiations with taxing authorities in various jurisdictions, outcomes of tax litigation and resolution of proposed assessments arising from federal and state audits. We have established estimated liabilities for uncertain federal and state income tax positions. Uncertain tax positions are recognized in the financial statements when it is more likely than not (for example, a likelihood of more than fifty percent) that a position taken or expected to be taken in a tax return would be sustained upon examination by tax authorities that have full knowledge of all relevant information. A recognized tax position is then measured as the largest amount of benefit that is greater than fifty percent likely to be realized upon ultimate settlement. We adjust our accruals for unrecognized tax benefits as facts and circumstances change, such as the progress of a tax audit. We believe that any potential audit adjustments will not have a material adverse effect on our financial condition or liquidity. However, any adjustments made may be material to our consolidated results of operations or cash flows for a reporting period. Penalties and interest, if incurred, would be recorded as a component of current income tax expense. Management plans to commence filing tax clearance certificates in states and related tax jurisdictions in which un-recognized tax benefits attributable to its former operating entities are recorded as long-term liabilities on the accompanying balance sheet. This process can range from 6 to 18 months before the Company receives clearance as to balances, if any, it may owe to a particular state or tax jurisdiction. Upon receipt and acknowledgment from a state or tax jurisdiction, the Company will settle the remaining obligation or reverse the recorded amount owed during the period in which the tax clearance certificate is obtained.

Significant judgment is also required in evaluating the need for and magnitude of appropriate valuation allowances against deferred tax assets. We currently have significant deferred tax assets resulting from net operating loss carryforwards and deductible temporary differences. The realization of these assets is dependent on generating future taxable income. We perform an analysis quarterly to determine whether the expected future income will more likely than not be sufficient to realize the deferred tax assets. Our recent operating for financial reporting purposes are not sufficient to generate future taxable income and realize our deferred tax assets and, as a result, we established a full federal and state valuation allowance for the net deferred tax assets at December 31, 2017 and 2016, as we determine that it was more likely than not that these assets would not be realized.

Stock Compensation Costs

The compensation cost associated with the granting of stock-based awards is based on the grant date fair value of the stock award. We recognize the compensation cost, net of estimated forfeitures, over the shorter of the vesting period or the period from the grant date to the date when retirement eligibility is achieved. Forfeitures are initially estimated based on historical information and subsequently updated over the life of the awards to ultimately reflect actual forfeitures. As a result, changes in forfeiture activity can influence the amount of stock compensation cost recognized from period-to-period.

We primarily use the Black-Scholes option pricing model to determine the fair value of stock options and stock-based stock appreciation rights (SARs). The determination of the fair value of stock-based payment awards is made on the date of grant and is affected by our stock price as well as assumptions made regarding a number of complex and subjective variables. These assumptions include: our expected stock price volatility over the term of the awards; actual and projected employee stock option exercise behaviors; the risk-free interest rate; and expected dividend yield.

Changes in the valuation assumptions could result in a significant change to the cost of an individual award. However, the total cost of an award is also a function of the number of awards granted, and as result, we have the ability to manage the cost and value of our equity awards by adjusting the number of awards granted.

CONSOLIDATED RESULTS OF OPERATIONS

The following table sets forth the selected statement of comprehensive loss data as a percentage of revenue for the periods indicated. The trends illustrated in this table may not be indicative of future operating results.

	Years Ended December 31,					
		2017	2017		2016	2016
Revenue, net	\$	15,897	100.0%	\$	13,085	100.0%
Cost of revenue		7,358	46.3%		6,641	50.8%
Gross profit		8,539	53.7%		6,444	49.2%
Operating expenses:						
Sales and marketing		6,567	41.3%		5,462	41.7%
Research and development		1,461	9.2%		1,647	12.6%
General and administrative		9,153	57.6%		10,504	80.3%
Acquisition related amortization expense		3,253	20.5%		3,770	28.8%
Asset impairment		-	0.0%		3,363	25.7%
Change in fair value of contingent consideration		(5,602)	-35.2%		(11,860)	-90.6%
Total operating expenses		14,832	93.3%		12,886	<u>98.5</u> %
Operating loss		(6,293)	-39.6%		(6,442)	-49.2%
Interest expense		(433)	-2.7%		(2,144)	-16.4%
Loss on extinguishment of debt		(4,278)	-26.9%		-	0.0%
Other (expense) income, net		(2,128)	-13.4%		14	0.1%
Loss from continuing operations before tax		(13,132)	-82.6%		(8,572)	-65.5%
Benefit from income taxes from continuing		())				
operations		(395)	-2.5%		(162)	-1.2%
Loss from continuing operations		(12,737)	-80.1%		(8,410)	-64.3%
Income (loss) from discontinued operations		1,124	7.1%		(886)	-6.8%
Gain on sale of assets		-	0.0%		1,326	10.1%
Income from discontinued operations		1,124	7.1%		440	3.4%
Provision for income tax on discontinued		,				
operations		603	3.8%		362	2.8%
Income from discontinued operations, net of						
tax		521	3.3%		78	0.6%
Net loss	\$	(12,216)	-76.8%	\$	(8,332)	-63.7%

Revenue, net

Consolidated revenue for the year ended December 31, 2017 increased by \$2.8 million, or 21.5%, to \$15.9 million, compared to the year ended December 31, 2016. This increase was principally attributable to increased test and collection volume for our thyroid tests and the change from cash basis to accrual for ThyraMIR in payer groups with substantiated collection histories, specifically, Medicare, Medicare Advantage and Direct Client Bill.

Cost of revenue

Consolidated cost of revenue for the year ended December 31, 2017 increased by \$0.7 million, or 10.8%, to \$7.4 million, compared to the year ended December 31, 2016 primarily due to the increase in test volume, discussed above.

Gross profit

Consolidated gross profit for the year ended December 31, 2017 increased \$2.1 million, or 32.5%, to \$8.5 million, compared to the year ended December 31, 2016 due primarily to the increase in revenue and a reduction in our royalty obligations.

Sales and marketing expense

Sales and marketing expense was \$6.6 million for the year ended December 31, 2017, as compared to \$5.5 million for the year ended December 31, 2016. As a percentage of revenue sales and marketing expense was approximately the same in both years. The increase in sales and marketing expense principally reflects an increase in sales representatives and related employee compensation expense as well as an increase in related marketing expenses.

Research and development

Research and development expense was \$1.5 million and as a percentage of revenue was 9.2%. For the year ended December 31, 2016, the expense was \$1.6 million and as a percentage of revenue, was 12.6%.

General and administrative

General and administrative expense for the year ended December 31, 2017 was \$9.2 million as compared to \$10.5 million for the year ended December 31, 2016. This decrease was primarily attributable to a reduction in severance expense of \$2.0 million due to the settlement of severance obligations with former executives and partially offset by the accruals associated with the negotiation of our DOJ settlement of \$1.0 million. As a percentage of revenue, general and administrative expense was 57.6% for the year ended December 31, 2017 as compared to 80.3% for the year ended December 31, 2016.

Acquisition related amortization expense

During the years ended December 31, 2017 and December 31, 2016, we recorded amortization expense of approximately \$3.3 million and \$3.8 million, respectively related to the amortization for RedPath and Asuragen acquired intangible assets. The decrease relates to the impact of certain intangibles being fully written off in 2016. See Asset impairment, below. As a result the amortization expense is reduced going forward.

Asset impairment

During the year ended December 31, 2016, we incurred an asset impairment charge of approximately \$3.4 million related to certain assets determined to be useless associated with the acquisition of assets from Asuragen.

Change in fair value of contingent consideration

During the year ended December 31, 2017, there was a \$5.8 million reduction in contingent consideration liability related to the elimination of amounts associated with future royalty payments for the assets acquired from Redpath, partially offset by a \$0.2 million increase in the liability associated with Asuragen. During the year ended December 31, 2016, we had an \$11.9 million reduction to our contingent consideration liability and recognized the credits to operating expenses in 2016. The 2017 RedPath reduction and elimination were due to the RedPath investors accepting 100,000 in five-year warrants exercisable at \$4.69 per share in exchange for terminating their Contingent Consideration Agreement in conjunction with the debt exchange transaction of the RedPath Note in March 2017.

Operating loss

There were operating losses from continuing operations of \$6.3 million and \$6.4 million during the years ended December 31, 2017 and 2016, respectively. The decrease in operating loss from continuing operations in the year ended December 31, 2017 was primarily attributable to the increase in revenues discussed above.



Provision for income taxes

We had income tax benefits of approximately \$0.4 million and \$0.2 million for the years ended December 31, 2017 and December 31, 2016, respectively. Income tax benefits for the years ended December 31, 2017 and December 31, 2016 were primarily due to the reclassification of CSO as discontinued operations and the tax adjustments associated with that reclass.

Income (loss) from discontinued operations, before tax

We had income from discontinued operations of \$1.1 million for the year ended December 31, 2017 as compared to a loss from discontinued operations of \$0.9 million for the year ended December 31, 2016. This increase was primarily related to favorable settlements of outstanding obligations including a reversal of severance expense of \$0.5 million.

Gain (loss) on sale

In 2016, the gain on sale of \$1.3 million related to the final working capital adjustment regarding the sale of the CSO business in December of 2015. See Note 4, Discontinued Operations, in the Consolidated Financial Statements for more details.

LIQUIDITY AND CAPITAL RESOURCES

For the fiscal year ended December 31, 2017, we had an operating loss of \$6.3 million. As of December 31, 2017, we had cash and cash equivalents of \$15.2 million and current liabilities of \$8.1 million.

It is anticipated that we may require additional capital to fund our operations in the future. There is no guarantee that additional capital can be raised to fund our future operations. We intend to meet our capital needs by driving revenue growth, containing costs as well as exploring other options and management believes that the Company has sufficient cash on hand to sustain operations through at least March 31, 2019.

During 2017, we completed various offerings and a private placement of warrants, which resulted in aggregate net proceeds to us of approximately \$29.9 million. See "Recent Equity Financings".

See Note 3, Liquidity in the consolidated financial statements for a discussion of the extinguishment of the RedPath Note and the termination of the line with SCM Specialty Finance Opportunities Fund, L.P.

During the year ended December 31, 2017, net cash used in operating activities was \$15.3 million, of which \$13.0 million was used in continuing operations and \$2.3 million was used in discontinued operations. The main component of cash used in operating activities during the year ended December 31, 2016 was our loss from continuing operations of \$12.7 million. During the year ended December 31, 2016, net cash used in operating activities was \$7.6 million, of which \$5.6 million was used in continuing operations and \$2.0 million was used in discontinued operating activities during the year ended December 31, 2016 was our loss from continuing operating activities during the year ended December 31, 2016 was used in discontinued operations. The main component of cash used in operating activities during the year ended December 31, 2016 was our loss from continuing operations of \$8.4 million.

For the year ended December 31, 2017, there was cash used in investing activities of \$29,000. For the year ended December 31, 2016, there was no cash from investing activities.

For the year ended December 31, 2017, there was net cash provided from financing activities of \$29.9 million, which resulted from the issuance of common stock in our various offerings completed in 2017 as well as the subsequent exercise of warrants related to those offerings. For the year ended December 31, 2016, there was net cash used in financing activities of \$0.1 million, which consisted of \$1.7 million resulting from the issuance of common stock in our first registered direct offering completed on December 22, 2016, offset by the \$0.5 million in payments of contingent consideration in the form of milestone payments and a \$1.3 million debt payment.



Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Inflation

We do not believe that inflation had a significant impact on our results of operations for the periods presented. On an ongoing basis, we attempt to minimize any effects of inflation on our operating results by controlling operating costs and whenever possible, seeking to insure that billing rates reflect increases in costs due to inflation.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a "smaller reporting company" for purposes of the disclosure requirements of Item 305 of Regulation S-K and, therefore, we are not required to provide this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and the financial statement schedule specified by this Item 8, together with the reports thereon of BDO USA, LLP, are presented following Item 15 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act as of December 31, 2017. 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 including that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In addition, management is required to apply its judgment in evaluating the benefits of possible disclosure controls and procedures relative to their costs to implement and maintain.

Based on the evaluation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) under the Exchange Act, our Chief Executive Officer and Chief Financial Officer, have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2017.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f).

All internal control systems, no matter how well designed, have inherent limitations including the possibility of human error and the circumvention or overriding of controls. Further, because of changes in conditions, the effectiveness of internal controls may vary over time. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Accordingly, even those systems determined to be effective can provide us only with reasonable assurance with respect to financial statement preparation and presentation.



Our internal control system was designed to provide reasonable assurance to our management and Board regarding the preparation and fair presentation of published financial statements. Management evaluated the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in Internal Control — Integrated Framework in 2013. Management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2017 and concluded that it is effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Changes in Internal Control over Financial Reporting

There were no changes in internal control over financial reporting that occurred during the fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Extension of Pittsburgh Lease

The Company entered into a second amendment (the "Amendment") as of March 15, 2018 to a lease agreement (the "Lease") with Saddle Lane Realty, LLC. The Amendment covers the 20,000 square feet of the Company's current laboratory building, located at 2515 Liberty Avenue, Pittsburgh, Pennsylvania. The Amendment extends the Lease through June 30, 2023. Under the Amendment, monthly base rent beginning July 1, 2018 will be \$33,333.33, escalating by twenty-five percent (25%) on July 1, 2019 to \$41,666.67 per month. The Company may, at its option, extend the term of the Lease for two consecutive terms of five years each, with the monthly based rent escalating by ten percent (10%) for each of the additional five year terms.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information relating to directors and executive officers of the registrant that is responsive to Item 10 of this Annual Report on Form 10-K will be included in our Proxy Statement for our 2018 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 11. EXECUTIVE COMPENSATION

Information relating to executive compensation that is responsive to Item 11 of this Annual Report on Form 10-K will be included in our Proxy Statement for our 2018 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information relating to security ownership of certain beneficial owners and management that is responsive to Item 12 of this Annual Report on Form 10-K will be included in our Proxy Statement for our 2018 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information relating to certain relationships and related transactions that is responsive to Item 13 of this Annual Report on Form 10-K will be included in our Proxy Statement for our 2018 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information relating to principal accounting fees and services that is responsive to Item 14 of this Annual Report on Form 10-K will be included in our Proxy Statement for our 2018 annual meeting of stockholders and such information is incorporated by reference herein.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Form 10-K:

- (1) Financial Statements See Index to Financial Statements on page F-1 of this Form 10-K.
- (2) Financial Statement Schedule

Schedule II: Valuation and Qualifying Accounts

All other schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

(3) Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc.,
	incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended
	September 30, 2014, filed with the SEC on November 5, 2014
2.2	Asset Purchase Agreement, dated as of October 30, 2015, by and between Publicis Touchpoint Solutions, Inc. and PDI, Inc. is
	incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed with the SEC on November 2,
	2015
3.1	Certificate of Incorporation of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.), incorporated by reference to the designated
	exhibit of the Company's Registration Statement on Form S-1 (File No. 333-46321), filed with the SEC on May 19, 1998
3.2	Certificate of Amendment of Certificate of Incorporation of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.), incorporated
	by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2001,
	filed with the SEC on March 13, 2002
3.3	Certificate of Amendment to the Certificate of Incorporation of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.),
	incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended
	June 30, 2012, filed with the SEC on August 14, 2012
3.4	Amended and Restated By-Laws of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.), incorporated by reference to the
	designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC
	<u>on March 6, 2014</u>

Exhibit No.	Description
3.5	Certificate of Amendment to the Certificate of Incorporation of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.), incorporated by reference to the designated exhibit of the Company's Form 8-K filed with the SEC on December 23, 2015
3.6	<u>Certificate of Amendment to the Certificate of Incorporation of PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.),</u> incorporated by reference to the designated exhibit of the Company's Form 8-K filed with the SEC on December 23, 2015
3.7	Certificate of Amendment to the Certificate of Incorporation of Interpace Diagnostics Group, Inc., incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on December 28, 2016
4.1	Specimen Certificate Representing the Common Stock, incorporated by reference to the designated exhibit of the Company's Registration Statement on Form S-1 (File No. 333-46321), filed with the SEC on May 19, 1998
4.2	Form of Prepaid Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on December 19, 2016
4.3	Form of Prepaid Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's
4.4	Current Report on Form 8-K filed with the SEC on January 3, 2017 Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on January 20, 2017
4.5	Warrant Agency Agreement, dated June 21, 2017, by and between Interpace Diagnostics Group, Inc. and American Stock Transfer & Trust Company, LLC, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on June 21, 2017
4.6	Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on March 23, 2017
4.7	Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on March 27, 2017
4.8	Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Registration
4.9	Statement on Form S-1 filed with the SEC on June 13, 2017 Form of Underwriters' Warrants, incorporated by reference to the designated exhibit of the Company's Registration Statement on Form S-1 filed with the SEC on June 13, 2017
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Exhibit No.	Description
4.10	Form of Warrant Agency Agreement by and between Interpace Diagnostics Group, Inc. and American Stock Transfer & Trust
	Company, LLC, incorporated by reference to the designated exhibit of the Company's Registration Statement on Form S-1
	filed with the SEC on June 13, 2017
4.11	Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current
	Report on Form 8-K filed with the SEC on June 21, 2017
4.12	Form of Common Stock Purchase Warrant, incorporated by reference to the designated exhibit of the Company's Current
	Report on Form 8-K filed with the SEC on October 12, 2017
10.1*	2000 Omnibus Incentive Compensation Plan, incorporated by reference to the designated exhibit of the Company's Current
	Report on Form 8-K filed with the SEC on October 20, 2014
10.2*	Executive Deferred Compensation Plan, incorporated by reference to the designated exhibit of the Company's Annual Report
10.2*	on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 8, 2010
10.3*	Amended and Restated 2004 Stock Award and Incentive Plan, incorporated by reference to the designated exhibit of the
10.44	Company's definitive proxy statement filed with the SEC on April 28, 2004
10.4*	Amended and Restated 2004 Stock Award and Incentive Plan, incorporated by reference to the designated exhibit of the
10.5*	Company's definitive proxy statement filed with the SEC on August 14, 2017
10.5*	Form of Restricted Stock Unit Agreement for Employees, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 8, 2009
10.6*	Form of Stock Appreciation Rights Agreement for Employees, incorporated by reference to the designated exhibit of the
10.0	Company's Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 8, 2009
10.7*	Form of Restricted Stock Unit Agreement for Directors, incorporated by reference to the designated exhibit of the Company's
10.7	Annual Report on Form 10-K for the year ended December 31, 2008, filed with the SEC on March 8, 2009
10.8*	Form of Restricted Share Agreement, incorporated by reference to the designated exhibit of the Company's Annual Report on
1010	Form 10-K for the year ended December 31, 2009, filed with the SEC on March 8, 2010
10.9	Morris Corporate Center Lease, incorporated by reference to the designated exhibit of the Company's Quarterly Report on
	Form 10-O for the guarter ended September 30, 2009, filed with the SEC on November 5, 2009
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Exhibit No.	Description
10.10	License Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30,
10.11	2014, filed with the SEC on November 5, 2014 CPRIT License Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended
10.12	September 30, 2014, filed with the SEC on November 5, 2014 Supply Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30,
10.13	2014, filed with the SEC on November 5, 2014 Guaranty, dated August 13, 2014 by the Company in favor of Asuragen, Inc., incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on
10.14	November 5, 2014 Lease, dated June 28, 2015, by and between WE 2 Church Street South LLC and JS Genetics, LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2014, filed with the
10.15	SEC on March 5, 2015 Amendment No. 1 to Lease, dated September 18, 2007, by and between WE 2 Church Street South LLC and JS Genetics, LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
10.16	December 31, 2014, filed with the SEC on March 5, 2015 Amendment No. 2 to Lease, dated August 29, 2008, by and between WE 2 Church Street South LLC and JS Genetics, LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
10.17	December 31, 2014, filed with the SEC on March 5, 2015 Amendment No. 3 to Lease, dated April 8, 2009, by and between WE 2 Church Street South LLC and JS Genetics, LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
10.18	December 31, 2014, filed with the SEC on March 5, 2015 Amendment No. 4 to Lease, dated September 16, 2010, by and between WE 2 Church Street South LLC and JS Genetics, LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
	December 31, 2014, filed with the SEC on March 5, 2015

Exhibit No.	Description
10.19	Amendment No. 5 to Lease, dated September 15, 2011, by and between WE 2 Church Street South LLC and JS Genetics,
	LLC, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year
	ended December 31, 2014, filed with the SEC on March 5, 2015
10.20	Amendment No. 6 to Lease, dated March 5, 2014, by and between WE 2 Church Street South LLC and JS Genetics, LLC,
	incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
	December 31, 2014, filed with the SEC on March 5, 2015
10.21	Amendment No. 7 to Lease, dated August 29, 2014, by and between WE 2 Church Street South LLC and JS Genetics, LLC,
	incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended
	December 31, 2014, filed with the SEC on March 5, 2015
10.22*	Amendment Agreement, dated December 7, 2015, by and between PDI, Inc. (n/k/a Interpace Diagnostics Group, Inc.) and
	Nancy S. Lurker, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed
	with the SEC on December 8, 2015
10.23*	Agreement and General Release, dated January 6, 2016, by and between Gerald Melillo and PDI, Inc. (n/k/a Interpace
	Diagnostics Group, Inc.), incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-
10.04*	K filed with the SEC on January 1, 2016
10.24*	Agreement and General Release, dated January 15, 2016, by and between Nancy S. Lurker and PDI, Inc. (n/k/a Interpace
	Diagnostics Group, Inc.), incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-
10.25*	K, filed with the SEC on January 22, 2016.
10.25*	Severance Agreement and General Release, dated March 28, 2016, by and between Graham Miao and Interpace Diagnostics
	Group, Inc., incorporated by reference the designated exhibit of the Company's Current Report on Form 8-K, filed with the
10.26*	SEC on March 29, 2016.
10.26*	Employment Separation Agreement between Interpace Diagnostics Group, Inc. and Nat Krishnamurti, effective as of June
	22, 2016, incorporated by reference to the designated exhibit of Amendment No. 2 to the Company's Current Report on Form 8-K filed with the SEC on June 22, 2016.
10.27*	Confidential Information, Non-Disclosure, Non-Solicitation, Non-Compete and Rights to Intellectual Property Agreement
10.27	between Interpace Diagnostics Group, Inc. and Nat Krishnamurti, dated as of June 22, 2016, incorporated by reference to
	the designated exhibit of Amendment No. 2 to the Company's Current Report on Form 8-K filed with the SEC on June 22,
	2016.
10.28*	Form of Indemnification Agreement by and between Interpace Diagnostics Group, Inc. and its directors and executive
10.20	officers, incorporated by reference to the designated exhibit to the Company's Current Report on Form 8-K filed with the
	SEC on August 8, 2016.
10.29	Credit Agreement and Security Agreement, dated as of September 28, 2016, by and among Interpace Diagnostics Group,
	Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and SCM Specialty Finance Opportunities Fund, L.P.,
	incorporated by reference to the designated exhibit to the Company's Current Report on Form 8-K filed with the SEC on
	October 4, 2016.
10.30	Intercreditor Agreement, dated as of September 28, 2016, by and between SCM Specialty Finance Opportunities Fund, L.P.
	and RedPath Equityholder Representative, LLC and acknowledged and agreed to by Interpace Diagnostics Group, Inc.,
	Interpace Diagnostics, LLC and Interpace Diagnostics Corporation, incorporated by reference to the designated exhibit to
	the Company's Current Report on Form 8-K filed with the SEC on October 4, 2016.
10.31	Management Engagement Letter, effective as of October 11, 2016, by and between Early Financial Consulting, LLC and
	Interpace Diagnostics Group, Inc., incorporated by reference to the designated exhibit to the Company's Current Report on
	Form 8-K filed with the SEC on October 14, 2016.

Exhibit No.	Description
10.32*	Incentive Stock Option Agreement between Interpace Diagnostics Group, Inc. and Jack E. Stover, incorporated by reference to
	the designated exhibit to the Company's Current Report on Form 8-K filed with the SEC on October 20, 2016.
10.33*	Incentive Stock Option Agreement between Interpace Diagnostics Group, Inc. and James Early, incorporated by reference to
	the designated exhibit to the Company's Current Report on Form 8-K filed with the SEC on October 20, 2016.
10.34*	Form of Incentive Stock Option Agreement, incorporated by reference to the designated exhibit to the Company's Current Report on Form 8-K filed with the SEC on October 20, 2016.
10.35*	Employment Agreement, dated as of October 28, 2016, by and between Interpace Diagnostics Group, Inc. and Jack E. Stover,
	incorporated by reference to the designated exhibit to the Company's Current Report on Form 8-K filed with the SEC on November 3, 2016.
10.36	Placement Agency Agreement by and between Interpace Diagnostics Group, Inc. and Maxim Group, LLC, incorporated by
	reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on December 19, 2016
10.37	Form of Securities Purchase Agreement by and between Interpace Diagnostics Group, Inc. and certain purchasers named
	therein, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on December 19, 2016
10.38	
10.58	Placement Agency Agreement, dated January 3, 2017, by and between Interpace Diagnostics Group, Inc. and Maxim Group LLC, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on
	January 3, 2017
10.39	Form of Securities Purchase Agreement, dated January 3, 2017, by and between Interpace Diagnostics Group, Inc. and certain
10.39	purchasers named therein, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K
	filed with the SEC on January 3, 2017
10.40	Amended and Restated Placement Agency Agreement, effective as of January 3, 2017, by and between Interpace Diagnostics
10.40	Group, Inc. and Maxim Group LLC, incorporated by reference to the designated exhibit of the Company's Current Report on
	Form 8-K filed with the SEC on January 5, 2017
10.41	Form of Amendment to Securities Purchase Agreement, effective as of January 3, 2017, by and between Interpace Diagnostics
10.11	Group, Inc. and certain purchasers named therein, incorporated by reference to the designated exhibit of the Company's
	Current Report on Form 8-K filed with the SEC on January 5, 2017
10.42	Placement Agency Agreement, dated January 20, 2017, by and between Interpace Diagnostics Group, Inc. and Maxim Group
	LLC, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K filed with the SEC on
	January 20, 2017
10.43	Form of Securities Purchase Agreement, dated January 20, 2017, by and between Interpace Diagnostics Group, Inc. and certain
	purchasers named therein, incorporated by reference to the designated exhibit of the Company's Current Report on Form 8-K
	filed with the SEC on January 20, 2017
10.44*	Employment Agreement between Interpace Diagnostics Group, Inc. and James Early, effective as of March 16, 2018, filed
10.44	herewith.
10.45	Amendment No. 2 to Lease, dated March 15, 2018, between Saddle Lane Realty, LLC and Interpace Diagnostics Corporation,
10.75	filed herewith.

Exhibit No.	Description
21.1	Subsidiaries of the Registrant, filed herewith
23.1	Consent of BDO USA, LLP, filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith
32.1	Certification 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, filed herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 as adopted Pursuant to Section 906 of the

- 32.2 <u>Certification 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, filed herewith</u>
- * Denotes compensatory plan, compensation arrangement or management contract.

ITEM 16. Form 10-K Summary

The Company has opted to not provide a summary.

Interpace Diagnostics Group, Inc. Annual Report on Form 10-K

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTERPACE DIAGNOSTICS GROUP, INC.

Date: March 23, 2018

/s/ Jack E. Stover Jack E. Stover

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed by the following persons on behalf of the registrant and in the capacities indicated and on the dates indicated.

Name	Title	Date
/s/ Jack E. Stover Jack E. Stover	President, Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2018
/s/ James Early James Early	Chief Financial Officer (Principal Financial Officer)	March 23, 2018
/s/ Thomas Freeburg Thomas Freeburg	Chief Accounting Officer (Principal Accounting Officer)	March 23, 2018
/s/ Stephen J. Sullivan Stephen J. Sullivan	Chairman of the Board of Directors	March 23, 2018
/s/ Joseph Keegan Joseph Keegan	Director	March 23, 2018
<u>/s/ Felice Schnoll-Sussman</u> Felice Schnoll-Sussman	Director	March 23, 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders and Board of Directors Interpace Diagnostics Group, Inc. Parsippany, New Jersey

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Interpace Diagnostics Group Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2017, and the related notes and schedule listed in the accompanying index (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.

Woodbridge, New Jersey March 22, 2018

INTERPACE DIAGNOSTICS GROUP, INC. CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	Dee	cember 31, 2017	December 31, 2016		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	15,199	\$	602	
Accounts receivable, net		3,437		2,209	
Other current assets		1,172		1,415	
Current assets from discontinued operations		-		14	
Total current assets		19,808		4,240	
Property and equipment, net		654		929	
Other intangible assets, net		33,105		36,358	
Other long-term assets		31		251	
Total assets	\$	53,598	\$	41,778	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	391	\$	2,326	
Accrued salary and bonus		1,394		3,551	
Other accrued expenses		5,004		6,236	
Current liabilities from discontinued operations		1,302		4,128	
Total current liabilities		8,091		16,241	
Contingent consideration		1,349		7,254	
Long-term debt, net of debt discount		-		7,908	
Other long-term liabilities		4,289		3,844	
Total liabilities		13,729		35,247	
Commitments and contingencies (Note 10)					
Stockholders' equity:					
Preferred stock, \$.01 par value; 5,000,000 shares authorized, no shares issued and					
outstanding		-		-	
Common stock, \$.01 par value; 100,000,000 shares authorized; 27,900,806 and 2,230,506 shares issued, respectively; 27,836,456 and 2,176,252 shares					
outstanding, respectively		278		22	
Additional paid-in capital		173,062		127,736	
Accumulated deficit		(131,800)		(119,584)	
Treasury stock, at cost (64,350 and 54,254 shares, respectively)		(1,671)		(1,643)	
Total stockholders' equity		39,869		6,531	
Total liabilities and stockholders' equity	\$	53,598	\$	41,778	

The accompanying notes are an integral part of these consolidated financial statements

INTERPACE DIAGNOSTICS GROUP, INC. CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except for per share data)

	For The Years Ended December 31,					
		2017		2016		
Revenue, net	\$	15,897	\$	13,085		
Cost of revenue (excluding amortization of \$3,253 and \$3,770 respectively)		7,358		6,641		
Gross profit		8,539		6,444		
Operating expenses:		- ,		-)		
Sales and marketing		6,567		5,462		
Research and development		1,461		1,647		
General and administrative		9,153		10,504		
Acquisition related amortization expense		3,253		3,770		
Asset impairment		-		3,363		
Change in fair value of contingent consideration		(5,602)		(11,860)		
Total operating expenses		14,832		12,886		
Operating loss		(6,293)		(6,442)		
Interest expense		(433)		(2,144)		
Loss on extinguishment of debt		(4,278)		-		
Other (expense) income, net		(2,128)		14		
Loss from continuing operations before tax		(13,132)		(8,572)		
Benefit from income taxes from continuing operations		(395)		(162)		
Loss from continuing operations		(12,737)		(8,410)		
Discontinued Operations						
Income (loss) from discontinued operations		1,124		(886)		
Gain on sale of assets		-		1,326		
Income from discontinued operations		1,124		440		
Provision for income tax on discontinued operations		603		362		
Income from discontinued operations, net of tax	\$	521	\$	78		
Net loss		(10.01.5)	.	(0.000)		
INET IOSS	\$	(12,216)	\$	(8,332)		
Basic and diluted (loss) income per share of common stock:						
From continuing operations	\$	(0.81)	\$	(4.63)		
From discontinued operations		0.03		0.04		
Net loss per basic and diluted share of common stock	\$	(0.78)	\$	(4.59)		
Weighted average number of common shares and common share equivalents outstanding:		`		`		
Basic		15,766		1,816		
Diluted		15,766		1,816		

The accompanying notes are an integral part of these consolidated financial statements

INTERPACE DIAGNOSTICS GROUP, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands)

	For The Years Ended December 31,								
	20	017	2016						
	Shares	Amoun	ıt	Shares		Amount			
Common stock:									
Balance at January 1	2,230	\$	22	1,870	\$	19			
Common stock issued	34		-	-		-			
Common stock issued through offerings	13,568		135	200		2			
Shares issued in debt exchange	3,795		38	-		-			
Exercise of warrants for cash	8,273		83	160		1			
Balance at December 31	27,900		278	2,230		22			
Treasury stock:									
Balance at January 1	54		(1,643)	104		(8,432)			
Treasury stock reissued	-		-	(50)		6,789			
Treasury stock purchased	10		(28)	-		-			
Balance at December 31	64		(1,671)	54		(1,643)			
= Additional paid-in capital:					_				
Balance at January 1		12	27,736			132,690			
Common stock issued through offerings, net of									
expenses		1	5,734			857			
Issuance of warrants, net of expenses			7,212			832			
Shares issued in debt exchange		1	1,605			-			
Exercise of warrants for cash, net of expenses			6,778			15			
Reclass of warrant liability upon exercise of pre-									
funded warrants			2,337			-			
Issuance of debt exchange warrants, vendor warrants,									
and other			600			-			
Treasury stock reissued			-			(6,789)			
Stock-based compensation expense			1,060			131			
Balance at December 31		17	73,062			127,736			
Accumulated deficit:									
Balance at January 1		(11	9,584)			(111,252)			
Net loss		(1	2,216)			(8,332)			
Balance at December 31		(13	31,800)			(119,584)			
Accumulated other comprehensive (loss) income:									
Balance at January 1			-			13			
Unrealized holding loss on available-for-sale									
securities, net of tax			-			-			
Realized loss, net of tax			-			(13)			
Balance at December 31			-			-			
Total stockholders' equity		\$ 3	39,869		\$	6,531			
· ·			. ,		+	0,001			

The accompanying notes are an integral part of these consolidated financial statements

INTERPACE DIAGNOSTICS GROUP, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited, in thousands)

	For The Years Ended December 31,				
		2017	2016		
Cash Flows From Operating Activities					
Net loss	\$	(12,216)	\$	(8,332)	
Adjustments to reconcile net loss to net cash used in operating activities:	-	(,*)	Ŧ	(0,000)	
Depreciation and amortization		3,690		4,483	
Realignment accrual accretion		-		34	
Interest accretion		312		2,144	
Provision for bad debt		35		899	
Other current assets		-		102	
Amortization of debt issuance costs		117		-	
Mark to market on warrants		141		-	
Mark to market on derivaties		61		_	
Stock-based compensation		1,060		131	
Reversal of severance accrual		(2,034)		-	
Non-employee share based payment		216		_	
Warrants issued in RedPath settlement		193		_	
Asset impairment		175		3,363	
Warrant issuance		2,016		5,505	
Loss on extinguishment of debt		4,278		_	
Change in fair value of contingent consideration		(5,795)		(11,860)	
Deferred taxes		(3,773)		(11,000)	
Other gains and expenses, net		5		(4)	
Other changes in assets and liabilities:		5		(+)	
Other changes in assets and naontites.		(1,228)		4,766	
(Increase) decrease in accounts receivable		(1,228)		4,700	
Decrease in unbilled receivable		-		16	
Decrease in other current assets		222		1,478	
Decrease in other long-term assets		220		3,004	
(Decrease) increase in accounts payable		(2,633)		143	
(Decrease) in unearned contract revenue		(2,000)		(11)	
Decrease in accrued salaries and bonus		(1,395)		(637)	
Decrease in accrued liabilities		(2,751)		(4,992)	
Increase (decrease) in long-term liabilities		223		(2,334)	
Net cash used in operating activities		(15,263)		(7,607)	
Net easi used in operating activities		(15,205)		(7,007)	
Cash Flows From Investing Activity					
Purchase of property and equipment		(29)		-	
Net cash provided by investing activity		(29)		-	
Carle Flame Francisco Anticitica					
Cash Flows From Financing Activities				(1.222)	
Repayment of long-term debt		-		(1,333)	
Payments of contingent consideration		(25)		(475)	
Issuance of common stock, net of expenses		23,081		1,707	
Exercise of warrants, net of expenses		6,861		-	
Treasury stock purchased		(28)		-	
Net cash provided by (used in) financing activities		29,889		(101)	
Net increase (decrease) in cash and cash equivalents		14,597		(7,708)	
Cash and cash equivalents – beginning		602		8,310	
	*		<u>ф</u>		
Cash and cash equivalents – ending	\$	15,199	\$	602	
Cash paid for taxes	\$	417	\$	71	
Cash paid for interest	\$		\$	-	

The accompanying notes are an integral part of these consolidated financial statements

1. Nature of Business and Significant Accounting Policies

Nature of Business

Interpace Diagnostics Group, Inc. (the "Company") is a fully integrated commercial and bioinformatics company that provides clinically useful molecular diagnostic tests and pathology services. We develop and commercialize molecular diagnostic tests and related first line assays principally focused on early detection of patients at high risk of cancer and leverage the latest technology and personalized medicine for improved patient diagnosis and management. We currently have four commercialized molecular diagnostic assays in the marketplace for which we are reimbursed by Medicare and multiple private payers: PancraGEN[®], which is a pancreatic cyst and pancreaticobiliary solid lesion molecular test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform; ThyGenX[®], which is a oncogenic mutation panel that helps identify malignant thyroid nodules ; and ThyraMIR[®], which assesses thyroid nodules for risk of malignancy; and ThyraMIR[®], which assesses thyroid nodules for risk of malignancy utilizing a proprietary gene expression assay. We also launched in September 2017 RespriDXTM for assessing metastatic versus primary lung cancer. RespriDXTM utilizes our PathFinderTG[®] platform and compares the mutational fingerprint of two or more sites of lung cancer to determine whether the neoplastic deposits are representative of a recurrence of cancer or a new primary (independent) cancer. We are also in the process of "soft launching" while we gather additional market data, BarreGEN[®], an esophageal cancer risk classifier for Barrett's Esophagus that also utilizes our PathFinderTG[®] platform.

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The consolidated financial statements include the accounts of Interpace Diagnostics Group, Inc., Interpace Diagnostics Corporation and Interpace Diagnostics, LLC.

Discontinued operations include the Company's wholly-owned subsidiaries: Group DCA, LLC ("Group DCA"); InServe Support Solutions (Pharmakon); and TVG, Inc. (TVG, dissolved December 31, 2014) and its Commercial Services ("CSO") business unit. All significant intercompany balances and transactions have been eliminated in consolidation.

Effective December 31, 2015, the Company has one reporting segment: the Company's molecular diagnostics business, after the divestiture of its CSO business on December 22, 2015, see Note 4, Discontinued Operations for further information. The Company's current reporting segment structure is reflective of the way the Company's management views the business, makes operating decisions and assesses performance. This structure allows investors to better understand Company performance, better assess prospects for future cash flows, and make more informed decisions about the Company.

Accounting Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities reported and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management's estimates are based on historical experience, facts and circumstances available at the time, and various other assumptions that are believed to be reasonable under the circumstances. Significant estimates include accounting for valuation allowances related to deferred income taxes, contingent consideration, allowances for doubtful accounts and notes, revenue recognition, unrecognized tax benefits, and asset impairments involving other intangible assets. The Company periodically reviews these matters and reflects changes in estimates as appropriate. Actual results could materially differ from those estimates.



Cash and Cash Equivalents

Cash and cash equivalents include unrestricted cash accounts, money market investments and highly liquid investment instruments with original maturity of three months or less at the date of purchase.

Accounts Receivable

The Company's accounts receivable are generated using its proprietary tests. The Company's services are fulfilled upon completion of the test, review and release of the test results. In conjunction with fulfilling these services, the Company bills the third-party payer or hospital. The Company recognizes accounts receivable related to billings for Medicare, Medicare Advantage, and hospitals (direct-bill clients) on an accrual basis, net of contractual adjustment, when collectability is reasonably assured. Contractual adjustments represent the difference between the list prices and the reimbursement rate set by Medicare and Medicare Advantage, or the amounts billed to hospitals. The Company records accounts receivable net of contractual allowances and net of estimated uncollectable amounts. Specific accounts may be written off after several appeals, which in some cases may take longer than twelve months.

The Company provides services for patients with health insurance coverage through commercial insurance carriers or governmental programs that do not have a contract in place for its proprietary tests, which may or may not be covered by these entities existing reimbursement policies. In addition, the Company does not enter into direct agreements with patients that commit them to pay any portion of the cost of the tests in the event that their commercial insurance carrier or governmental program does not pay the Company for its services. In the absence of an agreement with the patient, or other clearly enforceable legal right to demand payment from commercial insurance carriers or governmental agencies, no accounts receivable is recognized.

Other current assets

Other current assets consisted of the following as of December 31, 2017 and 2016:

	December 31, 2017		December 31, 2016		
Indemnification assets	\$	875	\$	875	
Other receivables		-		325	
Prepaid expenses		266		4	
Other		31		211	
Total other current assets	\$	1,172	\$	1,415	

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization is recognized on a straight-line basis, using the estimated useful lives of: seven to ten years for furniture and fixtures; two to five years for office and computer equipment; five to seven years for lab equipment; and leasehold improvements are amortized over the shorter of the estimated service lives or the terms of the related leases which are currently four to five years. Repairs and maintenance are charged to expense as incurred. Upon disposition, the asset and related accumulated depreciation are removed from the related accounts and any gains or losses are reflected in operations.

Software Costs

Internal-Use Software - It is the Company's policy to capitalize certain costs incurred in connection with developing or obtaining internal-use software. Capitalized software costs are included in property and equipment on the consolidated balance sheet and amortized over the software's useful life, generally three to seven years. Software costs that do not meet capitalization criteria are expensed immediately.

External-Use Software - It is the Company's policy to capitalize certain costs incurred in connection with developing or obtaining external-use software. Capitalized software costs are included in property and equipment on the consolidated balance sheet and amortized over the software's useful life, generally three years. Software costs that do not meet capitalization criteria are expensed immediately.

See Note 6, Property and Equipment for further information.

Long-Lived Assets, including Finite-Lived Intangible Assets

Finite-lived intangible assets are stated at cost less accumulated amortization. Amortization of finite-lived acquired intangible assets is recognized on a straight-line basis, using the estimated useful lives of the assets of approximately two years to nine years in acquisition related amortization expense in the Consolidated Statements of Operations.

The Company reviews the recoverability of long-lived assets and finite-lived intangible assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized by reducing the recorded value of the asset to its fair value measured by future discounted cash flows. This analysis requires estimates of the amount and timing of projected cash flows and, where applicable, judgments associated with, among other factors, the appropriate discount rate. Such estimates are critical in determining whether any impairment charge should be recorded and the amount of such charge if an impairment loss is deemed to be necessary.

During the year ended December 31, 2016, the Company recorded an asset impairment charge of approximately \$3.4 million, resulting from a decline in market value of certain assets associated with the acquisition of assets from Asuragen. See Note 7, Other Intangible Assets for further information.

Contingencies

In the normal course of business, the Company is subject to various contingencies. Contingencies are recorded in the consolidated financial statements when it is probable that a liability will be incurred and the amount of the loss is reasonably estimable, or otherwise disclosed, in accordance with ASC 450, Contingencies. Significant judgment is required in both the determination of probability and the determination as to whether a loss is reasonably estimable. In the event the Company determines that a loss is not probable, but is reasonably possible, and it becomes possible to develop what the Company believes to be a reasonable range of possible loss, then the Company will include disclosures related to such matter as appropriate and in compliance with ASC 450. To the extent there is a reasonable possibility that the losses could exceed the amounts already accrued, the Company will, when applicable, adjust the accrual in the period the determination is made, disclose an estimate of the additional loss or range of loss, indicate that the estimate is immaterial with respect to its financial statements as a whole or, if the amount of such adjustment cannot be reasonably estimated, disclose that an estimate cannot be made. The Company is not currently involved in any legal proceedings of a material nature and, accordingly, the Company has not accrued estimated costs related to any legal claims.

Revenue and Cost of Revenue

The Company's revenue is generated using the Company's proprietary tests. The Company's performance obligation is fulfilled upon completion, review and release of test results and subsequently billing the third-party payer or hospital. The Company recognizes revenue related to billings for Medicare, Medicare Advantage, and hospitals on an accrual basis, net of contractual adjustment, when there is a predictable pattern of collectability. Contractual adjustments represent the difference between the list prices and the reimbursement rate set by Medicare and Medicare Advantage, or the amounts billed to hospitals, which approximates the Medicare rate. Upon ultimate collection, the amount received from Medicare, Medicare Advantage and hospitals with a predictable pattern of payment is compared to the previous estimates and the contractual allowance is adjusted, if necessary.

Until a contract has been negotiated with a commercial insurance carrier or governmental program, the services may or may not be covered by these entities existing reimbursement policies. In addition, the Company does not enter into direct agreements with patients that commit them to pay any portion of the cost of the tests in the event that insurance declines to reimburse us. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment, the related revenue is only recognized upon the earlier of payment notification or cash receipt. Accordingly, the Company recognizes revenue from commercial insurance carriers and governmental programs without a contract when payment is received.

Persuasive evidence of an arrangement exists and delivery is deemed to have occurred upon completion, review, and release of the test results by the Company. The assessment of the fixed or determinable nature of the fees charged for diagnostic testing performed, and the collectability of those fees, requires significant judgment by management. Management believes that these two criteria have been met when there is contracted reimbursement coverage or a predictable pattern of collectability with individual third-party payers or hospitals and accordingly, recognizes revenue upon delivery of the test results. Under current accounting guidelines, in the absence of contracted reimbursement coverage or a predictable pattern of collectability, as in the case of commercial or other government payers, the Company recognizes revenue when payment is received.

Cost of services consists primarily of the costs associated with operating the Company's laboratories and other costs directly related to the Company's tests. Personnel costs, which constitute the largest portion of cost of services, include all labor related costs, such as salaries, bonuses, fringe benefits and payroll taxes for laboratory personnel. Other direct costs include, but are not limited to, laboratory supplies, certain consulting expenses, and facility expenses.

Stock-Based Compensation

The compensation cost associated with the granting of stock-based awards is based on the grant date fair value of the stock award. The Company recognizes the compensation cost, net of estimated forfeitures, over the shorter of the vesting period or the period from the grant date to the date when retirement eligibility is achieved. Forfeitures are initially estimated based on historical information and subsequently updated over the life of the awards to ultimately reflect actual forfeitures. As a result, changes in forfeiture activity can influence the amount of stock compensation cost recognized from period to period.

The Company primarily uses the Black-Scholes option-pricing model to determine the fair value of stock options and stock appreciation rights ("SARs"). The determination of the fair value of stock-based payment awards is made on the date of grant and is affected by the Company's stock price as well as assumptions made regarding a number of complex and subjective variables. These assumptions include: expected stock price volatility over the term of the awards; actual and projected employee stock option exercise behaviors; the risk-free interest rate; and expected dividend yield. The fair value of restricted stock units, or RSUs, and restricted shares is equal to the closing stock price on the date of grant.

See Note 13, Stock-Based Compensation for further information.

Treasury Stock

Treasury stock purchases are accounted for under the cost method whereby the entire cost of the acquired stock is recorded as treasury stock. Upon reissuance of shares, the Company records any difference between the weighted-average cost of such shares and any proceeds received as an adjustment to additional paid-in capital.

Rent Expense

Minimum rental expenses are recognized over the term of the lease. The Company recognizes minimum rent starting when possession of the property is taken from the landlord, which may include a construction period prior to occupancy. When a lease contains a predetermined fixed escalation of the minimum rent, the Company recognizes the related rent expense on a straight-line basis and records the difference between the recognized rental expense and the amounts payable under the lease as a deferred rent liability. The Company may also receive tenant allowances including cash or rent abatements, which are reflected in other accrued expenses and long-term liabilities on the consolidated balance sheet. These allowances are amortized as a reduction of rent expense over the term of the lease. Certain leases provide for contingent rents that are not measurable at inception. These contingent rents are primarily based upon use of utilities and the landlord's operating expenses. These amounts are excluded from minimum rent and are included in the determination of total rent expense when it is probable that the expense has been incurred and the amount is reasonably estimable.

Income taxes

Income taxes are based on income for financial reporting purposes calculated using the Company's expected annual effective rate and reflect a current tax liability or asset for the estimated taxes payable or recoverable on the current year tax return and expected annual changes in deferred taxes. Any interest or penalties on income tax are recognized as a component of income tax expense.

The Company accounts for income taxes using the asset and liability method. This method requires recognition of deferred tax assets and liabilities for expected future tax consequences of temporary differences that currently exist between tax bases and financial reporting bases of the Company's assets and liabilities based on enacted tax laws and rates. Deferred tax expense (benefit) is the result of changes in the deferred tax asset and liability. A valuation allowance is established, when necessary, to reduce the deferred income tax assets when it is more likely than not that all or a portion of a deferred tax asset will not be realized.

The Company operates in multiple tax jurisdictions and pays or provides for the payment of taxes in each jurisdiction where it conducts business and is subject to taxation. The breadth of the Company's operations and the complexity of the tax law require assessments of uncertainties and judgments in estimating the ultimate taxes the Company will pay. The final taxes paid are dependent upon many factors, including negotiations with taxing authorities in various jurisdictions, outcomes of tax litigation and resolution of proposed assessments arising from federal and state audits. Uncertain tax positions are recognized in the financial statements when it is more likely than not (i.e., a likelihood of more than fifty percent) that a position taken or expected to be taken in a tax return would be sustained upon examination by tax authorities that have full knowledge of all relevant information. A recognized tax position is then measured as the largest amount of benefit that is greater than fifty percent likely to be realized upon ultimate settlement. The Company adjusts accruals for unrecognized tax benefits as facts and circumstances change, such as the progress of a tax audit. However, any adjustments made may be material to the Company's consolidated results of operations or cash flows for a reporting period. Penalties and interest, if incurred, would be recorded as a component of current income tax expense.



Significant judgment is also required in evaluating the need for and magnitude of appropriate valuation allowances against deferred tax assets. Deferred tax assets are regularly reviewed for recoverability. The Company currently has significant deferred tax assets resulting from net operating loss carryforwards and deductible temporary differences, which should reduce taxable income in future periods, if generated. The realization of these assets is dependent on generating future taxable income.

Income (Loss) per Share

Basic earnings per common share are computed by dividing net income by the weighted average number of shares outstanding during the year including any unvested share-based payment awards that contain nonforfeitable rights to dividends. Diluted earnings per common share are computed by dividing net income by the sum of the weighted average number of shares outstanding and dilutive common shares under the treasury method. Unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid), are participating securities and are included in the computation of earnings per share pursuant to the two-class method. As a result of the losses incurred in both 2017 and 2016, the potentially dilutive common shares have been excluded from the earnings per share computation for these periods because its inclusion would have been anti-dilutive.

Reverse stock split

On December 28, 2016, the Company effected a one-for-ten reverse split of its issued and outstanding shares of common stock in order to achieve the requisite increase in the market price of our common stock to be in compliance with the NASDAQ minimum bid price requirement. All share amounts in prior periods have been adjusted to reflect the reverse split.

2. Recent Accounting Standards

Recently adopted standards

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which is intended to simplify the accounting and reporting for employee share-based payment transactions. The pronouncement is effective for interim and annual periods beginning after December 31, 2016 with early adoption permitted. The adoption of the guidance in ASU No. 2016-09 in the first quarter of 2017 did not have a material impact on the Company's consolidated financial statements.

New standards not yet adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which when effective will require organizations that lease assets to recognize assets and liabilities for the rights and obligations created by the leases on the balance sheet. A lessee will be required to recognize assets and liabilities for leases with terms that exceed twelve months. The standard will also require disclosures to help investors and financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. The disclosures include qualitative and quantitative requirements, providing additional information about the amounts recorded in the financial statements. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial position and results of operations. The expectation is that the adoption will include an increase in assets and liabilities.

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)." The standard, including subsequently issued amendments, will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The key focus of the new standard is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve this key focus, there is a five-step approach outlined in the standard. Entities are permitted to apply the new standard under the full retrospective method, subject to certain practical expedients, or the modified retrospective method that requires the application of the guidance only to contracts that are uncompleted on the date of initial application. The Company will adopt the new revenue standard and subsequently issued amendments as of January 1, 2018 using the modified retrospective method.

The Company has formed an implementation team, which includes internal accounting resources and a third-party consulting firm, to oversee the adoption of the new standard. The implementation team has performed a detailed review of the Company's contracts and revenue streams to identify potential differences in accounting as a result of the new standard and its appropriate application.

The Company's revenue is generated from the performance of its proprietary tests. The Company's performance obligation is fulfilled upon completion, review and release of test results and subsequent billing to the third-party payer or hospital. The Company currently recognizes revenue related to billings for Medicare, Medicare Advantage, and hospitals on an accrual basis, net of contractual adjustment, when there is a predictable pattern of collectability. Contractual adjustments represent the difference between the list prices and the reimbursement rate set by Medicare and Medicare Advantage, or the amounts billed to hospitals, which approximates the Medicare rate. Upon ultimate collection, the amount received from Medicare, Medicare Advantage and hospitals with a predictable pattern of payment is compared to the previous estimates and the contractual allowance is adjusted, if necessary. The net amount derived is referred to as the "net realizable value" for the particular test and payer group from which reimbursement is received. The derived "net realizable value" is then applied to future periods until recalculated.

Currently, for certain third-party payers that do not have established contractual reimbursement rates or a predictable pattern of collectability, including commercial insurance carriers, Medicaid and certain hospitals, the Company believes that the fee is fixed or determinable and collectability is reasonably assured only upon request of third-party payer notification of payment or when cash is received, and recognizes revenue at that time.

Under the new standard, the Company will be required to estimate the variable consideration within the transaction price for all thirdparty payers and proprietary tests and recognize revenue as the Company satisfies its performance obligations. For those third-party payers and proprietary tests where the Company currently recognizes revenue upon request of third-party payer notification of payment or when cash is received, the Company will recognize revenues upon completion, review and release of test results based on the estimated transaction price, subject to a constraint. As a result, the Company expects to recognize a significant portion of its revenues earlier under the new standard than it recognizes under current guidance, using the net realizable value for each test within each payer group.

The Company completed its preliminary analysis of the ASC 606 impact and plans to incorporate further analysis of first quarter 2018 collections from its commercial payer base in order to finalize its ASC 606 adjustments. This analysis will be completed prior to filing its first quarter 2018 Form 10-Q. Management currently estimates the impact of recording the cumulative catch-up adjustment under the modified retrospective method to be in the range of \$1.0 million to \$1.5 million, which will be recorded as an increase to opening retained earnings on January 1, 2018. Prior periods will not be retrospectively adjusted. The Company also continues to finalize its analysis of additional or modified internal controls over financial reporting and the required disclosures that will be required to be included in our Form 10-Q for the first quarter of 2018.

3. Liquidity

As of December 31, 2017, the Company had cash and cash equivalents of \$15.2 million, net accounts receivable of \$3.4 million, total current assets of \$19.8 million and total current liabilities of \$8.1 million. For the year ended December 31, 2017, the Company had a net loss of \$12.2 million and cash used in operating activities was \$15.3 million, including non-recurring charges.

During the year ended December 31, 2017, the Company closed on various equity offerings and a warrant issuance raising gross proceeds of \$34.0 million (or \$29.9 million, net of expenses). The details are as follows:

- On January 6, 2017, the Company completed a registered direct public offering (the "First Registered Direct Offering"), to sell 630,000 shares of its common stock at a price of \$6.81 per share to certain institutional investors, which resulted in gross proceeds to the Company of approximately \$4.3 million.
- On January 25, 2017, the Company completed a registered direct public offering (the "Second Registered Direct Offering"), to sell 855,000 shares of its common stock and a concurrent private placement of warrants to purchase 855,000 shares of its common stock (the "Concurrent Warrants"), to the same investors participating in the Second Registered Direct Offering, (or the "Private Placement"). The Second Registered Direct Offering and the Private Placement together resulted in gross proceeds to the Company of approximately \$4.0 million.
- On February 8, 2017, the Company completed an underwritten, confidentially marketed public offering ("CMPO"), to sell 1,200,000 shares of its common stock at a price of \$3.00 per share. The CMPO resulted in gross proceeds to the Company of approximately \$3.9 million, including the exercise of the over-allotment option.
- On June 21, 2017, pursuant to its S-1 filing of its preliminary prospectus to register shares on May 22, 2017, as amended thereafter, the Company completed a public offering (the "Offering") for 9,900,000 shares of common stock together with an equal number of common warrants (the "Base Warrants"), to purchase shares of its common stock (and the shares of common stock that are issuable from time to time upon exercise of the common warrants) for \$1.10 per share. The issuance of the 9,900,000 shares of common stock at \$1.10 per share, along with 2,600,000 prefunded warrants at \$1.09 per share resulted in combined gross proceeds of the Offering totaling \$13.7 million, with approximately \$12.3 million of net funds available to the Company after deducting underwriting discounts and other stock issuance expenses. On July 31, 2017 the Company and the underwriters closed on the exercise of the underwriters' over-allotment option to purchase an additional 875,000 shares of common stock at a price of \$1.09 per share for gross proceeds of \$0.960 million. During September 2017 the Company received approximately \$0.9 million from the exercise of 747,800 Base Warrants issued as part of the Offering.

Also in 2017 the Company received approximately \$6.2 million from the exercise of Base Warrants issued as part of the above Offering, as follows:

- During October 2017 the Company received approximately \$1.2 million from the exercise of approximately 925,000 Base Warrants.
- On October 12, 2017 the Company entered into an agreement with certain holders of Base Warrants to exercise 4 million Base Warrants at the exercise price of \$1.25 in exchange for the issuance of 3.2 million additional private placement warrants with an exercise price of \$1.80, resulting in gross proceeds to the Company of \$5.0 million. The new warrants may not be exercised for six months from the issue date and expire in five and one-half years from their issuance date. As a result of this transaction, the Company recorded a \$2.0 million charge within Other (expense) income, net within the consolidated statement of operations as such transaction was deemed to be an inducement to the existing warrant holders.



As part of our acquisition of RedPath Integrated Pathology, Inc., we issued a non-negotiable subordinated secured, non-interest bearing, promissory note, dated as of October 31, 2014, with an aggregate principal amount of \$10.7 million outstanding (the "RedPath Note"). In December 2016 we repaid \$1.33 million in principal of the RedPath Note resulting in an outstanding balance of \$9.34 million. The RedPath Note was subsequently acquired by a single institutional investor (the "Investor") for \$8.87 million on March 22, 2017. Also, on that date we and the Investor exchanged the RedPath Note for a senior secured convertible note in the aggregate principal amount of \$3.55 million. On April 18, 2017, we and the Investor exchanged the senior secured non-convertible note for \$3.55 million of our senior secured convertible note. Between March 23, 2017 and April 18, 2017, the senior secured convertible notes were converted in full for 3,795,429 shares of our common stock. We no longer have any outstanding secured debt, and any security interests and liens related to our former secured debt have been fully settled.

The Company entered into a Credit Agreement with SCM Specialty Finance Opportunities Fund, L.P. (the "Credit Agreement") on September 28, 2016 for \$1.2 million. The Credit Agreement contains customary representations and warranties in favor of the Lender and certain covenants, including, among other things, financial covenants relating to loan turnover rates, liquidity and revenue targets. On February 14, 2018 the Credit Agreement was terminated and no funds were ever drawn down under the Credit Agreement.

While the Company has significantly increased its cash balance and has eliminated all of its Long-term debt, the Company does not expect to generate positive cash flows from operations for the year ending December 31, 2018. The Company believes however, that it has sufficient cash balances to meet near term obligations and further intends to meet its capital needs by revenue growth, containing costs, entering into strategic alliances as well as exploring other options, including the possibility of raising additional debt or equity capital as necessary. There is, however, no assurance the Company will be successful in meeting its capital requirements prior to becoming cash flow positive.

4. Discontinued Operations

The Company accounts for business dispositions and its businesses held for sale in accordance with ASC 205-20, Discontinued Operations. ASC 205-20 requires the results of operations of business dispositions to be segregated from continuing operations and reflected as discontinued operations in current and prior periods.

In December 2015, the Company completed the sale (the "Asset Sale") of substantially all of the assets, goodwill and ongoing business comprising its CSO business to Publicis Healthcare Solutions, Inc., formerly known as Publicis Touchpoint Solutions, Inc. (the "Buyer"), pursuant to the Asset Purchase Agreement, dated as of October 30, 2015, by and between the Buyer and the Company (the "Asset Purchase Agreement"), for an aggregate cash purchase price at the closing of approximately \$28.5 million (the "Closing Purchase Price"), subject to a post-closing working capital adjustment, and the assumption by the Buyer of certain specified liabilities. The Closing Purchase Price included a \$25.5 million cash payment (the "Base Cash Payment"), and an estimated closing date working capital adjustment cash payment of \$3.0 million. Under the Asset Purchase Agreement, the Company was also entitled to receive an earn-out payment in 2017 equal to one-third of the 2016 revenues generated by the Commercial Services Business under certain specified contracts and client relationships, less the amount of the Base Cash Payment. The Company does not anticipate receiving this earn-out payment at this time. The Company recorded a \$1.3 million gain on the sale for the year ended December 31, 2016.

The components of liabilities classified as discontinued operations relate to Commercial Services and consist of the following as of December 31, 2017 and December 31, 2016:

	For the Years Ended December 31,													
	2017									2016				
		CSO		TVG		,	Fotal		CSO		TVG		, ,	Total
Accounts payable	\$	192	\$		-	\$	192	\$	890	\$		-	\$	890
Accrued salary and bonus		-			-		-		1,272			-		1,272
Other		1,110			-		1,110		1,966			-		1,966
Current liabilities from discontinued operations		1,302			-		1,302		4,128			-		4,128
Total liabilities	\$	1,302	\$		-	\$	1,302	\$	4,128	\$		-	\$	4,128

Company management is currently winding down certain legal entities which are no longer active within its corporate structure, none of which falls under the criteria of discontinued operations. However, this activity may result in the restructuring of past liabilities, which may result in further reductions based upon new estimates and third-party evaluations.

5. Fair Value Measurements

Cash and cash equivalents, accounts receivable, and accounts payable approximate fair value due to their relative short-term nature. The Company's financial liabilities reflected at fair value in the consolidated financial statements include contingent consideration and warrant liability. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In determining fair value, the Company uses various methods including market, income and cost approaches. Based on these approaches, the Company often utilizes certain assumptions that market participants would use in pricing the asset or liability, including assumptions about risk and/or the risks inherent in the inputs to the valuation technique. These inputs can be readily observable, market-corroborated, or generally unobservable inputs. The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. Based upon observable inputs used in the valuation techniques, the Company is required to provide information according to the fair value hierarchy. The fair value hierarchy ranks the quality and reliability of the information used to determine fair values into three broad levels as follows:

- Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources for market transactions involving identical assets or liabilities.
- Level 2: Valuations for assets and liabilities traded in less active dealer or broker markets. Valuations are obtained from third-party pricing services for identical or similar assets or liabilities.
- Level 3: Valuations for assets and liabilities include certain unobservable inputs in the assumptions and projections used in determining the fair value assigned to such assets or liabilities.

In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability. The valuation methodologies used for the Company's financial instruments measured on a recurring basis at fair value, including the general classification of such instruments pursuant to the valuation hierarchy, is set forth in the tables below.

	Α	As of December 31, 2017				Fair Value Measurements						
	Са	Carrying		Fair	As of December 31, 2017							
	A	mount		Value		Level 1	Level 2	L	evel 3			
Liabilities:												
Contingent consideration:												
Asuragen	\$	1,581	\$	1,581	\$	-	\$	- \$	1,581			
Other long-term liabilities:												
Warrant liability		473		473		-		-	473			
	\$	2,054	\$	2,054	\$	-	\$	- \$	2,054			
	Α	s of Decem	iber 31	, 2016	Fair Value Measurements							
	Са	rrying		Fair	As of December 31, 2016							
	A	mount		Value		Level 1	evel 1 Level 2		evel 3			
Liabilities:												
Contingent consideration:												
Asuragen	\$	1,545	\$	1,545	\$	-	\$	- \$	1,545			
RedPath		5,969		5,969		-		-	5,969			
	\$	7,514	\$	7,514	\$	-	\$	- \$	7,514			
			F-17									

In connection with the acquisition of certain assets from Asuragen and the acquisition of RedPath, the Company recorded contingent consideration related to contingent payments and other revenue-based payments. The Company determined the fair value of the contingent consideration based on a probability-weighted income approach derived from revenue estimates. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement. On March 22, 2017, the Company entered into a Termination Agreement with the RedPath Equityholder Representative. Under the terms of the Termination Agreement, the RedPath Equityholder Representative agreed to terminate all royalty and milestone rights under the contingent consideration agreement. As a result, the Company reversed approximately \$6.0 million in Redpath contingent consideration liabilities in the first quarter of 2017, of which \$5.8 million was a reversal within operating expenses in the Condensed Consolidated Statement of Operations with the balance consisting of the issuance of warrants. There was an \$11.9 million net reduction in the fair value of the contingent consideration during the period ended December 31, 2016.

On March 23, 2017, in connection with the Company entering into the Exchange Agreement, related to the RedPath Note (See Note 3, Liquidity and Note 18, Long-Term Debt) with the Investor, an embedded conversion option derivative liability was recorded due to a certain embedded conversion feature. The embedded conversion option is considered a liability and valued using the Black-Scholes Option-Pricing Model, the inputs for which include exercise price of the conversion feature, market price of the underlying common shares, expected term, volatility based on the Company's historical market price, and the risk-free rate corresponding to the expected term of the Exchange Agreement. Any changes to the estimated fair value of this liability were recorded in Interest Expense. Between March 23, 2017 and April 18, 2017, the Investor had fully converted all outstanding debt, and as a result there are no liabilities remaining subsequent to April 18, 2017.

On June 21, 2017, the Company closed on an Offering (See Note 3, Liquidity), issuing both Pre-Funded Warrants and Underwriters Warrants to purchase 2,600,000 shares and 575,000 shares of the Company's common stock, respectively. Both the Pre-Funded and Underwriters Warrants include a cash settlement feature in the event of certain circumstances. Accordingly, both the Pre-Funded and Underwriters Warrants are classified as liabilities and were fair valued using the Black Scholes Option-Pricing Model, the inputs for which include exercise price of the respective warrants, market price of the underlying common shares, expected term, volatility based on the Company's historical market price, and the risk-free rate corresponding to the expected term of the Exchange Agreement. Changes to the fair value of the warrant liabilities were recorded in Other (expense) income, net. The Pre-Funded Warrants were fully exercised in 2017 and therefore the Company has no remaining liability associated with those warrants.

	Dec	cember 31,	Ι	nitial					of	Cancellation Obligation/ Conversions	djustment Fair Value/ Mark to	De	cember 31,	
		2016	Li	ability	Pay	ments ⁽¹⁾	A	ccretion	Exercises		 Market		2017	
Contingent consideration:				<u> </u>										
Asuragen	\$	1,545			\$	(260)	\$	122	\$	-	\$ 174	\$	1,581	
Redpath		5,969				-		-		(5,969)	-		-	
Embedded conversion option		-		208		-		-		(269)	61		-	
Pre-Funded Warrants		-		2,247		-		-		(2,337)	90		-	
Underwriters Warrants		-		422		-		-		-	51		473	
	\$	7,514	\$	2,877	\$	(260)	\$	122	\$	(8,575)	\$ 376	\$	2,054	

(1) Royalty payments of \$235,000 are reflected within Cash Flows from Operations. The remaining \$25,000 represents a milestone payment related to financing the Asuragen acquisition and is reflected in Cash Flows from Financing Activities.

Certain of the Company's non-financial assets, such as other intangible assets and goodwill are measured at fair value on a nonrecurring basis when there is an indicator of impairment and recorded at fair value only when an impairment charge is recognized.

6. Property and Equipment

Property and equipment consisted of the following as of December 31, 2017 and 2016:

	December 31,						
	2	2016					
Furniture and fixtures	\$	62	\$	667			
Office equipment		1,348		1,503			
Computer equipment		115		3,473			
Internal-use software		113		113			
Leasehold improvements		175		878			
Property and equipment		1,813		6,634			
Less accumulated depreciation		(1,159)		(5,705)			
Net property and equipment	\$	654	\$	929			

Depreciation expense from continuing operations was approximately \$0.4 million and \$0.5 million for the years ended December 31, 2017 and 2016, respectively. There was no internal-use software amortization expense included in depreciation and amortization expense for either period. As of December 31, 2017, capitalized external-use software was fully amortized.

The decrease in gross property and equipment and accumulated depreciation in 2017 was the result of the expiration of the lease on the Company's former office space in Parsippany, NJ and the removal of the assets associated with those buildings as well as the removal of old IT equipment. The Company disposed of various property and equipment with a total cost of \$5.0 million and a net book value of five thousand dollars at disposition. Accordingly, it recognized a loss of five thousand on the disposition.

7. Other Intangible Assets

The net carrying value of the identifiable intangible assets as of December 31, 2017 and December 31, 2016 is as follows:

	Life (Years)	Dec	As of cember 31, 2017 Carrying Amount	(As of nber 31, 2016 Carrying Amount
Diagnostic assets:					
Asuragen acquisition:					
Thyroid	9	\$	8,519	\$	8,519
Pancreas	-		-		-
Biobank	-		-		-
RedPath acquisition:					
Pancreas test	7		16,141		16,141
Barrett's test	9		18,351		18,351
Total		\$	43,011	\$	43,011
Diagnostic lab:					
CLIA Lab	2.3	\$	609	\$	609
Total Cost		\$	43,620	\$	43,620
Accumulated Amortization		\$	(10,515)	\$	(7,262)
Net Carrying Value		\$	33,105	\$	36,358

Amortization expense was approximately \$3.3 million and \$3.8 million for the years ended December 31, 2017 and 2016, respectively. Estimated amortization expense for the next five years is as follows:

 2018	 2019	 2020	 2021	 2022
\$ 3,252	\$ 5,292	\$ 5,292	\$ 4,908	\$ 2,987

In 2016, the Company recorded an asset impairment charge of approximately \$3.4 million resulting from a decline in the market value of certain assets associated with the acquisition of assets from Asuragen.

8. Retirement Plans

The Company offers an employee 401(k) saving plan. Under the Interpace Diagnostics Group, Inc. 401(k) Plan, employees may contribute up to 50% of their pre- or post-tax base compensation. The Company currently offers a safe harbor matching contribution equal to 100% of the first 3% of the participant's contributed base salary plus 50% of the participant's base salary contributed exceeding 3% but not more than 5%. Participants are not allowed to invest any of their 401(k) funds in the Company's common stock. The Company's total contribution expense from continuing operations related to the 401(k) plan for the years ended December 31, 2017 and December 31, 2016 was approximately \$0.2 million and \$0.1 million, respectively.

9. Accrued Expenses and Other Long-Term Liabilities

Other accrued expenses consisted of the following as of December 31, 2017 and 2016:

	De	cember 31, 2017	December 31, 2016
Accrued royalties	\$	296	\$ 711
Indemnification liability		875	875
Contingent consideration		232	260
DOJ settlement		500	80
Accrued professional fees		700	1,746
Taxes payable		515	526
Unclaimed property		565	565
All others		1,321	1,473
Total other accrued expenses	\$	5,004	\$ 6,236

Other long-term liabilities consisted of the following as of December 31, 2017 and 2016:

	Decei	mber 31, 2017]	December 31, 2016
Warrant liability	\$	473	\$	-
Uncertain tax positions		3,734		3,594
DOJ settlement		-		250
Other		82		-
Total other long-term liabilities	\$	4,289	\$	3,844

10. Commitments and Contingencies

The Company leases facilities and certain equipment under agreements classified as operating leases, which expire at various dates through September 2022. Substantially all of the property leases provide for increases based upon use of utilities and landlord's operating expenses as well as pre-defined rent escalations. Total expense from continuing operations under these agreements for the years ended December 31, 2017 and 2016 was approximately \$0.7 million and \$0.9 million, respectively.

As of December 31, 2017, contractual obligations with terms exceeding one year and estimated minimum future rental payments required by non-cancelable operating leases with initial or remaining lease terms exceeding one year are as follows:

			Les	ss than	1	to 3	3	to 5		After
	Т	otal	1	Year	Ŋ	lears	Y	<i>lears</i>	5	Years
Operating lease obligations	\$	774	\$	160	\$	316	\$	298	\$	-
Contractual obligation		-		-		-		-		-
Total	\$	774	\$	160	\$	316	\$	298	\$	-

Litigation

Due to the nature of the businesses in which the Company is engaged it is subject to certain risks. Such risks include, among others, risk of liability for personal injury or death to persons using products the Company promotes or commercializes. There can be no assurance that substantial claims or liabilities will not arise in the future due to the nature of the Company's business activities and recent increases in litigation related to healthcare products.

As part of the closeout of its CSO business, the Company seeks to reduce its potential liability under its service agreements through measures such as contractual indemnification provisions with customers (the scope of which may vary from customer to customer, and the performance of which is not secured) and insurance. The Company could, however, also be held liable for errors and omissions of its employees in connection with the services it performs that are outside the scope of any indemnity or insurance policy. The Company could be materially adversely affected if it were required to pay damages or incur defense costs in connection with a claim that is outside the scope of an indemnification agreement; if the indemnity, although applicable, is not performed in accordance with its terms; or if the Company's liability exceeds the amount of applicable insurance or indemnity.

As of December 31, 2017, the Company's accrual for litigation and threatened litigation was not material to the consolidated financial statements.

RedPath - DOJ Settlement

In connection with the October 31, 2014 acquisition of RedPath, the Company assumed a liability for the Settlement Agreement entered into by the former owners of RedPath with the DOJ. Under the terms of the Settlement Agreement, the Company is obligated to make payments to the DOJ for the calendar years ended December 31, 2014 through 2017, up to a maximum of \$3.0 million. Payments are due on March 31st following the calendar year in which the revenue milestones are achieved. The Company made payments totaling \$0.5 million in the year ended December 31, 2017 related to fiscal 2016 and has accrued \$0.5 million for its estimate of the potential liability for the final year of the Settlement Agreement, 2017.

Prolias Technologies, Inc. v. PDI, Inc.

On April 8, 2015, Prolias Technologies, Inc. ("Prolias") filed a complaint (the "Complaint") against the Company with the Superior Court of New Jersey (Morris County) (the "Court") in a matter entitled Prolias Technologies, Inc. v. PDI, Inc. (Docket No. MRS-L-899-15). In the Complaint, Prolias alleged that it and the Company entered into an August 19, 2013 Collaboration Agreement and a First Amendment thereto (collectively, the "Agreement") whereby Prolias and the Company agreed to work in good faith to commercialize a diagnostic test known as "Thymira." On March 9, 2017, the Court entered a final judgment in the Company's favor against Prolias for the sum of \$636,053 plus ten percent interest continuing to accrue on the principal balance of \$500,000 (per diem \$136.99) unless and until paid. Final judgment was also entered in the Company's favor, and against Prolias, declaring Prolias is deemed to have executed and delivered to the Company a promissory note in the amount of \$1,000,000 and Prolias is obligated to repay the Company the principal amount and all interest in accordance with the terms of the promissory note and Article 10.2(a) of the Collaboration Agreement by and between Prolias and the Company will ever be able to recover on the judgment against Prolias.

Severance

During the first quarter ended March 31, 2016 the Company recorded severance obligations as it continued to right-size the organization and wind down its CSO business amounting to \$1.1 million, \$0.5 million of which was recorded in continuing operations.

The severance liability as of December 31, 2016 was approximately \$3.1 million, of which \$2.2 million was classified in continuing operations and \$0.9 million was in discontinued operations. In January 2017, five former executives agreed to a settlement of their severance obligations agreeing to 35% of the total amount due them. These remaining obligations were paid out in February 2017 in payments totaling approximately \$1.0 million. As a result of the settlement, the Company recorded a reversal of expense of approximately \$2.0 million in the first quarter of 2017. Within continuing operations, \$1.5 million of expense was reversed and was recorded in general and administrative expenses in the Condensed Consolidated Statements of Operations and \$0.5 million was recorded in discontinued operations. The Company has no severance obligations as of December 31, 2017.

11. Preferred Stock and Equity Offerings

Preferred Stock

The board of directors (the "Board") of the Company is authorized to issue, from time-to-time, up to 5,000,000 shares of preferred stock in one or more series. The Board is authorized to fix the rights and designation of each series, including dividend rights and rates, conversion rights, voting rights, redemption terms and prices, liquidation preferences and the number of shares of each series. As of December 31, 2017 and 2016, there were no issued and outstanding shares of preferred stock.

Public Equity Offerings

During the year ended December 31, 2017, the Company closed on various equity offerings and a warrant issuance raising net proceeds of \$29.9 million. The details are as follows:

- On January 6, 2017, the Company completed the First Registered Direct Offering to sell 630,000 shares of its common stock at a price of \$6.81 per share to certain institutional investors, which resulted in gross proceeds to the Company of approximately \$4.3 million.
- On January 25, 2017, the Company completed the Second Registered Direct Offering to sell 855,000 shares of its common stock and a concurrent private placement of warrants to purchase 855,000 shares of its common stock, or the Warrants, to the same investors participating in the Second Registered Direct Offering. The Warrants and the shares of the Company's common stock issuable upon the exercise of the Warrants were not registered under the Securities Act and were sold pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) of Regulation D promulgated thereunder. The shares of common stock sold in the Second Registered Direct Offering and the Warrants issued in the concurrent Private Placement were issued separately but sold together at a combined purchase price of \$4.69 per share of common stock and accompanying Warrant. The Second Registered Direct Offering and the Private Placement together resulted in gross proceeds to the Company of approximately \$4 million. The Company also used approximately \$1.0 million to satisfy the severance obligations due to five former senior executives. See Note 10, Commitments and Contingencies. The fair value of these warrants issued was determined using the Black-Scholes Option Pricing Model and amounted to \$1.67 million and are recorded within stockholders' equity. The following table sets forth the assumptions used in the Black-Scholes Option Pricing Model to estimate the fair value of the warrants upon issuance:



Market Price	\$ 4.33
Exercise Price	\$ 4.69
Risk-free interest rate	1.95%
Expected volatility	124.02%
Expected life in years	5.0
Expected dividend yield	0.00%

• On February 8, 2017, the Company completed a Confidentially Marketed Public Offering (CMPO) to sell 1,200,000 shares of our common stock at a price of \$3.00 per share. In addition, we granted the underwriters an option to purchase up to an additional 9% of the total number of shares of common stock sold by us in the CMPO, solely for the purpose of covering over-allotments, if any. The underwriters exercised the over-allotment option in full. The CMPO resulted in gross proceeds to us of approximately \$3.9 million.

On March 22, 2017, the Company entered into a Termination Agreement with the RedPath Equityholder Representative. Under the terms of the Termination Agreement, RedPath Equityholder Representative agreed to terminate all royalty and milestone rights under the contingent consideration agreement. In exchange for terminating the royalty and milestone rights of RedPath, the Company agreed to issue to the RedPath Equityholder Representative 5 year warrants to acquire an aggregate of 100,000 shares of the Company's common stock at a fixed price of \$4.69 per share. The fair value of the warrants issued was determined using the Black-Scholes Option Pricing Model and amounted to \$0.19 million and is recorded within stockholders' equity. The following table sets forth the assumptions used in the Black-Scholes Option Pricing Model to estimate the fair value of the warrants upon issuance:

Market Price	\$ 2.37
Exercise Price	\$ 4.69
Risk-free interest rate	1.95%
Expected volatility	125.58%
Expected life in years	5.5
Expected dividend yield	0.00%

As part of our acquisition of RedPath Integrated Pathology, Inc. in 2014, we issued the RedPath Note. In December 2016 we repaid \$1.33 million in principal of the RedPath Note resulting in an outstanding balance of \$9.34 million. The RedPath Note was subsequently acquired by an Investor for \$8.87 million plus the fair value of the warrants noted above amounting to \$0.5 million on March 22, 2017. Also, on that date, we and the Investor exchanged the RedPath Note for a senior secured convertible note in the aggregate principal amount of \$5.32 million and a senior secured non-convertible note in the aggregate principal amount of \$3.55 million. On April 18, 2017, we and the Investor exchanged the senior secured non-convertible note for \$3.55 million of our senior secured convertible note. Between March 23, 2017 and April 18, 2017, the senior secured convertible notes were converted in full for 3,795,429 shares of our common stock. In connection with the conversion of the Exchanged Convertible Note, the Company recorded a loss of \$4.3 million. We no longer have any outstanding secured debt, and any security interests and liens related to our former secured debt were released and/or terminated upon the completion of applicable filings.

On June 16, 2017, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Maxim as the representative of several underwriters (the "Underwriters") named therein with respect to the issuance and sale of an aggregate of (i) 9,900,000 shares ("Firm Shares") of the Company's common stock, (ii) Base Warrants to purchase 12,500,000 shares of common stock at an exercise price equal to \$1.25 per share, and (iii) Pre-Funded Warrants to purchase 2,600,000 shares of common stock at an exercise price equal to \$0.01 per share in the Offering pursuant to the Underwriting Agreement. Each Firm Share and accompanying Base Warrant was sold for a combined effective price of \$1.10, and each Pre-Funded Warrant and accompanying Base Warrant was sold for a combined effective price of \$1.09. The Underwriters were entitled to receive an underwriting discount equal to 7.5% of the offer price of the aggregate number of Firm Shares and Pre-Funded Warrants sold in the Offering and Over-Allotment and reasonable out-of-pocket expenses of \$0.1 million. The Company also granted the Underwriters a 45-day option to purchase up to an additional 1,875,000 Firm Shares and/or 1,875,000 Base Warrants to cover over-allotments, if any (the "Overallotment Warrants"). Additionally, the Company agreed to issue to the Underwriters warrants (the "Underwriter Warrant") to purchase a number of Firm Shares of common stock equal to an aggregate of 4% of the total number of shares of common stock, Pre-Funded Warrants, and base warrants to cover overallotments sold in the Offering.



The Company offered to each purchaser whose purchase of shares of common stock in this Offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this Offering, the opportunity to purchase, if the purchaser so chooses, Pre-Funded Warrants, in lieu of shares of common stock that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock. Subject to limited exceptions, a holder of Pre-Funded Warrants could not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock. The Offering also related to the shares of common stock issuable upon exercise of any Pre-Funded Warrants sold in the Offering. Each Pre-Funded Warrant was sold together with a common warrant with the same terms as the common warrant described above. The common warrants were exercisable immediately and will expire five years after the date of issuance, or June 22, 2022. The shares of common stock and Pre-Funded Warrants could only be purchased with the accompanying common warrants, but were issued separately, and were immediately separable upon issuance.

On June 21, 2017, the Company successfully closed its Offering, See Note 3, Liquidity. A public trading market for the Base Warrants was established on July 5, 2017 on the OTC market under the trading symbol IDGGW. As part of the offering the Underwriters purchased the full over-allotment of 1,875,000 Base Warrants available to them for the specified \$.01 per warrant, which are not exercisable for six months after the Offering. The full 2,600,000 of Pre-Funded Warrants were also sold on at the price of \$1.09 per warrant. The combined gross proceeds of the Offering totaled \$13.7 million with approximately \$12.3 million of net funds available to the Company after deducting underwriting discounts and other stock issuance expenses.

In summary, the Company issued 9,900,000 shares of common stock as well as Base Warrants, Overallotment Warrants, Pre-Funded Warrants and Underwriters Warrants to purchase 12,500,000, 1,875,000, 2,600,000 and 575,000 shares of the Company's common stock, respectively. The Pre-Funded and Underwriters Warrants were classified as liabilities because in certain circumstances they could require cash settlement. The Base and Overallotment Warrants are recorded within stockholders' equity. The Base Warrants are traded on the OTC market; however trading volume has been insufficient to determine fair value. The fair value at the date of issuance of the Base and Overallotment Warrants was determined using the Black-Scholes Option Pricing Model and amounted to \$5.3 million and \$0.8 million, respectively.

The following table sets forth the assumptions used in the Black-Scholes Option Pricing Model to estimate the fair value of the Base Warrants and Overallotment Warrants upon issuance:

Market Price	\$ 0.87
Exercise Price	\$ 1.25
Risk-free interest rate	1.75%
Expected volatility	134.21%
Expected life in years	5.0
Expected dividend yield	0.00%

As of July 7, 2017, all of the 2,600,000 Pre-Funded Warrants were exercised for \$.01 per warrant exercise price and all 2,600,000 common shares related to the warrants have been issued for \$26,000. The corresponding fair value of the warrants as of the date of exercise was \$2.3 million and said amount was reclassified from liabilities to additional paid in capital upon exercise. On July 31, the Underwriters exercised their right to purchase 875,000 Firm Shares for \$0.960 million net of \$0.072 million in underwriter discounts, or \$0.882 million.

On July 5, 2017, the Company entered into an agreement for investor relations services. In consideration for these services, the Company paid a fee for services incurred and agreed to issue a warrant expiring in August 2020, exercisable into 150,000 shares of common stock with an exercise price of \$1.25.

The warrant issuance is considered a share-based payment award issued to a nonemployee in exchange for services and falls within the scope of ASC 505-50. The fair value of the warrant was determined to be \$0.2 million and was fully expensed during the quarter ended September 30, 2017.

The following table sets forth the assumptions used in the Black-Scholes Option Pricing Model to estimate the fair value of the sharebased warrant upon issuance:

Market Price	\$ 1.62
Exercise Price	\$ 1.25
Risk-free interest rate	1.66%
Expected volatility	172.29%
Expected life in years	3.1
Expected dividend yield	

On October 12, 2017 the Company entered into an agreement with certain holders of Base Warrants to exercise 4 million Base Warrants at the exercise price of \$1.25 in exchange for the issuance of 3.2 million additional private placement warrants with an exercise price of \$1.80, resulting in gross proceeds to the Company of \$5.0 million. The new warrants may not be exercised for six months from the issue date and expire in five and one-half years from their issuance date. As a result of this transaction, the Company recorded a \$2.0 million charge within Other (expense) income, net within the consolidated statement of operations as such transaction was deemed to be an inducement to the existing warrant holders. The following table sets forth the assumptions used in the Black-Scholes Option Pricing Model to estimate the fair value of the share- based warrant upon issuance:

Market Price	\$ 1.57
Exercise Price	\$ 1.80
Risk-free interest rate	1.88%
Expected volatility	55.50%
Expected life in years	4.5
Expected dividend yield	

Additionally, approximately 1.7 million base warrants were exercised during 2017, which totaled approximately \$2.1 million in gross proceeds.

12. Warrants

There were no warrants outstanding as of December 31, 2016. Warrants outstanding and warrant activity for the year ended December 31, 2017 are as follows:

Description	Classification	ercise rice	Expiration Date	Warrants Issued	Warrants Exercised	Warrants Cancelled/ Expired	Balance December 31, 2017
Private Placement Warrants, issued							
January 25, 2017	Equity	\$ 4.69	June 2022	855,000	-	-	855,000
RedPath Warrants, issued March 22,			September				
2017	Equity	\$ 4.69	2022	100,000	-	-	100,000
Pre-Funded Warrants, issued June							
21, 2017	Liability	\$ 0.01	None	2,600,000	(2,600,000)	-	-
Underwriters Warrants, issued June			December				
21, 2017	Liability	\$ 1.32	2022	575,000	-	(40,000)	535,000
Base & Overallotment Warrants,							
issued June 21, 2017	Equity	\$ 1.25	June 2022	14,375,000	(5,672,852)	-	8,702,148
Vendor Warrants, issued August 6,			August				
2017	Equity	\$ 1.25	2020	150,000	-	-	150,000
Warrants issued October 12, 2017	Equity	\$ 1.80	April 2022	3,200,000	-	-	3,200,000
				21,855,000	(8,272,852)	(40,000)	13,542,148

13. Stock-Based Compensation

The Company's stock-incentive program is a long-term retention program that is intended to attract, retain and provide incentives for talented employees, officers and directors, and to align stockholder and employee interests. Currently, the Company is able to grant options, SARs and restricted shares from the Interpace Diagnostics Group, Inc. Amended and Restated 2004 Stock Award and Incentive

Plan, (the "Amended 2004 Plan"). Unless earlier terminated by action of the Board, the Amended 2004 Plan will remain in effect until such time as no stock remains available for delivery and the Company has no further rights or obligations under the Amended 2004 Plan with respect to outstanding awards thereunder.

Historically, stock options have been granted with an exercise price equal to the market value of the common stock on the date of grant, expire 10 years from the date they are granted, and generally vested over a one to three-year period for members of the Board of Directors and a one to three-year period for employees. Upon exercise, new shares can be issued by the Company. The Company granted stock options in 2017 and 2016, which vest monthly over a one-year period. SARs are generally granted with a grant price equal to the market value of the common stock on the date of grant, vest one-third each year on the anniversary of the date of grant and expire five years from the date of grant. The restricted shares and restricted stock units granted to employees generally have a three-year cliff vesting period and are subject to accelerated vesting and forfeiture under certain circumstances. Restricted shares and restricted stock units granted to board members generally have a three-year graded vesting period and are subject to accelerated vesting and forfeiture under certain circumstances.

The Company primarily uses the Black-Scholes option-pricing model to determine the fair value of stock options and SARs. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the Company's expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatility is based on historical volatility. As there is no trading volume for the Company's options, implied volatility is not representative of the Company's current volatility so the historical volatility of the Company's common stock is determined to be more indicative of the Company's expected future stock performance. The expected life is determined using the safe-harbor method. The Company expects to use this simplified method for valuing employee options and SARs grants until more detailed information about exercise behavior becomes available over time. The Company bases the risk-free interest rate on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options or SARs. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model. The Company is required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. The Company recognizes compensation cost, net of estimated forfeitures, arising from the issuance of stock options and SARs on a straight-line basis over the vesting period of the grant.

The estimated compensation cost associated with the granting of restricted stock and restricted stock units is based on the fair value of the Company's common stock on the date of grant. The Company recognizes the compensation cost, net of estimated forfeitures, arising from the issuance of restricted stock and restricted stock units on a straight-line basis over the shorter of the vesting period or the period from the grant date to the date when retirement eligibility is achieved.

The following table provides the weighted average assumptions used in determining the fair value of the stock options granted during the years ended December 31, 2017 and December 31, 2016.

	December 31, 2017	December 31, 2016
Risk-free interest rate	1.85%	0.66%
Expected life	4.9 years	4.7 years
Expected volatility	142.42%	145.71%
Dividend yield	-	-

The weighted-average fair value of stock options granted during the year ended December 31, 2017 was estimated to be \$1.49. The weighted-average fair value of stock options granted during the year ended December 31, 2016 was estimated to be \$1.40. There were no options or SARs exercised in 2017 or 2016. Historically, shares issued upon the exercise of options have been new shares and have not come from treasury shares.

The impact of RSUs and stock options on net loss for the years ended December 31, 2017 and 2016 is as follows:

	20	017	2016
RSUs	\$	65 \$	109
Options		995	22
Total stock-based compensation expense	\$	1,060 \$	131

A summary of stock option and SARs activity for the year ended December 31, 2017, and changes during such year, is presented below:

	Shares	Weighted- Average Grant Price	Weighted- Average Remaining Contractual Period (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2017	190,551	\$ 25.80	5.42	\$ 632
Granted	1,422,658	1.69	9.60	1
Exercised	-			
Forfeited or expired	(18,594)	62.46		
Outstanding at December 31, 2017	1,594,615	3.87	9.11	1
Exercisable at December 31, 2017	697,922	6.83	8.38	-
Vested and expected to vest	1,541,848	3.95	9.09	1

A summary of the status of the Company's nonvested options for the year ended December 31, 2017, and changes during such year, is presented below:

	Shares	Weighted- A Grant Date Value	U
Nonvested at January 1, 2017	73,217	\$	1.37
Granted	1,422,658		1.49
Vested	(599,182)		1.61
Forfeited	-		-
Nonvested at December 31, 2017	896,693	\$	1.40

The aggregate fair value of SARs and options vested during the years ended December 31, 2017 and 2016 was \$1.1 million and \$0.02 million, respectively. The weighted-average grant date fair value of options vested during the year ended December 31, 2016 was \$1.37.

A summary of the Company's nonvested shares of restricted stock units for the year ended December 31, 2017, and changes during such year, is presented below:

	Shares	A	Weighted- Average Grant Date Fair Value	Average Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested at January 1, 2017	102,369	\$	2.49	2.14	\$ 450
Granted	-	\$	-	-	-
Vested	(34,019)	\$	2.49	-	-
Forfeited	(350)	\$	2.30	-	-
Nonvested at December 31, 2017	68,000	\$	2.49	0.64	\$ 69

The aggregate fair value of restricted stock units vested during each of the years ended December 31, 2017 and 2016 was \$0.1 million and zero, respectively.

14. Revenue Sources

The Company's customers consist primarily of physicians, hospitals and clinics. Its revenue channels include Medicare, Medicare Advantage, Medicaid, Client Billings (hospitals, etc.), and commercial payers. The following sets forth the net revenue generated by revenue channel accounted for more than 10% of the Company's revenue from continuing operations during the period presented. For the years ended December 31, 2017 and December 31, 2016, revenue from Medicare was approximately 38.0% and 40.8% of total revenue, respectively.

	Ye	ars Ended	December 31,		
Customer		2017 2016			
Medicare	\$	6,046	\$	5,344	
Commercial Payors	\$	3,127	\$	3,150	
Client Billings	\$	4,241	\$	2,955	
Medicare Advantage	\$	2,217	\$	1,170	

15. Income Taxes

The benefit from income taxes on continuing operations for the years ended December 31, 2017 and 2016 is comprised of the following:

	201	7	2016
Current:			
Federal	\$	(382) \$	(154)
State		(13)	(8)
Total current		(395)	(162)
Deferred:			
Federal		-	-
State		-	-
Total deferred		-	-
Benefit from income taxes	\$	(395) \$	(162)

The Company performs an analysis each year to determine whether the expected future income will more likely than not be sufficient to realize the deferred tax assets. The Company's recent operating results and projections of future income weighed heavily in the Company's overall assessment. As a result of this analysis, the Company continues to maintain a full valuation allowance against its federal and state net deferred tax. The Tax Cuts and Jobs Act (the "TCJA") was enacted on December 22 assets at December 31, 2017 as the Company believes that it is more likely than not that these assets will not be realized. In the current year, the company maintains a full valuation allowance in consolidation and no separate company deferred tax liability recorded will be recorded.

The tax effects of significant items comprising the Company's deferred tax assets and (liabilities) as of December 31, 2017 and 2016 are as follows:

	2017		2016	
Deferred tax assets included in other current assets				
Allowances and reserves	\$	7,539	\$	9,715
Compensation		693		1,292
Valuation allowance on deferred tax assets		(8,232)		(11,007)
		-		-
Noncurrent deferred tax assets (liabilities) included in other long-term				
assets:				
State net operating loss carryforwards		4,762		7,338
Federal net operating loss carryforwards		31,943		51,685
Credit carryforward		239		250
State taxes		1,124		1,124
Property, plant and equipment		637		1,464
Intangible assets		(4,865)		(8,411)
Other reserves - restructuring		5		19
Deferred revenue		88		4
Valuation allowance on deferred tax assets		(33,933)		(53,473)
		-		_
Noncurrent deferred tax liabilities, net	\$	-	\$	-

The Company's current deferred tax asset and noncurrent deferred tax liability are included within *Other current assets and Other long-term liabilities*, respectively, within the consolidated balance sheet as of December 31, 2017. Federal tax attribute carryforwards at December 31, 2017, consist primarily of approximately \$152.1 million of federal net operating losses. In addition, the Company has approximately \$72.2 million of state net operating losses carryforwards. The utilization of the federal carryforwards as an available offset to future taxable income is subject to limitations under federal income tax laws. If the federal net operating losses are not utilized, they begin to expire in 2027, and current state net operating losses not utilized begin to expire this year.

The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. During December 2016 through October 2017, the Company executed five equity offerings, a debt exchange and warrant exercises issuing approximately 26 million shares of common stock. NOL, and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as similar state tax provisions. This could limit the amount of NOLs that we can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of our company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. Additionally, U.S. tax laws limit the time during which these carry forwards may be applied against future taxes, therefore, we may not be able to take full advantage of these carry forwards for federal income tax purposes. We are currently evaluating the ownership history of our company to determine if there were any ownership changes as defined under Section 382(g) of the Code and the effects any ownership change may have had.

A reconciliation of the difference between the federal statutory tax rates and the Company's effective tax rate from continuing operations is as follows:

	2017	2016
Federal statutory rate	34.0%	34.0%
State income tax rate, net of Federal tax benefit	2.2%	6.0%
Meals and entertainment	(0.3%)	(0.3%)
Contingent consideration	8.6%	42.4%
Tax reform change	(174.7%)	-
Valuation allowance	141.7%	(78.8%)
Gain/Loss on extinguishment of debt	(11.6%)	-
Other non-deductible	0.0%	(3.3%)
Discontinued operations allocation	3.1%	1.9%
Net change in Federal and state reserves	-	-
Effective tax rate	3.0%	1.9%

The following table summarizes the change in uncertain tax benefit reserves for the two years ended December 31, 2017:

	cognized Benefits
Balance of unrecognized benefits as of January 1, 2016	\$ 1,117
Additions for tax positions related to the current year	-
Additions for tax positions of prior years	-
Reductions for tax positions of prior years	-
Balance as of December 31, 2016	\$ 1,117
Additions for tax positions related to the current year	-
Additions for tax positions of prior years	-
Reductions for tax positions of prior years	-
Balance as of December 31, 2017	\$ 1,117

As of December 31, 2017 and 2016, the total amount of gross unrecognized tax benefits was \$1.1 million in each year. The total amount of unrecognized tax benefits that, if recognized, would affect the effective tax rate as of December 31, 2017 and 2016 was \$1.1 million in each year.

The Company recognized interest and penalties of \$0.2 million related to uncertain tax positions in income tax expense during each of the years ended December 31, 2017 and 2016. At December 31, 2017 and 2016, accrued interest and penalties, net were \$2.8 million and \$2.6 million, respectively, and included in the *Other long-term liabilities* in the consolidated balance sheets.

Management plans to commence filing tax clearance certificates in states and related tax jurisdictions in which un-recognized tax benefits attributable to its former operating entities are recorded as long-term liabilities on the accompanying balance sheet. This process can range from 6 to 18 months before the Company receives clearance as to balances, if any, it may owe to a particular state or tax jurisdiction. Upon receipt and acknowledgment from a state or tax jurisdiction, the Company will settle the remaining obligation or reverse the recorded amount owed during the period in which the tax clearance certificate is obtained.

The Company and its subsidiaries file a U.S. Federal consolidated income tax return and consolidated and separate income tax returns in numerous states and local tax jurisdictions. The following tax years remain subject to examination as of December 31, 2017:

Jurisdiction	Tax Years
Federal	2013 - 2017
State and Local	2012 - 2017

To the extent there was a failure to file a tax return in a previous year; the statute of limitation will not begin until the return is filed. There were no examinations in process by the Internal Revenue Service as of December 31, 2017. In 2014, the Company was selected for examination by the Internal Revenue Service for the tax periods ending December 31, 2012 and December 31, 2011 that concluded in 2016 with no adjustments.

The Tax Cuts and Jobs Act (the "TCJA") was enacted on December 22, 2017 and became effective January 1, 2018. The TCJA had significant changes to U.S. tax law, lowering U.S. corporate income tax rates, implementing a territorial tax system, imposing a one-time transition tax on deemed repatriated earnings of foreign subsidiaries and modified the taxation of other income and expense items.



The TCJA reduces the U.S. corporate income tax rate from 34% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 34% to 21% under the TCJA, we revalued deferred tax assets, net as of December 31, 2017. The tax impact of revaluation of the deferred tax assets, net was \$22,768,303, which was wholly offset by a corresponding reduction in our valuation allowance of \$22,768,303 resulting in a no net impact to our income tax expense.

The TCJA provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits. The Company did not have consolidated accumulated earnings and profits attributable to it foreign subsidiaries, accordingly, the Company did not record any income tax expense related to the transition tax.

Due to the timing of the new tax law and the substantial changes it brings, the staff of the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 118 ("SAB 118"), which provides registrants a measurement period to report the impact of the new US tax law. During the measurement period, provisional amounts for the effects of the law are recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies may recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA.

16. Historical Basic and Diluted Net Loss per Share

On December 28, 2016, the Company effected a one-for-ten reverse split of the issued and outstanding shares of its common stock in order to achieve the requisite increase in the market price of its common stock to be in compliance with the NASDAQ minimum bid price requirement. At the effective time of the reverse split, every 10 shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock, without any change in the par value per share. All historical share amount shave been adjusted to reflect the split.

A reconciliation of the number of shares used in the calculation of basic and diluted earnings per share for the years ended December 31, 2017 and 2016 is as follows:

	Years Ended December 31,		
	2017 2016		
Basic weighted average number of common shares	15,766	1,816	
Potential dilutive effect of stock-based awards	-	-	
Diluted weighted average number of common shares	15,766	1,816	

The following outstanding stock-based awards and warrants were excluded from the computation of the effect of dilutive securities on loss per share for the following periods as they would have been anti-dilutive:

	Years Ended Dec	Years Ended December 31,		
	2017	2016		
Options	1,510,529	87,871		
Stock-settled stock appreciation rights (SARs)	84,086	102,691		
Restricted stock units (RSUs)	68,000	102,369		
Warrants	13,542,148	-		
	15,204,763	292,931		
		· · · · · · · · · · · · · · · · · · ·		



17. Segment Information

Since December 22, 2015, the Company reports its operations as one segment, molecular diagnostics and bioinformatics. The Company's reporting segment structure is reflective of the way the Company's management views the business, makes operating decisions and assesses performance. This structure allows investors to better understand Company performance, better assess prospects for future cash flows, and make more informed decisions about the Company.

The Company's molecular diagnostics and bioinformatics business focuses on developing and commercializing molecular diagnostic tests, leveraging the latest technology and personalized medicine for better patient diagnostis and management. Through the Company's business, the Company aims to provide physicians and patients with diagnostic options for detecting genetic and other molecular alterations that are associated with gastrointestinal, endocrine and lung cancers, which are principally focused on early detection of patients at high risk of cancer. Customers in the Company's segment consist primarily of physicians, hospitals and clinics. The service offerings throughout the segment have similar long-term average gross margins, contract terms, types of customers and regulatory environments. They are promoted through one centrally managed marketing group and the chief operating decision maker views their results on a combined basis.

18. Long-Term Debt

On October 31, 2014, the Company and its subsidiary, Interpace LLC, entered into an agreement to acquire RedPath (the "Transaction"). In connection with the Transaction, the Company entered into a note payable (the "RedPath Note") requiring eight equal consecutive quarterly installments beginning October 1, 2016.

The obligations of the Company under the RedPath Note were guaranteed by the Company and its subsidiaries pursuant to a Guarantee and Collateral Agreement (the "Subordinated Guarantee") in favor of the RedPath Equityholder Representative. Pursuant to the Subordinated Guarantee, the Company and its subsidiaries also granted a security interest in substantially all of their assets, including intellectual property, to secure their obligations to the RedPath Equityholder Representative. Based on the Company's incremental borrowing rate under its Credit Agreement, the fair value of the RedPath Note at the date of issuance was \$7.5 million. During the years ended December 31, 2017 and 2016, the Company accreted approximately \$0.2 million and \$0.8 million in interest expense, respectively. At December 31, 2016, the fair value balance of the \$9.3 million RedPath Note was approximately \$7.9 million and the unamortized discount was \$1.4 million. As of April 18, 2017, the Note was exchanged and fully converted into the Company's common stock (see below).

Debt Exchange for RedPath Note

On December 23, 2016 we repaid \$1.33 million in principal of the RedPath Note resulting in an outstanding balance of \$9.34 million. The balance of the RedPath Note was subsequently acquired by an Investor, for \$8.87 million on March 22, 2017. Also on that date we and the Investor exchanged the RedPath Note for a senior secured convertible note (the "Exchanged Convertible Note") in the aggregate principal amount of \$5.32 million and a senior secured non-convertible note in the aggregate principal amount of \$3.55 million. On April 18, 2017, we and the Investor exchanged the senior secured non-convertible note for \$3.55 million of our senior secured convertible note (the "Senior Secured Convertible Note"). Between March 23, 2017 and April 18, 2017, the senior secured convertible notes were converted in full for 3,795,429 shares of our common stock. We no longer have any outstanding secured debt, and any security interests and liens related to our former secured debt have been fully released.

In connection with the conversion of the Exchanged Convertible Note, the Company recorded a loss of \$4.3 million. Maxim Group LLC ("Maxim") acted as agent in connection with the exchanges into the Exchanged Convertible Note and the Senior Secured Convertible Note. Maxim was paid a cash fee of \$0.6 million representing 6.5% of the balance of the \$8.85 million exchanged RedPath Note. These costs are directly related to the issuance of the Company's shares, and as a result are recorded against equity.



In connection with the Exchanged Convertible Note and the Senior Secured Convertible Note, the Company determined there to be an embedded conversion option feature. Accordingly, the embedded conversion option contained in the Exchange Convertible Note was accounted for as a derivative liability at the date of issuance and shall be adjusted to fair value through earnings at each reporting date. The fair value of the embedded conversion option derivative was determined using the Black-Scholes Option Pricing Model. On the initial measurement date, the fair value of the embedded conversion option derivative of \$208,427 was recorded as a derivative liability and was allocated as a debt discount to the Exchanged Convertible Note. At each conversion date, subsequent to the issuance of the Exchanged Convertible Note, the embedded conversion option derivative liability would be revalued, with any changes to its fair value being recorded to earnings. At March 31, 2017, the Company also revalued the embedded conversion option derivative liability resulting in a loss from the change in fair value. In connection with these revaluations, the Company recorded derivative losses of approximately \$0.1 million for the year ended December 31, 2017. The value of the derivative liability as of December 31, 2017 was zero. The Company incurred \$0.5 million of debt issuance costs, for investment banking, legal and placement fee services in connection with the Exchange Agreement. These costs were treated as a debt discount and amortized to interest expense over the term of the Exchanged Notes. In connection with the conversion of Agreement 20, the Company recorded a loss of \$2.3 million which is included in the total loss of \$4.3 million described above.

19. Supplemental Cash Flow Information

	For The Years Ended December 31,			cember 31,
	2	2017		2016
Net cash used in operating activities of discontinued operations	\$	(2,291)	\$	(2,000)
Net cash provided by investing activities of discontinued operations	\$	-	\$	-

Supplemental Disclosures of Non Cash Financing Activities

(in thousands)

		Years Ended December 31,		
	2	2017 2016		
Investing				
Acquisition of property and equipment	\$	54 \$	-	
Tenant incentives recorded as part of deferred rent	\$	84 \$	-	
Financing				
Settlement of the RedPath Note ⁽¹⁾	\$	(8,098) \$	-	
Issuance of the Exchange Notes ⁽¹⁾	\$	11,375 \$	-	
Common shares issued in debt exchange (3,795,429 shares)	\$	11,643 \$	-	

⁽¹⁾ Excludes approximately \$732 of transaction fees which are included in loss on extinguishment of debt.

20. Subsequent Events

On March 15, 2018 the Company entered into an agreement to extend its Pittsburgh lease through June 30, 2023. The lease amendment includes approximately \$2.5 million in minimum lease payments over the extended lease term.

INTERPACE DIAGNOSTICS GROUP, INC. VALUATION AND QUALIFYING ACCOUNTS YEARS ENDED DECEMBER 31, 2017 AND 2016

(\$ in thousands)

Balance at Beginning of Period		Additions (Reductions) Charged to Operations	(1) Deductions Other	Balance at end of Period	
\$	802	899	(1,338) \$	\$ 363	
\$	1,626	20	- 3	\$ 1,646	
\$	56,868	-	7,612	\$ 64,480	
\$	363	(363)	- 3	\$-	
\$	1,646	-	(777) \$	\$ 869	
\$	64,480	-	(22,315)	\$ 42,165	
	Ba 0 5 5 5 5 5 5 5 5	Beginning of Period \$ 802 \$ 1,626 \$ 56,868 \$ 363 \$ 1,646	Balance at Beginning of Period(Reductions) Charged to Operations\$ 802899\$ 1,62620\$ 56,868-\$ 363(363)\$ 1,646-	Balance at Beginning of Period (Reductions) Charged to Operations (1) Deductions Other \$ 802 899 (1,338) \$ 1,626 20 - \$ 56,868 - 7,612 \$ 363 (363) - \$ 1,646 - (777)	

(1) Includes payments and actual write offs, as well as changes in estimates in the reserves.

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EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is entered into as of March 16, 2018 (the "Effective Date") by and between Interpace Diagnostics Group, Inc. (together with Interpace Diagnostics, LLC and Interpace Diagnostics Corporation, the "Company") having its principal place of business at Morris Corporate Center, Building C, 300 Interpace Parkway, Parsippany, New Jersey 07054, and James Early (the "Chief Financial Officer, Corporate Secretary and Treasurer").

RECITALS

WHEREAS, the Executive is currently employed by the Company as its Chief Financial Officer, Corporate Secretary and Treasurer; and

WHEREAS, the Company desires to continue the Executive' employment with the Company as its Chief Financial Officer, Corporate Secretary and Treasurer, and the Executive agrees to accept such continued employment, in accordance with the terms and conditions set forth in this Agreement

NOW THEREFORE, in consideration of the above premises, the mutual covenants contained herein, and other good and valuable consideration, the Parties hereto agree as follows:

1. Employment

The Company will employ Chief Financial Officer, Corporate Secretary and Treasurer and Chief Financial Officer, Corporate Secretary and Treasurer agrees to be employed upon the terms and conditions set forth in this Agreement.

2. Position and Duties

Chief Financial Officer, Corporate Secretary and Treasurer shall be employed as a Chief Financial Officer, Corporate Secretary and Treasurer and shall have responsibilities and duties consistent with the operational needs of the Company and as agreed upon by Chief Financial Officer, Corporate Secretary and Treasurer and the Company.

3. Confidentiality and Restrictive Covenants

Chief Financial Officer, Corporate Secretary and Treasurer understands that a result of his employment by the Company, Chief Financial Officer, Corporate Secretary and Treasurer will be placed in a position of trust and confidence and will be entrusted with confidential information, as well as the Company's confidential proprietaly information and trade secrets, to enable him to carry out his job functions. Because Chief Financial Officer, Corporate Secretary and Treasurer and Treasurer will be receiving this confidential information, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer agrees that as a condition of employment, Chief Financial Officer, Corporate Secretary and Treasurer will execute a form of Confidential Information, Non-Disclosure, Non-Competition, Non-Solicitation, and Rights to Intellectual Property Agreement satisfactory to the Company and consistent with the form attached hereto as Exhibit A and will comply at all times with applicable policies and law relative to confidentiality and non-disclosure.

1		

4. Compensation and Other Benefits

Base Salary. During the Term of Employment, the Chief Financial Officer, Corporate Secretary and Treasurer shall receive a base salary per annum payable in accordance with the Company's normal payroll practices as in effect from time to time of \$250,000 ("Base Salary"). The Chief Financial Officer, Corporate Secretary and Treasurer's Base Salary may be reviewed by Jack E Stover, CEO and the Compensation Committee of the Board of Directors (the "Compensation Committee") on an annual basis and shall be subject to adjustment, as determined by the CEO in conjunction with the Compensation Committee. Effective as of the date of any such change, the Base Salary as so modified shall be the new Base Salary for all purposes of this Agreement.

Annual Bonus. During the Term of Employment, the Chief Financial Officer, Corporate Secretary and Treasurer shall be eligible to earn an annual performance bonus, subject to the attainment of annual performance goals as set and determined by the CEO in conjunction with the Compensation Committee of up to an annual targeted bonus of up to 30% of his Base Salary (the "Target Bonus"). Such bonus metrics shall be determined quarterly (but paid annually).

Benefit Plans. During the Term of Employment, the Chief Financial Officer, Corporate Secretary and Treasurer shall be eligible to participate in and be covered on the same basis as other senior management of the Company, under all employee benefit plans and programs maintained by the Company, including without limitation vacation, retirement, stock plans, health insurance and life insurance.

5. Termination

The Parties acknowledge that Chief Financial Officer, Corporate Secretary and Treasurer's employment with the Company is "at will" and that Chief Financial Officer, Corporate Secretary and Treasurer's employment may be terminated by Chief Financial Officer, Corporate Secretary and Treasurer or the Company at any time, for any reason or for no reason. In the event that Chief Financial Officer, Corporate Secretary and Treasurer employment is terminated by the Company for any reason other than death, Total Disability, or Cause, as defined by this Agreement, Chief Financial Officer, Corporate Secretary and Treasurer shall be entitled to severance equal to six (6) months of base salary payable in monthly installments over a six month period of time (the "Severance Payment") and Chief Financial Officer, Corporate Secretary and Treasurer shall also be entitled to health benefits continuation for six (6) months or reimbursement for COBRA payments for that period, whichever the Company deems appropriate at the time. In the event that the Chief Financial Officer, Corporate Secretary and Treasurer's employment is terminated by the Company on account of death, Total Disability, or Cause, Chief Financial Officer, Corporate Secretary and Treasurer's employment is terminated by the Company on account of death, Total Disability, or Cause, Chief Financial Officer, Corporate Secretary and Treasurer's employment is terminated by the Company on account of death, Total Disability, or Cause, Chief Financial Officer, Corporate Secretary and Treasurer's employment is terminated by the company on account of death, Total Disability, or Cause, Chief Financial Officer, Corporate Secretary and Treasurer's employment is terminated by the company on account of benefit continuation, other than as required by law in effect at such time.

6. Resignation

In the event that Chief Financial Officer, Corporate Secretary and Treasurer resigns his employment with the Company for Good Reason as defined by this Agreement, Chief Financial Officer, Corporate Secretary and Treasurer shall be entitled to severance equal to (6) months of base salary payable in monthly installments over a six month period of time. (the "Resignation Payment"). In the event that Chief Financial Officer, Corporate Secretary and Treasurer shall be entitled to any severance payment or benefit continuation, other than as required by law in effect at such time.

7. Severance Conditioned Upon Release

Notwithstanding any provision herein to the contrary, the continuation of health benefits and the Severance Payment provided for in Section 4 of this Agreement or the Resignation Payment provided for in Section 5, as applicable, is subject to and contingent upon the Chief Financial Officer, Corporate Secretary and Treasurer's execution of a Severance Agreement and General Release acceptable to the Company, which becomes effective within 60 days following the Termination Date. In addition to a release of all claims, such Severance Agreement and General Release may include Confidentiality, Non-Disparagement, No-Reapply, and/or other appropriate terms. The Severance Payment or the Resignation Payment, as applicable, will be made once the Severance Agreement and General Release becomes effective. Notwithstanding the foregoing, if the 60 day period following the Chief Financial Officer, Corporate Secretary and Treasurer's termination ends in a calendar year after the year in which the Chief Financial Officer, Corporate Secretary and Treasurer's employment terminates, the Severance Payment or the Resignation Payment, as applicable, shall be made no earlier than the first day of such later calendar year.

8. Section 409A Compliance

The following rules shall apply, to the extent necessary, with respect to distribution of the payments and benefits, if any, to be provided to Chief Financial Officer, Corporate Secretary and Treasurer under this Agreement. This Agreement is intended to comply with or be exempt from Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and the parties hereto agree to interpret, apply and administer this Agreement in the least restrictive manner necessary to comply therewith and without resulting in any increase in the amounts owed hereunder by the Company. Subject to the provisions in this Section, the severance payments pursuant to this Agreement shall begin only upon the date of Chief Financial Officer, Corporate Secretary and Treasurer's "separation from service" which occurs on or after the date of Chief Financial Officer, Corporate Secretary and Treasurer's termination of employment. It is intended that each installment of the severance payments and benefits provided under this Agreement shall be treated as a separate "payment" for purposes of Section 409A. If, as of the date of Chief Financial Officer, Corporate Secretary and Treasurer's "separation from service" from the Company, Chief Financial Officer, Corporate Secretary and Treasurer is a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments (including any lump sum payments) and benefits due under this Agreement, that would not otherwise be exempt from Section 409A (either pursuant to a short-term deferral exception, the exception for separation pay upon an involuntary separation from service or otherwise), above and that would, absent this subsection, be paid within the six-month period following Chief Financial Officer, Corporate Secretary and Treasurer's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, Chief Financial Officer, Corporate Secretary and Treasurer's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following Chief Financial Officer, Corporate Secretary and Treasurer's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein. All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A, to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (ii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iii) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit. Notwithstanding anything herein to the contrary, the Company shall have no liability to Chief Financial Officer, Corporate Secretary and Treasurer or to any other person if the payments and benefits provided in this Agreement that are intended to be exempt from or compliant with Section 409A are not so exempt or compliant.

9. Definitions of "Cause" and "Good Reason"

For purposes of this Agreement, "Cause" shall be defined as (1) material or willful failure to perform duties reasonably expected and/or requested of Chief Financial Officer, Corporate Secretary and Treasurer if such material or willful failure continues for more than thirty (30) days after notice of such material or willful failure to perform; (2) conviction of, guilty plea to, or confession of guilt of a felony or an act involving moral turpitude; (3) commission of a fraudulent, illegal, or dishonest act in commission of his duties or otherwise in respect to the Company; (4) willful misconduct or gross negligence; (5) material violation of the Company's policies or procedures; and/or (6) material violation of any Confidential Information, Non-Disclosure, Non-Competition, Non-Solicitation, and Rights to Intellectual Property Agreement between Chief Financial Officer, Corporate Secretary and Treasurer and the Company; (7) a material breach of any of the terms or conditions of this Agreement not cured within thirty (30) days written notice from the Company to Chief Financial Officer, Corporate Secretary and Treasurer specifying such breach; (8) the failure to adhere to moral and ethical business principles consistent with the Company's Code of Business Conduct and Guidelines on Corporate Governance as in effect from time to time; or (9) engaging in an act or series of acts constituting misconduct resulting in a misstatement of the Company's financial statements due to material non-compliance with any financial reporting requirement within the meaning of Section 304 of the Sarbanes-Oxley Act of 2002.

For purposes of this Agreement, "Total Disability" shall mean Chief Financial Officer, Corporate Secretary and Treasurer's substantial inability to perform his duties, with or without reasonable accommodation, due to physical or mental disablement which continues in excess of three (3) months as determined by an independent qualified Chief Financial Officer, Corporate Secretary and Treasurer of an appropriate specialty acceptable to the Company and Chief Financial Officer, Corporate Secretary and Treasurer, or in the event the Company and Chief Financial Officer, Corporate Secretary and Treasurer, or in the event the Company and Chief Financial Officer, Corporate Secretary and Treasurers of an appropriate specialty, one of whom shall be selected by the Company, one of whom shall be selected by the Company, one of whom shall be selected by the other two (2) panel Chief Financial Officer, Corporate Secretary and Treasurers.

For purposes of this Agreement, "Good Reason" shall mean a (1) substantial reduction in Chief Financial Officer, Corporate Secretary and Treasurer's base compensation; (2) material reduction in Chief Financial Officer, Corporate Secretary and Treasurer's duties and responsibilities (except a change in position or job title shall not be deemed a "material reduction" unless Chief Financial Officer, Corporate Secretary and Treasurer's duties are substantially reduced); or (3) relocation of Chief Financial Officer, Corporate Secretary and Treasurer's work site more than fifty (50) miles from the location at commencement of this Agreement. Notwithstanding the foregoing, Good Reason shall not be deemed to exist unless the Chief Financial Officer, Corporate Secretary and Treasurer gives the Company written notice within thirty (30) days after the occurrence of the event which Chief Financial Officer, Corporate Secretary and Treasurer believes constitutes the basis for Good Reason. If the Company fails to cure such act or failure to act, if curable, within thirty (30) days after receipt of such notice, Chief Financial Officer, Corporate Secretary and Treasurer for Good Reason.

10. Governing Law

This Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey.

11. Counterparts

This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one Agreement.

12. Representation

The Parties acknowledge that they have read and fully understand the contents of this Agreement and knowingly and voluntarily execute it after having had an opportunity to consult with legal counsel as they deem appropriate.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement to be effective as specified above.

Date of Signature	Chief Financial Officer, Corporate Secretary and Treasurer
	James Early
Date of Signature	Interpace Diagnostics Group, Inc.
	Jack E Stover, President and Chief Executive Officer

SECOND LEASE AMENDMENT

THIS SECOND LEASE AMENDMENT (this "Second Amendment") is made and entered into as of March 15, 2018 by and between SADDLE LANE REALTY, LLC, a Pennsylvania limited liability company ("Landlord") and INTERPACE DIAGNOSTICS CORPORATION, a Delaware corporation ("Tenant").

WITNESSTH:

WHEREAS, Landlord and Tenant are parties to that certain Lease Agreement dated March 31, 2017, as amended by that certain First Lease Amendment dated September 26, 2017 (the "Lease"),¹ for 20,000 leasable square feet located on the third and fourth floors of the building known as 2515 Liberty Avenue, Pittsburgh, Pennsylvania 15222.

WHEREAS, the parties seek to amend and extend the Lease as more particularly described herein.

NOW, THEREFORE, in consideration of the premises herein contained and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Landlord and Tenant, intending to be legally bound, agree as follows:

1. <u>Extension of Lease</u>. Subject to the terms and conditions of the Lease and this Second Amendment, Landlord and Tenant hereby agree that the Term of the Lease shall be extended to June 30, 2023. Monthly minimum rent during the Term shall be as follows:

			To	tal Minimum	Tot	al Minimum
Term	Square I	Footage Rate	Re	ent Per Year	Ren	t Per Month
Until 6/30/2018	\$	19.50	\$	390,000.00	\$	32,500.00
7/1/2018 - 6/30/2019	\$	20.00	\$	400,000.00	\$	33,333.33
7/1/2019 - 6/30/2023	\$	25.00	\$	500,000.00	\$	41,666.67

2. Option to Renew. Section 3.D. of the Lease (styled: *Option to Renew*) shall be deleted in its entirety and replaced with the following:

3.D. Option to Renew. If the Lease shall not have been terminated pursuant to any provision of the Lease and Tenant shall not be in default under the terms of the Lease, Tenant may, at Tenant's option, extend the term of the Lease for two (2) consecutive additional terms of five (5) years each, commencing on the expiration of the original term or the extended term (provided the immediately preceding renewal option is timely exercised by Tenant). Tenant shall exercise such option by giving Landlord irrevocable written notice at least eight (8) months prior to the expiration of the original term or, if applicable, the extended term (the "Renewal Notice"). TIME IS OF THE ESSENCE. If Tenant timely and properly delivers the Renewal Notice in accordance with the terms of this Section, the term of the Lease shall be deemed automatically extended upon all of the covenants, agreements, terms, provisions and conditions set forth in the Lease (as amended), except the minimum annual and monthly rent shall be as follows:

¹ Capitalized terms used herein but not otherwise defined shall have the meanings ascribed to them in the Lease.

		Square Footage	Тс	otal Minimum	Tot	al Minimum	Renewal Notice
Renewal Term	_	Rate	R	ent Per Year	Ren	t Per Month	Deadline
Option 1 (7/1/2023 – 6/30/2028)	\$	27.50	\$	550,000.00	\$	45,833.33	November 1, 2022
Option 2 (7/1/2028 – 6/30/2033)	\$	30.25	\$	605,000.00	\$	50,416.67	November 1, 2027

3. <u>Show Premises</u>. Section 14.D. of the Lease (styled: *Rights Reserved to Landlord - Show Premises*) shall be deleted in its entirety and replaced with the following:

14.D. Show Premises – To show the Premises to prospective tenants or brokers during the eight (8) month period prior to the expiration of the Term; and, to prospective purchasers, mortgagees and others having a legitimate interest, at all reasonable times upon prior notice given to Tenant at the Premises.

4. <u>Tenant's Proportionate Share</u>. The parties acknowledge and agree that Tenant's proportionate share of Additional Rent is 53.33% except for any Additional Rent incurred in or after April, 2018 related to the Parking Lot, in which case, Tenant's proportionate share shall be 40%. The first sentence of the second full paragraph of Section 3.B of the Lease shall be amended to add the underlined text as follows:

3.B. Tenant's proportionate share of Additional Rent shall be 53.33% based upon a fraction of which the numerator is the square footage of the Premises (i.e., 20,000 square feet) and the denominator is the total square feet of the Building (i.e., 37,500 square feet), except for any Additional Rent incurred in or after April, 2018 related to the Parking Lot which shall be allocated to Tenant as a 40% proportionate share based on the four (4) non-exclusive parking spaces allocated to Tenant out of ten (10) total spaces.

5. <u>Common Area Charges</u>. The following shall be inserted as Section 3.E. of the Lease:

3.E. Exclusions from common area charges: Notwithstanding anything to the contrary contained in this Lease, common area charges shall specifically exclude the following: (i) expenses for repairs or other work occasioned by fire, windstorm or other insured casualty; (ii) legal fees or expenses incurred in leasing or procuring new tenants (i.e. lease commissions, advertising expenses and expenses of renovating space for new tenants); (iii) legal expenses in enforcing the terms of any lease; (iv) interest or amortization payments on any mortgage or mortgages; (v) advertising and promotional expenses and other costs incurred in procuring tenants or in selling the reality; (vi) costs of relocating any tenant; (vii) rental on ground leases or other underlying leases and the costs of providing the same; (viii) wages, bonuses and other compensation of employees above the grade of building manager and fringe benefits other than insurance plans and tax qualified benefit plans; (ix) any liabilities, costs or expenses associated with or incurred in connection with the removal, enclosure, encapsulation or other handling of Hazardous Substances and/or mold and the cost of defending against claims in regard to the existence or release of Hazardous Substances and/or mold on the realty (except with respect to those costs for which Tenant is otherwise responsible pursuant to the express terms of this Lease); (x) increased insurance or real estate taxes assessed specifically to any tenant of the Building for which Landlord is entitled to reimbursement from any other tenant so that Landlord shall not recover more than the actual insurance cost or real estate tax; (xi) charges for electricity, water, or other utilities, services or goods and applicable taxes for which Tenant or any other tenant, occupant, person or other party is obligated to reimburse Landlord or to pay to third parties so that Landlord shall not recover any item of cost more than once; (xii) cost of any non-common area HVAC, janitorial or other services provided exclusively to other tenants of the Building; (xiii) cost of correcting defects in the design, construction or equipment of, or latent defects in, the reality; (xiv) lease payments for rental equipment (other than equipment for which depreciation is properly charged as an expense) that would constitute a capital expenditure if the equipment were purchased; (xv) charitable or political contributions; (xvi) all other items for which another party compensates or pays so that Landlord shall not recover any item of cost more than once; (xvii) Landlord's general overhead and any other expenses not directly attributable to the maintenance, repair, operation and management of the realty (e.g. the activities of Landlord's officers and executives or professional development expenditures), except to the extent included in the management fee permitted hereby; (xviii) costs and expenses incurred in connection with compliance with or contesting or settlement of any claimed violation of law or requirements of law, except to the extent attributable to Tenant's actions or inactions; (xix) costs of mitigation or impact fees or subsidies (however characterized), imposed or incurred prior to the date of the Lease or imposed or incurred solely as a result of another tenant's or tenants' use of the realty their respective premises; and (xx) capital expenditures.

6. Audit Rights. The following shall be inserted as Section 3.F. of the Lease:

3.F. <u>Audit Rights</u>. Provided Tenant is not in default of the terms of the Lease, Tenant shall have the right to audit and inspect the books and records of Landlord or request and obtain copies of invoices from Landlord with respect to any cost or item included in Additional Rent for the immediately preceding calendar year, available for Tenant's inspection at Landlord's principal place of business or at another place designated by Landlord in the Pittsburgh, Pennsylvania area during normal business hours and within ten (10) business days after receiving a written request from Tenant to inspect the same, no more than one time per calendar year. If the results of the audit show an overcharge to Tenant of more than five percent (5%) of the actual amount owed by Tenant, Landlord shall pay the reasonable cost of such non-contingency based audit, <u>provided however</u>, if Landlord provides Tenant copies of invoices evidencing such Additional Rent when Landlord bills for Additional Rent (as is Landlord's current practice), then Landlord shall not be required to reimburse Tenant for such non-contingency based audit even if the audit shows an overcharge to Tenant of more than five percent (5%) actual amount owed by Tenant. Landlord shall credit or refund to Tenant any overcharge of such item as discovered by the audit within thirty (30) days of the completion of such audit. In the event such audit discloses an undercharge of such items as billed to Tenant, Tenant shall pay to Landlord the amount of such undercharge within thirty (30) days of the completion of such audit.

7. <u>Approval of Landlord's Lender</u>. This Second Amendment is conditioned upon Landlord's lender approving the terms of this Second Amendment. Landlord shall seek its lender's approval of this Second Amendment promptly after Landlord and Tenant execute this Second Amendment.

8. <u>Ratification of Lease</u>. Except as modified by this Second Amendment, no other changes or modifications to the Lease are intended or implied and the Lease is hereby specifically ratified, confirmed and continues to remain in full force and effect.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto executed this Second Amendment as of the day and year first above written.

WITNESS / ATTEST:	SADDLE LANE REALTY, LLC			
	By:			
	David O. Brand, Sole Member			
	INTERPACE DIAGNOSTICS CORPORATION			
	By:			
	Name: Jack E. Stover			
	Title: President & CEO			
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NOTARY PAGE FOR TENANT

STATE / COMMONWEALTH OF NEW JERSEY

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COUNTY OF UNION

On this, the 15th day of March, 2018, before me, a Notary Public, the undersigned officer, personally appeared Jack E. Stover who acknowledged himself/herself to be the CEO of INTERPACE DIAGNOSTICS CORPORATION, a Delaware corporation, and that he/she as such CEO, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the corporation by himself/herself as CEO.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

Notary Public

SS:

My Commission Expires:

NOTARY PAGE FOR LANDLORD

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF ALLEGHENY

On this, the 15th day of March, 2018, before me, a Notary Public, the undersigned officer, personally appeared DAVID O. BRAND, who acknowledged himself to be the Sole Member of SADDLE LANE REALTY, LLC, a Pennsylvania limited liability company, and that he as such Sole Member, being authorized to do so, executed the foregoing instrument for the purposes therein contained by signing the name of the limited liability company by himself as Sole Member.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

Notary Public

SS:

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My Commission Expires:

Interpace Diagnostics Group, Inc. Subsidiaries

Interpace Diagnostics, LLC, a Delaware limited liability company, is a wholly-owned subsidiary of Interpace Diagnostics Group, Inc.

Interpace Diagnostics Corporation, a Delaware corporation, is a wholly-owned subsidiary of Interpace Diagnostics, LLC.

JS Genetics, Inc., a Delaware corporation, is a wholly-owned subsidiary of Interpace Diagnostics, LLC.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Interpace Diagnostics Group, Inc. Parsippany, New Jersey

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-207263) and Form S-8 (No. 333-61231, 333-60512, 333-177969, 333-201070, and 333-214260) of Interpace Diagnostics Group, Inc. of our report dated March 22, 2018, relating to the consolidated financial statements and financial statement schedule, which appear in this Form 10-K.

/s/ BDO USA, LLP

Woodbridge, New Jersey March 23, 2018

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jack E. Stover, certify that:

- 1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2017 of Interpace Diagnostics Group, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2018

/s/ Jack E. Stover Chief Executive Officer (Principal Executive Officer)

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Early, certify that:

- 1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2017 of Interpace Diagnostics Group, Inc. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2018

/s/ James Early Chief Financial Officer (Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Interpace Diagnostics Group, Inc. (the "Company") on form 10-K for the fiscal year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack E. Stover, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2018

/s/ Jack E. Stover Chief Executive Officer (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Interpace Diagnostics Group, Inc. (the "Company") on form 10-K for the fiscal year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Early, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2018

/s/ James Early Chief Financial Officer (Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.