UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

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	**22-2919486**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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 every Interactive Data File required to be submitted 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 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.

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [X] Smaller reporting company [X]
Emerging growth company [ ]

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, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was $25,050,548 (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 15, 2019, 38,096,038 shares of the registrant's common stock, $0.01 par value per share, were issued and outstanding.

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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:

- the limited revenue generated from our business thus far and our ability to commercially leverage our bioinformatics data and develop our pipeline products;
- our obligations to make royalty and milestone payments to our licensors;
- 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;
- our ability to comply with financial covenants under our current line of credit facility and comply with our debt obligations;
- whether we are able to successfully utilize our commercial and operating experience to sell our molecular diagnostic tests;
- our products continuing to perform as expected;
- our limited operating history;
- our ability to attract and retain key personnel;
- our dependence on a concentrated selection of third-party payers;
- our ability to obtain broad adoption of and ability to grow or continue to secure sufficient levels of reimbursement in a changing reimbursement environment, including obtaining clinical data to support sufficient levels of reimbursement;
- the demand for our molecular diagnostic tests from physicians and patients;
- our relationships with leading thought leaders and biopharmaceutical companies;

- demonstration of clinical relevance and value in utility studies;
- our ability to continue to expand our sales and marketing forces;
- our reliance on our commercial sales forces for continued business expansion;
- fluctuating quarterly operating results;
- our dependence on third parties for the supply of some of the materials used in our tests;
- our ability to scale our operations, testing capacity and processing technology;
- our ability to support demand for our molecular diagnostic tests and any of our future tests or solutions;
- our ability to compete successfully with physicians and members of the medical community who use traditional methods to diagnose gastrointestinal and endocrine cancers, competitors offering broader product lines outside of the molecular diagnostic testing market and having greater brand recognition than we do, and 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;
- our ability to license rights to use technologies in order to commercialize new products;
- our involvement in current and future litigation against us or our ability to collect on judgements found in our favor;
- our ability to continuously develop our technology and to work to develop new solutions to keep pace with evolving standards of care;
- our ability to enter into additional clinical study collaborations with highly regarded institutions;
- the effect of seasonal results and adverse weather conditions, such as hurricanes and floods, on our business;
- the effect current and future laws, licensing requirements and regulation have on our business including the changing U.S. Food and Drug Administration, or the FDA, environment as it relates to molecular diagnosis;
- our ability to obtain and maintain sufficient laboratory space to meet our processing needs as well as our ability to pass regulatory inspections and continue to be Clinical Laboratory Improvement Amendments ("CLIA") and the College of American Pathologists ("CAP") certified or accredited;
- legislative reform of the U.S. healthcare system, including the effect of pricing provisions of the Protecting Access to Medicare Act of 2014 ("PAMA") on our Advanced Diagnostic Laboratory Tests (ADLTs), adjustments or reductions in reimbursement rates of our molecular diagnostic tests by the Center for Medicare and Medicaid Services ("CMS") and changes or reductions in reimbursement rates or coverage of our tests by third party payers;
- compliance with numerous statutes and regulations pertaining to our business;
- the effect of potential adverse findings resulting from regulatory audits of our billing and payment practices and the impact such results could have on our business;
- business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States, including our ability to comply with international laws and regulations;

- compliance with the FCPA and anti-bribery laws;
- tax reform legislation;
- changes in financial accounting standards or practices;
- our use of hazardous materials;
- the susceptibility of our information systems to security breaches, loss of data and other disruptions;
- product liability claims against us;
- our ability to attract and retain qualified commercial representatives and other key employees and management personnel;
- our billing practices and our ability to collect on claims for the sale of our tests;
- our dependence on third-party medical billing providers to operate effectively without delays, data loss, or other disruptions;
- cost increases resulting from enacted healthcare reform legislation;
- changes in governmental regulations mandating price controls and limitations on patient access to our products;
- our ability to increase revenue and manage the size of our operations;
- our ability to successfully identify, complete and integrate any future acquisitions of companies and/or products that we believe meet our strategic goals and needs, and the effects of any such acquisitions on our revenues, profitability and ongoing business;
- our ability, and the ability of our third-party billing providers, to effectively maintain, upgrade and integrate the information systems on which we depend, including our partially customized Laboratory Information Management System (LIMS);
- the results of any future impairment testing for intangible assets as required under GAAP;
- the impact of contingent liabilities on our financial condition;
- our compliance with our license agreements and our ability to protect and defend our intellectual property rights;
- changes in U.S. patent law;
- patent infringement claims against us;
- our ability to maintain our listing with The Nasdaq Capital Market (“NASDAQ”);
- compliance with public company reporting requirements;
- the impact of future issuances of debt, common and preferred shares on stockholders’ interest and stock price;
- our ability to report financial results on a timely and accurate basis;

- the impact of anti-takeover defenses on an acquisition or stock price;
- the volatility of our stock price and fluctuations in our quarterly and annual revenues and earnings;
- publications, or the lack thereof, by equity research analysts about us, our business and our competitors;
- securities class action litigation; and
- cost of settlement or damage awards against our directors and officers.

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.

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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, 2018.

PART I

ITEM 1. BUSINESS

Company Overview

We are a fully integrated commercial and bioinformatics company that develops and provides clinically useful molecular diagnostic tests and pathology services. We develop and commercialize genomic tests and related first line assays principally focused on early detection of patients at high risk of cancer using the latest technology to help personalized medicine and improve patient diagnosis and management. Our tests and services provide mutational analysis of genomic material contained in suspicious cysts, nodules and lesions with the goal of better informing treatment decisions in patients at risk of thyroid, pancreatic, and other cancers. The molecular diagnostic tests we offer enable healthcare providers to better assess cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk. We currently have four commercialized molecular diagnostic tests in the marketplace for which we are receiving reimbursement: PancraGEN®, which is a pancreatic cyst and pancreaticobiliary solid lesion genomic test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG® platform; ThyGeNEXT®, which is an expanded oncogenic mutation panel that helps identify malignant thyroid nodules and replaced ThyGenX®; ThyraMIR®, which assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDx®, which is a genomic test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer and which also utilizes our PathFinderTG® platform to compare the genomic fingerprint of two or more sites of lung 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 medicine through genomics-based diagnostics and innovation to advance patient care based on rigorous science. Our laboratories are licensed pursuant to federal law under CLIA and are accredited by CAP and New York State. In August 2018, we acquired a majority of the Philadelphia laboratory equipment of Rosetta Genomics Ltd., a molecular diagnostics company, in order to further support our CLIA and CAP certified lab expansion in our New Haven, Connecticut and Pittsburgh, Pennsylvania laboratories. We are leveraging our licensed and 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 approximately $6.5 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 insurance coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our molecular diagnostic tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. We believe that BarreGen® is a potentially significant pipeline product, built on the PathFinderTG® platform which is synergistic to our capabilities in the gastrointestinal market, which is one of the sectors in which we operate.

Additional Reimbursement Coverage During 2018 and 2019 (to-date)

Reimbursement progress is key for any molecular diagnostic company. We expanded the reimbursement of our products in 2018. Specifically, the most significant progress we have made regarding payers in 2018 and 2019 is as follows:

- 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, had 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.

- In March 2018, we announced that we had entered into a new agreement with LabCorp to further expand our national network of cytology providers in support of our thyroid molecular business unit. The agreement amends our previous agreement with LabCorp, which established electronic ordering and result reporting through LabCorp, and allows physicians to be able to order both thyroid biopsy analysis and molecular testing from us, simplifying the test ordering process.

- In March 2018, we also announced that we had entered into a laboratory services agreement with Acupath Laboratories, Inc. based in Plainview, New York (Long Island) whereby Acupath's commercial team will be marketing ThyGenNEXT ® and ThyraMIR® for endocrinologists, endocrine surgeons, and other physicians focused on the diagnosis and treatment of thyroid cancer.

- In April 2018, we announced that we had entered into an agreement with BJC Healthcare of St. Louis, Missouri, one of the largest non-profit, integrated healthcare systems in the United States. The agreement enables physicians across the BJC system access to both ThyGenNEXT® and ThyraMIR® for patients with indeterminate thyroid nodules.

- In May 2018, we announced that 14 Blue Cross Blue Shield plans across the country had published favorable coverage policies since the beginning of 2018 for ThyGenX® and ThyraMIR®, the Company's molecular tests for indeterminate thyroid nodules. The list of plans includes many of the largest Blue Cross Blue Shield plans in the country, including Blue Shield of California and Horizon Blue Cross Blue Shield of New Jersey, previously announced by us. As a result of these 14 new policies, over 75 million members participating in these plans now have coverage for ThyGeNEXT® and ThyraMIR® testing.

- In May 2018, we also announced that we had entered into an agreement with Vanderbilt University Medical Center based in Nashville, TN, one of the largest and most prestigious academic medical centers in the country. The agreement enables physicians across the Vanderbilt system access to both ThyGeNEXT® and ThyraMIR® for patients with indeterminate thyroid nodules.

- In June 2018, we announced coverage of ThyGeNEXT® and ThyraMIR® by Blue Cross Blue Shield of Florida, the largest health plan in Florida with over three million members.

- In July 2018, we announced that CIGNA, one of the nation's largest health plan providers, agreed to cover ThyraMIR®, in addition to ThyGeNEXT®.

- In September 2018, we announced the receipt of approval to launch ThyGeNEXT® in the Commonwealth of Pennsylvania and New York State, which represent two of the largest state populations in the U.S. The Pennsylvania approval is final and the New York State Department of Health approval is conditioned upon receipt of additional information requested.

- In October 2018, we announced that we had entered into an agreement with Piedmont Healthcare, one of Georgia's largest healthcare system with nearly 600 locations, including 11 hospitals, that serves 2 million patients. The agreement enables physicians across the Piedmont Healthcare Network to use PancraGEN® for patients with indeterminate pancreatic cysts or other pancreaticobiliary lesions.

- In November 2018, we announced that one of the largest national Blue Cross Blue Shield plans, the Federal Employee Health Benefit Program, extended coverage of ThyGeNEXT® and ThyraMIR® to its 5.3 million covered lives including federal employees, retirees and their families. 30 Blue Cross Blue Shield plans with favorable coverage policies for our thyroid assays were added throughout 2018.

- In January 2019, we announced that we had entered into an Agreement with the University of Maryland Medical System ("UMMS") to provide physicians access to ThyGeNEXT®, ThyraMIR®, and PancraGEN® across the UMMS network, which includes 4,000 affiliated physicians who provide primary and specialty care in more than 150 locations and at 14 hospitals.

Corporate Information

We were originally incorporated in New Jersey in 1986 as PDI, Inc. and began commercial operations as a contract sales organization or "CSO" in 1987, which provided the personal promotion of pharmaceutical and medical device customers' products through outsourced sales teams. In connection with PDI's initial public offering, it reincorporated in Delaware in 1998. Having disposed of substantially all of the assets of the CSO business in 2015, we currently operate as Interpace Diagnostics Group, Inc. under one operating segment, which is our molecular diagnostic business. We conduct our business through our wholly-owned subsidiaries, Interpace Diagnostics, 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 become a leading personalized medicine and bioinformatics business focused on providing analytical results for the gastrointestinal, endocrine and lung cancer diagnostics and pharmaceutical markets. We seek to grow our business both organically as well as by selective partnering, which could potentially include licensing, acquisitions or mergers. The key elements of our strategy to achieve this goal include:

- Leveraging our existing commercial products, including PancraGEN®, ThyGeNEXT®, ThyraMIR®, and potentially growing our 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, seek key reimbursement support while seeking partners to collaborate with us and accelerate full market introduction;
- Targeting synergistic product and service opportunities to distribute through our commercial structure;
- Developing and commercializing other related first-line assays and expanding our service offerings such as PanDNA®, a DNA only version of PancraGEN®, and markers for aggressive Thyroid cancer;
- Expanding our commercial 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 50,000 patients), utilizing registries to improve our assays and leveraging data with potential collaborators;
- Continuing to expand internationally;
- Continuing to strengthen our balance sheet and improve our liquidity, and
- Improving our awareness and opportunities in the public markets, especially with higher quality health care investors

Recent Business Developments

Commercial Expansion

In 2018 we grew our commercial team by approximately 30% principally focused on our endocrine business. In 2018 our thyroid product revenues grew in both dollars and units over 2017. For 2018 our thyroid business was approximately 60% of our total revenues while our pancreatic product revenues were approximately 40% of our total revenues. Additionally, in 2018 we expanded our slide biopsy processing of thyroid samples, obtained a significant portion of the former business of Rosetta Genomics Inc., and subsequently acquired a majority of their Philadelphia laboratory equipment to support our expansion plans. We currently process thyroid samples under three distinct platforms: FNA (Fine-needle aspiration), slides and FFPE (Formalin-Fixed Paraffin-Embedded).

In March 2018 we announced that we executed a new agreement with LabCorp (NYSE:LH) to further expand our national network of cytology providers in support of our Thyroid molecular business unit. The arrangement builds on the parties' 2016 agreement, which established electronic ordering and result reporting through LabCorp for our proprietary ThyGenX® and ThyraMIR® tests, which can provide physicians and patients with more specific diagnostic information about the presence of thyroid cancer in patients whose initial biopsy does not conclusively indicate whether a thyroid nodule is malignant or benign. LabCorp, as of 2018, is now our single largest thyroid product customer.

In May 2018, we announced the launch of a proprietary new mutational panel for indeterminate thyroid nodules, ThyGeNEXT®, at the American Association of Clinical Endocrinologists (AACE) Annual Meeting in Boston, MA. ThyGeNEXT® includes additional molecular markers, gene mutations, and RNA fusions compared to ThyGenX®. The new product represents a more comprehensive set of indicators to not only identity malignant or benign nodules, but also ascertain aggressiveness and other characteristics.

In 2018, we also grew our gastrointestinal business revenues over 2017, which is approximately 40% of our total 2018 revenues. In July 2018 we announced the expanded application of PancraGEN® beyond pancreatic cysts to include both biliary strictures and solid pancreatic lesions while gaining further guideline support in the marketplace. PancraGEN® is the first and only commercially available integrated molecular pathology test for pancreaticobiliary cancers.

Our product extension progress has been principally focused on expanding our PancraGEN assay beyond pancreatic cysts to include both biliary strictures and solid pancreatic lesions and successfully launching ThyGeNEXT; our proprietary new expanded mutational panel for indeterminate thyroid nodules. Our pipeline is principally focused on further developing and launching BarreGEN.

Clinical Evidence

We continue to publish key clinical evidence related to our products, including ThyGenX® and ThyraMIR®, PancraGEN®, and BarreGEN®.

- A peer-reviewed manuscript was published in 2019 based on a 2018 clinical experience study that supports the use of BarreGEN® as an effective tool at identifying patients with Barrett's Esophagus at higher risk of progression to more advanced stages of disease associated with esophageal cancer, supporting the utility of BarreGEN® as an effective biomarker in identifying Barrett's patients in need of closer surveillance or cancer preventative measures. (Trindade AJ, et al. BMJ Open Gastro 2019;6:e000268. doi:10.1136/bmjgast-2018-000268).
- A peer-reviewed manuscript was published in 2018 describing the validity and utility of combination ThyGenX® and ThyraMIR® in microdissected stained cytology slides, providing physicians a useful alternative specimen type for combination molecular testing of indeterminate thyroid nodules. (Kumar G, et al. Diagnostic Cytopathology. 2018; 1-8. DOI: 10.1002/dc.24100).
- In 2018, new data from a large clinical experience study of over 300 patients was presented at the 88th Annual Meeting of the American Thyroid Association (ATA) with conclusions highlighting the clinical utility of the ThyGenX® thyroid oncogene panel in combination with its micro-RNA classifier, ThyraMIR®. (Sistrunk JW, et al. American Thyroid Association 88th Annual meeting. 2018. Short Call Poster 42: https://doi.org/10.1089/thy.2018.29065.abstracts).
- In 2018, new data was published at the 88th Annual Meeting of the American Thyroid Association (ATA) describing the validity of combination ThyGeNEXT® and ThyraMIR® testing. (Kumar G, et al. American Thyroid Association 88th Annual meeting. 2018. Poster 86: https://doi.org/10.1089/thy.2018.29065.abstracts).

- A peer-reviewed manuscript was published in 2018 describing a large study of 478 patients with pancreatic cysts, which concluded that DNA analysis using PancraGEN® can have a favorable impact on patient outcomes particularly in patients with cysts that have worrisome features, supporting more accurate surgery and surveillance decisions in such clinical scenarios. (Farrell JJ, et al. GIE. 2018. doi.org/10.1016/j.gie.2018.10.049).
- A peer-reviewed manuscript was published in 2018 supporting the diagnostic accuracy and comparative diagnostic accuracy of PancraGEN® to gold standard cytology testing and gold standard molecular testing using FISH methods for diagnosing malignancy in solid pancreaticobiliary lesions. In this prospective study of 101 patients the authors found that PancraGEN® testing of specimens obtained during routine endoscopic procedures improved detection of pancreaticobiliary malignancy and improved diagnostic yield of each endoscopic procedure compared to use of gold standard testing alone. (Kushnir VM et al. J Clin Gastroenterol. 2018. doi: 10.1097/MCG.0000000000001118).
- A clinical experience study was published in 2018 describing the utilization, diagnostic accuracy, and comparative diagnostic accuracy and negative predictive value (including follow-up) of PancraGEN® compared to cytology testing for diagnosing malignancy in solid pancreaticobiliary lesions. The authors found that PancraGEN® improved detection of pancreaticobiliary malignancy and changed physician management decisions in a way that could improve patient outcomes. (Khosaravi F, et al. JOP. J Pancreas. 2018 Jan 29; 19(1):1-6).

Intellectual Property

In December 2018, we announced that a Notice of Allowance was issued by the United States Patent and Trademark Office (USPTO) for a patent application, U.S. Application No. 13/692,727, supporting BarreGen®. We expect that the patent arising from U.S. Application No. 13/692,727 will issue in early 2019. Additionally, United States Patent No. 10,131,942 issued on November 20, 2018, for methods for treating subjects with a high risk of disease progression from Barrett's metaplasia to esophageal adenocarcinoma.

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, 2018 and 2017.

Our Business

In August 2014, we acquired certain assets from Asuragen Inc., or Asuragen, in the thyroid cancer sector, and in October 2014, we acquired RedPath Integrated Technologies Inc., or RedPath, which included our pancreatic, gastrointestinal, and lung assets. 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 public company known as Interpace Diagnostics Group, Inc. or (IDXG).

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 optimize shareholder value by growing our business revenues by expanding awareness of our unique offerings, launching additional products, improving patient outcomes and overall 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 an integrated pathology analysis and/or microRNA expression proprietary algorithms 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 uncertainty in cancer risk. Our thyroid tests are designed to provide higher levels of clarity in cancer risk 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 the robustness of our science in clinical studies. Patients and physicians can access a list of publications on our website. We continue to build upon our extensive library of bioinformatic data and clinical evidence. We also seek 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, ThyGeNext® 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 ThyGeNext® 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 lung assay, RespriDx® 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 as we are in the process of gathering data to potentially secure reimbursement by way of our CEP or Clinical Experience Program.

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 pharmaceutical companies that are developing therapeutically relevant products. Additionally, robust data and clinical studies are typically 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 typically 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 lower risk, thereby reducing healthcare costs and potential risks associated with surgery.

We offer PancraGEN®, an integrated molecular pathology diagnostic test designed for determining risk of malignancy in pancreatic cysts and solid pancreaticobiliary lesions, ThyGeNext®, our next-generation sequencing test in combination with ThyraMIR®, our novel microRNA gene expression risk classifier, designed to assist physicians in distinguishing between benign and malignant genotypes in indeterminate thyroid nodules, and RespriDx® our metastatic versus primary platform and lung cancer test. 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 Experience Program or CEP, while we gather additional data, perform clinical studies and plan to seek reimbursement.

Gastrointestinal Cancer Products

Our current gastrointestinal integrated pathology 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 pancreatic 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 oncology related commercial tests, and we also support our other gastrointestinal development activities through this laboratory.

Early detection of pancreatic cancer 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 risk of malignancy in pancreatic cysts and pancreaticobiliary solid lesions, which are more often than not benign lesions but have potential for cancer. We believe that PancraGEN® is the leader in the market for integrated molecular diagnostic tests for determining risk of pancreaticobiliary malignancy. 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 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 that PancraGEN® more accurately determines the malignant potential of pancreatic cysts than international consensus 2012 imaging criteria, helping to ensure that surgery is reserved for the most appropriate patients. When molecular analysis is not performed, the vast majority of all pancreatic cysts surgeries are for those that do not harbor malignancy. The American Gastroenterological Association 2015 Guidelines have cautioned that many pancreatic surgeries have been performed unnecessarily for lesions that will not progress to invasive adenocarcinoma. 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 and prognostic option that identifies cancer risk in circumstances where risk of cancer is otherwise uncertain.

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 or Clinical Experience Program allowing us to gather additional data, perform clinical studies and seek initial reimbursement. We preliminarily estimate that the total Barrett's risk assessment market is approximately $1.5 to $2 billion annually based on the current size of the patient population and anticipated reimbursement rates. We are currently assessing the opportunity to partner BarreGEN®, while simultaneously working to gather sufficient data to gain insurance reimbursement for BarreGEN® in 2019.

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. ThyGeNext® is a next generation DNA and RNA sequencing oncogene panel when applied to indeterminate biopsies. ThyGeNext® works synergistically with our second endocrine cancer diagnostic test ThyraMIR®, which is based on measuring the relative expression of 10 distinct microRNAs. The combination of ThyGeNeXT® and ThyraMIR® is designed to provide a highly sensitive "rule-in" and "rule-out" test to accurately risk stratify indeterminate thyroid nodules.

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 biopsies and reimbursement rates. ThyGeNext® is used by some customers as a base line oncogene panel assessment and approximately 85% of such users will reflex to ThyraMIR® for a more specific evaluation.

Endocrinologists evaluate thyroid nodules for possible cancer by collecting cells through various forms of biopsies that are then analyzed by cytopathologists to determine whether or not a thyroid nodule is cancerous. While we have been previously validated for both FNA's and slide biopsies, in 2018 we obtained multiple slide customers that were previously working with Rosetta Genomics prior to their bankruptcy. It is estimated that up to 35% or up to approximately 100,000 biopsies analyzed annually yield indeterminate results, meaning they cannot be diagnosed as definitely being malignant or benign by cytopathology alone. In the past, 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. According to a study published by Wang, et al. in 2011, in approximately 77% of these cases, the thyroid nodule proves to be benign.

Lung Cancer Product

RespriDx® Test and Metastatic versus Primary Platform

RespriDx® 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, which currently provides only nominal revenues, 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. RespriDx® 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 tests. We may enter into collaborative relationships with research and academic institutions for the development of additional or enhanced tests to further increase the depth and breadth of our test offerings. Where appropriate, we may also enter into licensing agreements with our collaborative partners to both license intellectual property for use in our test panels as well as licensing such intellectual property out, as appropriate.

Our research and development costs are primarily clinical costs and were approximately $2.1 million and $1.5 million in 2018 and 2017, respectively.

Customers

Our customers consist primarily of physicians, hospitals and clinics. Our largest customer for Endocrine products in 2018 was LabCorp. 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 on endocrinology, gastroenterology and lung cancers. Communication of our marketing messaging and value proposition is done principally through our two field-based commercial sales teams of approximately 26 representatives and managers. In addition, we employ medical science liaisons or MSLs to respond to clinician inquiries. Additionally, we communicate through print, digital advertising, a web presence, peer-reviewed publications, and trade show exhibits. We believe that our molecular diagnostic tests 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 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 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.

Clinical Evidence

There have been numerous peer-reviewed manuscripts published in journals that have described the clinical validity, clinical utility, and health economic benefit of our commercial tests including:

- Gonda et al (2016) published a peer-reviewed manuscript describing the diagnostic accuracy and comparative diagnostic accuracy of PancraGEN® as compared to gold standard cytology testing and gold standard molecular testing using FISH methods for diagnosing malignancy in solid pancreaticobiliary lesions. In this prospective study of 100 patients the authors found that PancraGEN® testing of specimens obtained during routine endoscopic procedures improved detection of pancreaticobiliary malignancy and provided superior diagnostic yield for each endoscopic procedure as compared to gold standard testing. (Gonda TA, et al. Clinical Gastroenterology and Hepatology. 2016. doi: 10.1016/j.cgh.2016.12.013).
- Loren et al (2016) describes the effectiveness and utilization of PancraGEN®, reporting a real-world increase in the rate of surveillance and real-world reduction in rate of surgeries in patients with worrisome guideline clinical features that are reclassified as low risk by PancraGEN®. PancraGEN® provided a low-risk reclassification in 70% of nearly 300 patients with worrisome guideline clinical features. Importantly, the authors also show that nearly all patients with worrisome features (99%) reclassified as low risk by PancraGEN® who went underwent surveillance rather than surgery in real-life had benign outcomes at long term follow-up. (Loren D, et al. Diagn Pathol. 2016;11:5).
- Kowalski et al (2016) describes the utility of PancraGEN® in extending surveillance interval lengths and reducing unnecessary surgeries in patients with worrisome features that are in fact at low long-term risk of malignancy. Importantly, the publication reports a patient management algorithm based on PancraGEN® results that is supported by long-term patient outcomes follow-up data from patients who underwent clinical PancraGEN® testing. (Kowalski T, et al. J Clin Gastroenterol. 2016;50(8):649-57).
- Al-Haddad et al (2015) describes the effectiveness of PancraGEN®, reporting long-term cancer-free survival of patients with worrisome guideline clinical features that are reclassified by ancillary PancraGEN® test results. The authors describe the efficacy of PancraGEN® in a real-world setting, reporting cancer-free survival and diagnostic accuracy based on PancraGEN® test results in patients who have undergone surgery or long-term follow-up. The authors compare the cancer-free survival and diagnostic accuracy of PancraGEN® to that of guideline clinical criteria without ancillary molecular testing in the same patients and perform multivariate analysis to assess results given co-existing clinical pathological risk factors. (Al-Haddad MA, et al. Endoscopy. 2015;47(2):136-42).
- Das et al (2015) describes the functional outcomes (quality adjusted life years gained) of patients who undergo PancraGEN® reclassification. The authors compare the functional outcomes of patients reclassified by PancraGEN® to those achieved by guideline clinical criteria without ancillary molecular testing and conclude that incorporation of PancraGEN® testing into patient management is cost effective. (Das A, et al. Endosc Int Open. 2015;3(5):E479-86).
- Kung et al (2015) describes the diagnostic accuracy of the molecular components of PancraGEN® in real-world clinical practice at UCLA. (Kung JS, et al. JOP. 2014;15(5):427-32).
- Eluri et al (2015) describes a published multicenter blinded, longitudinal case-control validation study supporting BarreGEN®'s ability to identify patients with early stages of Barrett's Esophagus who are at risk of future progression to esophageal cancer. The study demonstrates that genomic instability measured by BarreGEN® occurs far enough in advance of progression to make BarreGEN® clinically relevant and useful to risk stratifying patients with early stages of Barrett's, supporting the use of BarreGEN® as part of routine Barrett's endoscopic surveillance programs aimed at identifying patients who need early cancer preventative treatment. (Eluri S, et al. Am J Gastroenterol. 2015; 110, 828).
- Das et al (2016) published a comparative health economics study that evaluated the cost-effectiveness of using BarreGEN® as a biomarker to selectively ablate non-dysplastic Barrett's Esophagus patients in efforts to prevent cancer. The authors conclude that selective ablation of patients based on BarreGEN® results make ablation of patients with early stage Barrett's disease cost beneficial, providing patients with additional years of good quality of life and reducing risk of cancer. (Das A, et al. Endoscopy International Open. 2016; DOI: 10.1055/s-0042-103415).
- Khara et al (2014) established the performance of BarreGEN® in predicting the presence of dysplasia, showing that the addition of BarreGEN® testing to traditional histological diagnoses of Barrett's Esophagus can help identify subgroups of patients that share the same level of genomic instability as advanced disease associated with esophageal cancer, concluding that such information could aid in treatment decision-making by increasing confidence in the presence or absence of true dysplasia in patients. (Khara HS, et al. J Gastrointest Cancer. 2014; 45, 137).
- Labourier et al (2015) published a multicenter validation study for the overall performance of ThyraMIR® and ThyGenX® combination testing demonstrating that the performance of combination testing far exceeds that of other commercially available molecular tests. (Labourier E, et al. JCEM. 2015; jc20151158).
- Wylie et al (2016) published a study demonstrating that, independent of mutational status, miRNA expression profiles measured by ThyraMIR® are strongly associated with altered molecular pathways underlying thyroid tumorigenesis. The authors demonstrate that combination ThyGenX® and ThyraMIR® testing is a novel diagnostic strategy that can improve the preoperative diagnosis and surgical management of patients with indeterminate thyroid nodules. (Wylie D, et al. J Path: Clin Res. 2016; 2: 93-103).
- Labourier et al (2016) published a study concluding that molecular testing of indeterminate thyroid nodules can generate both positive health outcomes and positive economic cost savings, when molecular testing has a clinical performance consistent with that of combination ThyGenX® and ThyraMIR® testing. (Labourier E, et al. Clinical Endocrinology. 2016. doi: 10.1111/cen.13096).

See "Recent Business Developments – Clinical Evidence" for a discussion of more recent clinical evidence.

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, 2018, we owned four 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; treating the identified patient and to methods of measuring carcinoembryonic antigen in a biological sample; methods for treating subject with a high risk of disease progression from Barrett's metaplasia to esophageal adenocarcinoma; and methods of treating a subject identified with a papillary thyroid carcinoma. As of December 31, 2018, we owned eight issued patents outside of the United States, two each in Australia, Europe (validated in certain European countries), and Japan, and one each in Israel and Canada. As of December 31, 2018, we owned ten pending patent applications in the United States and one pending patent application in each of Brazil, Canada, and Israel. Provided all maintenance fees and annuities are paid, our issued United States patents expire from 2031 through 2034 and our foreign patents expire in 2027 or 2031, and our pending patent applications, if issued, are expected to expire between 2027 and 2038, 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. On February 25, 2019, the European Patent Office Opposition Division issued a decision revoking the patent on grounds that the claims were not supported by a valid basis. We are studying the decision and will determine our next steps, which may include appealing the Opposition Division's decision. We continue to believe that the patent is valid. 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 non-disclosure 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®, RespriDx® 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 pursuant to an asset purchase agreement, or the Asuragen Asset Purchase 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 Asuragen Asset Purchase 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 tests based on the miR*Inform*® pancreas platform, if developed, on the future net sales of tests based on the miR*Inform*® thyroid platform (i.e., ThyGeNEXT®) and potentially on certain other thyroid diagnostics tests.

In October 2014, we acquired RedPath Integrated Pathology Inc. (Redpath) which included its pancreatic and gastrointestinal assets. Additionally, we have a broad and growing trademark portfolio. We have secured trademark registrations for the marks AccuCEA® (or TM), PancraGEN®, PanDNA®, BarreGEN® and miR*Inform*® in the United States, and miR*Inform*® with the World Intellectual Property Organization.

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 competitors of ours 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 ThyGeNEXT® and ThyraMir® tests. Quest Diagnostics Incorporated, or Quest, currently offers a diagnostic test similar to the earlier version of our ThyGeNEXT® test and 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. 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. The University of Pittsburgh Medical Center now offers PancreaSeq, a Next Generation Sequencing "gene only" panel that focuses on the analysis of mutations in oncogenes and 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. Some 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. Additionally, we validated and launched a DNA only version of PancraGEN®, known as PanDNA®.

It is also possible that we face future competition from other laboratory-developed tests (LDT's), 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 more 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 regulations. 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. We are currently approved to perform ThyGeNEXT®, ThyraMIR®, PancraGEN®, and RespriDx® 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, life-supporting 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, 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.

In March 2017, a draft bill "The Diagnostics Accuracy and Innovation Act" (DAIA) was introduced in Congress. The bill would establish a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. Following review and comment from FDA on the provisions of DAIA, a revised version of the bill, now called "The Verifying Accurate, Leading-edge IVCT Development Act" (VALID) was introduced in Congress in December 2018. A risk-based approach will be used to regulate IVCTs. Each test will be classified as high-risk or low-risk. Pre-market review will be required for high-risk tests. To market a high-risk IVCT, reasonable assurance of analytical and clinical validity for the intended use must be established. Under VALID, a precertification process would be established which will allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, low-risk IVCTs will not be subject to pre-market review. The new regulatory framework will include quality control and post-market reporting requirements. The FDA will have the authority to withdraw from the market IVCTs that present an unreasonable and substantial risk of illness or injury when used as intended.

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, and state equivalents. 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.

Additionally, the Federal Civil Monetary Penalties Law 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.

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 with healthcare providers 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 penalties, damages and fines.

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.

"Affordable Care Act"

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act), as amended by the Health Care and Education Reconciliation Act, a sweeping law intended to broaden access to health insurance and coverage for patients, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, coordinate and promote research on comparative clinical effectiveness of different technologies and procedures, and impose additional health policy reforms. 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 pricing and implemented changes which significantly affect the pharmaceutical, medical device and clinical laboratory industries. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs. Under the current administration and Congress, there have been efforts to make additional legislative changes, including repeal and replacement of certain provisions of the PPACA. It is unclear what impact such legislative changes will have on the availability of healthcare and/or containing or lowering the costs of healthcare.

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 previously announce 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, President Obama 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 payer 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. However, on July 26, 2018, we received a coding update from CMS, which changed the billable procedure code (CPT) for ThyGeNEXT®. This code change resulted in a reduction of the fee schedule for payments to us. We plan to present data to CMS to obtain a restoration of its previously approved rate of Medicare reimbursement. There can be no assurances that our attempt will be successful and that our previously approved rate of Medicare reimbursement for ThyGeNEXT® will be reinstated.

Any reductions to payment rates in the future 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 PPACA 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, 2019, we had approximately 89 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 PDI. Inc., a Contract Sales Organization (CSO) in 1987. In connection with PDI's initial public offering, it reincorporated in Delaware in 1998. In 2015 the CSO business and assets were sold, and since then we have been operating as Interpace Diagnostics Group, Inc. (IDXG) under one operating segment, which is our molecular diagnostic business. We conduct our business through our wholly-owned subsidiaries, Interpace Diagnostics, 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

We are an emerging growth company with a history of losses, and our molecular diagnostics business has generated limited revenue. We expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.

We are a fully integrated commercial and bioinformatics company that currently offers four products commercially: PancraGEN®, ThyGeNEXT®, ThyraMIR® and RespriDx® and to a limited extent via our clinical experience program, BarreGEN®. For the year ended December 31, 2018, we had a net loss of $12.2 million and as of December 31, 2018, we had an accumulated deficit of $141.5 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 tests and assays and to use our bioinformatics data to develop and enhance our products and services 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, as well as cause the market price of our common stock to decline.

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

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, and the market price of our common stock could decline.

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 42% of our revenue for the fiscal year ended December 31, 2018. 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 change their reimbursed amounts.

Novitas Solutions has been and is the current regional MAC that handles claims processing for Medicare services with jurisdiction for PancraGEN®, ThyGeNEXT®, ThyraMIR®, and RespriDx®. 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®, ThyraMIR® and ThyGeNEXT® tests are reimbursed by Medicare based on applicable CPT codes. RespriDx® is currently only covered by the Medicare Advantage program and our BarreGEN® assay is not reimbursed at all. Any future reductions from the current reimbursement rates would have a material adverse effect on business and results of operations. On July 26, 2018, we received a coding update from CMS, which changed the billable procedure code (CPT) for ThyGeNEXT®. This code change resulted in a reduction of the fee schedule for payments to us. We plan to present data to CMS to obtain a restoration of our previously approved rate of Medicare reimbursement. There can be no assurances that our attempt will be successful and that our previously approved rate of Medicare reimbursement for ThyGeNEXT® will be reinstated.

Although we have entered into contracts with certain third-party payers which establish 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 allowable rates of reimbursement for our PancraGEN®, ThyGeNEXT®, ThyraMIR® and RespriDx® assays, payers may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, may impose pre-authorization requirements 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 PancraGEN®, ThyGeNEXT® and ThyraMIR® and to a limited extent, RespriDx®. 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 sufficient demand for our molecular diagnostic tests 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 clinical trials, published papers, presentations at scientific conferences and one-on-one education by our commercial sales force, which are costly and time-consuming. 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 use 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 provided coverage for patients, particularly in the individual market, who were previously either uninsured or faced high premiums. However, premiums for many of 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 markets or the program altogether. In addition, President Trump has announced that he favors repealing PPACA. In 2018, Congress passed legislation revising certain provisions of PPACA and federal agencies also have issued final rules to repeal or revise regulations governing the implementation of certain provisions of PPACA which may negatively impact our revenues. The scope and timing of any further legislation, judicial action or federal regulations to limit, revise, or replace PPACA or regulations governing its implementation is uncertain, but if enacted could have a significant impact on the U.S. healthcare system and our revenues. These events may result in an increase of uninsured patients, increases in premiums, and reductions in coverage for some patients. Patients may therefore delay or forego medical checkups or treatment due to their inability to pay for our molecular tests, which could have a negative effect on 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.

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.

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

In connection with our acquisition of certain assets of Asuragen in 2014, we currently license certain patents and know-how from Asuragen relating to (i) miRInform® 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. Pursuant to the Asuragen License Agreement and the CPRIT License Agreement, we are obligated to make certain royalty and milestone payments to Asuragen and the Cancer Prevention & Research Institute of Texas, or CPRIT. Under the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of tests utilizing the miRInform® thyroid platform (i.e. ThyGeNEXT®), potentially on certain other thyroid diagnostics tests and potentially on other tests in development for thyroid cancer. A similar obligation exists if we elect to launch any molecular tests utilizing the miRInform ® pancreas platform. We are also required by the CPRIT License Agreement with Asuragen to make certain related royalty payments to CPRIT. We have been in discussions with CPRIT regarding royalty payments and no assurances can be given as to whether we owe such royalties and the amount thereof.

When performing the ThyraMIR® test, we use products supplied by Exiqon A/S (now a part of Qiagen), subject to a license agreement with Exiqon A/S. The license agreement obligates us to pay royalties on the future net sales of our assays that utilize licensed patents and know-how obtained from Exiqon A/S.

Our profitability will be impaired by our obligations to make royalty payments to our licensors. Although we believe, under such circumstances, that the increase in revenue will exceed the corresponding royalty payments, our obligations to our 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.

While our overall cash position has improved since 2016, 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 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, limitations on our ability to enter into mergers or acquisition of assets, and other operating restrictions that could adversely affect our ability to conduct our business.

Our future inability to comply with financial covenants under our current line of credit facility and a future inability to comply with our debt obligations could result in our creditors declaring all amounts owed to them due and payable with immediate effect, or result in the collection of collateral by the creditor, both of which would have an adverse material impact on our business and our ability to continue operations.

We entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), providing for up to $4.0 million of debt financing consisting of a term loan (the "Term Loan") of up to $850,000 and a revolving line of credit based on our outstanding accounts receivable (the "Revolving Line") of up to $4.0 million. Currently, we have not borrowed any funds under either The Revolving Line or the Term Loan. The Revolving Line and the Term Loan are both secured by a first priority lien on all our assets, except for intellectual property. We may not sell or encumber our intellectual property without SVB's prior written consent (a negative pledge).

The SVB Loan Agreement contains a number of affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the SVB Loan Agreement. These restrictive covenants could adversely affect our ability to conduct our business, raise capital or sell or dispose of assets to raise capital. The SVB Loan Agreement also contains a number of customary events of default. A failure to comply with these restrictive covenants and/or repay any of our debt obligations could result in an event of default, which, if not cured or waived, could result in the Company being required to pay much higher costs associated with the indebtedness and/or enable our creditors to declare all amounts owed to them due and payable with immediate effect. If we are forced to refinance our debt on less favorable terms, our results of operations and financial condition could be adversely affected by increased costs and rates. We may also be forced to pursue one or more alternative strategies, such as restructuring, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all, or that future borrowings or equity financing would be available for the payment of any indebtedness we may have. In addition, in an event of default, our creditors could begin proceedings to sell the collateral securing the debt. This would have a material adverse effect on our ability to continue 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.

From the beginning of our commercial operations in 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 Diagnostics, 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 less than 100 employees, the success of our business depends largely on the skills, experience and performance of members of our senior management team, including our chief executive officer and chief commercial officer, 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, and limited liquidity 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.

If we lose the support of key opinion leaders, it may be difficult to establish products enabled by our Laboratory Information Management System (LIMS) 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 opinion leaders at premier cancer institutions and oncology networks. If these key opinion leaders determine that our LIMS, 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 LIMS 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 to leverage our bioinformatics data, we may be unable to recognize revenues from biopharmaceutical companies and our product development could be delayed.

Clinical utility studies are important in demonstrating to both customers and payers a molecular diagnostic test's clinical relevance and value. If we are unable to identify collaborators willing to work with us to conduct clinical utility studies, or the results of those studies do not demonstrate that a molecular diagnostic test provides clinically meaningful information and value, commercial adoption of such test may be slow, which would negatively impact our business.

Clinical utility studies show when and how to use a molecular diagnostic clinical test and describe the particular clinical situations or settings in which it can be applied and the expected results. Clinical utility studies also show the impact of the molecular diagnostic test results on patient care and management. Clinical utility studies are typically performed with collaborating oncologists or other physicians at medical centers and hospitals, analogous to a clinical trial, and generally result in peer-reviewed publications. Sales and marketing representatives use these publications to demonstrate to customers how to use a molecular diagnostic clinical test, as well as why they should use it. These publications are also used with payers to obtain coverage for a test, helping to assure there is appropriate reimbursement. We will need to conduct additional studies for our diagnostic tests and other diagnostic tests we plan to introduce, to increase the market adoption and obtain coverage and adequate reimbursement. Should we not be able to perform these studies, should the costs or length of time required for these studies exceed their value, or should their results not provide clinically meaningful data and value for oncologists and other physicians, adoption of our molecular diagnostic tests could be impaired, and we may not be able to obtain coverage and adequate reimbursement for them.

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 commercial 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 commercial 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.

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" (or "ASC 606") effective January 1, 2018. Under this accounting revenue standard, revenues are now recognized on the accrual basis, based upon actual collection histories for our tests and respective payers or payer groups. This change in accounting has resulted in fluctuations in our quarterly revenue when compared to prior periods. As we recognize revenue from payers on an accrual basis under ASC 606, we may subsequently determine that certain judgments underlying estimated reimbursement change, or that our estimates we used at the time we accrued such revenue vary materially from the actual reimbursements subsequently realized, and 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.

Historically, for the time periods through December 2017, we recognized a significant portion of our revenue only when the following revenue recognition criteria were met: 1) persuasive evidence of an arrangement existed; 2) services have been rendered; 3) the selling price was fixed or determinable; and 4) collectability was reasonably assured. We determined the amount we expect to collect based on a per payer per contract or agreement basis. In situations where we were not able to make a reasonable estimate of reimbursement, we recognized revenue upon the earlier 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 was ultimately compared to previous estimates and the contractual allowance adjusted accordingly.

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 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 in the molecular diagnostics market, 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 non molecular testing like cytology or diagnostic 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, Inc. has thyroid nodule cancer diagnostic tests which are currently on the market that compete with our ThyGeNEXT® and ThyraMIR® tests. Quest Diagnostics Incorporated, or Quest, currently offers Veracyte, Inc.'s tests via a co-marketing agreement, and CBLPath, Inc. is offering a diagnostic test performed via the University of Pittsburgh Medical Center ("UPMC") that analyzes genetic alterations using next-generation sequencing mutation panel for pancreatic cysts. While we do not believe we currently have significant direct competition for PancraGEN® in the gastrointestinal market, technology such as a next-generation sequencing mutation panel could in the future lead to increased competition.

It is also possible that we face future competition from laboratory developed tests, or 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 testing 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 and maintain 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 third-party 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 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.

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 changes its enforcement policy as to laboratory developed tests (LDTs) or disagrees with our position that our molecular diagnostic tests are LDTs covered by the FDA's current enforcement discretion policy, we could be subject to a number of enforcement actions, any of which could have a material adverse effect on our business and/or incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and comply with applicable post-market requirements.

Clinical laboratory tests like our molecular diagnostic tests are regulated under CLIA as well as by applicable State laws and may also be subject to FDA regulation, depending on how the test is classified. For example, the FDA regulates *in vitro* diagnostic tests (also called *in vitro* devices or "IVDs"), specimen collection kits, analyte specific reagents (ASRs), and instruments used in conducting diagnostic testing. Tests that qualify as LDTs are currently subject to enforcement discretion by the FDA, but there is substantial uncertainty regarding the scope of the FDA's enforcement discretion policy and the proper interpretation of the definition of LDTs (as set forth in the 2014 draft guidance described below, which defines LDTs as "those *in vitro* diagnostic devices (IVD) that are intended for clinical use and are designed, manufactured and used within a single laboratory"). 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 Centers for Medicare & Medicaid Services, or 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 the 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. This goal would be achieved through a precertification process. The evidence of the analytical and clinical validity of all LDTs will be made publicly 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.

In March 2017, a draft bill "The Diagnostics Accuracy and Innovation Act" (DAIA) was introduced in Congress. The bill would establish a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. Following review and comment from FDA on the provisions of DAIA, a revised version of the bill, now called "The Verifying Accurate, Leading-edge IVCT Development Act" (VALID) was introduced in Congress in December 2018. A risk-based approach will be used to regulate IVCTs. Each test will be classified as high-risk or low-risk. Pre-market review will be required for high-risk tests. To market a high-risk IVCT, reasonable assurance of analytical and clinical validity for the intended use must be established. Under VALID, a precertification process would be established which will allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, low-risk IVCTs it develops will not be subject to pre-market review. The new regulatory framework will include quality control and post-market reporting requirements. The FDA will have the authority to withdraw from the market IVCTs that present an unreasonable and substantial risk of illness or injury when used as intended. We cannot predict whether this draft bill will become law or the ultimate impact of its passage would have on our business. If the FDA implements a new framework for enforcement of its regulations against LDTs, our existing products that are classified as LDTs, if any, and/or any of our future LDTs we seek to develop and market for clinical use, we may be required to obtain clearance or approval before continuing to market such tests in the U.S. We may not be able to obtain such approvals on a timely basis or at all. Our business could be negatively impacted as a result of commercial delay that may be caused by any new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market approval 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. Any other regulatory or legislative proposals that would increase general FDA oversight of clinical laboratories and LDTs could negatively impact our business if additional requirements are imposed. 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.

Similarly, notwithstanding any change in existing enforcement policies, if the FDA determines that any of our tests are IVDs, rather than LDTs and, accordingly, seeks to enforce the applicable medical device regulations against us, we could be subject to a wide range of penalties and would likely be prohibited from continuing to offer the applicable tests in interstate commerce until we have obtained FDA approval or clearance through the Premarket Approval (PMA) process or the 510(k) process, respectively, as applicable. Additionally, we could be subject to enforcement for noncompliance with the FDA's regulations on marketing and promotional communications, manufacturing, quality and safety standards, labeling, storage, registration and listing, recordkeeping, adverse event reporting, and any other regulations applicable to IVDs. Any adverse enforcement action against us may have a material adverse effect on our business.

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 laboratories 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 certain states, including 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® (predecessor to ThyGeNEXT®) and ThyraMIR® assays in New York State. If we were unable to obtain or maintain 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, if such licenses expired or were not renewed, or if we failed to obtain and maintain a State license that we are required to hold, we may be subject to significant fines, penalties and liability, and may be forced to cease testing specimens from those States, which could have a material adverse effect on our business, financial condition and results of operations. 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.

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. Under PPACA, since 2013, each medical device manufacturer must pay an excise 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. 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 legislation has been proposed to permanently repeal the excise tax. If the moratorium is not repealed, 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 physicians, lower thresholds for violations and increasing potential penalties for such violations. The effect of PPACA and any potential changes that may be necessitated by the legislation is uncertain, any of which may potentially affect our business.

Our current position is that we do not meet the definition of an "Applicable Manufacturer" under the Physician Payments Sunshine Act of the PPACA 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 payers. 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 repeal, revise, or replace 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.

On January 20, 2017, President Trump signed an executive order directing federal agencies to exercise existing authorities to reduce burdens associated with PPACA pending further action by Congress. In April 2018, CMS issued a final rule and guidance documents which changed requirements for health plans sold through PPACA marketplaces for 2019. These changes include, for example, turning over responsibility for ensuring that marketplace plans have enough health care providers in their networks to the states that rely on the federal HealthCare.gov exchange; allowing states to alter aspects of the essential health benefits required of health plans sold through the federal and state insurance marketplaces; eliminating certain Small Business Health Options Program (SHOP) regulatory requirements; and outlining criteria by which insurers may reduce the percentage of income allocated to patient care. The U.S. Department of Labor issued a final rule in June 2018 to expand the availability of association health plans available to small business owners and self-employed individuals, beginning on September 1, 2018. These association health plans will not be required to provide the essential health benefits mandated by PPACA. These and other regulations may impact coverage of certain health care services.

In 2018, Congress has proposed further legislation to repeal or revise PPACA, which if enacted, may have a significant impact on the health care system. Further legislative changes to PPACA or to regulations implementing provisions of PPACA remain possible. Repeal of or changes to PPACA may affect coverage, reimbursement, and utilization of laboratory services, as well as administrative requirements, in ways that are currently unpredictable and therefore we cannot predict the impact on our revenues.

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.

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, certain 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 Medicare patients, which may increase our costs and reduce the amount ultimately collected.

CMS bundles payments for clinical laboratory tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS has exempted certain molecular diagnostic tests from this bundling provision. 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.

In April 2014, President Obama 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. 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). 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 2018 through 2020 and to 15% per test per year in each of the years 2021 through 2023. 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 was reduced in 2018 and is scheduled to be reduced in 2019 and 2020. 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 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. The federal and state laws which may apply to us include, but are not limited to:

- 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 and Medicaid billing and payment regulations applicable to clinical laboratories;
- The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), which prohibits the solicitation, receipt, payment or offer of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers;
- 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 physician self-referral law, commonly referred to as the "Stark 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;

- The federal transparency requirements under the PPACA, including the provisions commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;

- Other Federal and State fraud and abuse laws, prohibitions on self-referral and kickbacks, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, transparency, reporting, and disclosure requirements, 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.

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 or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to 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, maintain a commercial sales force, and contract for marketing services. These arrangements, like any arrangement that includes compensation to a healthcare provider or potential referral source, may trigger Federal or State anti-kickback, Stark Law liability, and False Claims Act liability. 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 be commercially reasonable and compensation must be fair market value. These terms require some subjective analysis. 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, sales force members, or other parties. 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.

In addition, federal law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. Entities found in violation may be liable for civil monetary penalties of up to $10,000 for each wrongful act. Further, Federal and state anti-kickback statutes or similar laws may be implicated by arrangements with patients to waive, reduce, or limit copays or other payment amounts, such as our Patient Assistance Program. Third-party payers, including commercial payers and government payers, may prohibit, limit, or restrict certain financial arrangements with patients. Violation of these laws or payment policies could result in significant fines, penalties, liability, recoupment, and exclusion from Medicare and Medicaid, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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.

Our current international operations are not material to our overall financial results, 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 payer reimbursement regimes, government payers, 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 could result in the disruption of our activities in these 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.

Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.

We have incurred net losses since 2015 and may never achieve profitability. As of the fiscal year ended December 31, 2018, we had U.S. federal and state net operating losses, or NOLs, of approximately $186.7 million and $80.3 million, respectively. Subject to the final two sentences of this paragraph, the federal and state NOL carryforwards will begin to expire, if not utilized, beginning in 2028. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. We may be limited in the portion of NOL and tax credit carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes. Sections 382 and 383 of Internal Revenue Code limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The limitation could prevent us from using some or all of our NOLs and tax credits, as it places a formula limit of how much of our NOL and tax credit carryforwards we would be permitted to use in a tax year. 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. In the event we have undergone or will undergo an ownership change under Section 382 of the Internal Revenue Code, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may become subject to these limitations, which could potentially result in increased future tax liability to us.

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

The U.S. government has recently enacted comprehensive tax legislation, commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "TCJA"), 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 35% 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 35% 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, effective January 1, 2018. The impact of the new revenue standard implementation in 2018 resulted in recognizing more revenue on an accrual basis than in prior periods for certain payer groups that were previously reported on a cash basis. 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. As a covered entity, we must comply with the HIPAA privacy and security regulations, which may increase our operational costs. Furthermore, the privacy and security regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, or PHI, including potential civil and criminal fines and penalties. 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 is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure 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. In 2017, we discovered malware installed on certain servers. After an internal investigation, we do not believe that any PHI or other sensitive data on the affected servers was accessed or compromised. We removed the malware, and enhanced our cybersecurity procedures. Additionally, we share PHI with third-party contractors who are contractually obligated to safeguard and maintain the confidentiality of PHI. Unauthorized persons may be able to gain access to PHI stored in such third-party contractors' computer networks. Any wrongful use or disclosure of PHI by us or our third-party contractors, including disclosure due to data theft or unauthorized access to our or our third-party contractors' computer networks, could subject us to fines or penalties that could adversely affect our business and results of operations. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information by us or our third-party contractors. 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 less than 100 employees. We may increase the number of employees in the future depending on the progress and growth of our business Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our future financial performance and our ability to sell or promote 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 third-parties to process and transmit claims to payers, and any delay in either could have an adverse effect on our revenue and financial condition.

We rely on third-party providers 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 again 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. As of February 2019, we transitioned from Quadax, Inc. to XIFIN, Inc. to handle all claim submissions and corresponding collections. We continue to rely on Quadax, Inc. for the collection of those amounts billed through December 31, 2018, which are substantial. There can be no assurance that the transition to XIFIN as our new third-party billing service provider will occur without any interruption or collection delay for our 2019 billings, an occurrence of which may adversely impact our revenue and financial condition.

We may not receive reimbursement for all tests provided to Medicare patients due to Medicare billing rules.

Prior to January 1, 2018, based on the existing Medicare rules, hospitals were required to bill for our tests when performed on Medicare beneficiaries who were hospital outpatients at the time of tissue specimen collection when these tests were ordered less than 14 days following the date of the patient's discharge.

Effective January 1, 2018, CMS revised its billing rules to allow the performing laboratory to bill Medicare directly for molecular pathology tests performed on specimens collected from hospital outpatients, even when those tests are ordered less than 14 days after the date of discharge, if certain conditions are met. We believe our tests are covered by this policy. Accordingly, we bill Medicare for these tests when we perform them and meet the conditions set forth in CMS's revised billing rules.

This change does not apply to tests performed on specimens collected from hospital inpatients. We will continue to bill hospitals for tests performed on specimens collected from hospital inpatients when the test was ordered less than 14 days after the date of discharge. While we believe the impact of these revisions are favorable to us, we cannot predict with certainty the impact on our business. CMS may change this regulatory policy in the future, which could negatively impact our business.

Our failure to comply with fraud and abuse laws or payer regulations could result in our being excluded from participation in Medicare, Medicaid, or other governmental payer programs, subject to fines, penalties, and repayment obligations, decrease our revenues and adversely affect our results of operations and financial condition.

The Medicare program is administered by CMS, which, like the states that administer their respective state Medicaid programs, imposes extensive and detailed requirements on diagnostic services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims and how we provide our specialized diagnostic services. In addition, federal and state laws prohibit fraudulent billing and provide for the recovery of overpayments. In particular, if we fail to comply with federal and state documentation, coding and billing rules, we could be subject to liability under the federal False Claims Act, including criminal and/or civil penalties, loss of licenses and exclusion from the Medicare and Medicaid programs. The False Claims Act prohibits individuals and companies from knowingly submitting false claims for payments to, or improperly retaining overpayments from, the government. Private payers also have complex documentation, coding, and billing rules, and can bring civil actions against laboratories. Our failure to comply with applicable Medicare, Medicaid and other third party payer rules could result in liability under the False Claims Act, our inability to participate in a governmental payer program, recoupment or returning funds already paid to us, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory, all of which could adversely affect our results of operations and financial condition.

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, we discovered malware installed on certain servers. We do not believe that any data on the affected servers was accessed or compromised. We removed the malware, and enhanced our cybersecurity procedures. Additionally, our core business is largely dependent on our partially internally developed and partially purchased Laboratory Information Management System or LIMS, which is our automated basis of managing operations and storing data and customer information. 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 OUR INTELLECTUAL PROPERTY

If we breach certain agreements with Asuragen, it could have a material adverse effect on our sales and commercialization efforts for our thyroid cancer diagnostic tests as well as any potential tests in development for thyroid cancer utilizing their technology and the sale of diagnostic devices and the performance of certain services relating to thyroid cancer.

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 3.5% 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. We have been in discussions with CPRIT and no assurances can be given as to whether we owe such royalties and the amount thereof.

If we materially breach or fail to perform any provision under the CPRIT License Agreement, Asuragen will have the right to terminate our license from CPRIT, 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 pancreatic 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 covering our 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 applications. On January 16, 2018, we were notified that an Opposition had been filed against EP patent #2772550 alleging that the patent is invalid. On February 25, 2019, the European Patent Office Opposition Division issued a decision revoking the patent on grounds that the claims were not supported by a valid basis. We are studying the decision and will determine our next steps, which may include appealing the Opposition Division's decision. 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, such as oppositions or post-grant reviews 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 miRInform® platforms (including ThyGeNEXT®), 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 Mayo 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 3, 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. On February 6, 2019, the Federal Circuit for Court of Appeals issued a decision in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, which relied on the decisions in Mayo and Ariosa, to find a claim directed to a method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase not eligible for patenting under 35 U.S.C. § 101. What constitutes a law of nature and a sufficient inventive concept continues to remain uncertain, and it is possible that certain aspects of molecular diagnostics tests will continue to 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. Defending any litigation, and particularly patent litigation, is expensive and time-consuming, and the outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us. It is also possible that 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

If we do not meet certain of NASDAQ's continued listing requirements, 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, among others, 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 day period, we would not be in compliance with NASDAQ's continued listing requirements and our stock could be delisted from NASDAQ.

On May 4, 2018, we were notified by NASDAQ that we were no longer in compliance with the rule requiring us to maintain a minimum bid price of $1.00 per share, and that we had until October 31, 2018 to regain compliance with this minimum bid price requirement or face delisting. We regained compliance with the minimum bid price requirement effective July 27, 2018, and the matter was determined to be closed.

There can be no assurance that we will be able to 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 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.

If we are unable to maintain and implement effective internal controls over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have only recently compiled the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

RISKS RELATING TO OUR CORPORATE STRUCTURE AND OUR COMMON STOCK

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 8, 2019, we had 61,903,962 shares of common stock and 5,000,000 shares of preferred stock available for issuance. As of March 8, 2019, we have reserved 3,124,529 shares of our common stock for issuance upon the exercise of outstanding awards under our stock incentive plan and 1,945,113 additional shares available for future grants of awards under our stock incentive plan as well as warrants for 14,196,482 shares of our common stock outstanding at prices ranging from $0.9375 to $4.69 per warrant share. Provided that we have a sufficient number of unreserved authorized capital stock available, 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.

The addition of a substantial number of shares of our common stock into the market or the registration of any of our other securities under the Securities Act may significantly and negatively affect the prevailing market price for our common stock. The future sales of shares of our common stock issuable upon the exercise of outstanding warrants and options may have a depressive effect on the market price of our common stock, as such warrants and options would be more likely to be exercised at a time when the price of our common stock is greater than the exercise price.

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 by the rights of holders of warrants currently outstanding or issued in the future.

We have not declared any cash dividends on our common 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 common 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, the SVB Loan Agreement contains restrictive covenants that prohibit us from paying cash dividends on our common stock. 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:

- uncertainty about the net realizable value of sales of our tests;
- the commencement, delay, cancellation or completion of sales and marketing programs;
- regulatory developments;

- 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;
- fluctuations in net revenue due to changes in the valuation of our patient accounts;
- periodic stock-based compensation and awards;
- mark to market fluctuations in the valuation of our warrant liabilities;
- changes in valuation for contingent consideration related to acquired assets;
- fluctuations in R&D, business development and spending for clinical trials;
- 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 2018, our common stock traded at a low of $0.76 and a high of $1.78. During 2017, our common stock traded at a low of $0.72 and a high of $14.25. 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.

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 downgrade our common stock or if those 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, 2018, our accrual for litigation and threatened litigation was not material to the consolidated financial statements. Legal fees are expensed as incurred.

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." 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.

	2018		2017	
	HIGH	LOW	HIGH	LOW
First quarter	$ 1.19	$ 0.85	$ 14.25	$ 2.10
Second quarter	$ 0.99	$ 0.77	$ 4.45	$ 0.80
Third quarter	$ 1.78	$ 0.88	$ 1.77	$ 0.72
Fourth quarter	$ 1.74	$ 0.76	$ 1.80	$ 0.90

Holders of Record

We had 192 stockholders of record as of February 28, 2019. 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

On June 13 and 15, 2018, the Company issued an aggregate of 325,000 shares of common stock in consideration of services to be rendered in respect of two consulting agreements it entered into during the quarter ended June 30, 2018. On September 12, 2018 the Company issued an additional 100,000 shares of common stock with respect to one of these consulting agreements. On October 1, 2018 and December 19, 2018, the Company issued 300,000 shares and 100,000 shares, respectively, of common stock in respect to an extension of one of these consulting agreements. The issuances were exempt from registration pursuant to the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof.

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 develops and provides clinically useful molecular diagnostic tests and pathology services. We develop and commercialize genomic tests and related first line assays principally focused on early detection of patients at high risk of cancer using the latest technology to help provide personalized medicine and improve patient diagnosis and management. Our tests and services provide mutational analysis of genomic material contained in suspicious cysts, nodules and lesions with the goal of better informing treatment decisions in patients at risk of thyroid, pancreatic, and other cancers. The molecular diagnostic tests we offer enable healthcare providers to better assess cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk. We currently have four commercialized molecular diagnostic tests in the marketplace for which we are receiving reimbursement: PancraGEN®, which is a pancreatic cyst and pancreaticobiliary solid lesion genomic test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG® platform; ThyGeNEXT®, which is an expanded oncogenic mutation panel that helps identify malignant thyroid nodules and replaced ThyGenX®; ThyraMIR®, which assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDx®, which is a genomic test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer and which also utilizes our PathFinderTG® platform to compare the genomic fingerprint of two or more sites of lung 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.

In August 2018, we acquired a majority of the Philadelphia laboratory equipment of Rosetta Genomics Ltd., a molecular diagnostics company, in order to further support our CLIA and CAP certified lab expansions in our New Haven, Connecticut and Pittsburgh, Pennsylvania laboratories. Also during the third quarter 2018 we hired several former key Rosetta employees and began to perform tests for Rosetta customers, who transitioned their business to our labs utilizing our previously approved "slide biopsy" technology.

Our mission is to provide personalized medicine through genomic-based diagnostics and innovation to advance patient care based on rigorous science. Our laboratories are licensed pursuant to federal law under CLIA and are accredited by CAP and New York State.

We continue to leverage our licensed and 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 approximately $6.5 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 insurance coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our molecular diagnostic tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. We believe that BarreGen®, is a potentially significant pipeline product, built on the PathFinderTG® platform which we believe is synergistic to our capabilities in the gastrointestinal market, which is one of the sectors in which we operate.

Additional Reimbursement Coverage During 2018 and 2019 (to-date)

Reimbursement progress is key for any molecular diagnostic company. We have expanded the reimbursement of our products in 2018. Specifically the most significant progress we have made regarding payers in 2018 is as follows:

- 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, had 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.

- In March 2018, we announced that we had entered into a new agreement with LabCorp to further expand our national network of cytology providers in support of our thyroid molecular business unit. The agreement amends our previous agreement with LabCorp, which established electronic ordering and result reporting through LabCorp, and allows physicians to be able to order both thyroid biopsy analysis and molecular testing from us, simplifying the test ordering process.

- In March 2018 we also announced that we had entered into a laboratory services agreement with Acupath Laboratories, Inc. based in Plainview, New York (Long Island) whereby Acupath's commercial team will be marketing ThyGenX ® and ThyraMIR® for endocrinologists, endocrine surgeons, and other physicians focused on the diagnosis and treatment of thyroid cancer.

- In April 2018, we announced that we had entered into an agreement with BJC Healthcare of St. Louis, Missouri, one of the largest non-profit, integrated healthcare systems in the United States. The agreement enables physicians across the BJC system access to both ThyGenX® and ThyraMIR® for patients with indeterminate thyroid nodules.

- In May 2018, we announced that we had entered into an agreement with Vanderbilt University Medical Center (VUMC) based in Nashville, TN, one of the largest and most prestigious academic medical centers in the country. The agreement enables all physicians across the Vanderbilt system access to both ThyGenX® (and now ThyGeNEXT®) and ThyraMIR® for patients with indeterminate thyroid nodules.

- In May 2018 we announced that 14 Blue Cross Blue Shield plans across the country had published favorable coverage policies since the beginning of 2018 for ThyGenX® and ThyraMIR®, the Company's molecular tests for indeterminate thyroid nodules. The list of plans includes many of the largest Blue Cross Blue Shield plans in the country, including Blue Shield of California and Horizon Blue Cross Blue Shield of New Jersey, previously announced by us. As a result of these 14 new policies, over 75 million members participating in these plans now have coverage for ThyGeNEXT® and ThyraMIR® testing.

- In June 2018, we announced coverage of ThyGeNEXT® and ThyraMIR® by Blue Cross Blue Shield of Florida, the largest health plan in Florida with over three million members.

- In July 2018, we announced that CIGNA, one of the nation's largest health plan providers, agreed to cover ThyraMIR®, in addition to ThyGeNEXT®.

- In September 2018, we announced the receipt of approval to launch ThyGeNEXT® in the Commonwealth of Pennsylvania and New York State, which represent two of the largest state populations in the U.S. The Pennsylvania approval is final and the New York State Department of Health approval is conditioned upon receipt of additional information requested.

- In October 2018, we announced that we had entered into an agreement with Piedmont Healthcare, one of Georgia's largest healthcare systems with nearly 600 locations, including 11 hospitals that serves 2 million patients. The agreement enables physicians across the Piedmont Healthcare Network to use PancraGEN® for patients with indeterminate pancreatic cysts or other pancreaticobiliary lesions.

- In November 2018, we announced that one of the largest national Blue Cross Blue Shield plans, the Federal Employee Health Benefit Program, extended coverage of ThyGeNEXT® and ThyraMIR® to its 5.3 million covered lives including federal employees, retirees and their families. 30 Blue Cross Blue Shield plans with favorable coverage policies for our thyroid assays were added throughout 2018.

- In January 2019, we announced that we had entered into an Agreement with the University of Maryland Medical System ("UMMS") to provide physicians access to ThyGeNEXT®, ThyraMIR®, and PancraGEN® across the UMMS network, which includes 4,000 affiliated physicians who provide primary and specialty care in more than 150 locations and at 14 hospitals.

Recent Notices of NASDAQ Listing Compliance

On May 4, 2018, NASDAQ notified us that that, for the last thirty consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until October 31, 2018, to regain compliance. The letter stated that the Nasdaq staff would provide written notification that the Company had achieved compliance with Rule 5550(a)(2) if at any time before October 31, 2018, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days.

On July 30, 2018, we received written notice from Nasdaq staff notifying us that for 10 consecutive business days the closing bid price of the Company's common stock had been at $1.00 per share or greater and that accordingly, we had regained compliance with Listing Rule 5550(a)(2) and the matter was now closed.

DESCRIPTION OF REPORTING SEGMENTS

We currently operate under one operating segment, which is our molecular diagnostic and bioinformatics 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

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, hospital or service provider.

Revenue Recognition Prior to the Adoption of ASC 606

Historically, for the fiscal periods through December 2017, the Company 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. The Company recognized revenue related to billings for Medicare, Medicare Advantage, and direct-bill payers on an accrual basis, net of contractual adjustment, when there was 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 direct-bill payers, which approximates the Medicare rate. For certain third-party payers that did not have established contractual reimbursement rates or a predictable pattern of collectability, including commercial insurance carriers and Medicaid, the Company believed that the fee was fixed or determinable and collectability was reasonably assured only upon request of third-party payer notification of payment or when cash is received, and recognized revenue at that time.

Until a contract had 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 was only recognized upon the earlier of payment notification or cash receipt. Accordingly, we recognized revenue from commercial insurance carriers, government programs, and certain direct-bill healthcare providers without contracts when payment was received.

Revenue Recognition after the Adoption of ASC 606

Beginning January 1, 2018 under ASC 606, the Company began to recognize revenue for billings less contractual allowances and estimated uncollectable amounts for all payer groups on the accrual basis based upon a thorough analysis of historical receipts. The net amount derived and used for revenue recognition is referred to as the "net realizable value" or ("NRV") for the particular test and payer group from which reimbursement is received. This derived NRV will be evaluated quarterly or as needed and then applied to future periods until recalculated.

The Company completed its analysis of the ASC 606 impact and incorporated further analysis of first quarter 2018 collections from its commercial payer base in finalizing its ASC 606 adjustments. The impact of recording the cumulative catch-up adjustment under the modified retrospective method was $2.5 million, recorded as an increase to opening retained earnings on January 1, 2018. Prior periods have not been retrospectively adjusted.

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. We recorded no asset impairment charges in 2017 or 2018.

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 and 2018, 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 results and projections of future income weighed heavily in our overall assessment. The existing and forecasted levels of pretax earnings 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, 2018 and 2017, as we determined 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 statements of operations 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,			
	2018	2018	2017	2017
Revenue, net	$ 21,896	100.0%	$ 15,897	100.0%
Cost of revenue	10,197	46.6%	7,358	46.3%
Gross profit	11,699	53.4%	8,539	53.7%
Operating expenses:				
Sales and marketing	8,421	38.5%	6,567	41.3%
Research and development	2,124	9.7%	1,461	9.2%
General and administrative	8,499	38.8%	9,153	57.6%
Acquisition related amortization expense	3,252	14.9%	3,253	20.5%
Change in fair value of contingent consideration	1,522	7.0%	(5,602)	-35.2%
Total operating expenses	23,818	108.8%	14,832	93.3%
Operating loss	(12,119)	-55.3%	(6,293)	-39.6%
Interest expense	(331)	-1.5%	(433)	-2.7%
Loss on extinguishment of debt	-	0.0%	(4,278)	-26.9%
Other income (expense), net	263	1.2%	(2,128)	-13.4%
Loss from continuing operations before tax	(12,187)	-55.7%	(13,132)	-82.6%
Provision (benefit) for income taxes	18	0.1%	(395)	-2.5%
Loss from continuing operations	(12,205)	-55.7%	(12,737)	-80.1%
Income from discontinued operations	7	0.0%	1,124	7.1%
(Benefit) provision for income tax on discontinued operations	(9)	0.0%	603	3.8%
Income from discontinued operations, net of tax	16	0.1%	521	3.3%
Net loss	$ (12,189)	-55.7%	$ (12,216)	-76.8%

Revenue, net

Consolidated revenue for the year ended December 31, 2018 increased by $6.0 million, or 38%, to $21.9 million, compared to the year ended December 31, 2017. This increase was principally attributable to increased test volume and commercial coverage for our thyroid tests and the change in revenue recognition under ASC 606 from cash basis to accrual of approximately $0.7 million for certain payer groups. The majority of our growth continues to be our thyroid business, however, both our thyroid and pancreatic businesses are growing.

Cost of revenue

Consolidated cost of revenue for the year ended December 31, 2018 increased by $2.8 million, or 39%, to $10.2 million, compared to the year ended December 31, 2017 primarily due to the increase in test volume, discussed above.

Gross Profit

Consolidated gross profit for the year ended December 31, 2018 increased $3.2 million, or 37%, to $11.7 million, compared to the year ended December 31, 2017 due primarily to the increase in revenue discussed above.

Sales and marketing expense

Sales and marketing expense was $8.4 million for the year ended December 31, 2018, as compared to $6.6 million for the year ended December 31, 2017. As a percentage of revenue sales and marketing expense decreased to 38% from 41% in the comparable prior year period. 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 marketing spending.

Research and development

Research and development expense reflects clinical and research costs for supplies, laboratory tests and evaluations, scientific and administrative staff involved in clinical research, statistical research and product development related to new tests, products and programs. Research and development expense was $2.1 million and as a percentage of revenue was 10%. For the year ended December 31, 2017, the expense was $1.5 million and as a percentage of revenue was 9%.

General and administrative

General and administrative expense for the year ended December 31, 2018 was $8.5 million as compared to $9.2 million for the year ended December 31, 2017. The decrease was primarily attributable to a net decrease in accruals and settlement costs related to the Department of Justice ("DOJ") liability of approximately $1.4 million, partially offset by an increase in professional services costs. As a percentage of revenue, general and administrative expense was 39% for the year ended December 31, 2018 as compared to 58% for the year ended December 31, 2017.

Acquisition related amortization expense

During the years ended December 31, 2018 and December 31, 2017, we recorded amortization expense of approximately $3.3 million, respectively related to the amortization for RedPath and Asuragen acquired intangible assets.

Change in fair value of contingent consideration

During the year ended December 31, 2018, there was a $1.5 million increase in contingent consideration liability related to an increase in estimated future royalty payments payable to Asuragen. 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. 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 $12.1 million and $6.3 million during the years ended December 31, 2018 and 2017, respectively. The increase in operating loss from continuing operations in the year ended December 31, 2018 was primarily attributable to the $5.8 million reduction in contingent consideration liability for the year ended December 31, 2017 discussed above.

Provision for income taxes

We had income tax expense of approximately $0.02 million for the year ended December 31, 2018 and an income tax benefit of approximately $0.4 million for the year ended December 31, 2017. The income tax benefit for the year ended December 31, 2017 was primarily due to the reclassification of CSO as discontinued operations and the tax adjustments associated with that reclassification.

Income (loss) from discontinued operations, before tax

We had income from discontinued operations of $0.01 million for the year ended December 31, 2018 as compared to income from discontinued operations of $1.1 million for the year ended December 31, 2017. The income for the year ended December 31, 2017 was primarily related to favorable settlements of outstanding obligations including a reversal of severance expense of $0.5 million.

LIQUIDITY AND CAPITAL RESOURCES

For the fiscal year ended December 31, 2018, we had an operating loss of $12.1 million. As of December 31, 2018, we had cash and cash equivalents of $6.1 million, total current assets of $17.7 million and current liabilities of $8.5 million.

During the year ended December 31, 2018, net cash used in operating activities was $8.7 million, of which $8.3 million was used in continuing operations and $0.4 million was used in discontinued operations. The main component of cash used in operating activities was our loss from continuing operations of $12.2 million. 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, 2017 was our loss from continuing operations of $12.7 million.

For the year ended December 31, 2018, there was cash used in investing activities of $0.4 million primarily for the purchase of lab equipment. For the year ended December 31, 2017, there was cash used in investing activities of $29,000.

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.

In November 2018, we entered into a secured Line of Credit facility of up to $4.0 million, including a 3-year term loan for $850,000 with Silicon Valley Bank. The proceeds of the term loan are expected to be used for laboratory capital expenditures and will be repaid monthly. The balance of the Line of Credit is available for working capital purposes as a revolving line of credit and has a three-year term. The Line of Credit facility includes a number of affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the Line of Credit facility. These restrictive covenants could adversely affect our ability to conduct our business. The Line of Credit facility also contains a number of customary events of default. Currently, the Company has not borrowed any funds under the Line of Credit.

In January 2019, we sold approximately 9.3 million shares in an underwritten public offering, with net proceeds of approximately $6.1 million. For more details, see Note 21, *Subsequent Events* of the footnotes to the financial statements.

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. Management believes that the Company has sufficient cash on hand to sustain operations through at least March 31, 2020.

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, 2018. 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, 2018.

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, 2018 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

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The names, offices held and ages of our directors and executive officers as of February 28, 2019 are as follows:

Name	Age	Position
Jack E. Stover	65	President, Chief Executive Officer and Director
James Early	64	Chief Financial Officer, Secretary and Treasurer
Gregory Richard	52	Senior Vice President, Chief Commercial Officer
Stephen J. Sullivan	72	Chairman of the Board
Joseph Keegan	65	Director
Felice Schnoll-Sussman	49	Director

Jack E. Stover has been a member of the Board since 2005 and previously served as Chairman of the Audit Committee of the Board from 2005 to December 22, 2015. He was appointed as our President and Chief Executive Officer effective June 21, 2016. Mr. Stover served as our Interim President and Chief Executive Officer from December 22, 2015 to June 20, 2016. Mr. Stover has been a member of the Board of Directors, Chairman of the Audit Committee, and a member of the Compensation Committee of Onconova Therapeutics, Inc., a publicly held biopharmaceutical company since May 2016. Mr. Stover also was a member of the board of Cernostics, Inc., a privately held molecular diagnostic company, from March 2015 until July 2016. Further, Mr. Stover served as a director and Chairman of the Audit Committee of Viatar CTC Solutions, Inc., a publicly held circulating tumor cell company. From May 2016 until December 2016. Mr. Stover was also previously chief executive officer of Zebec Therapeutics LLC (the successor to Quadrant Pharmaceuticals LLC), a privately held clinical stage specialty pharmaceutical company, from April 2014 until December 2015. From 2009 to February 2012, Mr. Stover served as the executive chairman of Targeted Nano Therapeutics LLC, a privately held biotechnology company focused on targeted delivery of peptides and proteins. Mr. Stover also provided consulting and advisory services through JE Stover Consulting, LLC from 2008 through 2015. Mr. Stover was chairman of the audit committee and a member of the board of directors of Arbios Systems Inc., a publicly held bioartificial liver company from 2005 to 2008 and a member of the board of directors of Influmedix, Inc. a privately held vaccine company from 2010 to 2011. From 2004 to 2008, he served as chief executive officer, president and director of Antares Pharma Inc., a publicly held specialty pharmaceutical and medical device company listed at the time on the American Stock Exchange. Prior to that, Mr. Stover was executive vice president and chief financial officer of Sicor, Inc., a publicly held company which manufactured and marketed injectable pharmaceutical products, and which was acquired by Teva Pharmaceutical Industries. Prior to that, Mr. Stover was executive vice president and director of a privately held proprietary women's pharmaceutical company, Gynetics, Inc., and before that he was senior vice president, Chief Financial Officer and director of B. Braun Medical, Inc., a privately held global medical device and pharmaceutical company. From 1975 to 1995, Mr. Stover was employed by PricewaterhouseCoopers LLC (then Coopers and Lybrand), and was a partner from 1985, working in the bioscience industry division in Pennsylvania and New Jersey. Mr. Stover received his B.A. in Accounting from Lehigh University and is a Certified Public Accountant.

On March 16, 2018, James Early was appointed as our Chief Financial Officer. Since August 29, 2016, we had engaged Mr. Early as a consultant to perform the role of interim chief financial officer. Mr. Early previously served as the interim and subsequently permanent Chief Financial Officer of AbGenomics International Inc., a clinical stage drug development company with a product pipeline in immunology and oncology, from September 2015 to July 2016. Mr. Early also previously served as the Chief Financial Officer of Zebec Therapeutics, LLC (the successor to Quadrant Pharmaceuticals LLC), a privately held specialty pharmaceutical company, from October 2014 to September 2015. In addition, Mr. Early has provided interim chief financial officer and business development services for pharmaceutical, life science and other similar companies as a sole proprietor from August 2009 to December 2013 and through Early Financial Consulting, LLC ("Early Financial") from January 2014 to March 2018. Prior to his consulting role, Mr. Early was Senior Vice President of Finance and Administration and Corporate Secretary for Synageva BioPharma, an orphan drug development company, from February 2006 to January 2009. Mr. Early is a Certified Public Accountant and has an M.B.A. in Finance and Accounting from the UCLA-Anderson School of Management and a B.B.A. in Accounting from the University of Notre Dame.

Gregory Richard has been our Chief Commercial Officer and Senior Vice President since April 2014. Prior to his employment by us, Mr. Richard was a Senior Vice President, responsible for sales, marketing and reimbursement, for Strata Pathology Services from April 2012 through April 2014. From 2010 to 2012, Mr. Richard worked with founder Bennet LeBow to form Signal Genetics and launch its first molecular product for multiple myeloma, MyPRS. From 2007-2010 he ran the international Sales and Marketing team for Synarc/CCBR, a specialized CRO providing central imaging services to pharmaceutical companies in support of osteoporosis and cancer trials. Mr. Richard has been in the healthcare business for over 25 years in various industries including managed care, biotech pharmaceuticals, CRO services, and diagnostics. He started his career in sales at Aetna and moved to Genentech as the Director of Managed Care. He transitioned in to the diagnostics industry as the Vice President of Managed Care for Quest Diagnostics and served in this role for 8 years. Mr. Richard also led the international clinical trials sales team while at Quest. He also served as the Sr. Vice President of Sales for the Northeast Division of LabCorp. Mr. Richard is a certified Six Sigma Green Belt and frequent speaker at healthcare industry conferences such as the G2 Lab Institute and the NextGen Dx Summit and has a Bachelor of Arts from Westminster College, Fulton, Missouri.

Stephen J. Sullivan was appointed Chairman of the Board effective June 21, 2016. Mr. Sullivan served as Interim Chairman of the Board from January 1, 2016 to June 20, 2016. Mr. Sullivan joined us as a director in September 2004 and has served as Chairman of various committees of the Board. Mr. Sullivan currently serves as Chairman of the Company's Compensation and Management Development Committee. In early 2010, Mr. Sullivan founded CRO Advisors LLC, a specialty consulting firm he continues to head. Previously, Mr. Sullivan was the president and chief executive officer and a member of the board of directors of Harlan Laboratories, Inc. ("Harlan"), a privately held global provider of preclinical research tools and services, from February 2006 through January 2010, when he retired from that position. Prior to joining Harlan in 2006, Mr. Sullivan was a senior vice president of Covance, Inc. ("Covance") and the president of Covance Central Laboratories, Inc., a major division of Covance. Prior to joining Covance, Mr. Sullivan was chairman and chief executive officer of Xenometrix, Inc. ("Xenometrix"), a biotechnology company with proprietary gene expression technology. He assisted with the merger of Xenometrix with Discovery Partners International. Prior to Xenometrix, Mr. Sullivan was vice president and general manager of a global diagnostic sector of Abbott Laboratories. From June 2013 through January 2016, when the company was sold, Mr. Sullivan was the chairman of the board of BioreclamationIVT, LLC, a privately owned bio-materials company. From May 2013 through March 2015, when the company was sold, Mr. Sullivan was a member of the board of directors of PHT Corporation, a privately owned leader in electronic patient recorded outcomes in clinical trials. From April 2011 through March 2019, Mr. Sullivan was chairman of the board of MI Bioresearch, Inc. (formerly known as Molecular Imaging, Inc.), a privately held venture-backed drug discovery services company. Since May 2015, Mr. Sullivan has been chairman of the board of Microbiology Research Associates (now known as Analytical Lab Group since an August, 2016 merger with Accuratus Labs), a privately held microbiology services company. In January 2016, Mr. Sullivan became chairman of the board of H2O Clinical. In July 2016, Mr. Sullivan became chairman of the board of PharmaStart. As of June 2017, both H20 Clinical and PharmaStart are doing business as Firma Clinical Research, a privately held specialty contract research organization. As of July 2018, Firma Clinical Research has been sold and Mr. Sullivan is no longer a member of its board. From November 2015 until August 2017, Mr. Sullivan was a member of the board of Accel Clinical Research, a phase 1 contract research organization. Since April 2018, Mr. Sullivan has been a member of the board of Transnetyx, Inc., a privately held genotyping company. Mr. Sullivan graduated from the University of Dayton, was a commissioned officer in the Marine Corps, and completed his M.B.A. in Marketing and Finance at Rutgers University. Mr. Sullivan is currently an adjunct Professor of Management at Georgetown University.

Joseph Keegan, Ph.D. was appointed to the Board effective January 1, 2016 and was subsequently appointed Chairman of our Audit Committee and our Nominating and Corporate Governance Committee. Dr. Keegan has more than 30 years of experience in life science businesses. From 2007 to 2012, when it was sold to Pall Corporation, Dr. Keegan was CEO at ForteBio, Inc., a life science tool company, where he helped to lead a financing round and established product development and sales strategies for that company. From 1998 to 2007, Dr. Keegan was CEO at Molecular Devices Corporation (NASDAQ: MDCC), a provider of bioanalytical measurement systems, software and consumables, where Dr. Keegan helped grow the company both internally and through acquisitions. From 1992 to 1998, Dr. Keegan worked at Becton Dickinson and Company, a medical technology company that manufactures and sells medical devices and instrument systems, where he served as President of Worldwide Tissue Culture and Vice President, General Manager of Worldwide Flow Cytometry. From 1988 to 1992, Dr. Keegan was Vice President of the Microscopy and Scientific Instruments Division of Leica, Inc., a life science tool and semiconductor equipment provider. He currently serves on the boards of directors of the following privately held companies: Labcyte Corporation (as chairman) (not since January 2019 when the company was sold), Nanomedical Diagnostics, Inc., Halo Labs (formerly known as Optofluidics, Inc.), and Carterra (formerly known as Wasatch Microfluidics, Inc.). In April, 2017, he joined the board of ArrayJet, a privately held Scottish company. Dr. Keegan is a member of the Board of Directors of Bio-Techne Corporation, a publicly held biotech company. Dr. Keegan is also on the board of the San Francisco Opera. Dr. Keegan holds a B.A. in Chemistry from Boston University and a Ph.D. in Physical Chemistry from Stanford University.

Dr. Felice Schnoll-Sussman was appointed as a member of the Board on September 13, 2017. Dr. Schnoll-Sussman was promoted to Professor of Clinical Medicine at Weill Medical College of Cornell University on March 1, 2019. She has been Associate Professor of Clinical Medicine at Weill Medical College of Cornell University since 2013 and Associate Attending Physician in Gastroenterology at New York Presbyterian Hospital since May 2013. She has been an Attending Physician at Weill Cornell Medical College of Cornell University, Division of Gastroenterology and Hepatology since July 2001. Dr. Schnoll-Sussman has been the Director of the Jay Monahan Center for Gastrointestinal Health at Weill Cornell Medical College since July 2014 and has overall responsibility for all administrative, operational and financial aspects of the Center. She has been Director of Endoscopy since January 2017. Dr. Schnoll-Sussman has her medical degree from the Mount Sinai School of Medicine and has also completed Executive Leadership Training at the Wharton School of Business.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors and persons who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act to file reports of securities ownership and changes in such ownership with the SEC. Officers, directors and greater than 10% beneficial owners ("10% stockholders") also are required by SEC rules to furnish us with copies of all Section 16(a) forms they file. Based solely upon a review of the copies of such forms furnished to us during or with respect to the fiscal year ended December 31, 2018, as the case may be, and upon written representations from these reporting persons, we believe that none of our officers, directors or 10% stockholders failed to file on a timely basis, as disclosed in the forms described above, reports required by Section 16(a) during fiscal 2018.

GOVERNANCE OF THE COMPANY

Corporate Governance and Code of Business Conduct

Our Board has adopted a written Code of Business Conduct that applies to our directors, officers, and employees, as well as Corporate Governance Guidelines applicable specifically to our Board. You can find links to these documents in the "Investor Relations" section of our website page at www.interpacediagnostics.com. The content contained in, or that can be accessed through, our website is not incorporated into this Form 10-K. Disclosure regarding any amendments to, or any waivers from, a provision of our Code of Business Conduct that applies to one or more of our directors, our principal executive officer, our principal financial or our principal accounting officer will be included in a current report on Form 8-K within four business days following the date of the amendment or waiver, or posted on our website (www.interpacediagnostics.com).

Board Leadership and Structure

The Chairman of the Board, who is currently an independent director, presides at all meetings of the Board. Mr. Sullivan serves as the Chairman of the Board, and Mr. Stover, our Chief Executive Officer, serves as a director.

The Board believes that having an independent director serve as Chairman of the Board is in the best interests of our stockholders. This structure provides more direct independent oversight and active participation of our independent directors in setting agendas and establishing policies and procedures of our Board. Further, this structure permits our Chief Executive Officer to focus on the management of our day-to-day operations.

The Board does not have a policy on whether or not the roles of Chief Executive Officer and Chairman of the Board should be separate. The Board believes that it should be free to make a choice from time to time in any manner that is in the best interests of the Company and our stockholders.

Audit Committee

The Audit Committee is currently comprised of Dr. Keegan (Chairperson), Dr. Schnoll-Sussman and Mr. Sullivan. The primary purposes of our Audit Committee are to assist the Board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, auditing, financial reporting, internal control, legal compliance and risk management functions of the Company, including, without limitation, assisting the Board's oversight of: (i) the integrity of our financial statements; (ii) the effectiveness of our internal control over financial reporting; (iii) our compliance with legal and regulatory requirements; (iv) the qualifications and independence of our independent registered public accounting firm; and (v) the performance of our internal audit function and independent registered public accounting firm. The Audit Committee is also responsible for preparing the report of the Audit Committee required by the rules and regulations of the SEC for inclusion in our annual proxy statement.

Our Board has determined that each member of our Audit Committee is independent within the meaning of the rules of NASDAQ and as required by the Audit Committee charter. Our Board has determined that the chairperson of the Audit Committee, Dr. Keegan, is an "audit committee financial expert," as that term is defined in Item 407(d) of Regulation S-K under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Our Audit Committee charter is posted and can be viewed in the "Investor Relations" section of our website at www.interpacediagnostics.com.

Compensation & Management Development Committee

The Compensation Committee is currently comprised of Dr. Keegan, Mr. Sullivan (Chairperson) and Dr. Schnoll-Sussman. Each member of our Compensation Committee is "independent" within the meaning of the rules of NASDAQ and as required by the Compensation Committee charter. The primary purposes of our Compensation Committee are: (i) to establish and maintain our executive compensation policies consistent with corporate objectives and stockholder interests; (ii) to oversee the competency and qualifications of our senior management personnel and the provisions of senior management succession planning; and (iii) to advise the Board with respect to director compensation issues. The Compensation Committee also administers our equity compensation plans.

The Compensation Committee, which is composed solely of independent directors, provides overall guidance for our executive compensation policies and determines the value and elements of compensation for our executive officers. In March 2018, we engaged Radford, an Aon Hewitt company, to gather long-term incentives market data for the Board and our executive officers (the "Radford Report"). In addition to the Radford Report, the Compensation Committee used its experience in working with emerging life science companies as the basis for establishing compensation for 2018.

Our Compensation Committee charter is posted and can be viewed in the "Investor Relations" section of our website at www.interpacediagnostics.com.

Nominating and Corporate Governance Committee

The Nominating Committee is currently comprised of Dr. Keegan (Chairperson), Mr. Sullivan and Dr. Schnoll-Sussman. Each member of our Nominating Committee is "independent" within the meaning of the rules of NASDAQ and as required by the Nominating Committee charter. The primary purposes of the Nominating Committee are: (i) to recommend to the Board the nomination of individuals who are qualified to serve as our directors and on committees of the Board; (ii) to advise the Board with respect to the composition, size, structure and procedures of the Board; (iii) to advise the Board with respect to the composition, size and membership of the Board's committees; (iv) to advise the Board with respect to corporate governance principles applicable to the Company; and (v) to oversee the evaluation of the Board as a whole and the evaluation of its individual members standing for re-election. The Nominating Committee also has responsibility for reviewing and approving all transactions that are "related party" transactions under SEC rules.

The Nominating Committee does not set specific, minimum qualifications that nominees for director must meet in order for the Nominating Committee to recommend them to the Board, but rather believes that each nominee should be evaluated based on his or her individual merits, taking into account our needs and the composition of the Board. Members of the Nominating Committee discuss and evaluate possible candidates in detail, and suggest individuals to explore in more depth. Once a candidate is identified whom the Nominating Committee wants to seriously consider and move toward nomination, the chairperson of the Nominating Committee enters into a discussion with that nominee candidate. Subsequently, the chairperson will discuss the qualifications of the candidate with the other members of the Nominating Committee, and the Nominating Committee will then make a final recommendation with respect to that candidate to the Board.

ITEM 11. EXECUTIVE COMPENSATION

INFORMATION ABOUT OUR EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth certain information concerning compensation for 2017 and 2018 paid to our Chief Executive Officer and our other two most highly compensated executive officers who served in this capacity as of December 31, 2018.

SUMMARY COMPENSATION TABLE FOR 2018 and 2017

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Awards ($)[2]	Option Awards ($)	Non-Equity Incentive Compensation[4]	All Other Compen-sation[5]	Total
Jack E. Stover								
CEO	2018	$ 337,634	$ 270,000	$ 150,520	$ 535,680	$ -	$ 14,046	$ 1,307,880
	2017	$ 318,500	$ 92,000	$ -	$ 695,993	$ 937,058	12,910	2,056,461
James Early [3]								
CFO	2018	333,842	75,000	17,380	61,920	-	1,128	489,270
	2017	535,300	45,000[3]	-	69,902	-	-	650,202
Gregory Richard								
Chief Commercial	2018	280,000	126,000	42,752	152,256	-	18,235	619,243
Officer	2017	266,250	100,000	-	399,085	-	18,418	783,753

(1) The amounts set forth in this column represents annual cash incentive bonus earned for 2017 and 2018.

(2) The dollar amounts set forth under the heading "Stock Awards" represent aggregate grant date fair value computed in accordance with FASB ASC Topic 718. For purposes of computing such amounts, we disregarded estimates of forfeitures related to service-based vesting conditions. For additional information regarding our valuation assumptions, please refer to Note 13 – Stock-Based Compensation.

(3) Mr. Early's salary for 2018 includes $135,925 in fees paid to his consulting firm, Early Financial Consulting, LLC, for financial services as Chief Financial Officer. In March 2018, Mr. Early was hired by the Company to be its Chief Financial Officer, Secretary and Treasurer for an annual salary of $250,000. His prior compensation had been based on an hourly rate. Mr. Early received in April 2018 a discretionary bonus of $45,000.

(4) For the named executive officers, this column includes the following amounts in 2018:

	401(k) Company Match ($)	Term Life/Disability Insurance Payment ($)	Other ($) (1)	Totals ($)
Jack E. Stover	$ 11,000	$ 3,046	$ -	$ 14,046
James Early	-	1,128	-	1,128
Gregory Richard	5,600	635	12,000	18,235

(1) The amounts set forth in this column for Mr. Richard represent an auto allowance generally available to members of the sales team.

NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE

Base Salary

Initially, base salaries are generally set according to the executive officer's agreement with the Company and adjusted based on the individual's current and historical performance. The base salary levels and any changes to those levels for each executive are reviewed each year by the Compensation Committee and adjustments may be based on factors such as new roles and/or responsibilities assumed by the executive and the executive's impact on our strategic goals and financial performance. While our executives' base salaries are generally targeted to be consistent with median base salaries for similar positions based on competitive market data, there is no specific weighting applied to any one factor in setting the level of salary, and the process ultimately relies on the evaluation of various factors considered by the Compensation Committee with respect to each named executive officer. The Compensation Committee also takes into account additional factors such as historical compensation, the financial condition of the Company in general and the individual's potential to be a key contributor as well as special recruiting and retention situations.

Upon his appointment as our Interim Chief Executive Officer, Mr. Stover's annual base salary was set at $300,000, which was not subject to an employment agreement. Mr. Stover entered into an employment agreement with the Company as President and Chief Executive Officer on October 28, 2016 and an amended and restated employment agreement on December 5, 2018 which set his annual base salary at $450,000. Mr. Early's fees for services as a consultant were $135,925 during 2018. On March 7, 2018 the Board approved the employment agreement (the "Early Employment Agreement") of Mr. Early, the Company's Chief Financial Officer, Secretary and Treasurer. Mr. Early is currently entitled to receive an annual base salary of $250,000 paid in accordance with the Company's payroll practices. Such base salary is subject to adjustment on an annual basis by the Company's Chief Executive Officer, in consultation with the Board's Compensation Committee. Mr. Richard's base salary is not determined by an employment contract. Mr. Stover and Mr. Richard received raises of 7% and 8%, respectively, in 2018 based upon the Compensation Committee's appraisal of their performance.

Annual Cash Incentives

The annual cash incentive program provides our executive officers with an opportunity to receive a cash award at the discretion of the Compensation Committee. Annual cash incentive targets and performance metrics are usually determined by the Compensation Committee typically during the first quarter of each fiscal year, based on competitive market data generally available to the Compensation Committee as well as consideration based upon the financial condition of the Company.

Pursuant to Mr. Stover's employment agreement, the Board approved a target annual cash bonus of 60% of his annual base salary based principally upon meeting specific financial goals and objectives as recommended by the Compensation Committee and approved by the Board in its sole discretion. Based on our achievement of our commercial, business development, finance, operations, clinical and science goals, the Compensation Committee recommended and the Board approved a discretionary bonus for Mr. Stover of $270,000 based on 2018 performance. This bonus is to be paid in April 2019.

Mr. Richard will receive a discretionary bonus paid in April 2019 in the amount of $126,000. Mr. Early will receive a discretionary bonus paid in April 2019 in the amount of $75,000. Such bonus amounts were determined by the Compensation Committee based on its discretion.

Sign-on bonuses may be granted from time to time at the discretion of our Compensation Committee in connection with new hires at the executive officer level. There were no cash sign-on bonuses for any named executive officer in 2018.

Long-Term Equity Incentives

Our executives are also eligible to participate in a long-term equity incentive program each year, which is administered under the Interpace Diagnostics Group, Inc. Amended and Restated 2004 Stock Award and Incentive Plan, (the "Amended 2004 Plan"). The long-term equity incentive component of our compensation program is used to promote alignment with stockholders and to balance the short-term focus of the annual cash incentive component by linking a substantial part of compensation to our long-term stockholder returns. The Compensation Committee believes that long-term stock-based compensation enhances our ability to attract and retain high quality talent and provides the motivation to improve our long-term financial performance and increase stockholder value. In 2018, Mr. Stover was granted 224,000 stock options with an exercise price of $1.01 and 348,000 stock options with an exercise price of $1.08, and 143,000 restricted stock units. In 2018, Mr. Early was granted 56,000 stock options with an exercise price of $1.01 and 12,000 stock options with an exercise price of $1.08, and 17,000 restricted stock units. In 2018, Mr. Richard was granted 112,000 stock options with an exercise price of $1.01 and 53,600 stock options with an exercise price of $1.08, and 41,400 restricted stock units. The option and restricted stock unit grants listed above vest one-third each year over a three-year period.

Perquisites

As a matter of practice, we provide only limited perquisites to our executive officers that are not generally provided to all employees. Executives are eligible for the standard benefits and programs generally available to all of our employees. The value of special perquisites, as well as additional benefits that are available generally to all of our employees, that were provided to each named executive officer in 2018 are set forth in footnote 5 to the Summary Compensation Table.

Compensation Features Intended to Prevent Excessive Risk Taking

The Compensation Committee reviewed our compensation policies and practices for all employees, including executive officers, and believes that such policies and practices do not create risks that are reasonably likely to have a material adverse effect on us. In particular, the Compensation Committee believes that the following factors help mitigate against any such risks: (a) annual cash incentive compensation and long-term equity incentive compensation are based on a mix of our overall performance, business unit performance and individual performance; (b) the annual cash incentive compensation plan has no minimum funding levels, such that employees will not receive any rewards if satisfactory financial performance is not achieved by us; and (c) base salaries are consistent with employees' responsibilities and general market practices so that they are not motivated to take excessive risks to achieve a reasonable level of financial security.

Outstanding Equity Awards

The following table provides information concerning the number and value of unexercised options, SARs, restricted stock awards and RSUs for the named executive officers outstanding as of the year ended December 31, 2018:

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 2018

	Options/SARs Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options/SARs (#) Exercisable	Number of Securities Underlying Unexercised Options/SARs (#) Unexercisable	Option/ SAR Exercise Price ($)	Option/ SAR Expiration Date	Number of Shares/RSUs that have not Vested (#)	Market Value of Shares/RSUs that have not Vested ($)
Jack E. Stover	32,636	-	1.60	10/14/2026	3,333(2)	2,666
	134,602	-	2.12	3/16/2027	-	-
	345,000	-	1.45	9/26/2027	-	-
	-	224,000(3)	1.01	3/7/2028	56,000(5)	44,800
	-	348,000(4)	1.08	12/5/2028	87,000(6)	69,600
James Early	8,000	-	1.60	10/14/2026	-	-
	14,475	-	2.12	3/16/2027	-	-
	40,000	-	1.45	9/26/2027	-	-
	-	56,000(3)	1.01	3/7/2028	14,000(5)	11,200
	-	12,000(4)	1.08	12/5/2028	3,000(6)	2,400
Gregory Richard	3,742	-	45.70	4/2/2019	2,000(7)	1,600
	12,257	-	1.60	10/14/2026	-	-
	17,134	-	2.12	3/16/2027	-	-
	50,269	-	2.46	5/10/2027	-	-
	200,000	-	1.45	9/26/2027	-	-
	-	112,000(3)	1.01	3/7/2028	28,000(5)	22,400
	-	53,600(4)	1.08	12/5/2028	13,400(6)	10,720

(1) The market value is based on the closing price of $0.80 on December 31, 2018, the last day of trading in 2018.

(2) Restricted stock units that vest February 3, 2019.

(3) Stock options that vest one-third on each of March 7, 2019, March 7, 2020, and March 7, 2021.

(4) Stock options that vest one-third on each of December 5, 2019, December 5, 2020, and December 5, 2021.

(5) Restricted stock units that vest one-third on each of March 7, 2019, March 7, 2020, and March 7, 2021.

(6) Restricted stock units that vest one-third on each of December 5, 2019, December 5, 2020, and December 5, 2021.

(7) Restricted stock units that vest on February 26, 2019.

Equity Compensation Grants Subsequent to December 31, 2018

On March 13, 2019, Mr. Stover was granted 86,922 restricted stock units and 347,688 stock options; Mr. Early was granted 26,340 restricted stock units and 105,360 stock options; and Mr. Richard was granted 39,528 restricted stock units and 158,112 stock options. Both the restricted stock units and the stock options vest annually, in equal installments, over a three-year period. The stock options have an exercise price of $0.98.

Potential Payments upon Termination or Change in Control

The following table reflects the estimated amount of compensation that would be payable to each of our 2018 named executive officers upon termination of such executive's employment in accordance with their respective employment separation agreements and stock agreements. In general RSUs and stock options vest upon a change of control. The amounts shown below assume that such termination was effective as of December 31, 2018, and are estimates of the amounts which would be paid out upon termination. The actual amounts to be paid out can only be determined at the time of separation from the Company.

POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL

Name	Cash Payment ($)	Continuation of Medical/ Welfare Benefits (Present Value) ($)	Acceleration of Equity Awards ($) (1)	Total Termination Benefits ($)
Termination Without Cause or Resignation for Good Reason:				
Jack E. Stover (2)	$ 891,630	$ 28,404	$ 117,066	$ 1,037,100
James Early (3)	125,000	14,202	13,600	152,802
Gregory Richard (4)	336,667	28,404	34,720	399,791
Upon a Change in Control (Not in connection with a termination)				
Jack E. Stover	$ -	$ -	$ 117,066	$ 117,066
James Early	-	-	13,600	13,600
Gregory Richard	-	-	34,720	34,720
Termination Without Cause or Resignation for Good Reason Upon a Change in Control				
Jack E. Stover	$ 1,251,630	$ 42,605	$ 117,066	$ 1,411,302

(1) These amounts are based on the value of RSUs held at December 31, 2018 that would become immediately vested upon retirement or a change of control pursuant to the applicable restricted stock grant agreement. Stock options that would become immediately vested upon a change in control pursuant to the Incentive Plan were not included as they were out of the money (option exercise price is greater than the stock price). The market value of all equity reflected in the above table is based on the closing stock price of $0.80 on December 31, 2018, the last day of trading in 2018.
(2) Mr. Stover's cash payment would be paid in nine monthly installments.
(3) Mr. Early's cash payment would be in six monthly installments.
(4) Mr. Richard's cash payment would be paid in a lump sum within 60 days of termination.

Employment Arrangements

Jack E. Stover –Chief Executive Officer

On October 30, 2016, we entered into an employment agreement with Mr. Stover (the "2016 Employment Agreement") pursuant to which he receives an annual base salary of $300,000, subject to annual cost of living adjustments, and is eligible to receive an annual performance bonus with a target of 50% of his base salary, based on the attainment of certain quarterly performance targets.

In addition, upon the occurrence of a capital raising "Transaction" (as such term is defined in the 2016 Employment Agreement), provided he remains employed through the closing of such Transaction, Mr. Stover would receive non-equity incentive compensation calculated based on 3% of the net transaction proceeds received in connection with such Transaction.

In the event of a termination of Mr. Stover's employment by the Company without "Cause" or a resignation by Mr. Stover for "Good Reason" (as such terms are defined in the 2016 Employment Agreement), Mr. Stover would be entitled to receive monthly payments of $25,000 for nine months following such termination and, provided that Mr. Stover timely elected COBRA continuation coverage, the Company would pay his applicable COBRA premium for 12 months following such termination. Such payments and benefits would be subject to an effective release of claims and would cease upon breach by Mr. Stover of any applicable restrictive covenants.

On December 5, 2018, the Board approved the amended and restated employment agreement (the "Stover Employment Agreement") of Jack E. Stover, President, Chief Executive Officer and Director of the Company. Under the Stover Employment Agreement, Mr. Stover is to receive an annual base salary of $450,000, which is subject to annual upward adjustment by the Board, and is eligible to receive an annual performance bonus with a target of 60% of his base salary, based on the attainment of certain annual corporate and/or individual performance goals as determined by the Board of

Directors of the Company. Under the Stover Employment Agreement, Mr. Stover is not eligible to receive any transaction incentive compensation. On December 5, 2018, Mr. Stover received an option to purchase 348,000 shares of the Company's common stock and 143,000 restricted stock units of the Company, each with a three-year vesting period. Mr. Stover shall be eligible to receive a grant of options to purchase common stock and restricted stock units each year on the anniversary of the date of the Stover Employment Agreement. The number of shares underlying this annual grant will be determined by the Compensation Committee of the Board of Directors. Mr. Stover is also eligible to participate in all employee benefit plans and programs maintained by the Company on the same basis as other senior management. These include vacation, retirement, health insurance and life insurance.

Under the Stover Employment Agreement, in the event of a termination by the Company without "Cause" or a resignation by Mr. Stover for "Good Reason" (as such terms are defined in the Stover Employment Agreement), not within 24 months following a Transaction (as such term is defined in the Stover Employment Agreement, which includes, among other things, any merger of the Company into another corporation, any acquisition of the Company and the acquisition of beneficial ownership of the Company's voting securities having voting power equal to 51% or more of the combined voting power of the Company's outstanding voting securities), Mr. Stover would be entitled to receive: any earned but unpaid bonus for any fiscal year ending prior to Mr. Stover's termination date, one times Mr. Stover's then current base salary, to be paid in nine equal installments, provided that Mr. Stover timely elected COBRA continuation coverage, payment by the Company of his applicable COBRA premium for 12 months following such termination and all outstanding non-qualified stock option and restricted stock unit awards that were scheduled to vest during the 24 months following the termination date shall become fully vested and exercisable and Mr. Stover shall also receive a lump sum payment equal to the greater of 60% of his base salary or the largest discretionary bonus paid to Mr. Stover in the three years preceding the termination date. Such payments and benefits would be subject to an effective release of claims and would cease upon breach by Mr. Stover of any applicable restrictive covenants.

Under the Stover Employment Agreement, if, within 24 months following a Transaction, Mr. Stover's employment is terminated by Mr. Stover for Good Reason or by the Company without Cause, Mr. Stover would be entitled to receive: any earned but unpaid bonus for any fiscal year ending prior to Mr. Stover's termination date, one and one half times Mr. Stover's then current base salary, to be paid in nine equal installments, one and one-half times Mr. Stover's annual target bonus, to be paid in nine equal installments, provided that Mr. Stover timely elected COBRA continuation coverage, payment by the Company of his applicable COBRA premium for 18 months following such termination, and all outstanding non-qualified stock option and restricted stock unit awards that were scheduled to vest during the 36 months following the termination date shall become fully vested and exercisable.

Under the Stover Employment Agreement, if Mr. Stover is terminated for Cause (as such term is defined in the Stover Employment Agreement), he will be entitled to receive any earned but unpaid base salary and bonus for any fiscal year ending prior to the termination date.

James Early – Chief Financial Officer

On October 11, 2016, Mr. Early was appointed as Chief Financial Officer for the Company by means of an Engagement Letter Agreement executed between the Company and Early Financial Consulting, LLC. Professional fees under this agreement were charged at the hourly rate of $250 per hour for the first 30 hours per week and $200 per hour for time in excess of 30 hours per week. Fees and travel expenses were required to be invoiced weekly under fifteen day payment terms. Services could have been suspended if payments were deemed delinquent, and either party may have terminated the agreement upon thirty days written notice with no severance or other termination payments due.

On March 7, 2018 the Board approved the employment agreement of James Early, the Company's Chief Financial Officer, Corporate Secretary and Treasurer. Mr. Early is entitled to receive an annual base salary of $250,000 effective March 16, 2018 paid in accordance with the Company's payroll practices. Such base salary is subject to adjustment on an annual basis by the Company's Chief Executive Officer, in consultation with the Board's compensation committee. Mr. Early is also eligible to receive an annual performance bonus, subject to the attainment of annual performance goals as set and determined by the Company's Chief Executive Officer, in consultation with the Board's compensation committee. Mr. Early's target bonus is up to 30% of his annual base salary. Mr. Early is also eligible to participate in an annual stock based incentive plan under which he may be awarded restricted stock options and restricted stock grants at the end of each year, subject to certain performance goals. Mr. Early is also eligible to participate in any benefit plans that may be offered from time to time by the Company to its senior management. Mr. Early is an at-will employee of the Company. However, in the event that Mr. Early is terminated by the Company for any reason other than death, total disability or "Cause" (as defined in the Early Employment Agreement), or if Mr. Early resigns for "Good Reason" (as defined in the Early Employment Agreement), Mr. Early is entitled to (i) payment of six months of his then current base salary and (ii) six months continuation of his health benefits. Such payment and benefits would be subject to an effective release of claims.

Gregory Richard – Senior Vice President, Chief Commercial Officer

Mr. Richard is an at-will employee of the Company and his base salary is not determined by an employment contract. Mr. Richard's employment is subject to the terms of an Employment Separation Agreement entered into by the Company and Mr. Richard on March 25, 2015 (the "Richard Agreement").

In the event of a termination of Mr. Richard's employment by the Company without "Cause" or a resignation by Mr. Richard for "Good Reason" (as such terms are defined in the Richard Agreement), Mr. Richard would be entitled to receive a lump sum equal to (i) 12 times his then current base monthly salary plus (ii) the average of the annual amounts paid to Mr. Richard during the prior three full fiscal years pursuant to any cash-based incentive or bonus plan in which he participates. The Company would also pay his applicable COBRA premium for up to 12 months following such termination. Such payments and benefits would be subject to an effective release of claims.

INFORMATION ABOUT THE COMPENSATION OF OUR DIRECTORS

Each of our non-employee directors receives an annual director's fee of $30,000, payable quarterly in arrears. The Chairman of the Board receives an additional fee of $20,000 and the Chairperson of each of the Audit Committee, Compensation Committee and Nominating Committee receive an additional annual fee of $15,000, $10,000 and $5,000, respectively. In addition, those non-employee directors sitting on more than one committee receive additional compensation of $5,000 annually. From time to time, the Board may form special committees to address discrete issues and the non-employee directors sitting on such special committees may receive additional compensation. In addition, our non-employee directors are entitled to reimbursement for travel and related expenses incurred in connection with attendance at Board and committee meetings.

Commencing in 2017, upon initial appointment to the Board, each non-employee director receives 20,000 stock options which vest in equal annual installments over a three-year period. In addition, each non-employee director thereafter receives an annual grant of 10,000 stock options (with the exception of the Chairman of the Board who receives 13,000 options).

The following table presents information relating to total compensation for our non-employee directors for the year ended December 31, 2018. Information regarding the compensation of Mr. Stover can be found above, under the heading "Information About Our Executive Compensation."

DIRECTOR COMPENSATION IN 2018

Name	Fees earned ($)	Stock awards ($) [1]	Option awards ($)	Total ($)
Stephen J. Sullivan [2]	65,000	4,848	17,280	87,128
Joseph Keegan [3]	55,000	4,848	17,280	77,128
Felice Schnoll-Sussman [4]	35,000	4,848	17,280	57,128

[1] The dollar amounts set forth under the heading "Stock Awards" represent aggregate grant date fair value computed in accordance with FASB ASC Topic 718. For purposes of computing such amounts, we disregarded estimates of forfeitures related to service-based vesting conditions. For additional information regarding our valuation assumptions, please refer to Note 13 - "Stock-Based Compensation". Outstanding stock awards held by the non-employee Directors as of December 31, 2018 consisted of 8,133 RSUs for Mr. Sullivan, 9,056 RSUs for Dr. Keegan and 4,800 RSUs for Dr. Schnoll-Sussman as well as 45,200 options for Mr. Sullivan, 39,200 options for Dr. Keegan, and 39,200 options for Dr. Schnoll-Sussman.

[2] Mr. Sullivan's fees represent the annual director's fee of $30,000, plus the $20,000 Chairman of the Board fee, plus the $10,000 Chair of the Compensation Committee fee, and a fee of $5,000 for serving on multiple committees.

[3] Dr. Keegan's fees represent the annual director's fee of $30,000, plus the $15,000 Chair of the Audit Committee fee, plus the $5,000 Chair of the Nominating Committee fee, and a fee of $5,000 for serving on multiple committees.

[4] Dr. Schnoll-Sussman's fees represent the annual director's fee of $30,000 plus a fee of $5,000 for serving on multiple committees.

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

The following table provides information as of December 31, 2018 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
Equity compensation plans approved by security holders			
Incentive Plan	2,877,595	$ 2.07	1,945,113
Equity compensation plans not approved by security holders	11,718	17.90	-
Total	2,889,313	$ 2.14	1,945,113

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows, as of March 1, 2019 (unless otherwise indicated), the number of shares of our common stock beneficially owned by: (i) each stockholder who is known by us to own beneficially in excess of 5% of our outstanding common stock; (ii) each of our current directors; (iii) each of our named executive officers included in the section of this Form 10-K entitled "Summary Compensation Table"; and (iv) all directors and executive officers as a group.

Except as otherwise indicated, the persons listed below have sole voting and investment power with respect to all shares of common stock owned by them and all information with respect to beneficial ownership has been furnished to us by the respective stockholder. The address of the persons listed below is c/o Interpace Diagnostics Group, Inc., Morris Corporate Center 1, Building C, 300 Interpace Parkway, Parsippany, New Jersey 07054. The percentage of beneficial ownership is based on 38,051,785 shares of common stock outstanding on March 1, 2019.

Name of Beneficial Owner	Number of Shares Beneficially Owned [1]	Percent of Shares Outstanding
Executive officers and directors:		
Jack E. Stover [2]	746,266[7]	1.9%
James Early [3]	85,807[8]	*
Gregory Richard [4]	332,881[9]	*
Stephen J. Sullivan [5]	56,983[10]	*
Joseph Keegan [6]	40,769[11]	*
Felice Schnoll-Sussman [6]	14,666[12]	*
as a group (6 persons)	1,277,372[7] [8] [9] [10] [11] [12]	3.3%

(1) Beneficial ownership and percentage ownership are determined in accordance with the rules and regulations of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we include shares underlying common stock derivatives, such as options and RSUs that a person has the right to acquire within 60 days of March 1, 2019. Such shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

(2) Currently serves as our President and Chief Executive Officer and as a member of the Board.

(3) Currently serves as our Chief Financial Officer, Secretary and Treasurer.

(4) Currently serves as our Senior Vice President, Chief Commercial Officer.

(5) Currently serves as Chairman of the Board.

(6) Member of the Board.

(7) Includes 143,000 RSUs that would vest immediately upon retirement and 586,904 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

(8) Includes 4,666 RSUs that vest within 60 days of March 1, 2019 and 81,141 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

(9) Includes 9,333 RSUs that vest within 60 days of March 1, 2019 and 316,993 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

(10) Includes 4,800 RSUs that would vest immediately upon retirement and 32,400 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

(11) Includes 1,600 RSUs that vest within 60 days of March 1, 2019 and 26,400 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

(12) Includes 1,600 RSUs that vest within 60 days of March 1, 2019 and 13,066 shares issuable pursuant to options exercisable within 60 days of March 1, 2019.

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

Certain Relationships and Related Transactions

We are required to disclose transactions since January 1, 2018, to which we have been a party, in which the amount involved in the transaction exceeds $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or an affiliate or immediate family member thereof had or will have a direct or indirect material interest, other than employment, compensation, termination and change in control arrangements with our named executive officers, which are described in Item 11 - "Executive Compensation." We are not a party to a current transaction with a related person, have not been a party to such a transaction since January 1, 2018, and no transaction is currently proposed, in which the amount of the transaction exceeds $120,000 and in which a related person had or will have a direct or indirect material interest.

Corporate Governance and Code of Business Conduct

Our Board has adopted a written Code of Business Conduct that applies to our directors, officers, and employees, as well as Corporate Governance Guidelines applicable specifically to our Board. You can find links to these documents in the "Investor Relations" section of our website page at www.interpacediagnostics.com. The content contained in, or that can be accessed through, our website is not incorporated into this Form 10-K. Disclosure regarding any amendments to, or any waivers from, a provision of our Code of Business Conduct that applies to one or more of our directors, our principal executive officer, our principal financial or our principal accounting officer will be included in a current report on Form 8-K within four business days following the date of the amendment or waiver, or posted on our website (www.interpacediagnostics.com).

Board Leadership and Structure

The Chairman of the Board, who is currently an independent director, presides at all meetings of the Board. Mr. Sullivan serves as the Chairman of the Board, and Mr. Stover, our Chief Executive Officer, serves as a director.

The Board believes that having an independent director serve as Chairman of the Board is in the best interests of our stockholders. This structure provides more direct independent oversight and active participation of our independent directors in setting agendas and establishing policies and procedures of our Board. Further, this structure permits our Chief Executive Officer to focus on the management of our day-to-day operations.

The Board does not have a policy on whether or not the roles of Chief Executive Officer and Chairman of the Board should be separate. The Board believes that it should be free to make a choice from time to time in any manner that is in the best interests of the Company and our stockholders.

Risk Oversight by the Board

The Board and, in particular, the Audit Committee view enterprise risk management as an integral part of the Company's planning process. The subject of risk management is a recurring agenda item. The Audit Committee evaluates enterprise risk with management and the Company's independent registered public accountants on a regular basis and also receives updates from the Company's internal audit consultants, and the Audit Committee in turn calls the Board's attention to items in such reports as it deems appropriate for review by the full board of directors.

Additionally, the charters of certain of the Board's committees assign oversight responsibility for particular areas of risk. For example, our Audit Committee oversees management of enterprise-wide risks, including those related to accounting, auditing and financial reporting and maintaining effective internal control over financial reporting, and for compliance with the Code of Business Conduct. Our Nominating Committee oversees compliance with listing standards for independent directors, committee assignments and related party transactions and other conflicts of interest. Our Compensation Committee oversees the risk related to our compensation plans, policies and practices. All of these risks are discussed with the entire Board in the ordinary course of the chairperson's report of committee activities at regular Board meetings.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

BDO, an independent registered public accounting firm, has served as our independent accountants beginning in 2012. Fees for services provided by BDO for the past two completed years ended December 31 were as follows:

PRINCIPAL ACCOUNTANT FEES AND SERVICES

	2018	2017
Audit Fees	$ 266,295	$ 562,101
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 266,295	$ 562,101

Audit fees include the audit of our consolidated financial statements.

Included within audit fees for the year ended December 31, 2018 are those fees totaling $78,000 associated with our public offerings in 2018.

Included within audit fees for the year ended December 31, 2017 are those fees totaling $252,106 associated with our public offerings and debt exchange in 2017.

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 on March 6, 2014

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	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
3.7	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 Current Report on Form 8-K filed with the SEC on January 3, 2017
4.4	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 Statement on Form S-1 filed with the SEC on June 13, 2017
4.9	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

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
4.13	Form of Restricted Stock Unit Agreement for Employees, incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018
4.14	Form of Restricted Stock Unit Agreement for Directors, incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018
4.15	Form of Non-Qualified Stock Option Agreement, incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018
4.16	Form of Incentive Stock Option Agreement, incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018
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 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 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 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 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 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 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-Q for the quarter ended September 30, 2009, filed with the SEC on November 5, 2009

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, 2014, filed with the SEC on November 5, 2014
10.11	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 September 30, 2014, filed with the SEC on November 5, 2014
10.12	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, 2014, filed with the SEC on November 5, 2014
10.13	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 November 5, 2014
10.14	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 SEC on March 5, 2015
10.15	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 December 31, 2014, filed with the SEC on March 5, 2015
10.16	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 December 31, 2014, filed with the SEC on March 5, 2015
10.17	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 December 31, 2014, filed with the SEC on March 5, 2015
10.18	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*	Form of Indemnification Agreement by and between Interpace Diagnostics Group, Inc. and its directors and executive 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
10.23	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
10.24*	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
10.25*	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
10.26*	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
10.27*	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
10.28	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
10.29	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
10.30	Form of Securities Purchase Agreement, dated January 3, 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 3, 2017
10.31	Amended and Restated Placement Agency Agreement, effective as of 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 5, 2017
10.32	Form of Amendment to Securities Purchase Agreement, effective as of January 3, 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 5, 2017
10.33	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
10.34	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
10.35	Form of Warrant Exercise Agreement dated October 12, 2017, incorporated by reference to the designated exhibit of the Company's Quarterly Report on Form 10-Q filed with the SEC on October 12, 2017
10.36	Amendment No. 2 to Lease, dated March 15, 2018, between Saddle Lane Realty, LLC and Interpace Diagnostics Corporation, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 23, 2018
10.37	Employment Agreement between Interpace Diagnostics Group, Inc. and James Early, effective as of March 16, 2018, incorporated by reference to the designated exhibit of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 23, 2018
10.38	Amended and Restated Employment Agreement dated December 5, 2018, between the Company 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 December 11, 2018
10.39	Employment Separation Agreement between Interpace Diagnostics, LLC and Gregory Richard, effective as of March 25, 2015, 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 Sarbanes-Oxley Act of 2002, filed herewith
*	Denotes compensatory plan, compensation arrangement or management contract.

ITEM 16. Form 10-K Summary

The Company has opted to not provide a summary.

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 21, 2019

/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 21, 2019
/s/ James Early James Early	Chief Financial Officer (Principal Financial Officer)	March 21, 2019
/s/ Thomas Freeburg Thomas Freeburg	Chief Accounting Officer (Principal Accounting Officer)	March 21, 2019
/s/ Stephen J. Sullivan Stephen J. Sullivan	Chairman of the Board of Directors	March 21, 2019
/s/ Joseph Keegan Joseph Keegan	Director	March 21, 2019
/s/ Felice Schnoll-Sussman Felice Schnoll-Sussman	Director	March 21, 2019

Interpace Diagnostics Group, Inc.
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and Financial Statement Schedules

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, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

On January 1, 2018, the Company adopted Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606). The effects of the adoption are described in Note 2 to the consolidated financial statements.

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 21, 2019

INTERPACE DIAGNOSTICS GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,068	$ 15,199
Accounts receivable, net	9,483	3,437
Other current assets	2,170	1,172
Total current assets	17,721	19,808
Property and equipment, net	837	654
Other intangible assets, net	29,853	33,105
Other long-term assets	31	31
Total assets	$ 48,442	$ 53,598
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,059	$ 391
Accrued salary and bonus	1,424	1,394
Other accrued expenses	5,091	5,004
Current liabilities from discontinued operations	918	1,302
Total current liabilities	8,492	8,091
Contingent consideration	2,693	1,349
Other long-term liabilities	4,319	4,289
Total liabilities	15,504	13,729
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; 28,767,344 and 27,900,806 shares issued, respectively; 28,694,275 and 27,836,456 shares outstanding, respectively	287	278
Additional paid-in capital	175,820	173,062
Accumulated deficit	(141,489)	(131,800)
Treasury stock, at cost (73,069 and 64,350 shares, respectively)	(1,680)	(1,671)
Total stockholders' equity	32,938	39,869
Total liabilities and stockholders' equity	$ 48,442	$ 53,598

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,	
	2018	**2017**
Revenue, net	$ 21,896	$ 15,897
Cost of revenue (excluding amortization of $3,252 and $3,253, respectively)	10,197	7,358
Gross profit	11,699	8,539
Operating expenses:		
Sales and marketing	8,421	6,567
Research and development	2,124	1,461
General and administrative	8,499	9,153
Acquisition related amortization expense	3,252	3,253
Change in fair value of contingent consideration	1,522	(5,602)
Total operating expenses	23,818	14,832
Operating loss	(12,119)	(6,293)
Interest expense	(331)	(433)
Loss on extinguishment of debt	-	(4,278)
Other income (expense), net	263	(2,128)
Loss from continuing operations before tax	(12,187)	(13,132)
Provision (benefit) for income taxes	18	(395)
Loss from continuing operations	(12,205)	(12,737)
Discontinued Operations		
Income from discontinued operations	7	1,124
(Benefit) provision for income tax on discontinued operations	(9)	603
Income from discontinued operations, net of tax	$ 16	$ 521
Net loss	$ (12,189)	$ (12,216)
Basic and diluted (loss) income per share of common stock:		
From continuing operations	$ (0.43)	$ (0.81)
From discontinued operations	0.00	0.03
Net loss per basic and diluted share of common stock	$ (0.43)	$ (0.77)
Weighted average number of common shares and common share equivalents outstanding:		
Basic	28,155	15,766
Diluted	28,155	15,766

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,			
	2018		2017	
	Shares	Amount	Shares	Amount
Common stock:				
Balance at January 1	27,900	$ 278	2,230	$ 22
Common stock issued	867	9	34	-
Common stock issued through offering	-	-	13,568	135
Shares issued in debt exchange	-	-	3,795	38
Exercise of warrants for cash	-	-	8,273	83
Balance at December 31	28,767	287	27,900	278
Treasury stock:				
Balance at January 1	64	(1,671)	54	(1,643)
Treasury stock purchased	9	(9)	10	(28)
Balance at December 31	73	(1,680)	64	(1,671)
Additional paid-in capital:				
Balance at January 1		173,062		127,736
Common stock issued through offering, net of expenses		-		15,734
Common stock issued		1,024		-
Issuance of warrants, net of expenses		-		7,212
Shares issued in debt exchange		-		11,605
Exercise of warrants for cash, net of expenses		-		6,778
Reclass of warrant liability upon exercise of pre-funded warrants		-		2,337
Issuance of debt exchange warrants, vendor warrants, and other		-		600
Stock-based compensation expense		1,734		1,060
Balance at December 31		175,820		173,062
Accumulated deficit:				
Balance at January 1		(131,800)		(119,584)
Net loss		(12,189)		(12,216)
Adoption of ASC 606, see Note 3		2,500		-
Balance at December 31		(141,489)		(131,800)
Total stockholders' equity		$ 32,938		$ 39,869

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

INTERPACE DIAGNOSTICS GROUP, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For The Years Ended December 31,	
	2018	**2017**
Cash Flows From Operating Activities		
Net loss	$ (12,189)	$ (12,216)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,464	3,690
Interest accretion	331	312
Provision for bad debt	-	35
Reversal of DOJ accrual	(350)	-
Amortization of debt issuance costs	-	117
Mark to market on warrants	112	141
Mark to market on derivatives	-	61
Stock-based compensation	2,270	1,060
Reversal of severance accrual	-	(2,034)
Non-employee share based payment	-	216
Warrants issued in RedPath settlement	-	193
Warrant issuance	-	2,016
Loss on extinguishment of debt	-	4,278
Change in fair value of contingent consideration	1,522	(5,795)
Other gains and expenses, net	-	5
Other changes in operating assets and liabilities:		
Increase in accounts receivable	(3,546)	(1,228)
(Increase) decrease in other current assets	(501)	222
Decrease in other long-term assets	-	220
Increase (decrease) in accounts payable	668	(2,633)
Increase (decrease) in accrued salaries and bonus	30	(1,395)
Decrease in accrued liabilities	(402)	(2,751)
(Decrease) increase in long-term liabilities	(82)	223
Net cash used in operating activities	(8,673)	(15,263)
Cash Flows From Investing Activity		
Purchase of property and equipment	(449)	(29)
Net cash used in investing activity	(449)	(29)
Cash Flows From Financing Activities		
Payments of contingent consideration	-	(25)
Issuance of common stock, net of expenses	-	23,081
Exercise of warrants, net of expenses	-	6,861
Treasury stock purchased	(9)	(28)
Net cash (used in) provided by financing activities	(9)	29,889
Net (decrease) increase in cash and cash equivalents	(9,131)	14,597
Cash and cash equivalents – beginning	15,199	602
Cash and cash equivalents – ending	$ 6,068	$ 15,199
Cash paid for taxes	$ 324	$ 417
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 develops and provides clinically useful molecular diagnostic tests and pathology services. The Company develops and commercializes genomic tests and related first line assays principally focused on early detection of patients at high risk of cancer using the latest technology to help provide personalized medicine and improve patient diagnosis and management. The Company's tests and services provide mutational analysis of genomic material contained in suspicious cysts, nodules and lesions with the goal of better informing treatment decisions in patients at risk of thyroid, pancreatic, and other cancers. The molecular diagnostic tests the Company offers enable healthcare providers to better assess cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk. The Company currently has four commercialized molecular diagnostic tests in the marketplace for which it is receiving reimbursement: PancraGEN®, which is a pancreatic cyst and pancreaticobiliary solid lesion genomic test that helps physicians better assess risk of pancreaticobiliary cancers using its proprietary PathFinderTG® platform; ThyGeNEXT®, which is an expanded oncogenic mutation panel that helps identify malignant thyroid nodules and replaced ThyGenX®; ThyraMIR®, which assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDx®, which is a genomic test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer and which also utilizes the Company's PathFinderTG® platform to compare the genomic fingerprint of two or more sites of lung cancer. The Company is also in the process of "soft launching" while it gathers additional market data, BarreGen®, an esophageal cancer risk classifier for Barrett's Esophagus that also utilizes the Company's 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.

(tabular information in thousands, except share and per share data)

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 receivables represent unconditional rights to consideration and 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 direct-bill payer. Prior to the adoption of ASC 606 on January 1, 2018, the Company recognized accounts receivable related to billings for Medicare, Medicare Advantage, and direct-bill payers on an accrual basis, net of contractual adjustment, when collectability was reasonably assured. Under ASC 606 accounts receivable is now recognized for all payer groups, net of contractual adjustment and net of estimated uncollectable amounts. Contractual adjustments represent the difference between the list prices and the reimbursement rates set by third party payers, including Medicare, commercial payers, and amounts billed to direct-bill payers. Specific accounts may be written off after several appeals, which in some cases may take longer than twelve months.

Other current assets

Other current assets consisted of the following as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Indemnification assets	$ 875	$ 875
Prepaid expenses	1,230	266
Other	65	31
Total other current assets	$ 2,170	$ 1,172

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. 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; three 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 and amortization 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.

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 Recognition Prior to the Adoption of ASC 606

Historically, for the time periods through December 2017, the Company 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. The Company recognized revenue related to billings for Medicare, Medicare Advantage, and direct-bill payers on an accrual basis, net of contractual adjustment, when there was 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 direct-bill payers, which approximates the Medicare rate. For certain third-party payers that did not have established contractual reimbursement rates or a predictable pattern of collectability, including commercial insurance carriers and Medicaid, the Company believed that the fee was fixed or determinable and collectability was reasonably assured only upon request of third-party payer notification of payment or when cash is received, and recognized revenue at that time.

Until a contract had 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 was only recognized upon the earlier of payment notification or cash receipt. Accordingly, we recognized revenue from commercial insurance carriers, government programs, and certain direct-bill healthcare providers without contracts when payment was received.

Revenue Recognition after the Adoption of ASC 606

Beginning January 1, 2018 under ASC 606, the Company began to recognize revenue for billings less contractual allowances and estimated uncollectable amounts for all payer groups on the accrual basis based upon a thorough analysis of historical receipts (see Note 2, *Recent Accounting Standards*). The net amount derived and used for revenue recognition is referred to as the "net realizable value" or ("NRV") for the particular test and payer group from which reimbursement is received. This derived NRV will be evaluated quarterly or as needed and then applied to future periods until recalculated.

The Company completed its analysis of the ASC 606 impact and incorporated further analysis of first quarter 2018 collections from its commercial payer base in finalizing its ASC 606 adjustments. The impact of recording the cumulative catch-up adjustment under the modified retrospective method was $2.5 million, recorded as an increase to opening retained earnings on January 1, 2018. Prior periods have not been retrospectively adjusted. The Company also finalized its analysis of modified internal controls over financial reporting and the disclosures required starting with Form 10-Q for the first quarter of 2018.

Cost of services

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, royalty 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 2018 and 2017, 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.

(tabular information in thousands, except share and per share data)

2. Recent Accounting Standards

Recently adopted standards

Adoption of Accounting Standards Codification Topic 606 ("ASC 606"), "Revenue from Contracts with Customers"

Effective January 1, 2018, the Company adopted ASC 606 which amends the guidance for the recognition of revenue from contracts with customers for the transfer of goods and services, by using the modified-retrospective method applied to any contracts that were not completed as of January 1, 2018. The results for the reporting period beginning after January 1, 2018, are presented in accordance with the new standard, although comparative information has not been restated and continues to be reported under the accounting standards and policies in effect for those periods.

Upon adoption, the Company performed a comprehensive analysis of existing revenue arrangements as of January 1, 2018 following the five-step model outlined in ASC 606. Based on our analysis, we recorded a cumulative adjustment to opening accumulated deficit and an increase in accounts receivable of $2.5 million as of January 1, 2018. The cumulative impact was driven by a change in the timing of revenue recognition for certain payer categories and the related proprietary tests performed. The balance of accounts receivable related to the adjustment is approximately $0.6 million as of December 31, 2018.

The following tables present the effect of the adoption of ASC Topic 606 on our consolidated balance sheet and statement of operations as of and for the year ended December 31, 2018:

Balance Sheet:

	December 31, 2018		
	As reported	Balances without Adoption of ASC 606	Effect of Change Increase/(Decrease)
Accounts receivable, net	$ 9,483	$ 8,346	$ 1,137*
Accumulated deficit	(141,489)	(143,989)	(2,500)

Statement of Operations:

	For the year ended December 31, 2018		
	As reported	Balances without Adoption of ASC 606	Effect of Change Increase/(Decrease)
Revenue, net	$ 21,896	$ 21,243	$ 653

*Includes approximately $0.6 million of 2017 accounts receivables related to the adoption of ASC 606 as of January 1, 2018.

Historically, for certain third-party payers that did not have established contractual reimbursement rates or a predictable pattern of collectability, including commercial insurance carriers, Medicaid and certain direct-bill payers (primarily hospitals, but also laboratories), the Company previously recognized revenues when the fee was fixed or determinable and collectability was reasonably assured, which was upon request of third-party payer notification of payment or when cash was received. Under the new standard, the Company estimates the variable consideration within the transaction price for all third-party payers and proprietary tests and recognizes revenue as the Company satisfies its performance obligations.

In addition, the Company updated its estimates of the expected transaction price for its payer categories and related proprietary tests based on the variable consideration guidance in ASC 606. This consisted of updating the reimbursement rates realized by the Company's proprietary tests based on historical amounts received by each payer category for the corresponding tests performed.

Overall, other than an initial acceleration in the timing of our revenue recognition for certain payer categories, the adoption of this new standard will not have a significant impact on our reported total revenues and operating results as compared to amounts that would have been reported under the prior revenue recognition standard over our typical revenue cycle. Our accounting policies under the new standard were applied prospectively and are discussed further below.

Revenue Recognition after adoption of ASC 606

Upon adoption of ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience.

The Company derives its revenues from the performance of its proprietary tests. The Company's performance obligation is fulfilled upon completion, review and release of test results to the customer. The Company subsequently bills third-party payers or direct-bill payers for the proprietary tests performed. Revenue is recognized based on the estimated transaction price or net realizable value ("NRV"), which is determined based on historical collection rates by each payer category for each proprietary test offered by the Company. The Company regularly reviews the ultimate amounts received from the third-party payers and related estimated reimbursement rates and adjusts the NRV's and related contractual allowances accordingly. If actual collections and related NRV's vary from our estimates, we will adjust the estimates of contractual allowances, which would affect net revenue in the period such variances become known.

Disaggregated Revenues

We operate in a single operating segment and, therefore, the results of our operations are reported on a consolidated basis for purposes of segment reporting, which is consistent with internal management reporting. For the years ended December 31, 2018 and December 31, 2017, substantially all of the Company's revenues were derived from its molecular diagnostic tests.

Financing and Payment

Our payment terms vary by third-party payers and type of proprietary testing services performed. The term between invoicing and when payment is due is not significant.

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in sales and marketing expense in the consolidated statements of operations.

New standards not yet adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which is effective for public companies for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Topic 842 establishes a right-of-use model that requires a lessee to record a right-of-use asset and a lease liability, measured on a discounted basis, on the balance sheet for all leases with terms longer than 12 months. Leases are to be classified as either finance or operating leases, with such classification affecting the pattern or expense recognition in the statement of operations.

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 Company will adopt the provisions of Topic 842 in the first quarter of Fiscal 2019 using the alternative modified transition method, with a cumulative effect adjustment to the opening balance of retained earnings on the date of adoption, and prior periods not restated, as allowed under the provisions of Topic 842. The Company will also elect to use the practical expedients permitted under the transition guidance of Topic 842, which provides for the following: the carryforward of our historical lease classification, no requirement for reassessment of whether an expired or existing contract contains an embedded lease, no reassessment of initial direct costs for any leases that exist prior to the adoption of the new standard, and the election to consolidate lease and non-lease components. The Company is also electing to keep all leases with an initial term of 12 months or less off the balance sheet and to recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

The Company is in the process of completing its assessment of calculating and recording the recognition of right-of-use assets, lease liabilities and related expense recognition. We estimate that based on our lease arrangements as of December 31, 2018, we anticipate between $2.0 million and $3.0 million of right-of-use lease assets and lease liabilities will be recognized on our consolidated balance sheet upon adoption, primarily relating to rentals of space for our corporate headquarters and laboratories.

(tabular information in thousands, except share and per share data)

3. Liquidity

As of December 31, 2018, the Company had cash and cash equivalents of $6.1 million, net accounts receivable of $9.5 million, total current assets of $17.7 million and total current liabilities of $8.5 million. For the year ended December 31, 2018, the Company had a net loss of $12.2 million and cash used in operating activities was $8.7 million.

The Company does not expect to generate positive cash flows from operations for the year ending December 31, 2019. 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.

In January 2019, the Company completed a public offering generating net proceeds of approximately $6.1 million to the Company. For more details, see Note 21, *Subsequent Events*.

In November 2018, the Company entered into up to a $4.0 million secured Line of Credit facility including a 3-year term loan for $850,000 with Silicon Valley Bank ("SVB"). The proceeds of the term loan are expected to be used for laboratory capital expenditures and will be repaid monthly. The balance of the Line of Credit is available for working capital purposes as a revolving line of credit and has a three-year term. The borrowing limit of the revolving line of credit is the lower of 80% of the Company's eligible accounts receivable (as adjusted by SVB) and the aggregate amount of cash collections with respect to accounts receivable during the three prior calendar months. Term loan outstanding amounts incur interest at a rate per annum equal to the greater of the Wall Street Journal Prime Rate (the "Prime Rate") and 5.00%. Revolving Line outstanding amounts incur interest at a rate per annum equal to the Prime Rate plus 0.5%. As of December 31, 2018, no amounts have been borrowed.

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.

The components of liabilities classified as discontinued operations relate to Commercial Services and consist of the following as of December 31, 2018 and December 31, 2017:

	December 31, 2018	December 31, 2017
Accounts payable	$ 192	$ 192
Other	726	1,110
Current liabilities from discontinued operations	918	1,302
Total liabilities	$ 918	$ 1,302

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.

(tabular information in thousands, except share and per share data)

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.

	As of December 31, 2018		Fair Value Measurements As of December 31, 2018		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen	$ 3,127	$ 3,127	$ -	$ -	$ 3,127
Other long-term liabilities:					
Warrant liability	361	361	-	-	361
	$ 3,488	$ 3,488	$ -	$ -	$ 3,488

(tabular information in thousands, except share and per share data)

	As of December 31, 2017		Fair Value Measurements As of December 31, 2017		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 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

In connection with the acquisition of certain assets from Asuragen, 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 June 21, 2017, the Company closed on a public offering 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 included 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 underlying agreement. Changes to the fair value of the warrant liabilities are recorded in Other expense, net. The Pre-Funded Warrants were fully exercised in 2017 and therefore the Company has no remaining liability associated with those warrants.

	December 31, 2017	Payments [1]	Accretion	Cancellation of Obligation/ Conversions Exercises	Adjustment to Fair Value/ Mark to Market	December 31, 2018
Asuragen	$ 1,581	$ (307)	$ 331	$ -	$ 1,522	$ 3,127
Underwriters Warrants	473	-	-	-	(112)	361
	$ 2,054	$ (307)	$ 331	$ -	$ 1,410	$ 3,488

(1) Royalty payments of $307,000 are reflected within Cash Flows from Operations.

Certain of the Company's non-financial assets, such as other intangible assets 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.

(tabular information in thousands, except share and per share data)

6. Property and Equipment

Property and equipment consisted of the following as of December 31, 2018 and 2017:

	December 31,	
	2018	**2017**
Furniture and fixtures	$ 62	$ 62
Office equipment	1,686	1,348
Computer equipment	172	115
Internal-use software	113	113
Leasehold improvements	175	175
Property and equipment	2,208	1,813
Less accumulated depreciation and amortization	(1,371)	(1,159)
Net property and equipment	$ 837	$ 654

Depreciation and amortization expense from continuing operations was approximately $0.2 million and $0.4 million for the years ended December 31, 2018 and 2017, respectively. There was no internal-use software amortization expense included in depreciation and amortization expense for either year. As of December 31, 2018, capitalized external-use software was fully amortized.

7. Other Intangible Assets

The net carrying value of the identifiable intangible assets as of December 31, 2018 and December 31, 2017 is as follows:

	Life (Years)	As of December 31, 2018 Carrying Amount	As of December 31, 2017 Carrying Amount
Diagnostic assets:			
Asuragen acquisition:			
Thyroid	9	$ 8,519	$ 8,519
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
Accumulated Amortization		$ (13,767)	$ (10,515)
Net Carrying Value		$ 29,853	$ 33,105

Amortization expense was approximately $3.3 million for the years ended December 31, 2018 and 2017, respectively. Estimated amortization expense for the next five years is as follows:

2019	2020	2021	2022	2023
$ 3,252	$ 4,272	$ 4,908	$ 2,987	$ 2,987

(tabular information in thousands, except share and per share data)

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, 2018 and December 31, 2017 was approximately $0.2 million, respectively, in both years.

9. Accrued Expenses and Other Long-Term Liabilities

Other accrued expenses consisted of the following as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Accrued royalties	$ 1,399	$ 296
Indemnification liability	875	875
Contingent consideration	434	232
DOJ settlement	-	500
Accrued professional fees	701	700
Taxes payable	285	515
Unclaimed property	565	565
All others	832	1,321
Total other accrued expenses	$ 5,091	$ 5,004

Other long-term liabilities consisted of the following as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Warrant liability	$ 361	$ 473
Uncertain tax positions	3,838	3,734
Other	120	82
Total other long-term liabilities	$ 4,319	$ 4,289

10. Commitments and Contingencies

The Company leases facilities and certain equipment under agreements classified as operating leases, which expire at various dates through June 2023. 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, 2018 and 2017 was approximately $0.7 million and $0.7 million, respectively.

As of December 31, 2018, 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:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Operating lease obligations	$ 2,814	$ 613	$ 1,322	$ 879	$ -
Contractual obligation	-	-	-	-	-
Total	$ 2,814	$ 613	$ 1,322	$ 879	$ -

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.

The Company could 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, 2018, 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 Integrated Pathology, Inc., ("RedPath"), the Company assumed a liability for the settlement agreement entered into by the former owners of RedPath with the Department of Justice ("DOJ"). Under the terms of the settlement agreement, the Company was 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 were due on March 31st following the calendar year in which the revenue milestones were achieved. The Company made payments totaling $0.5 million during the year ended December 31, 2017 related to fiscal 2016 and had accrued $0.5 million for its potential liability for fiscal 2017, the final year of the settlement agreement. During the second quarter of 2018, the Company entered into an agreement with the DOJ to settle in full the outstanding fiscal 2017 liability at approximately $0.15 million and paid this amount as the final settlement payment in July 2018.

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 Consolidated Statements of Operations and $0.5 million was recorded in discontinued operations. The Company had 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, 2018 and 2017, there were no issued and outstanding shares of preferred stock.

(tabular information in thousands, except share and per share data)

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:

First Registered Direct Offering - On January 6, 2017, the Company sold 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.

Second Registered Direct Offering - On January 25, 2017, the Company completed the sale of 855,000 shares of common stock and a concurrent private placement of warrants to purchase 855,000 shares of its common stock, (the "Warrants"), to the same investors in the First Registered Direct Offering. The Warrants and 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. The shares of common stock and Warrants were issued separately but sold together at a combined purchase price of $4.69 per share of common stock and accompanying Warrant and resulted in gross proceeds to the Company of approximately $4 million. The fair value of these warrants issued was $1.67 million (determined using the Black-Scholes Option Pricing Model) 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%

Confidentially Marketed Public Offering (CMPO) - On February 8, 2017, the Company sold 1,200,000 shares of common stock at a price of $3.00 per share and an additional 9% of the total number of shares of common stock for the purpose of covering over-allotments which was exercised by the Underwriter in full. The CMPO resulted in gross proceeds to us of approximately $3.9 million.

Redpath Warrants - On March 22, 2017, the Company entered into a termination agreement with the existing RedPath equity holder representative which terminated all of their royalty and milestone rights under the existing contingent consideration agreement in exchange for 5 year warrants to acquire an aggregate of 100,000 shares of the Company's common stock at a price of $4.69 per share. The fair value of the warrants issued was $0.19 million (determined using the Black-Scholes Option Pricing Model) 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%

Senior Secured Convertible Note - Between March 23, 2017 and April 18, 2017, the Company converted its existing outstanding senior secured convertible note in the principal amount of $3,547,775 for 3,795,429 shares of our common stock and recorded a loss of $4.3 million.

(tabular information in thousands, except share and per share data)

Underwriting Agreement - On June 16, 2017, the Company entered into an underwriting agreement to sell 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.

On June 21, 2017, the Company successfully closed this offering (see Note 3, Liquidity) and, in summary, 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 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 $0.01 per warrant exercise price and all 2,600,000 common shares related to the warrants were issued for $26,000. The corresponding fair value of the warrants as of the date of exercise was $2.3 million and this 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 $960 thousand net of $72 thousand in underwriter discounts.

Warrant for Investor Relations Services - On July 5, 2017, the Company entered into an agreement for investor relations services and, in consideration for these services, paid a fee 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 share- based 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		0.00%

(tabular information in thousands, except share and per share data)

Base Warrant Exercise - 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 Company recorded a $2.0 million charge within Other (expense) income, net in 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		0.00%

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

Additionally, during 2018 we issued 833,000 shares of common stock in connection with contracts for consulting services.

(tabular information in thousands, except share and per share data)

12. Warrants

Warrants outstanding and warrant activity for the year ended December 31, 2018 are as follows:

Description	Classification	Exercise Price	Expiration Date	Warrants Issued	Warrants Exercised	Warrants Cancelled/ Expired	Balance December 31, 2017	Balance December 31, 2018
Private Placement Warrants, issued January 25, 2017	Equity	$ 4.69	June 2022	855,000	-	-	855,000	855,000
RedPath Warrants, issued March 22, 2017	Equity	$ 4.69	September 2022	100,000	-	-	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 21, 2017	Liability	$ 1.32	December 2022	575,000	-	(40,000)	535,000	535,000
Base & Overallotment Warrants, issued June 21, 2017	Equity	$ 1.25	June 2022	14,375,000	(5,672,852)	-	8,702,148	8,702,148
Vendor Warrants, issued August 6, 2017	Equity	$ 1.25	August 2020	150,000	-	-	150,000	150,000
Warrants issued October 12, 2017	Equity	$ 1.80	April 2022	3,200,000	-	-	3,200,000	3,200,000
				21,855,000	(8,272,852)	(40,000)	13,542,148	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 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 2018 which vest one-third each year on the anniversary of the grant date. The Company granted stock options in 2017 which vested 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 graded 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.

(tabular information in thousands, except share and per share data)

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, 2018 and December 31, 2017.

	December 31, 2018	December 31, 2017
Risk-free interest rate	2.71%	1.85%
Expected life	6.0 years	4.9 years
Expected volatility	127.18%	142.42%
Dividend yield	-	-

The weighted-average fair value of stock options granted during the year ended December 31, 2018 was estimated to be $0.93. The weighted-average fair value of stock options granted during the year ended December 31, 2017 was estimated to be $1.49. There were no options or SARs exercised in 2018 or 2017. 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, 2018 and 2017 is as follows:

	2018	2017
RSUs	$ 301	$ 65
Options	1,433	995
Total stock-based compensation expense	$ 1,734	$ 1,060

(tabular information in thousands, except share and per share data)

A summary of stock option and SARs activity for the year ended December 31, 2018, 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, 2018	1,594,615	$ 3.87	9.11	$ 1
Granted	1,320,000	1.04	9.51	-
Exercised	-			
Forfeited or expired	(25,302)	54.40		
Outstanding at December 31, 2018	2,889,313	2.14	8.83	-
Exercisable at December 31, 2018	1,548,479	3.08	8.25	-
Vested and expected to vest	2,825,153	1.99	9.03	-

A summary of the status of the Company's non-vested options for the year ended December 31, 2018, and changes during such year, is presented below:

	Shares	Weighted- Average Grant Date Fair Value
Nonvested at January 1, 2018	896,693	$ 1.40
Granted	1,320,000	0.93
Vested	(875,859)	1.40
Forfeited	-	-
Nonvested at December 31, 2018	1,340,834	$ 0.93

The aggregate fair value of SARs and options vested during the years ended December 31, 2018 and 2017 was $1.2 million and $1.1 million, respectively. The weighted-average grant date fair value of options vested during the year ended December 31, 2017 was $1.61.

A summary of the Company's non-vested shares of restricted stock units for the year ended December 31, 2018, and changes during such year, is presented below:

	Shares	Weighted-Average Grant Date Fair Value	Average Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested at January 1, 2018	68,000	$ 2.49	0.64	$ 69
Granted	330,000	1.04	-	-
Vested	(33,538)	2.50	-	-
Forfeited	(2,265)	2.30	-	-
Nonvested at December 31, 2018	362,197	$ 1.17	1.37	$ 289,758

The aggregate fair value of restricted stock units vested during each of the years ended December 31, 2018 and 2017 was $0.1 million, respectively in both periods.

As of December 31, 2018, there was approximately $1.1 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and restricted stock units.

(tabular information in thousands, except share and per share data)

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, 2018 and December 31, 2017, revenue from Medicare was approximately 41% and 38% of total revenue, respectively.

	Years Ended December 31,	
Customer	2018	2017
Medicare	$ 9,114	$ 6,046
Commercial Payors	$ 4,079	$ 3,127
Client Billings	$ 3,621	$ 4,241
Medicare Advantage	$ 3,011	$ 2,217

15. Income Taxes

The benefit from income taxes on continuing operations for the years ended December 31, 2018 and 2017 is comprised of the following:

	2018	2017
Current:		
Federal	$ (2)	$ (382)
State	19	(13)
Total current	17	(395)
Deferred:		
Federal	-	-
State	-	-
Total deferred	-	-
Benefit from income taxes	$ 17	$ (395)

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 assets at December 31, 2018 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.

(tabular information in thousands, except share and per share data)

The tax effects of significant items comprising the Company's deferred tax assets and (liabilities) as of December 31, 2018 and 2017 are as follows:

	2018	2017
Deferred tax assets:		
Federal net operating loss carryforwards	$ 40,158	$ 31,943
State net operating loss carryforwards	4,541	4,762
Compensation	1,100	693
Allowances and reserves	1,007	7,539
State taxes	794	1,124
Credit carryforward	233	239
Deferred revenue	89	88
Property, plant and equipment	16	637
Other Reserves-restructuring	-	5
	47,938	47,030
Deferred tax liability:		
Intangible assets	(4,371)	(4,865)
Net Deferred tax assets	43,567	42,165
Less: valuation allowance	(43,567)	(42,165)
Deferred tax asset-net valuation allowance	$ -	$ -

The Company's deferred tax asset and deferred tax liabilities are included within *Other long-term liabilities*, respectively, within the consolidated balance sheet as of December 31, 2018. Federal tax attribute carryforwards at December 31, 2018, consist primarily of approximately $186.7 million of federal net operating losses. In addition, the Company has approximately $80.3 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 2028, 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.

(tabular information in thousands, except share and per share data)

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

	2018	2017
Federal statutory rate	21.0%	34.0%
State income tax rate, net of Federal tax benefit	2.9%	2.2%
Meals and entertainment	(0.3)%	(0.3)%
Contingent consideration	0.0%	8.6%
Tax reform change	0.0%	(174.7)%
Valuation allowance	(23.7)%	141.7%
Gain/Loss on extinguishment of debt	0.0%	(11.6)%
Other non-deductible	(0.1)%	0.0%
Discontinued operations allocation	0.0%	3.1%
Net change in Federal and state reserves	-	-
Effective tax rate	(0.2)%	3.0%

The following table summarizes the change in uncertain tax benefit reserves for the two years ended December 31, 2018:

	Unrecognized Tax Benefits
Balance of unrecognized benefits as of January 1, 2017	$ 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
Additions for tax positions related to the current year	-
Additions for tax positions of prior years	-
Reductions for tax positions of prior years	(323)
Balance as of December 31, 2018	$ 794

As of December 31, 2018 and 2017, the total amount of gross unrecognized tax benefits was $0.8 million and $1.1 million, respectively. The decrease in unrecognized tax benefits is related to the change in tax rate from 34% to 21% and a reduction of the unrecognized tax benefit in the current year. The total amount of unrecognized tax benefits that, if recognized, would affect the effective tax rate as of December 31, 2018 and 2017 was $0.8 million and $1.1 million, respectively.

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, 2018 and 2017. At December 31, 2018 and 2017, accrued interest and penalties, net were $3.0 million and $2.8 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, 2018:

Jurisdiction	Tax Years
Federal	2014 - 2018
State and Local	2013 - 2018

(tabular information in thousands, except share and per share data)

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, 2018. 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 for tax years beginning after December 31, 2017. 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.

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. The Company did not have any changes to provisional estimates.

16. Historical Basic and Diluted Net Loss per Share

A reconciliation of the number of shares used in the calculation of basic and diluted earnings per share for the years ended December 31, 2018 and 2017 is as follows:

	Years Ended December 31,	
	2018	2017
Basic weighted average number of common shares	28,155	15,766
Potential dilutive effect of stock-based awards	-	-
Diluted weighted average number of common shares	28,155	15,766

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 December 31,	
	2018	2017
Options	2,831	1,511
Stock-settled stock appreciation rights (SARs)	59	84
Restricted stock units (RSUs)	362	68
Warrants	13,542	13,542
	16,794	15,205

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 principally on developing and commercializing molecular diagnostic tests, leveraging the latest technology and personalized medicine for better patient diagnosis 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. Line of Credit

On November 13, 2018, the Company and its subsidiaries entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), providing for up to $4.0 million of debt financing consisting of a term loan (the "Term Loan") of up to $850,000 and a revolving line of credit based on its outstanding accounts receivable (the "Revolving Line") of up to $4.0 million. The available amount of the Revolving Line will be reduced by the outstanding amount of the Term Loan. The Company intends to use the proceeds of the Term Loan for capital expenditures in connection with its laboratory expansion and the proceeds of the Revolving Line for working capital purposes.

The Term Loan may be borrowed in up to two advances until March 31, 2019, unless there has been an event of default. Term Loan outstanding amounts bear interest at a rate per annum equal to the greater of the Wall Street Journal Prime Rate (the "Prime Rate") and 5.00% and are repayable in 36 equal monthly installments of principal commencing on June 3, 2019 through and including April 1, 2022. In addition, the Company is required to pay a Term Loan final payment to SVB (the "Term Loan Final Payment") equal to 5.0% of the original principal amount of all Term Loan advances at the earliest to occur of the maturity of the Term Loan, the prepayment of the Term Loan, or the acceleration of the Term Loan upon an event of default.

The Company may prepay outstanding amounts of the Term Loan in whole, but not in part. Prepayment of the Term Loan requires payment of the Term Loan Final Payment and a Term Loan prepayment fee equal to 3.0% of the original principal amount of all Term Loan advances if prepaid in the first year of the SVB Loan Agreement, 2.0% of the original principal amount of the Term Loan advances if prepaid in the second year of the SVB Loan Agreement and 1.0% of the original principal amount of the Term Loan advances if paid in the third year of the SVB Loan Agreement.

The amount that may be borrowed under the Revolving Line is the lower of (i) $4.0 million or (ii) 80% of the Company's eligible accounts receivable (as adjusted by SVB) minus any outstanding amounts under the Term Loan. Revolving Line outstanding amounts incur interest at a rate per annum equal to the Prime Rate plus 0.5%. The Company is also required to pay an unused Revolving Line facility fee monthly in arrears in an amount equal to 0.35% per annum of the average unused but available portion of the Revolving Line. The Revolving Line has a three year maturity. If the Company's accounts receivable fail to satisfy certain financial requirements specified by the terms of the Revolving Loan, the Company may be required to repay the Revolving Loan in whole or in part.

Upon termination of the SVB Loan Agreement or the termination of the Revolving Line for any reason prior to the Revolving Line maturity date, in addition to the payment of any other amounts then-owing, the Company is required to pay a Revolving Line termination fee in an amount equal to 3.0% of the Revolving Line if the termination occurs in the first year of the SVB Loan Agreement, 2.0% of the Revolving Line if the termination occurs in the second year of the SVB Loan Agreement and 1.0% of the Revolving Line if the termination occurs in the third year of the SVB Loan Agreement.

The Revolving Line and the Term Loan are both secured by a first priority lien on all assets of the Company and its subsidiaries, except for intellectual property. The Company's intellectual property may not be sold or encumbered without the Bank's prior written consent (a negative pledge).

The SVB Loan Agreement contains a number of affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the SVB Loan Agreement. These restrictive covenants could adversely affect our ability to conduct our business. The SVB Loan Agreement also contains a number of customary events of default. No amounts are outstanding at December 31, 2018.

19. Long-Term Debt

On October 31, 2014, the Company and its subsidiary, Interpace Diagnostics, 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 the Senior Secured Convertible Note on April 18, 2017, the Company recorded a loss of $2.3 million which is included in the total loss of $4.3 million described above.

The Company had no long-term debt as of December 31, 2018 or December 31, 2017, and has not incurred any long-term debt since the RedPath Debt Exchange.

20. Supplemental Cash Flow Information

	For The Years Ended December 31,	
	2018	**2017**
Net cash used in operating activities of discontinued operations	$ (361)	$ (2,291)
Net cash provided by investing activities of discontinued operations	$ -	$ -

Supplemental Disclosures of Non Cash Activities
(in thousands)

	Years Ended December 31,	
	2018	**2017**
Operating		
Adoption of ASC 606	$ 2,500	$ -
Prepaid stock grants issued to vendors	$ 497	$ -
Investing		
Acquisition of property and equipment	$ -	$ 54
Tenant incentives recorded as part of deferred rent	$ -	$ 84
Financing		
Settlement of the RedPath Note	$ -	$ (8,098)
Issuance of the Exchange Notes	$ -	$ 11,375
Common shares issued in debt exchange	$ -	$ 11,643

21. Subsequent Events

On January 25, 2019, the Company entered into an underwriting agreement (the "Underwriting Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") with respect to the issuance and sale of an aggregate of 9,333,334 shares (the "Firm Shares") of the Company's common stock, par value $0.01 per share (the "Common Stock"), in an underwritten public offering. Pursuant to the Underwriting Agreement, the Company also granted Wainwright an option, exercisable for 30 days, to purchase an additional 1,400,000 shares of Common Stock. The option expired unexercised. The Firm Shares were offered to the public at a price of $0.75 per Share. Wainwright purchased the Firm Shares from the Company pursuant to the Underwriting Agreement at a price of $0.6975 per share.

In addition, the Company issued to Wainwright's designees warrants (the "Underwriter Warrants") to purchase up to 654,334 shares of Common Stock (representing 7% of the aggregate number of Firm Shares), at an exercise price of $0.9375 per share (representing 125% of the public offering price). The Underwriter Warrants are exercisable immediately and expire three years from the date of issuance.

The Company received net proceeds, after deducting underwriter discounts and commissions and other estimated expenses related to the offering, in the amount of approximately $6.1 million. The Company intends to use the net proceeds from the offering for working capital, capital expenditures, business development and research and development expenditures, and acquisition of new technologies and businesses.

INTERPACE DIAGNOSTICS GROUP, INC.
VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 2018 AND 2017
($ in thousands)

Description	Balance at Beginning of Period	Additions (Reductions) Charged to Operations	(1) Deductions Other	Balance at end of Period
2017				
Allowance for doubtful accounts	$ 363	(363)	-	$ -
Allowance for doubtful notes	$ 1,646	-	(777)	$ 869
Tax valuation allowance	$ 64,480	-	(22,315)	$ 42,165
2018				
Allowance for doubtful notes	$ 869	-	-	$ 869
Tax valuation allowance	$ 42,165	-	1,402	$ 43,567

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

EMPLOYMENT SEPARATION AGREEMENT

This Employment Separation Agreement (the "Agreement") is effective as of March 25, 2015, and is made by and between **Interpace Diagnostics, LLC** (together with Interpace Diagnostics Corporation and PDI, Inc. the "Company"), having its principal place of business at 300 Interpace Parkway, Parsippany, New Jersey 07054, and **Gregory Richard** (the "Executive"), residing at 282 11th Avenue, New York, NY 10001, collectively referred to as the "Parties," pursuant to which the Parties agree:

1. **Employment**. In consideration of and conditioned upon the Executive's execution of a Confidential Information, Non-Disclosure, Non-competition Non-Solicitation, and Rights to Intellectual Property Agreement acceptable to the Company and substantially in the form attached hereto as Exhibit A, the Company will continue to employ Executive as the Senior Vice President and General Manager of IDX. *The Parties acknowledge and agree that Executive's employment with the Company is "at will" and that Executive's employment may be terminated by Executive or the Company at any time, for any reason or for no reason.*

2. **Compensation and Benefits Payable Upon Involuntary Termination without Cause or Resignation for Good Reason.**

a. **Triggering Event**. In further consideration for Executive's employment, Executive will receive the compensation and benefits set forth in Section 2(b) if the following requirements (hereinafter referred to as the "Triggering Event") are met:

i. Executive's employment is terminated involuntarily by the Company at any time for reasons other than death, Total Disability, or Cause, as defined in this Agreement, or Executive resigns from employment for Good Reason, as defined in this Agreement; and

ii. As of the 45th day following his termination date, Executive has executed and delivered to the Company, a Severance Agreement and General Release acceptable to the Company (the "Release"), and thereafter, any applicable revocation period has expired and Executive has not revoked the Release during such revocation period. Such Release shall include a release of all claims against the Company, all affiliated and related entities and/or persons deemed necessary by the Company. The Release may also include Confidentiality, Non-Disparagement, No-Reapply, Tax Indemnification, and/or other appropriate terms.

b. **Compensation and Benefits.** Following the occurrence of a Triggering Event, the Company will provide the following compensation and benefits to Executive:

i. The Company will pay Executive a lump sum payment equal to the product of twelve (12) times Executive's Base Monthly Salary (excluding incentives, bonuses, and other compensation), plus the average of the annual amounts paid to Executive under any cash-based incentive or bonus plan in which Executive participates with respect to the last three (3) full fiscal years of Executive's participation in such plan prior to the date of termination of Executive's employment with the Company (or, if Executive's number of full fiscal years of participation in any such plan prior to the date of termination of Executive's employment is less than three (3), the average of the annual amounts paid to Executive over the number of full fiscal years of Executive's participation in such plan prior to the date of termination of Executive's employment). Subject to Section 2(c) below, such payment shall be made within sixty (60) days after Executive's termination date. Notwithstanding the foregoing, if the 60 day period following the Executive's termination ends in a calendar year after the year in which the Executive's Employment terminates, the Severance Payment shall be made no earlier than the first day of such later calendar year.

ii. The Company will reimburse Executive for the cost of the premiums for COBRA group health continuation coverage under the Company's group health plan paid by Executive for coverage during the period beginning on Executive's termination date and ending on the earlier of either: (A) the first anniversary of Executive's termination date; or (B) the date on which Executive becomes eligible for other group health coverage, provided that no reimbursement shall be paid unless and until Executive submits proof of payment acceptable to the Company within ninety (90) days after Executive incurs such expense. Any reimbursements of the COBRA premium that are taxable to the Executive shall be made on or before the last day of the year following the year in which the COBRA incurred, the amount of the COBRA premium eligible for reimbursement during one year shall not affect the amount of COBRA premium eligible for reimbursement in any other year, and the right to reimbursement shall not be subject to liquidation or exchange for another benefit.

c. **Delay of Payment to Comply with Code Section 409A.** Notwithstanding anything herein to the contrary, if at the time of Executive's termination of employment with the Company, Executive is a "specified employee" within the meaning of Code Section 409A, and the regulations promulgated thereunder, then if and to the extent required in order to avoid the imposition on Executive of any excise tax under Code Section 409A the Company shall delay the commencement of such payments (without any reduction) by a period of six (6) months after Executive's termination date. Any payments that would have been paid during such six (6) month period but for the provisions of the preceding sentence shall be paid in a lump sum to Executive six (6) months and one (1) day after Executive's termination date. The 6-month payment delay requirement of this Section 2(c) shall apply only to the extent that the payments under this Section 2 are subject to Code Section 409A. With respect to payments or benefits under this Agreement that are subject to Code Section 409A, whether Executive has had a termination of employment shall be determined in accordance with Code Section 409A and applicable guidance issued thereunder.

d. **Limitation of Payments.** If any payment or benefit due under this Agreement, together with all other payments and benefits Executive receives or is entitled to receive from the Company or any of its Affiliates, would (if paid or provided) constitute an excess parachute payment (within the meaning of Section 280G(b)(1) of the Code), the amounts otherwise payable and benefits otherwise due under this Agreement will be limited to be minimum extent necessary to ensure that no portion thereof will fail to be tax-deductible to the Company by reason of Section 280G of the Code. The determination of whether any payment or benefit would (if paid or provided) constitute an excess parachute payment will be made by the Board, in its sole discretion. Any such reduction in the preceding sentence shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced (if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (ii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced. Notwithstanding the foregoing, the Company shall use commercially reasonable efforts to bring the issue to a shareholder vote in accordance with Section 280G(b)(5) of the Code and the Treasury Regulations thereunder.

e. **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 the Executive 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 409 A") 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 the Executive's "separation from service" which occurs on or after the date of the Executive'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 409 A.

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 the Executive 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.**

3. **Other Compensation.**

a. Except as may be provided under this Agreement, any benefits to which Executive may be entitled pursuant to the plans, policies and arrangements of the Company shall be determined and paid in accordance with the terms of such plans, policies, and arrangements, and Executive shall have no right to receive any other compensation or benefits, or to participate in any other plan or arrangement, following the termination of Executive's employment by either party for any reason.

b. Notwithstanding any provision contained herein to the contrary, in the event of any termination of employment, the Company shall pay Executive his or her earned, but unpaid, base salary within ten (10) days of Executive's termination date and shall reimburse Executive for any accrued, but unpaid, reasonable business expenses, in each case, earned or accrued as of the date of termination. Executive shall submit documentation of any business expenses within ninety(90) days of his or her termination date and any reimbursements of such expenses that are taxable to the Executive shall be made on or before the last day of the year following the year in which the expense was incurred, the amount of the expense eligible for reimbursement during one year shall not affect the amount of reimbursement in any other year, and the right to reimbursement shall not be subject to liquidation or exchange for another benefit.

4. **Withholding.** All amounts payable under this Agreement shall be subject to customary withholding and other employment taxes, and shall be subject to such other withholding as may be required in accordance with the terms of this Agreement or applicable law.

5. **Confidentiality, Non-Solicitation and Covenant Not to Compete Agreement.** In the event Executive's employment with the Company is terminated by either party for any reason, Executive shall continue to be bound by the Confidential Information, Non-Disclosure, Non-Competition, Non-Solicitation, and Rights to Intellectual Property Agreement signed at or about the time this Agreement is executed and/or the Confidentiality, Non-Solicitation and/or Covenant Not to Compete Agreement most recently signed by Executive prior to the termination date for the period set forth therein.

6. **Definitions.**

a. **Cause** shall mean (i) the failure of Executive to use Executive's best efforts in accordance with Executive's position, skill and abilities to achieve Executive's goals as periodically set by the Company and such failure shall not be cured by the Executive within thirty (30) days written notice from the Company to the Executive specifying such failure; (ii) the failure by Executive to comply with and follow reasonable instructions of the Chief Executive Officer and/or the Company's Board of Directors (the Board"); (iii) a material breach by Executive of any of the terms or conditions of this Agreement and such breach shall not be cured by the Executive within thirty (30) days written notice from the Company to the Executive specifying such failure; (iv) the failure by Executive to adhere to the Company's documented policies and procedures; (v) breach by Executive of any Confidentiality, Non-Solicitation and/or Covenant Not to Compete Agreement signed by Executive; (vi) the failure of Executive 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;(vii) Executive's conviction of a criminal offense (including the entry of a guilty or nolo contendere plea); (viii) any documented act of material dishonesty or fraud by the Executive in the commission of his or her duties; or (ix) Executive engages in an act or series of acts constituting misconduct resulting in a misstatement of the Company's financial statements due to material noncompliance with any financial reporting requirement within the meaning of Section 304 of The Sarbanes-Oxley Act of 2002.

b. **Base Monthly Salary** shall mean an amount equal to one-twelfth of Executive's then current annual base salary. Base Monthly Salary shall not include incentives, bonus(es), health and welfare benefits, car allowances, long term disability insurance or any other compensation or benefit provided to executive employees of the Company.

c. **Change of Control** shall mean: (i) any merger by the Company into another corporation or corporations which results in the stockholders of the Company immediately prior to such transaction owning less than 51% of the surviving corporation; (ii) any acquisition (by purchase, lease or otherwise) of all or substantially all of the assets of the Company by any person, corporation or other entity or group thereof acting jointly; (iii) the acquisition of beneficial ownership of voting securities of the Company (defined as common stock of the Company or any securities having voting rights that the Company may issue in the future) or rights to acquire voting securities of the Company (defined as including, without limitation, securities that are convertible into voting securities of the Company (as defined above) and rights, options, warrants and other agreements or arrangements to acquire such voting securities) by any other person, corporation or other entity or group thereof acting jointly, in such amount or amounts as would permit such person, corporation or other entity or group thereof acting jointly to elect a majority of the members of the Board, as then constituted; or (iv) the acquisition of beneficial ownership, directly or indirectly, of voting securities and rights to acquire voting securities having voting power equal to 51% or more of the combined voting power of the Company's then outstanding voting securities by any person, corporation or other entity or group thereof acting jointly. Notwithstanding the preceding sentence, any transaction that involves a mere change in identity, form or place of organization with the meaning of Section 368(a)(l)(F) of the Code, or a transaction of similar effect, shall not constitute a Change of Control.

d. **Good Reason** Executive's termination of employment with the Company shall be for Good Reason if (i) Executive notifies the Company in writing that one of the Good Reason Events (as defined in subparagraphs d. i. and ii. below) has occurred, which notice shall be provided within ninety (90) days after he or she first becomes aware of the occurrence of such Good Reason Event; (ii) the Company fails to cure such Good Reason Event within thirty (30) days after receipt of the written notice from Executive (the "Cure Period"); and (iii) Executive resigns employment within thirty (30) days following expiration of the Cure Period. For purposes of this Agreement, a "Good Reason Event" shall mean any of the following which occur without Executive's consent:

i. Prior to a Change of Control,

A. The failure by the company to pay Executive any material amount of his or her current base salary, or any material amount of his or her compensation deferred under any plan, agreement or arrangement of or with the Company that is currently due and payable;

B. A material reduction of Executive's annual base salary; provided that a reduction consistent with reductions made to the annual base salaries for similarly situated senior executives of no more than 15% shall not constitute Good Reason; or

C. The relocation of Executive's principal place of employment to a location more than fifty (50) miles from Executive's current principal place of employment.

ii. During the two (2) year period following any Change of Control,

A. The failure by the Company to pay Executive any material amount of his or her current base salary, or any material amount of his or her compensation deferred under any plan, agreement or arrangement of or with the Company that is currently due and payable;

B. A material reduction in Executive's annual base salary; provided that a reduction consistent with reductions made to the annual base salaries for similarly situated senior executives of no more than fifteen percent (15%) shall not constitute Good Reason;

C. The relocation of Executive's principal place of employment to a location more than fifty (50) miles from Executive's current principal place of employment;

D. A material adverse alteration of Executive's authority, duties or responsibilities from those in effect immediately prior to the Change of Control.

E. An intentional, material reduction by the Company of Executive's aggregate target incentive awards under any short-term and/or long term incentive plans; and

F. The failure of the Company to maintain the Executive's benefit, retirement, or fringe benefit plans, policies, practices or arrangements in which Executive participates (individually and collectively "Fringe Benefits") at or above the level in effect immediately before the Change of Control, unless such change is a global change made to Fringe Benefits for all employees at or above Executive's level.

e. **Code** shall mean the Internal Revenue Code of 1986, as amended.

f. **Total Disability** shall mean incapacity due to a medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continued period of not less than twelve (12) months and prevents Executive from performing the essential functions of his position, with or without reasonable accommodation, for a period in excess of twelve (12) months.

7. **Integration: Amendment.** This Agreement (including any Exhibits) shall constitute the entire agreement between the parties hereto with respect to the matters set forth herein and supersede and render of no force and effect all prior understandings and agreements between the parties with respect thereto. No amendments or additions to this Agreement shall be binding unless in writing and signed by both parties, provided, however, that this Agreement may be unilaterally amended by the Company where necessary to ensure any benefits payable hereunder are either excepted from Code Section 409 A or otherwise comply with Code Section 409A.

8. **Governing Law; Headings.** This Agreement will be construed and governed by the laws of the State of New Jersey, without regard to principles of conflicts of law and the parties to this Agreement hereby submit to the jurisdiction of the Courts of the State of New Jersey with regard to enforcement of this Agreement.

Headings and titles herein are included solely for convenience and shall not affect, or be used in connection with, the interpretation of this Agreement.

9. **Notices.** All notices and other communications required or permitted to be given or made hereunder by either party shall be in writing and shall be deemed to be duly given if delivered personally or transmitted by first class certified mail, postage and fees prepaid, return receipt requested, or sent by prepaid overnight delivery service to the parties at the following addresses (or at such other addresses as shall be specified by the parties by like notice):

If to the Company:

President
Interpace Diagnostics, LLC
Morris Corporate Center 1
Building A
300 Interpace Parkway
Parsippany, NJ 07054

If to the Executive:

Gregory Richard
282 11th A venue
New York, NY 10001

10. **Severability.** Whenever possible, each provision and term of this Agreement will be interpreted in a manner to be effective and valid but if any provision or term of this Agreement is held to be prohibited by applicable law or invalid, then such provision or term will be ineffective only to the extent of such prohibition or invalidity, without invalidating or affecting in any manner whatsoever the remainder of such term or provision or the remaining provisions or terms of this Agreement.

11. **Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

12. **Assignment.** The Company may assign all of its rights and obligations hereunder to an affiliate or subsidiary of the Company.

IN WITNESS WHEREOF the parties have duly executed this Agreement as of the date first above written.

EXECUTIVE

By: */s/ Gregory Richard*

INTERPACE DIAGNOSTICS, LLC

By: */s/ Nancy L. Lurker*
Nancy L. Lurker
Chief Executive Officer

Exhibit 21.1

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.

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

Exhibit 23.1

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-1 (Nos. 333-218140 and 333-218780), Form S-3 (Nos. 333-207263 and 333-227728) and Form S-8 (Nos. 333-61231, 333-60512, 333-177969, 333-201070, and 333-214260) of Interpace Diagnostics Group, Inc. of our report dated March 21, 2019, relating to the consolidated financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ BDO USA, LLP

Woodbridge, New Jersey
March 21, 2019

Exhibit 31.1

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, 2018 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 21, 2019

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

Exhibit 31.2

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, 2018 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 21, 2019

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

Exhibit 32.1

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, 2018 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 21, 2019

/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.

Exhibit 32.2

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, 2018 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 21, 2019

/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.