

THE INFORMATION IN THIS PRELIMINARY PROSPECTUS SUPPLEMENT IS NOT COMPLETE AND MAY BE CHANGED. THIS PRELIMINARY PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS ARE NOT AN OFFER TO SELL THESE SECURITIES, AND WE ARE NOT SOLICITING OFFERS TO BUY THESE SECURITIES IN ANY JURISDICTION WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED JANUARY 24, 2019.

**Filed pursuant to Rule 424(b)(5)
Registration No. 333-227728**

**PRELIMINARY PROSPECTUS SUPPLEMENT
(To Prospectus dated October 19, 2018)**



[●] Shares of Common Stock

We are offering [●] shares of our common stock at a price of \$[●] per share in a firm commitment underwritten public offering.

The aggregate market value of our outstanding shares of common stock held by non-affiliates was \$25,782,015 based on 28,694,275 shares of common stock outstanding as of January 24, 2019, of which 28,646,683 shares are held by non-affiliates, and a per share price of \$0.90 based on the closing sale price of our common stock on January 24, 2019, as reported by The Nasdaq Capital Market. During the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement, we have offered no securities pursuant to General Instruction I.B.6 of Form S-3. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million.

Our common stock is listed on The Nasdaq Capital Market under the symbol "IDYG." On January 24, 2019, the last reported sale price of our common stock on The Nasdaq Capital Market was \$0.90 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" on page S-13 of this prospectus supplement, page 2 of the accompanying prospectus and under similar headings in the other documents that are incorporated by reference in this prospectus supplement and the accompanying prospectus before purchasing any of the securities offered by this prospectus.

| | Per Share | | Total | |
|---|-----------|-----|-------|-----|
| Public Offering Price | \$ | [●] | \$ | [●] |
| Underwriting discounts and commissions ⁽¹⁾ | \$ | [●] | \$ | [●] |
| Proceeds to us before expenses | \$ | [●] | \$ | [●] |

(1) We have agreed to underwriting discounts and commissions equal to 7% and a management fee equal to 1% of the gross proceeds in this offering. In addition, we have agreed to issue the underwriter or its designees warrants to purchase a number of shares of common stock equal to 7% of the aggregate number of shares of common stock sold in this offering at an exercise price of \$ per share, which represents 125% of the public offering price per share, and to reimburse the underwriters for certain expenses incurred by them. For additional information on the underwriters' discounts and commissions, underwriter's warrants and expense reimbursement, see "Underwriting" in this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

The offering is being underwritten on a firm commitment basis. We have also granted the underwriter a period of 30 days from the date of this prospectus to purchase up to an additional [] shares of common stock from us at the public offering price, less the underwriting discounts and commissions. If the underwriter exercises this option in full, the total underwriting discounts and commissions payable by us will be \$[], and the total proceeds to us, before expenses, will be \$[].

Delivery of the securities offered hereby is expected to be made on or about [], 2019.

H.C. Wainwright & Co.

The date of this prospectus supplement is January [●], 2019.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a “shelf” registration statement on Form S-3 (File No. 333-227728) that we initially filed with the Securities and Exchange Commission, or the SEC, on October 5, 2018, and that was declared effective by the SEC on October 19, 2018.

This document consists of two parts. The first part is this prospectus supplement, which describes the terms of this offering of our securities and adds to, changes, and updates the information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated October 19, 2018, including the documents incorporated by reference, provides more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date - for example, a document incorporated by reference in the accompanying prospectus - the statement in the document having the later date modifies or supersedes the earlier statement.

This prospectus supplement and the accompanying prospectus relate to the offering of our securities. Before buying any of our securities offered hereby, we urge you to read carefully this prospectus supplement and the accompanying prospectus, together with any free writing prospectus that we have authorized for use in connection with this offering and the information incorporated herein by reference as described below under the headings “*Where you can find more information*” and “*Incorporation of Certain Information by Reference*.” You should read this prospectus supplement and the accompanying prospectus, including the information incorporated by reference and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision.

You should rely only on the information contained in, or incorporated by reference into, this prospectus supplement, the accompanying prospectus or in any related free writing prospectus that we have authorized for use in connection with this offering. We have not, and the underwriters and their affiliates have not, authorized anyone to provide you with different or additional information. We do not, and the underwriters and their affiliates do not, take any responsibility for, and can provide no assurance as to the reliability of, any information that others may provide to you. This prospectus is not an offer or solicitation to sell or an offer or solicitation to buy securities in any jurisdiction where offers and sales are not permitted. Regardless of the time of delivery of this prospectus, or any sale of a security registered under the registration statement of which this prospectus is a part, you should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the respective dates of those documents and that our business, financial condition, results of operations and prospects may have changed since those dates. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated herein by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section entitled “*Where You Can Find More Information*.”

For investors outside the United States, neither we nor the underwriters have done anything that would permit a public offering of the securities or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside of the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “Interpace Diagnostics Group, Inc.,” the “Company,” “we,” “us,” “our” and similar references refer to Interpace Diagnostics Group, Inc. and our subsidiaries.

This prospectus supplement, the accompanying prospectus and the information incorporated by reference includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are intended to qualify for the “safe harbor” created by those sections. In addition, we may make forward-looking statements in other documents filed with or furnished to the SEC, and our management and other representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others.

Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as “can”, “may”, “could”, “should”, “assume”, “forecasts”, “believe”, “designated to”, “will”, “expect”, “plan”, “anticipate”, “estimate”, “potential”, “position”, “predicts”, “strategy”, “guidance”, “intend”, “seek”, “budget”, “project” or “continue”, or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other “forward-looking” information.

We believe it is important to communicate our expectations. However, forward-looking statements involve risks and uncertainties and our actual results and the timing of certain events could differ materially from those discussed in forward-looking statements as a result of certain factors, including those set forth under “Risk Factors” in this prospectus supplement and the documents incorporated herein by reference.

Accordingly, our actual results and the timing of certain events may differ materially from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth in this prospectus supplement under “Risk Factors” and those set forth from time to time in our other filings with the SEC.

All forward-looking statements and risk factors included in this prospectus supplement and the documents incorporated herein by reference are made as of the date hereof, based on information available to us as of such date, and we assume no obligations to update any forward-looking statement or risk factor, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Forward-looking statements may include our plans and objectives for future operations, including plans and objectives relating to our products and our future economic performance, projections, business strategy and timing and likelihood of success. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our technologies, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Any of the assumptions underlying the forward-looking statements contained in this prospectus supplement could prove inaccurate and, therefore, we cannot assure you that the results contemplated in any of such forward-looking statements will be realized.

Forward-looking statements are only predictions and are not guarantees of future performance. Based on the significant uncertainties inherent in these forward-looking statements, the inclusion of any such statement should not be regarded as a representation or as a guarantee by us that our objectives or plans will be achieved, and we caution you against relying on any of the forward-looking statements contained herein. These statements are based on current expectations (including revenue projections) 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. 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 discretionary use of the net proceeds from this offering;
- dilution as a result of this offering and future equity issuances;
- the limited revenue generated from our molecular diagnostics business thus far and our ability to commercially leverage our bioinformatics data;
- 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 operating experience to sell our molecular diagnostic tests;
- our products continuing to perform as expected;
- our limited operating history as a molecular diagnostics company;
- our ability to attract and retain key personnel;
- our dependence on a concentrated selection of payers for our molecular diagnostic tests;
- our ability to obtain broad adoption of and ability to grow or continue to secure sufficient levels of reimbursement for our molecular diagnostic tests 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 oncology thought leaders and biopharmaceutical companies;
- demonstration of clinical relevance and value in utility studies;
- our ability to expand our sales and marketing forces;
- our reliance on our internal sales forces for business expansion;
- fluctuating quarterly operating results;
- our dependence on third parties for the supply of some of the materials used in our molecular diagnostic tests;

- our ability to scale our operations, testing capacity and processing technology;
- our ability to support demand for our molecular diagnostic tests and any of our future tests or solutions;
- our ability to compete successfully with companies with greater financial resources;
- our ability to obtain sufficient data and samples to cost effectively and timely perform sufficient clinical trials in order to support our current and future products;
- 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 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 certified Clinical Laboratory Improvement Amendments (“CLIA”) laboratories and be certified by the College of American Pathologists (“CAP”);
- 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 molecular diagnostics and bioinformatics 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;
- 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 sales representatives and other key employees and management personnel;
- our billing practices and our ability to collect on claims for the sale of our molecular diagnostic 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 and the effects of any such items 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 System (LIMS);
- the results of any future impairment testing for intangible assets;
- 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 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 use of our future earnings for growth;
- 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.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Please see Part I – Item 1A – “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2017, filed March 23, 2018, as well as other documents we file with the SEC from time-to-time, for other important factors that could cause our actual results to differ materially from our current expectations as expressed in the forward-looking statements discussed in this prospectus supplement. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus supplement, particularly as set forth and incorporated by reference in the “Risk Factors” section below, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. In addition, these statements speak only as of the date of this prospectus supplement and, except as may be required by law, we undertake no obligation to revise or update publicly any forward-looking statements for any reason.

You should read this prospectus supplement, the accompanying prospectus and the documents that we incorporate by reference herein and therein completely and with the understanding that our actual future results may be materially different from what we expect. Before making an investment decision, you should carefully consider the risk factors discussed and incorporated by reference in this prospectus supplement and the accompanying prospectus.

INDUSTRY DATA

This prospectus supplement and the accompanying prospectus contain and incorporate by reference market data and industry statistics and forecasts that are based on our own internal estimates as well as independent industry publications and other publicly-available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus supplement, accompanying prospectus or the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the headings “Risk Factors” in this prospectus supplement and the accompanying prospectus, and under similar headings in the other documents that are incorporated herein by reference. Accordingly, investors should not place undue reliance on this information.

TRADEMARKS

We have secured trademark registrations for the marks BarreGEN®, ThyGenX®, ThyraMIR®, PancraGEN®, PathFinderTG®, RespriDx® and MiRInform® in the United States, and MiRInform® with the World Intellectual Property Organization. This prospectus contains references to our trademarks. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references, or the lack thereof, are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

SUMMARY OF PROSPECTUS SUPPLEMENT

This summary highlights selected information about us and this offering and does not contain all of the information that you should consider in making your investment decision. You should carefully read this entire prospectus supplement and the accompanying prospectus, including the risks and uncertainties discussed under the heading “Risk Factors” beginning on page S-13 of this prospectus supplement, page 2 of the accompanying prospectus and the information incorporated by reference herein and therein, including our financial statements, before making an investment decision. If you invest in our securities, you are assuming a high degree of risk.

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 molecular diagnostic tests and related first line assays principally focused on early detection of patients at high risk of cancer and leverage the latest technology and personalized medicine for improved patient diagnosis and management. Our tests and services provide mutational analysis of genetic material contained in suspect cysts, nodules and lesions that helps physicians risk-stratify thyroid, pancreatic, and other cancers to better inform treatment decisions. The molecular diagnostic tests we offer enable healthcare providers to avoid unnecessary surgeries and better assess the risk of cancer progression in their patients. We currently have four commercialized molecular diagnostic assays in the marketplace for which we are receiving reimbursement: PancraGEN[®], which is a pancreatic cyst and pancreaticobiliary solid lesion molecular test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform; ThyGeNEXT[®], which is an oncogenic mutation panel that helps identify malignant thyroid nodules and replaced ThyGenX[®]; ThyraMIR[®], which assess thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDX[®], launched in September 2017, which is a molecular 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 molecular 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 \$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 coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our four commercialized innovative tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. We believe that BarreGen[®] is a major pipeline product, built on the PathFinderTG[®] platform which we believe is synergistic to our capabilities and potentially is a significant product opportunity in the gastrointestinal market, which is one of the sectors in which we operate.

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

Reimbursement progress is key for any molecular diagnostic company. We have been successful to date in expanding the reimbursement of our products in 2018. Specifically the most significant progress we have made regarding payers to date 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 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 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 ThyGenX® (and now ThyGeNEXT®) and ThyraMIR® testing.
- 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 physicians across the Vanderbilt system access to both ThyGenX® (and now ThyGeNEXT®) and ThyraMIR® for patients with indeterminate thyroid nodules.
- In June 2018, we announced coverage of ThyGenX® (and now 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 ThyGenX® (and now 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.

New Developments with respect to our 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 supporting BarreGen®, United States Patent Application No. 13/692,727, for methods treating patients with Barrett’s metaplasia that are identified as being at high risk to develop esophageal adenocarcinoma.

Corporate Information

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

THE OFFERING

| | |
|---|---|
| Common stock offered by us | [●] shares |
| Public offering price per share of common stock | \$[●] per share |
| Common stock to be outstanding immediately after this offering | [●] shares ([●] shares if the underwriter exercises its option to purchase additional shares in full). |
| Option to purchase additional securities | The underwriter has an option to purchase up to an additional [] shares of common stock from us at the public offering price, less underwriting discounts and commissions. The underwriter may exercise this option at any time and from time to time within 30 days from the date of this prospectus. |
| Use of Proceeds | We estimate that our net proceeds from this offering will be approximately \$ million after deducting estimated underwriting discounts and commissions and other estimated offering expenses payable by us (assuming the sale of all shares covered by this prospectus supplement). We intend to use the net proceeds from this offering for working capital, capital expenditures, business development and research and development expenditures, and acquisition of new technologies and businesses. For a more complete description of our anticipated use of proceeds from this offering, see “ <i>Use of Proceeds</i> ” on page S-43 of this prospectus supplement. |
| Risk Factors | An investment in our common stock involves a high degree of risk. See the information contained in or incorporated by reference under “ <i>Risk Factors</i> ” on page S-13 of this prospectus supplement, page 2 of the accompanying prospectus, page 21 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and under similar headings in the other documents that are incorporated by reference herein, as well as the other information included in or incorporated by reference in this prospectus supplement and the accompanying prospectus. |
| The Nasdaq Capital Market symbol | Our common stock is quoted and traded on The Nasdaq Capital Market under the symbol “IDXC.” |
| The number of shares of our common stock to be outstanding immediately after this offering is based on 28,294,275 shares of common stock outstanding as of September 30, 2018. Unless specifically stated otherwise, the information in this prospectus supplement is as of September 30, 2018 and excludes: | |
| <ul style="list-style-type: none">• 218,597 shares of common stock issuable upon the settlement of restricted stock units, or RSUs, issued to our employees and directors;• 58,784 shares of common stock issuable upon settlement of stock appreciate rights, or SARs, issued to certain executive officers and members of senior management, at a weighted average exercise price of \$38.41 per share, of which 58,784 shares of common stock are vested and exercisable; | |

- 2,256,129 shares of common stock issuable upon exercise of outstanding options, issued to certain executive officers and directors, at a weighted average exercise price of \$1.46 per share, of which 1,319,194 shares of common stock are vested and exercisable;
- 2,629,740 shares of common stock reserved for future issuance under our Amended and Restated 2004 Stock Award and Incentive Plan;
- 13,542,148 shares of common stock issuable upon exercise of warrants at prices ranging from a \$1.25 to \$4.69 per warrant share; and
- shares of common stock issuable upon the exercise of the underwriter's warrants to be issued to the underwriter or its designees in connection with this offering.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise of the underwriter's option to purchase additional shares of common stock and no exercise of the underwriter's warrants to be issued to the underwriter or its designees in connection with this offering.

SUMMARY FINANCIAL DATA

The following table presents summary condensed consolidated statements of comprehensive loss for the periods indicated. The information is only a summary and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and the financial information and related notes incorporated by reference in this prospectus supplement. See “*Incorporation of Certain Documents by Reference*” on page S-51 of this prospectus supplement and “*Where You Can Find Additional Information*” on page S-51 of this prospectus supplement. We have derived the summary condensed consolidated statements of comprehensive loss for the nine months ended September 30, 2018 and September 30, 2017 from our unaudited condensed consolidated statements of comprehensive loss that are incorporated by reference in this prospectus supplement. We have derived the summary condensed statements of comprehensive loss for the years ended December 31, 2017 and December 31, 2016 from our audited consolidated statements of comprehensive loss that are incorporated by reference in this prospectus supplement.

INTERPACE DIAGNOSTICS GROUP, INC. CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except for per share data)

| | Nine Months Ended September 30, 2018 (unaudited) | Nine Months Ended September 30, 2017 (unaudited) | For The Years Ended December 31, 2017 | December 31, 2016 |
|---|---|---|--|------------------------------|
| Revenue, net | \$ 16,062 | \$ 11,527 | \$ 15,897 | \$ 13,085 |
| Gross profit | 8,472 | 5,808 | 8,539 | 6,444 |
| Operating loss | (7,611) | (2,995) | (6,293) | (6,442) |
| Net loss | (8,152) | (7,208) | (12,216) | (8,332) |
| Net loss per basic and diluted share of common stock | \$ (0.29) | \$ (0.60) | \$ (0.78) | \$ (4.59) |
| Weighted average number of common shares and common share equivalents outstanding: | | | | |
| Basic and diluted | 28,002 | 12,022 | 15,766 | 1,816 |

CONSOLIDATED BALANCE SHEETS

| | <u>September 30, 2018</u> | <u>September 30, 2017</u> | <u>December 31, 2017</u> | <u>December 31, 2016</u> |
|--|---------------------------|---------------------------|--------------------------|--------------------------|
| Cash and cash equivalents | 8,002 | 11,703 | 15,199 | 602 |
| Total assets | 49,801 | 50,391 | 53,598 | 41,778 |
| Total liabilities | 13,772 | 14,013 | | 35,247 |
| Stockholders’ equity | | | | |
| Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized, no shares issued and outstanding | — | — | — | — |
| Common stock, par value \$.01 per share; As of September 30, 2018 and September 30, 2017: 100,000,000 shares authorized; 28,367,344 and 22,975,754 shares issued, respectively; 28,294,275 and 22,911,404 shares outstanding, respectively. As of December 31, 2017 and December 31, 2016: 100,000,000 shares authorized; 27,900,806 and 2,230,506 shares issued, respectively; 27,836,456 and 2,176,252 shares outstanding, respectively. | 283 | 230 | 278 | 22 |
| Additional paid-in capital | 174,878 | 164,611 | 173,062 | 127,736 |
| Accumulated deficit | (137,452) | (126,792) | (131,800) | (119,584) |
| Treasury stock, at cost (73,069, 64,350, 64,350 and 54,254 shares, respectively) | (1,680) | (1,671) | (1,671) | (1,643) |
| Total stockholders’ equity | 36,029 | 36,378 | 39,869 | 6,531 |
| Total liabilities and stockholders’ equity | 49,801 | 50,391 | 53,598 | 41,778 |

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before investing in our common stock, you should carefully consider the risks described below, together with all of the other information contained in this prospectus supplement and the accompanying prospectus and incorporated by reference herein and therein, including from our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. Some of these factors relate principally to our business and the industry in which we operate. Other factors relate principally to your investment in our securities. The risks and uncertainties described therein and below are not the only risks facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially and adversely affect our business and operations.

If any of the matters included in the following risks were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially and adversely affected. In such case, you may lose all or part of your investment.

RISKS RELATED TO THIS OFFERING

Our management has broad discretion as to the use of the net proceeds from this offering.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus supplement entitled “*Use of Proceeds*.” Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds. Our management may spend a portion or all of the net proceeds from this offering in ways that holders of our common stock may not desire or that may not yield a significant return or any return at all. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may also invest the net proceeds from this offering in a manner that does not produce income or that loses value.

If you purchase the common stock sold in this offering, you will experience immediate substantial dilution as a result of this offering and additional dilution in any future equity issuances.

Because the price per share of our common stock being offered is higher than the book value per share of our common stock, you will suffer immediate substantial dilution in the net tangible book value of the common stock you purchase in this offering. See the section entitled “*Dilution*” of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

We are generally not restricted from issuing additional securities, including shares of common stock, securities that are convertible into or exchangeable for, or that represent the right to receive, common stock or substantially similar securities. The issuance of additional shares of our common stock in future offerings could be dilutive to stockholders, including investors in this offering. In order to raise additional capital, such securities may be at prices that are not the same as the price per share in this offering. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, including investors who purchase shares in this offering. Moreover, to the extent that we issue options or warrants to purchase, or securities convertible into or exchangeable for, shares of our common stock in the future and those options, warrants or other securities are exercised, converted or exchanged, stockholders may experience further dilution.

RISKS RELATING TO OUR BUSINESS

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

In 2014, we acquired RedPath Integrated Pathology, Inc., and certain assets from Asuragen, Inc. or Asuragen. As a result, we now offer four products commercially: PancraGEN®, ThyGeNEXT®, ThyraMIR® and RespriDX® and to a limited extent via our clinical experience program, BarreGEN®. The revenue generated from our molecular diagnostics and bioinformatics business was \$15.9 million for the fiscal year ended December 31, 2017 and \$16.1 million for the nine months ended September 30, 2018. For the fiscal year ended December 31, 2017 and the nine months ended September 30, 2018, we had operating losses of approximately \$6.3 million and \$ 7.6 million, respectively. Although we expect our revenue to grow in the future, there can be no assurance that we will achieve revenue sufficient to offset expenses. Over the next several years, we expect to continue to devote resources to increase adoption of, and reimbursement for, our molecular diagnostic tests, 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.

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 are obligated to make certain royalty and milestone payments to Asuragen and the Cancer Prevention & Research Institute of Texas, or CPRIT. Under the license agreement with Asuragen under which we currently license certain patents and know-how from Asuragen relating to miRInform® thyroid and pancreas cancer diagnostic tests and other tests in development for thyroid cancer, or the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of the miRInform® thyroid platform (i.e. ThyGeNEXT®) through August 13, 2024 and on certain other thyroid diagnostics tests (i.e. ThyraMIR®) for a period of ten years following a qualifying sale. A similar obligation exists for the same periods, if we elect to launch any molecular tests from the miRInform® pancreas platform. We are also required by our license agreement with Asuragen and an agreement with CPRIT to make certain related royalty payments to CPRIT.

When performing the ThyraMIR® test, we use products supplied by Exiqon A/S, 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.

We expect capital expenditures and operating expenses to increase over the next several years as we expand our infrastructure and commercial operations. As of September 30, 2018, we had cash and cash equivalents of \$8.0 million, net accounts receivable of \$8.6 million, total current assets of \$18.2 million and total current liabilities of \$7.8 million. For the year ended December 31, 2017, we had a net loss of \$12.2 million and cash used in operating activities was \$15.3 million, including non-recurring charges. During 2017, we completed various offerings and a warrant exchange, which resulted in aggregate net proceeds to us of approximately \$29.9 million. 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 inability to comply with financial covenants under our current line of credit facility and an 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. 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.

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

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.

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.

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 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 approximately 88 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.

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

Revenue for tests performed on patients covered by Medicare was approximately 38% of our revenue for the fiscal year ended December 31, 2017. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue increases, as additional payers provide reimbursement for our molecular diagnostic tests or if one or more payers were to stop reimbursing for our molecular diagnostic tests or 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®, BarreGEN® 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. PancraGEN® is currently reimbursed by Medicare at \$3,038 per test, ThyGeNEXT® is currently reimbursed by Medicare at \$586 per test, and ThyraMIR® is currently reimbursed by Medicare at \$2,195 per test. RespriDX® is currently only covered by the Medicare Advantage program and our BarreGEN® assay is not reimbursed at all. Any future reduction from the current rate would have a material adverse effect on business and results of operations.

Although we have entered into contracts with certain third-party payers which establish 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 internal 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 (also known as the Affordable Care Act) provided coverage for patients, particularly in the individual market, who were previously either uninsured or faced high premiums. However, premiums for 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, the President of the United States 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 we lose the support of key opinion leaders, it may be difficult to establish products enabled by our Laboratory Information 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, molecular diagnostics is a new area of science, and we continue to focus and refine our efforts to sell, market and receive reimbursement for our products. We may not be able to market, sell, or distribute our existing products or other products we may develop effectively enough to support our planned growth.

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

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

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

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

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

Historically, for the time periods through December 2017, we recognized a significant portion of our revenue when the following four revenue recognition criteria were met: persuasive evidence of an arrangement existed; services have been rendered; the selling price was fixed or determinable; and collectability was reasonably assured. We have little visibility as to when we will receive payment for our molecular diagnostic tests because of our reliance on third party reimbursements, and we must appeal negative payment decisions, which delays collections. For molecular diagnostic tests performed where we have an agreed upon reimbursement rate or we are able to make a reasonable estimate of reimbursement at the time delivery is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to collect. We determined the amount we expect to collect based on a per payer, per contract or agreement basis. In situations where we 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 is compared to previous estimates and the contractual allowance is adjusted accordingly.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)” (or “ASC 606”) 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. Revenue recognized for the nine months ended September 30, 2018 was approximately \$ 1.3 million higher than it would have been without the adoption of ASC 606. 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.

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

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

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

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

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

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

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

If we are unable to compete successfully 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 by 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, the UPMC next-generation sequencing mutation panel marketed by CBLPath, Inc. could in the future be a significant competitor.

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.

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

PPACA made changes that significantly affected the pharmaceutical, medical device and clinical laboratory industries. 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, the President 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, the President signed PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. PAMA removed CMS's authority to adjust the CLFS based and established a new method for setting CLFS rates. Implementation of this new method for setting CLFS rates began in 2016. 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 Medicare Administrative Contractors (MACs) are in the process of implementing these revisions and we cannot predict whether these revisions will delay coverage for our test products, which could have a material negative impact on revenue.

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

We are subject to regulation by both the Federal government and the governments of the states in which we conduct our molecular diagnostics and bioinformatics business. 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 payors;
- 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 an internal 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 payors, including commercial payors and government payors, 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.

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

- multiple, conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent);
- testing of genetic material and reporting the results of such testing and other governmental approvals, permits, and licenses, or government delays in issuing such approvals, permits, and licenses;
- failure by us to obtain regulatory approvals for the manufacture, sale, and use of our products in various countries;
- additional, potentially relevant third-party intellectual property rights;
- complexities and difficulties in obtaining protection for and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with obtaining reimbursement from and managing multiple 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.

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 its 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 payor groups that were previously reported on a cash basis. For the year to date period, ended September 30, 2018, this impact was measured at an additional \$1.3 million recognized. 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. 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 approximately 88 employees. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress and growth of our business. Our future financial performance and our ability to sell our existing molecular diagnostic tests and develop and commercialize new molecular diagnostic tests and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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

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

- differences between the list price for our molecular diagnostic tests and the reimbursement rates of payers;
- compliance with complex Federal and State regulations related to billing Medicare;
- disputes among payers as to which party is responsible for payment;

- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

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

We rely on 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 January 1, 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.

Our failure to comply with fraud and abuse laws or payor regulations could result in our being excluded from participation in Medicare, Medicaid, or other governmental payor 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 payors 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 comprised. 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 THE ASSET SALE

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

We have agreed to indemnify Publicis Healthcare Solutions, Inc., or Publicis, the purchaser of assets of our CSO business, for damages resulting from or arising out of any inaccuracy or breach of any representation, warranty or covenant of ours in the Publicis Asset Purchase Agreement against any and all liabilities of ours not assumed by Publicis in the Publicis Asset Purchase Agreement and for certain other matters. Significant indemnification claims by Publicis could have a material adverse effect on our financial condition. We will not be obligated to indemnify Publicis for any breach of certain of the representations and warranties by us under the Publicis Asset Purchase Agreement until the aggregate amount of claims for indemnification exceed \$250,000. In the event that claims for indemnification exceed this threshold, we will be obligated to indemnify Publicis for any damages or loss resulting from such breach up to 25% of the total purchase price paid or due and payable by Publicis to us. Claims for indemnification for breaches of covenants made by us under the Publicis Asset Purchase Agreement and for breaches of representations and warranties classified as fundamental representations or any provision of the Publicis Asset Purchase Agreement relating to taxes will not be subject to the deductible or aggregate liability cap described above. The Publicis Asset Purchase Agreement also allows Publicis to withhold monies due against an earn-out payment if indemnification claims are asserted. In addition, under the Publicis Asset Purchase Agreement, we will retain all of our debts and liabilities not assumed by Publicis.

Although the indemnification requirement provided by the Publicis Asset Purchase Agreement was limited to an eighteen month term from its closing date of December 22, 2015, the Publicis Asset Purchase Agreement provides that regulatory claims resulting from wage and hour issues for former employees are subject to indemnification for the appropriate statute of limitations for such claims, if any.

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.

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. Under the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of the miRInform® pancreas platform for a period of ten years following a qualifying sale, on the future net sales of the miRInform® thyroid platform (i.e. ThyGeNEXT®) through August 13, 2024 and on certain other thyroid diagnostics tests including ThyraMIR® for a period of ten years following a qualifying sale. Under the CPRIT License Agreement, we are obligated to pay 5% of net sales on sales of certain diagnostic devices and the performance of services relating to thyroid cancer that incorporate technology developed and funded under an agreement between Asuragen and the Cancer Prevention and Research Institute of Texas, subject to a maximum deduction of 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. 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 pancreas cancer molecular diagnostic tests and other tests in development for thyroid cancer, and the sale of molecular diagnostic tests and the performance of certain services relating to thyroid cancer.

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

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technology. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. While we apply for patents 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. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

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

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

As is the case with other molecular diagnostics companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents of molecular diagnostics tests, like our molecular diagnostic tests in our PancraGEN® and 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. What constitutes a law of nature and a sufficient inventive concept remains uncertain, and it is possible that certain aspects of molecular diagnostics tests would be considered natural laws and, therefore, ineligible for patent protection. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending or issued claims will be patentable or upheld as valid as a result of such evolving standards. In addition, patents we own or license that issued before these recent cases may be subject to challenge in court or before the USPTO in view of these current legal standards. Accordingly, the evolving interpretation and application of patent laws in the United States governing the eligibility of diagnostics for patent protection may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. Changes in either the patent laws or in interpretations and application of patent laws may also diminish the value of our existing intellectual property or intellectual property that we continue to develop. We cannot predict the breadth of claims that may be allowed or enforceable in our patents or in third-party patents.

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

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties’ proprietary rights from time to time and some of these claims may lead to litigation. We cannot assume that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. No assurance can be given that other patent applications will not have priority over our patent applications. If third parties bring these proceedings against our patents, we could incur significant costs and experience management distraction. Litigation may be necessary for us to enforce our patents and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. 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 "IDXC." 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.

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 September 30, 2018, we had 71,632,656 shares of common stock and 5,000,000 shares of preferred stock available for issuance. As of September 30, 2018, we have reserved 2,533,510 shares of our common stock for issuance upon the exercise of outstanding awards under our stock incentive plan and 2,629,740 additional shares available for future grants of awards under our stock incentive plan as well as warrants for 13,542,148 shares of our common stock outstanding at prices ranging from a \$1.25 to \$4.69 per warrant share. Provided that we have a substantial 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 by 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:

- the commencement, delay, cancellation or completion of sales and marketing programs;
- regulatory developments;
- uncertainty about the net realizable value of sales of our tests; timing and amount of expenses for implementing new programs and accuracy of estimates of resources required for ongoing programs;
- adoption of and coverage and reimbursement for our tests;
- 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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$[●] million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's option to purchase additional shares of common stock. If the underwriter exercises its option to purchase additional shares of common stock in full, we estimate that our net proceeds will be approximately \$[●] million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for working capital, capital expenditures, business development and research and development expenditures, and acquisition of new technologies and businesses. From time to time we are engaged in discussions with third parties regarding potential business combinations, acquisitions, joint ventures, licenses, corporate alliances or other transactions. It is possible that a portion of the net proceeds of this offering will be employed in such a transaction.

The amounts and timing of our actual expenditures will depend on numerous factors, including our development and commercialization efforts with respect to our product candidates; business combination, acquisitions, joint ventures, licenses and corporate alliance activity; and the amount of cash used in our operations. We therefore cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds, if any, from this offering in a short term investment account maintained by our commercial bank in accordance with our bank covenants and board-approved investment policy.

PRICE RANGE OF COMMON STOCK

Our common stock trades on The Nasdaq Capital Market under the symbol “IDXG.” The last reported sale price for our common stock on January 24, 2019 was \$0.90 per share. As of January 24, 2019, we had approximately 183 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. A description of the common stock that we are issuing in this offering is set forth under the heading “*Description of Securities*” beginning on page S-50 of this prospectus supplement.

The following table sets forth for the periods indicated the high and low sale prices per share of our common stock as reported on The Nasdaq Capital Market, but as adjusted to reflect applicable reverse stock splits:

| | High | Low |
|---|-------------|------------|
| Fiscal Year ended December 31, 2016 | | |
| First Quarter | \$ 4.80 | \$ 1.90 |
| Second Quarter | \$ 6.40 | \$ 2.20 |
| Third Quarter | \$ 5.10 | \$ 1.50 |
| Fourth Quarter | \$ 19.80 | \$ 0.70 |
| Fiscal Year ended December 31, 2017 | | |
| First Quarter | \$ 14.25 | \$ 2.10 |
| Second Quarter | \$ 4.45 | \$ 0.80 |
| Third Quarter | \$ 1.77 | \$ 0.72 |
| Fourth Quarter | \$ 1.80 | \$ 0.90 |
| Fiscal Year ending December 31, 2018 | | |
| First Quarter | \$ 1.19 | \$ 0.85 |
| Second Quarter | \$ 0.99 | \$ 0.77 |
| Third Quarter | \$ 1.78 | \$ 0.88 |
| Fourth Quarter | \$ 1.74 | \$ 0.76 |
| | \$ 1.74 | \$ 0.76 |
| Fiscal Year ending December 31, 2019 | | |
| First Quarter (through January 24, 2019) | \$ 1.12 | \$ 0.80 |

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2018:

- on an actual basis; and
- on an as adjusted basis to give effect to this offering, based on a public offering price of \$[●] per share of common stock, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The information set forth in the following table should be read in conjunction with and is qualified in its entirety by our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and consolidated financial statements and notes thereto incorporated by reference in this prospectus supplement and the accompanying prospectus. See “*The Offering*” in this prospectus supplement for information relating to the expected number of shares of our common stock to be outstanding after this offering.

| | Actual as of September 30, 2018 (Unaudited) | As Adjusted for this Offering |
|---|--|--|
| Cash and cash equivalents | \$ 8,002 | \$ [●] |
| Total assets | 49,801 | [●] |
| Total liabilities | 13,772 | [●] |
| Stockholders’ equity | | |
| Preferred stock, par value \$0.01 per share; 5,000,000 shares authorized, no shares issued and outstanding | — | [●] |
| Common stock, par value \$0.01 per share; 100,000,000 shares authorized; 28,367,344 shares issued and 28,294,275 outstanding, actual; _____ issued and _____ outstanding, as adjusted to give effect to this offering | 283 | [●] |
| Additional paid-in capital | 174,878 | [●] |
| Accumulated deficit | (137,452) | [●] |
| Treasury stock, at cost (73,069 shares) | (1,680) | [●] |
| Total stockholders’ equity | 36,029 | [●] |
| Total liabilities and stockholders’ equity | <u>\$ 49,801</u> | <u>\$ [●]</u> |

DILUTION

Purchasers of common stock in this offering will experience immediate dilution to the extent of the difference between the public offering price per share of common stock, and the net tangible book value per share of common stock immediately after this offering.

Our net tangible book value as of September 30, 2018 was approximately \$5.4 million, or \$0.19 per share. Net tangible book value per share is determined by dividing the net of total tangible assets less total liabilities, by the aggregate number of shares of common stock outstanding as of September 30, 2018. After giving effect to the sale by us of [●] shares of common stock in this offering at a public offering price of \$[●] per share of common stock, and after deducting the underwriting discounts and commissions and estimated offering expenses, our as adjusted net tangible book value as of September 30, 2018 would have been approximately \$[●], or \$[●] per share of common stock. This represents an immediate increase in net tangible book value of \$[●] per share to our existing stockholders and an immediate dilution of \$[●] per share of common stock issued to the new investors purchasing securities in this offering.

The following table illustrates this per share dilution:

| | |
|--|--------|
| Public offering price per share of common stock | [●] |
| Net tangible book value per share as of September 30, 2018 | \$0.19 |
| Increase per share attributable to new investors after this offering | [●] |
| Net tangible book value per share after this offering | [●] |
| Dilution per share to new investors | [●] |

If the underwriter exercises in full its option to purchase an additional [] shares of common stock at the public offering price, less underwriting discounts and commissions, our as adjusted net tangible book value after this offering would be approximately \$[], or \$[] per share, representing an immediate increase in net tangible book value of \$[●] per share to our existing stockholders and an immediate dilution of \$[●] per share of common stock issued to the new investors purchasing securities in this offering.

The above table is based on 28,294,275 shares of common stock outstanding as of September 30, 2018 and excludes:

- 218,597 shares of common stock issuable upon the settlement of restricted stock units, or RSUs, issued to our employees and directors;
- 58,784 shares of common stock issuable upon settlement of stock appreciate rights, or SARs, issued to certain executive officers and members of senior management, at a weighted average exercise price of \$38.41 per share, of which 58,784 shares of common stock are vested and exercisable;
- 2,256,129 shares of common stock issuable upon exercise of outstanding options, issued to certain executive officers and directors, at a weighted average exercise price of \$1.46 per share, of which 1,319,194 shares of common stock are vested and exercisable;
- 2,629,740 shares of common stock reserved for future issuance under our Amended and Restated 2004 Stock Award and Incentive Plan;
- 13,542,148 shares of common stock issuable upon exercise of our outstanding warrants at prices ranging from a \$1.25 to \$4.69 per warrant share; and
- shares of common stock issuable upon the exercise of the undewriter's warrants to be issued to the underwriter or its designees in connection with this offering.

To the extent that options or warrants are exercised, new options are issued under our equity incentive plan, or we issue additional shares of common stock in the future, there may be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

UNDERWRITING

We have entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as underwriter, with respect to the common stock being offered hereby. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase from us the number of shares of our common stock set forth opposite its name below.

| Underwriter | Number of Shares |
|----------------------------|------------------|
| H.C. Wainwright & Co., LLC | |
| Total | |

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act of 1933, as amended (the “Securities Act”), and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Option to Purchase Additional Shares. We have granted to the underwriter an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares of common stock from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions.

Underwriting Discounts and Commissions. The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us.

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$[] and are payable by us. We have agreed to reimburse the expenses of the underwriter in the non-accountable sum of \$50,000, \$10,000 for the clearing expenses in connection with this offering and the other actual expenses of the underwriter, including its legal fees, up to \$100,000 in connection with this offering. We have also agreed to pay the underwriter a management fee equal to 1% of the aggregate gross proceeds in this offering.

| | Per Share | Total |
|--|-----------|-------|
| Public offering price | \$ | \$ |
| Underwriting discounts and commissions | \$ | \$ |
| Proceeds, before expenses | \$ | \$ |

The underwriter proposes to offer the shares of common stock to the public at the public offering price set forth on the cover of this prospectus. The underwriter may offer the shares of common stock to securities dealers at the public offering price less a concession not in excess of \$ per share. If all of the shares are not sold at the public offering price, the underwriter may change the offering price and other selling terms.

In addition, we have agreed to issue to the underwriter warrants to purchase up to _____ shares of common stock (representing 7% of the aggregate number of shares of common stock sold in this offering), at an exercise price of \$ _____ per share (representing 125% of the public offering price for a share of common stock to be sold in this offering). The underwriter warrants will be exercisable immediately and for three years from the date of the underwriting agreement. Pursuant to FINRA Rule 5110(g), the underwriter warrants and any shares issued upon exercise of the underwriter warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the underwriter or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have also agreed to pay the underwriter a tail fee equal to the cash and warrant compensation in this offering, if any investor, who was contacted or introduced to us by the underwriter during the term of engagement, provides us with capital in any public or private offering or other financing or capital raising transaction, during the twelve month period following expiration or termination of our engagement of the underwriter.

Discretionary Accounts. The underwriter does not intend to confirm sales of the shares to any accounts over which they have discretionary authority.

Stabilization. In connection with this offering, the underwriter may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions and penalty bids in connection with our common stock.

- Stabilizing transactions permit bids to purchase shares of common stock so long as the stabilizing bids do not exceed a specified maximum.
- Overallotment transactions involve sales by the underwriter of shares of common stock in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that it may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the overallotment option. The underwriter may close out any short position by exercising its overallotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Lock-Up Agreements. Each of our directors and executive officers have entered into lock-up agreements that prevent them from selling any shares of our common stock or any securities convertible into or exercisable or exchangeable into share of common stock, subject to certain exceptions, for a period of 90 days after the date of this prospectus. The underwriter, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release the common stock and other securities from lock-up agreements, the underwriter will consider, among other factors, the holder's reasons for requesting the release and the number of shares of common stock or other securities for which the release is being requested.

We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our common stock or any securities convertible into, or exercisable or exchangeable for, common stock, for 30 days following the date of this prospectus, or the Lock-up Period. This agreement does not apply to, in addition to certain customary exceptions, the issuance by us of any shares of capital stock or securities convertible into shares of capital stock pursuant to acquisitions, mergers or strategic transactions approved by a majority of our disinterested directors not for the purpose of raising capital, provided that such securities are issued as "restricted securities" (as defined in Rule 144 under the Securities Act) and carry no registration rights that require or permit the filing of any registration statement in connection therewith within the Lock-up Period.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriter and its respective affiliates, with a view to the final placement of the securities as contemplated in this prospectus supplement. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriter.

Electronic Offer, Sale and Distribution of Shares. A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

Other Relationships. The underwriter and its affiliates may in the future provide, various other investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

Offers outside the United States. Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the shares offered by this prospectus in any jurisdiction where action for that purpose is required. The shares offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such shares be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any shares offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

DESCRIPTION OF SECURITIES

Common Stock

On December 22, 2015, we filed a certificate of amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of common stock from 40,000,000 to 100,000,000, par value \$0.01 per share. As of January 24, 2019, 28,694,275 shares of our common stock were outstanding.

The following is qualified in its entirety by reference to our certificate of incorporation, as amended, and our amended and restated bylaws, and by the provisions of applicable law. A copy of our certificate of incorporation, as amended, and our amended and restated bylaws are included as exhibits to our most recent Annual Report on Form 10-K.

Holders of our common stock are entitled to one vote for each share on all matters submitted to a vote of stockholders, and do not have cumulative voting rights. Generally, in matters other than the election of directors, the affirmative vote of a majority of the votes cast authorizes such an action, except where Delaware General Corporation Law prescribes a different percentage of votes or a different exercise of voting power. For the election of directors, directors are elected by a plurality of the votes of the shares present in person or represented by proxy and entitled to vote. Holders of our common stock are entitled to receive, as, when and if declared by our board of directors from time to time, such dividends and other distributions in cash, stock or property from our assets or funds legally available for such purposes, subject to any preferential dividend or other rights of any then outstanding preferred stock.

No preemptive, conversion, or other subscription rights apply to our common stock. All outstanding shares of our common stock are fully paid and non-assessable. In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets available for distribution, subject to any preferential or other rights of any then outstanding preferred stock. The voting, dividend and liquidation rights of the holders of our common stock are subject to and qualified by the rights of the holders of the preferred stock.

Anti-Takeover Effects of Provisions of Our Outstanding Warrants

Certain provisions of certain of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. Such warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under such warrants. Further, such warrants provide that, in the event of certain transactions constituting “fundamental transactions,” with some exception, holders of such warrants will have the right, at their option, to require us to repurchase such warrants at a price described in such warrants. These and other provisions of such warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus supplement is being passed upon for us by Pepper Hamilton LLP, New York, New York. Haynes and Boone, LLP, New York, New York is acting as counsel for the underwriter in connection with the shares of common stock offered hereby.

EXPERTS

The financial statements and schedule of Interpace Diagnostics Group, Inc. as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 incorporated by reference in this prospectus supplement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement and the accompanying prospectus are part of the registration statement on Form S-3 we filed with the SEC under the Securities Act and do not contain all the information set forth in the registration statement. Whenever a reference is made in this prospectus supplement and the accompanying prospectus to any of our contracts, agreements or other documents, the reference may not be complete and you should refer to the exhibits that are a part of the registration statement or the exhibits to the reports or other documents incorporated herein by reference for a copy of such contract, agreement or other document. Because we are subject to the information and reporting requirements of the Exchange Act, we file or furnish, as applicable, annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains an Internet website at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers that file or furnish, as applicable, electronically with the SEC. The documents we file or furnish, as applicable, with the SEC are accessible through the Internet at that website. Our reports on Forms 10-K, 10-Q and 8-K, and amendments to those reports, are also available for download, free of charge, as soon as reasonably practicable after these reports are filed with or furnished to, as applicable, the SEC, at our website at www.interpacediagnostics.com. The content contained in, or that can be accessed through, our website is not a part of this prospectus. In addition, you may request copies of these documents filed or furnished, as applicable, at no cost, by writing or telephoning us at the following address or telephone number:

Interpace Diagnostics Group, Inc.
Morris Corporate Center I, Building C
300 Interpace Parkway, Parsippany, NJ 07054
(855) 776-6419

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed on March 23, 2018;
- our Definitive Proxy Statement on Schedule 14A filed on April 30, 2018;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018 filed on May 15, 2018;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018 filed on August 9, 2018;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2018 filed on November 14, 2018;
- our Current Reports on Form 8-K filed on March 13, 2018, May 7, 2018, June 14, 2018, July 31, 2018 and December 11, 2018; and
- the description of our common stock contained in our Form 8-A that we filed with the SEC on May 13, 1998 pursuant to the Exchange Act and any amendment or report filed for the purpose of further updating such description.

We also incorporate by reference any future filings (except as specifically enumerated above, other than any filings or portions of such reports that are not deemed “filed” under the Exchange Act in accordance with the Exchange Act and applicable SEC rules, including current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus supplement forms a part, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus supplement and will become a part of this prospectus supplement from the date that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus supplement. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

To obtain copies of these filings, see “Where You Can Find More Information” on page S-51 of this prospectus.

PROSPECTUS

\$50,000,000

INTERPACE DIAGNOSTICS GROUP, INC.

Common Stock
Preferred Stock
Debt Securities
Warrants
Rights
Units

We may offer and sell, from time to time in one or more offerings, up to \$50,000,000 of our common stock, preferred stock, debt securities, warrants and rights, or any combination of these securities, and/or units consisting of one or more of these securities. We may also offer common stock or preferred stock upon conversion of debt securities and common stock upon conversion of preferred stock. All of the securities listed above may be sold separately or as units with other securities.

This prospectus describes some of the general terms that may apply to these securities. When we decide to sell a particular class or series of securities, we will provide specific terms of the offered securities in one or more prospectus supplements. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings.

The prospectus supplement, any free writing prospectus and any documents incorporated by reference, may also add, update or change information contained in or incorporated by reference into this prospectus. However, no prospectus supplement shall offer a security that is not registered and described in this prospectus at the time of its effectiveness. You should read this prospectus and any prospectus supplement, as well as the documents incorporated by reference or deemed to be incorporated by reference into this prospectus, and any free writing prospectus carefully before you invest. This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.

Our common stock is listed on The NASDAQ Capital Market under the symbol "IDYG." Each prospectus supplement will contain information, where applicable, as to our listing on any securities exchange of the securities covered by the prospectus supplement. The aggregate market value of our outstanding common stock held by non-affiliates was approximately \$47,968,603 based on 28,594,275 shares of outstanding common stock, of which 41,535 shares are held by affiliates, and a price of \$1.68 per share, which was the last reported sale price of our common stock as quoted on The NASDAQ Capital Market on October 1, 2018. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered in a public primary offering with a value exceeding more than one-third of our public float (the market value of our common stock held by our non-affiliates) in any 12 calendar month period so long as our public float remains below \$75,000,000. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the prior 12 calendar month period that ends on and includes the date of this prospectus. As of October 1, 2018, one-third of our public float is equal to approximately \$15,989,534.

These securities may be sold by us directly to purchasers, through dealers or agents, or to or through underwriters, or through a combination of these methods. See "Plan of Distribution" in this prospectus. We may also describe the plan of distribution for any particular offering of our securities in a prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

An investment in our securities involves a high degree of risk. See the section entitled "Risk Factors" on page 3 of this prospectus and in our most recent Annual Report on Form 10-K and in any Quarterly Report on Form 10-Q, as well as in any prospectus supplement or free writing prospectus related to these specific offerings.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required or related free writing prospectuses. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 19, 2018

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ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement that we filed with the Securities and Exchange Commission (“SEC”) using a “shelf” registration process. Under this shelf registration process, we may offer from time to time securities described in this prospectus having a maximum aggregate offering price of \$50,000,000 in one or more offerings. Each time we offer securities, we will prepare and file with the SEC a prospectus supplement or information that is incorporated by reference into this prospectus that describes the specific amounts, prices and terms of the securities we offer. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings and securities. The prospectus supplement also may add, update or change information contained in this prospectus or the documents incorporated herein by reference. You should read carefully this prospectus, any applicable prospectus supplement and any related free writing prospectus together with additional information described below under the caption “Where You Can Find More Information.”

This prospectus does not contain all the information provided in the Registration Statement we filed with the SEC. For further information about us or our securities offered hereby, you should refer to that Registration Statement, which you can obtain from the SEC as described below under “Where You Can Find More Information.”

You should rely only on the information contained or incorporated by reference in this prospectus, any prospectus supplement and any related free writing prospectus. Unless otherwise specified, references to any free writing prospectus refer to a free writing prospectus that we have authorized to be provided to you in connection with an offering. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, any prospectus supplement, any related free writing prospectus as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date of those documents only. Our business, financial condition, results of operations and prospects may have changed since those dates.

We may sell securities through underwriters or dealers, through agents, directly to purchasers or through any combination of these methods. We and our agents reserve the sole right to accept or reject in whole or in part any proposed purchase of securities. The prospectus supplement, which we will prepare and file with the SEC each time we offer securities, will set forth the names of any underwriters, agents or others involved in the sale of securities, and any applicable fee, commission or discount arrangements with them. See “Plan of Distribution.”

In this prospectus, unless otherwise indicated, the “Registrant,” “our company,” “we,” “us” or “our” refer to Interpace Diagnostics Group, Inc., a Delaware corporation and its consolidated subsidiaries.

PROSPECTUS SUMMARY

This prospectus summary highlights certain information about our company and other information contained elsewhere in this prospectus or in documents incorporated by reference. This summary does not contain all of the information that you should consider before making an investment decision. You should carefully read the entire prospectus, any prospectus supplement, and any related free writing prospectus, including the section entitled “Risk Factors” and the documents incorporated by reference into this prospectus, before making an investment decision.

The Offering

This prospectus is part of a Registration Statement that we filed with the SEC utilizing a shelf registration process. Under this shelf registration process, we may sell any combination of:

- common stock;
- preferred stock;
- debt securities, in one or more series;
- warrants to purchase any of the securities listed above;
- rights to purchase common stock, preferred stock or warrants; and/or
- units consisting of one or more of the foregoing

in one or more offerings up to a total dollar amount of \$50,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that specific offering and include a discussion of any risk factors or other special considerations that apply to those securities. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus, any prospectus supplement and any related free writing prospectus together with the additional information described under the heading “Where You Can Find More Information.”

Our 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 molecular diagnostic tests and related first line assays principally focused on early detection of patients at high risk of cancer and leverage the latest technology and personalized medicine for improved patient diagnosis and management. Our tests and services provide mutational analysis of genetic material contained in suspect cysts, nodules and lesions that helps physicians risk-stratify thyroid, pancreatic, and other cancers to better inform treatment decisions. The molecular diagnostic tests we offer enable healthcare providers to avoid unnecessary surgeries and better assess the risk of cancer progression in their patients. We currently have four commercialized molecular diagnostic assays in the marketplace for which we are receiving reimbursement: PancreGEN[®], which is a pancreatic cyst and pancreaticobiliary solid lesion molecular test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform; ThyGeNEXT[®], which is an oncogenic mutation panel that helps identify malignant thyroid nodules; ThyraMIR[®], which assess thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDX[®], launched in September 2017, which is a molecular 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 molecular 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 \$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 coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our four commercialized innovative tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. BarreGen® is a major pipeline product, built on the PathFinderTG® platform which we believe is synergistic to our capabilities and potentially is a significant product opportunity in the gastrointestinal market, which is one of the sectors in which we operate.

Corporate Information

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

RISK FACTORS

Investing in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider and evaluate the specific factors discussed under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 filed on March 23, 2018, with the SEC, and any updates described in subsequent Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. The risks and uncertainties we have described are not the only risks that we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of these known or unknown risks might cause you to lose all or part of your investment.

See also the statements contained under the heading "Forward-Looking Statements."

FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are intended to qualify for the "safe harbor" created by those sections. In addition, we may make forward-looking statements in other documents filed with or furnished to the SEC, and our management and other representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others.

Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as "can," "may," "could," "should," "assume," "forecasts," "believe," "designated to," "will," "expect," "plan," "anticipate," "estimate," "potential," "position," "predicts," "strategy," "guidance," "intend," "seek," "budget," "project" or "continue," or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, forward-looking statements involve risks and uncertainties and our actual results and the timing of certain events could differ materially from those discussed in forward-looking statements as a result of certain factors, including those set forth under "Risk Factors" and "Our Company" in this prospectus and the documents incorporated herein by reference.

Accordingly, our actual results and the timing of certain events may differ materially from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth in this prospectus under “Risk Factors” and those set forth from time to time in our other filings with the SEC.

All forward-looking statements and risk factors included in this prospectus and the documents incorporated herein by reference are made as of the date hereof, based on information available to us as of such date, and we assume no obligations to update any forward-looking statement or risk factor, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Forward-looking statements may include our plans and objectives for future operations, including plans and objectives relating to our products and our future economic performance, projections, business strategy and timing and likelihood of success. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our technologies, all of which are difficult or impossible to predict accurately and many of which are beyond our control.

Any of the assumptions underlying the forward-looking statements contained in this prospectus could prove inaccurate and, therefore, we cannot assure you that the results contemplated in any of such forward-looking statements will be realized. Based on the significant uncertainties inherent in these forward-looking statements, the inclusion of any such statement should not be regarded as a representation or as a guarantee by us that our objectives or plans will be achieved, and we caution you against relying on any of the forward-looking statements contained herein.

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

- our ability to profitably grow our business, including our ability to finance our business on acceptable terms and successfully compete in the market;
- our ability to obtain broad adoption of and ability to grow or continue to secure sufficient levels of reimbursement for our molecular diagnostic tests in a changing reimbursement environment, including obtaining clinical data to support sufficient levels of reimbursement;
- whether we are able to successfully utilize our operating experience to sell our molecular diagnostic tests;
- our limited operating history as a molecular diagnostics company;
- our dependence on a concentrated selection of payers for our molecular diagnostic tests;
- the demand for our molecular diagnostic tests from physicians and patients;
- our reliance on our internal sales forces for business expansion;
- our dependence on third parties for the supply of some of the materials used in our molecular diagnostic tests;
- our ability to scale our operations, testing capacity and processing technology;
- our ability to compete successfully with companies with greater financial resources;
- our ability to obtain sufficient data and samples to cost effectively and timely perform sufficient clinical trials in order to support our current and future products;
- product liability claims against us;
- patent infringement claims against us;
- our involvement in current and future litigation against us or our ability to collect on judgements found in our favor;
- 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;
- the effect of potential adverse findings resulting from regulatory audits of our billing practices and the impact such results could have on our business;
- our exposure to environmental liabilities as a result of our business;

- the susceptibility of our information systems to security breaches, loss of data and other disruptions;
- our ability to effectively maintain, upgrade and integrate our information systems, including third-party billing providers, as needed;
- our ability to enter into effective electronic data interchange arrangements with our customers and third-party payers;
- our billing practices and our ability to collect on claims for the sale of our molecular diagnostic tests;
- our dependence on third-party medical billing providers to operate effectively without delays, data loss, or other disruptions;
- our ability to attract and retain qualified sales representatives and other key employees and management personnel;
- competition in the segment of the molecular diagnostics industry in which we operate or expect to operate;
- our ability to obtain additional funding when necessary, in order to implement our business models and strategies;
- the results of any future impairment testing for other intangible assets;
- our ability to successfully identify, complete and integrate any future acquisitions and the effects of any such items on our revenues, profitability and ongoing business;
- our compliance with our license agreements and our ability to protect and defend our intellectual property rights;
- our ability to maintain our listing with The Nasdaq Capital Market ("NASDAQ");
- the effect of adverse weather conditions, such as hurricanes and floods, on our business;
- failure of third-party service providers to perform their obligations to us;
- the volatility of our stock price and fluctuations in our quarterly and annual revenues and earnings;
- our ability to obtain and maintain sufficient laboratory space to meet our processing needs as well as our ability to pass regulatory inspections and continue to be certified Clinical Laboratory Improvement Amendments ("CLIA") laboratories and be certified by the College of American Pathologists ("CAP");
- our ability to commercially leverage our bioinformatics data with pharmaceutical and other potential partners in new revenue lines;
- the ability to obtain or maintain supportive "guidelines" from trade and/or therapeutic related organizations focused on the clinical efficacy and utility of molecular diagnostics in our areas of focus;
- determination that our Advanced Diagnostic Laboratory Tests (ADLTs) have become affected by the pricing provisions of the Protecting Access to Medicare Act of 2014 which could result in an across the board reduction in our reimbursement rates;
- our ability to continue to develop and support our partially customized Laboratory Information System (LIMS), which is our automated basis of managing operations, storing data and customer information; and
- Our ability to successfully and profitably be able to integrate acquisitions of companies and/or products.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly as set forth and incorporated by reference in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. In addition, these statements speak only as of the date of this prospectus and, except as may be required by law, we undertake no obligation to revise or update publicly any forward-looking statements for any reason.

You should read this prospectus and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. Before making an investment decision, you should carefully consider the risk factors discussed and incorporated by reference in this prospectus.

USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds from the sale of the securities covered by this prospectus for general corporate purposes, which may include, but is not limited to, working capital, capital expenditures, business development and research and development expenditures and acquisitions of new technologies or businesses. The precise amount, use and timing of the application of such proceeds will depend upon our funding requirements and the availability and cost of other capital. Additional information on the use of net proceeds from an offering of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.

RATIO OF EARNINGS TO FIXED CHARGES

If we offer debt securities and/or preference equity securities under this prospectus and at the time of such offer we are no longer a smaller reporting company, then we will, at that time, provide a ratio of earnings to fixed charges and/or ratio of combined fixed charges and preference dividends to earnings, respectively, in the applicable prospectus supplement for such offering.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We do not anticipate paying any cash dividends to stockholders in the foreseeable future. In addition, any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as our board of directors deem relevant.

DESCRIPTIONS OF THE SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with any applicable prospectus supplement or free writing prospectus, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement or free writing prospectus relating to a particular offering the specific terms of the securities offered by that prospectus supplement or free writing prospectus. We will indicate in the applicable prospectus supplement if the terms of the securities differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, regarding material United States federal income tax considerations relating to the securities.

We may sell from time to time, in one or more offerings:

- shares of our common stock;
- shares of our preferred stock;
- debt securities;
- warrants to purchase any of the securities listed above;
- rights to purchase common stock, preferred stock or warrants; and/or
- units consisting of one or more of the foregoing.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

CAPITAL STOCK

General

The following description of common stock and preferred stock, together with the additional information we include in any applicable prospectus supplement or free writing prospectus, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus but is not complete. For the complete terms of our common stock and preferred stock, please refer to our certificate of incorporation, as may be amended from time to time, any certificates of designation for our preferred stock, that may be authorized from time to time, and our amended and restated bylaws, as amended from time to time. The Delaware General Corporation Law (“DGCL”) may also affect the terms of these securities. While the terms we have summarized below will apply generally to any future common stock or preferred stock that we may offer, we will describe the specific terms of any series of these securities in more detail in the applicable prospectus supplement or free writing prospectus. If we so indicate in a prospectus supplement or free writing prospectus, the terms of any common stock or preferred stock we offer under that prospectus supplement may differ from the terms we describe below.

As of October 1, 2018, our authorized capital stock consists of 100,000,000 shares of common stock, par value \$0.01 per share, of which 28,594,275 shares were issued and outstanding, held by approximately 179 stockholders of record and 5,000,000 shares of preferred stock, par value \$0.01 per share, of which no shares were issued and outstanding. The actual number of stockholders is greater than the number of stockholders of record and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities. In addition, as of October 1, 2018, we had options to purchase 2,256,129 shares of common stock issued and outstanding. The authorized and unissued shares of common stock and preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors will not seek stockholder approval for the issuance and sale of our common stock.

Common Stock

Holders of our common stock are entitled to one vote for each share on all matters submitted to a vote of stockholders, and do not have cumulative voting rights. Generally, in matters other than the election of directors, the affirmative vote of a majority of the votes cast authorizes such an action, except where Delaware General Corporation Law prescribes a different percentage of votes or a different exercise of voting power. For the election of directors, directors are elected by a plurality of the votes of the shares present in person or represented by proxy and entitled to vote. Holders of our common stock are entitled to receive, as, when and if declared by our board of directors from time to time, such dividends and other distributions in cash, stock or property from our assets or funds legally available for such purposes, subject to any preferential dividend or other rights of any then outstanding preferred stock.

No preemptive, conversion, or other subscription rights apply to our common stock. All outstanding shares of our common stock are fully paid and non-assessable. In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets available for distribution, subject to any preferential or other rights of any then outstanding preferred stock. The voting, dividend and liquidation rights of the holders of our common stock are subject to and qualified by the rights of the holders of the preferred stock.

Our common stock is listed on The NASDAQ Capital Market under the symbol "IDXG." The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Preferred Stock

Our board of directors has the authority, without action by our stockholders, to designate and issue preferred stock in one or more classes or one or more series of stock within any class and to designate the rights, preferences and privileges of each class or series, which may be greater than the rights of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until our board of directors determines the specific rights of the holders of such preferred stock. However, the effects might include, among other things:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing a change in our control without further action by the stockholders.

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, as Amended, Our Amended and Restated Bylaws and Delaware Law

Provisions of Delaware law and our certificate of incorporation, as amended, and amended and restated bylaws could make the following more difficult:

- the acquisition of us by means of a tender offer;
- the acquisition of us by means of a proxy contest or otherwise; or
- the removal of our incumbent officers and directors.

These provisions, summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging such proposals because negotiation of such proposals could result in an improvement of their terms:

- *Classified Board of Directors.* Under our certificate of incorporation, as amended, our board of directors is divided into three classes of directors serving staggered three-year terms which means that the entire board of directors will not be up for election each year.
- *Stockholder meetings.* Under our certificate of incorporation, as amended, only our board of directors, the chairman of our board of directors and the chief executive officer (or the president if there is no chief executive officer) may call special meetings of stockholders.
- *Preferred stock.* Under our certificate of incorporation, as amended, we are authorized to issue 5,000,000 shares of preferred stock, which could make it more difficult for a third party to acquire voting control of our company.
- *Requirements for advance notification of stockholder proposals and director nominations.* Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders.
- *No action by written consent.* Under our certificate of incorporation, as amended, stockholders may only take action at an annual or special meeting of stockholders and may not act by written consent when our capital stock is registered under Section 12 of the Exchange Act or any similar successor statute.
- *Supermajority voting.* In order to amend certain provisions of our certificate of incorporation, as amended, including the prohibition on action by written consent of stockholders and the provision relating to calling of a special meeting of stockholders, the affirmative vote of holders of at least 75% of our outstanding capital stock is required.
- *No cumulative voting.* Our certificate of incorporation, as amended, does not provide for cumulative voting.

Anti-Takeover Effects of Delaware Law

Section 203 of the DGCL (“[Section 203](#)”) provides that, subject to exceptions specified therein, an “interested stockholder” of a Delaware corporation shall not engage in any “business combination,” including general mergers or consolidations or acquisitions of additional shares of the corporation, with the corporation for a three-year period following the time that such stockholder becomes an interested stockholder unless:

- prior to such time, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an “interested stockholder,” the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced (excluding specified shares); or
- on or subsequent to such time, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specified business combinations proposed by an interested stockholder following the announcement or notification of one of specified transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation’s directors, if such transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors. The restrictions described above also do not apply to specified business combinations with a person who is an “interested stockholder” prior to the time when the corporation’s common stock is listed on a national securities exchange, so these restrictions would not apply to a business combination with any person who is one of our stockholders prior to this offering.

Except as otherwise specified in Section 203, an “interested stockholder” is defined to include:

- any person that is the owner of 15% or more of the outstanding voting stock of the corporation, or is an affiliate or associate of the corporation and was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the date of determination; and
- the affiliates and associates of any such person.

Under some circumstances, Section 203 makes it more difficult for a person who is an interested stockholder to effect various business combinations with us for a three-year period.

Limitation of Liability

Our certificate of incorporation, as amended, limits the liability of directors and officers to the fullest extent permitted by Delaware law and require that we indemnify our directors and officers to such extent, except that we will not be obligated to indemnify any such person for claims brought voluntarily and not by way of defense, or for any amounts paid in settlement of an action without our prior written consent.

In addition, our certificate of incorporation, as amended, provides that a director is not personally liable to us or our stockholders for monetary damages for breach of his or her fiduciary duty as director, except for liability (i) for any breach of the director’s duty of loyalty to us or our stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for willful or negligent conduct in paying dividends or repurchasing stock out of any other lawfully available funds, or (iv) for any transaction from which the director derives an improper personal benefit.

WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplement or free writing prospectus, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and any related warrant agreement and warrant certificate. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the specific terms of any series of warrants in more detail in the applicable prospectus supplement or free writing prospectus. If we indicate in the prospectus supplement or free writing prospectus, the terms of any warrants offered under that prospectus supplement may differ from the terms described below.

We may issue the warrants under a warrant agreement which we may enter into with a warrant agent to be selected by us. We use the term “warrant agreement” to refer to any of these warrant agreements. We use the term “warrant agent” to refer to the warrant agent under any of these warrant agreements. The warrant agent will act solely as an agent of ours in connection with the warrants and will not act as an agent for the holders or beneficial owners of the warrants.

The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement applicable to a particular series of warrants. We urge you to read the applicable prospectus supplement and any free writing prospectus related to the warrants that we sell under this prospectus, as well as the complete warrant agreements that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement or free writing prospectus the terms relating to a series of warrants. If warrants for the purchase of common stock or preferred stock are offered, the prospectus supplement or a free writing prospectus will describe the following terms, to the extent applicable:

- the offering price and the aggregate number of warrants offered;
- the total number of shares that can be purchased if a holder of the warrants exercises them and, in the case of warrants for preferred stock, the designation, total number and terms of the series of preferred stock that can be purchased upon exercise;

- the designation and terms of any series of preferred stock with which the warrants are being offered and the number of warrants being offered with each share of common stock or preferred stock;
- the number of shares of common stock or preferred stock that can be purchased if a holder exercises the warrant and the price at which such common stock or preferred stock may be purchased upon exercise, including, if applicable, any provisions for changes to or adjustments in the exercise price and in the securities or other property receivable upon exercise;
- the terms of any rights to redeem or call, or accelerate the expiration of, the warrants;
- the date on which the right to exercise the warrants begins and the date on which that right expires;
- federal income tax consequences of holding or exercising the warrants; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the warrants.

If warrants for the purchase of debt securities are offered, the prospectus supplement or a free writing prospectus will describe the following terms, to the extent applicable:

- the offering price and the aggregate number of warrants offered;
- the currencies in which the warrants are being offered;
- the designation, aggregate principal amount, currencies, denominations and terms of the series of debt securities that can be purchased if a holder exercises a warrant;
- the designation and terms of any series of debt securities with which the warrants are being offered and the number of warrants offered with each such debt security;
- the principal amount of the series of debt securities that can be purchased if a holder exercises a warrant and the price at which and currencies in which such principal amount may be purchased upon exercise;
- the terms of any rights to redeem or call, or accelerate the expiration of, the warrants;
- the date on which the right to exercise the warrants begins and the date on which such right expires;
- federal income tax consequences of holding or exercising the warrants; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the warrants.

If the warrants are offered attached to common stock, preferred stock or debt securities, the prospectus supplement or a free writing prospectus will also describe the date on and after which the holder of the warrants can transfer them separately from the related common stock, series of preferred stock or debt securities.

A holder of warrant certificates may exchange them for new certificates of different denominations, present them for registration of transfer and exercise them at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement or free writing prospectus. Until any warrants to purchase debt securities are exercised, the holder of the warrants will not have any of the rights of holders of the debt securities that can be purchased upon exercise, including any rights to receive payments of principal, premium or interest on the underlying debt securities or to enforce covenants in the applicable indenture. Until any warrants to purchase common stock or preferred stock are exercised, holders of the warrants will not have any rights of holders of the underlying common stock or preferred stock, including any rights to receive dividends or to exercise any voting rights, except to the extent set forth under “—Warrant Adjustments” below.

Exercise of Warrants

Each holder of a warrant is entitled to purchase the principal amount of debt securities or number of shares of common stock or preferred stock, as the case may be, at the exercise price described in the applicable prospectus supplement or free writing prospectus. After the close of business on the day when the right to exercise terminates (or a later date if we extend the time for exercise), unexercised warrants will become void.

A holder of warrants may exercise them by following the general procedure outlined below:

- delivering to the warrant agent the payment required by the applicable prospectus supplement or free writing prospectus to purchase the underlying security, which could include cashless exercise;
- properly completing and signing the reverse side of the warrant certificate representing the warrants; and
- delivering the warrant certificate representing the warrants to the warrant agent within five business days of the warrant agent receiving payment of the exercise price.

If you comply with the procedures described above, your warrants will be considered to have been exercised when the warrant agent receives payment of the exercise price, subject to the transfer books for the securities issuable upon exercise of the warrant not being closed on such date. After you have completed those procedures and subject to the foregoing, we will, as soon as practicable, issue and deliver to you the debt securities, common stock or preferred stock that you purchased upon exercise. Holders of warrants will be required to pay any tax or governmental charge that may be imposed in connection with transferring the underlying securities in connection with the exercise of the warrants.

Amendments and Supplements to the Warrant Agreements

We may amend or supplement a warrant agreement without the consent of the holders of the applicable warrants to cure ambiguities in the warrant agreement, to cure or correct a defective provision in the warrant agreement, or to provide for other matters under the warrant agreement that we and the warrant agent deem necessary or desirable, so long as, in each case, such amendments or supplements do not materially and adversely affect the interests of the holders of the warrants.

Warrant Adjustments

Unless the applicable prospectus supplement or free writing prospectus states otherwise, the exercise price of, and the number of securities covered by, a common stock warrant or preferred stock warrant will be adjusted proportionately if we subdivide or combine our common stock or preferred stock, as applicable. In addition, unless the prospectus supplement or a free writing prospectus states otherwise, if we:

- issue capital stock or other securities convertible into or exchangeable for common stock or preferred stock, or any rights to subscribe for, purchase or otherwise acquire any of the foregoing, as a dividend or distribution to holders of our common stock or preferred stock;
- pay any cash to holders of our common stock or preferred stock other than a cash dividend paid out of our current or retained earnings or other than in accordance with the terms of the preferred stock;
- issue any evidence of our indebtedness or rights to subscribe for or purchase our indebtedness to holders of our common stock or preferred stock; or
- issue common stock or preferred stock or additional stock or other securities or property to holders of our common stock or preferred stock by way of spinoff, split-up, reclassification, combination of shares or similar corporate rearrangement,

then the holders of common stock warrants and preferred stock warrants, as applicable, will be entitled to receive upon exercise of the warrants, in addition to the securities otherwise receivable upon exercise of the warrants and without paying any additional consideration, the amount of stock and other securities and property such holders would have been entitled to receive had they held the common stock or preferred stock, as applicable, issuable under the warrants on the dates on which holders of those securities received or became entitled to receive such additional stock and other securities and property.

Except as stated above or as otherwise set forth in the applicable prospectus supplement or free writing prospectus, the exercise price and number of securities covered by a common stock warrant and preferred stock warrant, and the amounts of other securities or property to be received, if any, upon exercise of those warrants, will not be adjusted or provided for if we issue those securities or any securities convertible into or exchangeable for those securities, or securities carrying the right to purchase those securities or securities convertible into or exchangeable for those securities.

Holders of common stock warrants and preferred stock warrants may have additional rights under the following circumstances:

- certain reclassifications, capital reorganizations or changes of our common stock or preferred stock, as applicable;
- certain share exchanges, mergers, or similar transactions involving us and which result in changes of our common stock or preferred stock, as applicable; or
- certain sales or dispositions to another entity of all or substantially all of our property and assets.

If one of the above transactions occurs and holders of our common stock or preferred stock are entitled to receive stock, securities or other property with respect to or in exchange for their securities, the holders of the common stock warrants and preferred stock warrants then outstanding, as applicable, will be entitled to receive upon exercise of their warrants the kind and amount of shares of stock and other securities or property that they would have received upon the applicable transaction if they had exercised their warrants immediately before the transaction.

Enforceability of Rights by Holders of Warrants

Any warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action the holder's right to exercise, and receive the securities purchasable upon exercise of, its warrants in accordance with their terms.

Warrant Agreement Will Not Be Qualified Under Trust Indenture Act

No warrant agreement will be qualified as an indenture, and no warrant agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of warrants issued under a warrant agreement will not have the protection of the Trust Indenture Act with respect to their warrants.

Governing Law

Each warrant agreement and any warrants issued under the warrant agreements will be governed by New York law.

Calculation Agent

Any calculations relating to warrants may be made by a calculation agent, an institution that we appoint as our agent for this purpose. The prospectus supplement or free writing prospectus for a particular warrant will name the institution that we have appointed to act as the calculation agent for that warrant as of the original issue date for that warrant, if any. We may appoint a different institution to serve as calculation agent from time to time after the original issue date without the consent or notification of the holders. The calculation agent's determination of any amount of money payable or securities deliverable with respect to a warrant will be final and binding in the absence of manifest error.

Outstanding Warrants

As of October 1, 2018, we had outstanding warrants to purchase 13,542,148 shares of our common stock at a weighted average exercise price of \$1.63.

Warrants issued January 25, 2017 to purchase 855,000 shares of our common stock at an exercise price of \$4.69 expire in June 2022.

Warrants issued March 22, 2017 to purchase 100,000 shares of our common stock at an exercise price of \$4.69 expire in June 2022.

Warrants issued June 21, 2017 to purchase 535,000 shares of our common stock at an exercise price of \$1.32 expire in June 2022.

Warrants issued June 21, 2017 to purchase 8,702,148 shares of our common stock at an exercise price of \$1.25 expire in June 2022.

Warrants issued August 6, 2017 to purchase 150,000 shares of our common stock at an exercise price of \$1.25 expire in August 2020.

Warrants issued October 12, 2017 to purchase 3,200,000 shares of our common stock at an exercise price of \$1.80 expire in August 2020.

DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplement or free writing prospectus, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will generally apply to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement or a free writing prospectus. As of the date of this prospectus, we have no outstanding registered debt securities. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below.

We will issue senior notes under a senior indenture, which we will enter into with the trustee to be named in the senior indenture. We will issue subordinated notes under a subordinated indenture, which we will enter into with the trustee to be named in the subordinated indenture. We have filed forms of these documents as exhibits to the Registration Statement of which this prospectus is a part. We use the term “indentures” to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939, unless an exemption from the qualification provisions is applicable. References to the Trust Indenture Act of 1939 include all amendments thereto. We use the term “debenture trustee” to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the senior notes, the subordinated notes and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities, and all supplements thereto. We urge you to read the applicable prospectus supplement and any free writing prospectus related to the debt securities that we may sell under this prospectus, as well as the complete indentures that contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior and the subordinated indentures are identical.

General

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement or free writing prospectus.

We will describe in the applicable prospectus supplement or free writing prospectus the terms of the series of debt securities being offered, including

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;
- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;
- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;
- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depositary for such global security or securities;
- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or the holders' option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;
- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;
- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;
- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;

- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;
- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;
- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;
- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;
- any restrictions on transfer, sale or assignment of the debt securities of the series; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement or free writing prospectus the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than a subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Events of Default under the Indenture

Unless we provide otherwise in the prospectus supplement or free writing prospectus applicable to a particular series of debt securities, the following are events of default under the indenture with respect to any series of debt securities that we may issue:

- if we fail to pay any installment of interest on any series of debt securities, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of interest for this purpose;
- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; provided, however, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of principal or premium, if any;

- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indenture, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

- the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity, to the debenture trustee to institute the proceeding as trustee; and
- the debenture trustee does not institute the proceeding and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters, including:

- to fix any ambiguity, defect or inconsistency in the indenture or in the debt securities of any series;
- to comply with the provisions described above under “Description of Debt Securities—Consolidation, Merger or Sale;”
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities;
- to add to our covenants, restrictions, conditions or provisions such new covenants, restrictions, conditions or provisions for the benefit of the holders of all or any series of debt securities, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred upon us in the indenture;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to make any change that does not adversely affect the interests of any holder of debt securities of any series in any material respect;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided above under “Description of Debt Securities—General” to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment under any indenture by a successor trustee; or
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of the series of debt securities;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except that the following obligations, among others survive until the maturity date or the redemption date:

- provide for payment;
- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- pay principal of and premium and interest on any debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement or free writing prospectus, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, New York, New York, known as DTC, or another depository named by us and identified in a prospectus supplement or free writing prospectus with respect to that series.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement or free writing prospectus, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement or free writing prospectus, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in a board resolution the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of any series being redeemed in part during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indenture at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement or free writing prospectus, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement or free writing prospectus any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

Subordination of Subordinated Debt Securities

The subordinated debt securities will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement or free writing prospectus. The indentures in the forms initially filed as exhibits to the registration statement of which this prospectus is a part do not limit the amount of indebtedness which we may incur, including senior indebtedness or subordinated indebtedness, and do not limit us from issuing any other debt, including secured debt or unsecured debt.

RIGHTS

We may issue rights to purchase common stock, preferred stock or warrants that we may offer to our security holders in one or more series. The rights may or may not be transferable by the persons purchasing or receiving the rights. In connection with any rights offering, we may enter into a standby underwriting or other arrangement with one or more underwriters or other persons pursuant to which such underwriters or other persons would purchase any offered securities remaining unsubscribed for after such rights offering. Each series of rights will be issued under a separate rights agent agreement to be entered into between us and a bank or trust company, as rights agent, that we will name in the applicable prospectus supplement or free writing prospectus. The rights agent will act solely as our agent in connection with the rights and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights. A copy of the form of rights agent or subscription agent agreement, including the form of rights certificate representing a series of rights, will be filed with the SEC in connection with the offering of a particular series of rights.

The prospectus supplement and any free writing prospectus relating to any rights that we offer will include specific terms relating to the offering, including, among other matters:

- the title of the rights;
- the securities for which the rights are exercisable;
- the date of determining the security holders entitled to the rights distribution;
- the aggregate number of rights issued and the aggregate number of shares of common stock or preferred stock or warrants purchasable upon exercise of the rights;
- the extent to which the rights are transferable;
- the exercise price;

- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the rights;
- the conditions to completion of the rights offering;
- any applicable federal income tax considerations;
- if applicable, the material terms of any standby underwriting or other purchase arrangement that we may enter into in connection with the rights offering;
- the date on which the right to exercise the rights will commence and the date on which the rights will expire; and
- any other terms of the rights, including terms, procedures and limitations relating to the exchange and exercise of the rights.

Each right would entitle the holder of the rights to purchase for cash the amount of shares of common stock or preferred stock or warrants at the exercise price set forth in the applicable prospectus supplement or free writing prospectus. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement or free writing prospectus. After the close of business on the expiration date, all unexercised rights will become void.

We may determine to offer any unsubscribed securities directly to persons other than our security holders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement or free writing prospectus.

Until a holder exercises the rights to purchase shares of our common stock or preferred stock or warrants, the holder will not have any rights as a holder of shares of our common stock or preferred stock or warrants, as the case may be, by virtue of ownership of the rights.

UNITS

We may issue units consisting of one or more of the other securities described in this prospectus, in any prospectus supplement or a free writing prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder, with the rights and obligations of a holder, of each security included in the unit. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date or upon the occurrence of a specified event or occurrence.

The applicable prospectus supplement or free writing prospectus will describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any unit agreement under which the units will be issued;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- whether the units will be issued in fully registered or global form.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee or depositary or warrant agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement or free writing prospectus. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depositary or its participants. Consequently, for global securities, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in "street name." Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with depositary participants or customers or by law, to pass it along to the indirect holders but does not do so.

Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the legal holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the legal holders.

Special Considerations For Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;

- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are global securities, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security which represents one or any other number of individual securities held by a depositary. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement or free writing prospectus, DTC will be the depositary for all global securities issued under this prospectus.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under “-Special Situations When a Global Security Will Be Terminated.” As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement or any free writing prospectus for a particular security indicates that the security will be issued as a global security, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations For Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a legal holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only as a global security, an investor should be aware of the following:

- An investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- An investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- An investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- An investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- The depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in the global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in the global security. We and the trustee also do not supervise the depositary in any way;

- The depositary may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and
- Financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When A Global Security Will Be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

A global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement or a free writing prospectus may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities offered pursuant to this prospectus from time to time in one or more transactions, including, without limitation:

- to or through underwriters;
- through broker-dealers (acting as agent or principal);
- through agents;
- directly by us to one or more purchasers (including our affiliates and stockholders), through a specific bidding or auction process, a rights offering or otherwise;
- through a combination of any such methods of sale; or
- through any other methods described in a prospectus supplement or free writing prospectus.

The distribution of securities may be effected, from time to time, in one or more transactions, including:

- block transactions (which may involve crosses) and transactions on The Nasdaq Capital Market or any other organized market where the securities may be traded;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its own account pursuant to a prospectus supplement or free writing prospectus;
- ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers;
- sales “at the market” to or through a market maker or into an existing trading market, on an exchange or otherwise; and
- sales in other ways not involving market makers or established trading markets, including direct sales to purchasers.

The applicable prospectus supplement or free writing prospectus will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, if, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters’ compensation;
- any discounts or concessions allowed or re-allowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed or traded.

We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to such prevailing market prices; or
- negotiated prices.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement or free writing prospectus. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement or free writing prospectus, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent, and the underwriters will be obligated to purchase all of the offered securities, if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement or free writing prospectus. The terms of any over-allotment option will be set forth in the prospectus supplement or free writing prospectus for those securities.

If a dealer is used in the sale of the securities, we, or an underwriter, will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement, document incorporated by reference or free writing prospectus, as applicable, the name of the dealer and the terms of the transactions.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement or free writing prospectus pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement or free writing prospectus.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the securities for whom they act as agents, in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase securities directly for the purpose of resale or distribution, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act. No FINRA member firm may receive compensation in excess of that allowable under FINRA rules, including Rule 5110, in connection with the offering of the securities.

We may provide agents, underwriters and other purchasers with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents, underwriters or other purchasers may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

To facilitate the public offering of a series of securities, persons participating in the offering may engage in transactions in accordance with Regulation M under the Exchange Act that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Unless otherwise specified in the applicable prospectus supplement or free writing prospectus, any common stock sold pursuant to a prospectus supplement will be eligible for trading as listed on The NASDAQ Capital Market. Any underwriters who are qualified market makers to whom securities are sold by us for public offering and sale may make a market in the securities in accordance with Rule 103 of Regulation M, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

So long as the aggregate market value of our voting and non-voting common equity held by non-affiliates is less than \$75,000,000 and so long as required by the rules of the SEC, the amount of securities we may offer hereunder will be limited such that the aggregate market value of securities sold by us during a period of 12 calendar months cannot exceed one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

The validity of the issuance of the offered securities will be passed upon for us by Pepper Hamilton LLP, New York, New York.

EXPERTS

The consolidated financial statements and schedule as of December 31, 2017 and 2016 and for the years then ended incorporated by reference in this Prospectus have been so incorporated in reliance on the reports of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus and any subsequent prospectus supplements and free writing prospectuses do not contain all of the information in the Registration Statement. We have omitted from this prospectus some parts of the Registration Statement as permitted by the rules and regulations of the SEC. Statements in this prospectus concerning any document we have filed as an exhibit to the Registration Statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified in their entirety by reference to these filings. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any documents that we have filed with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about the operation of the Public Reference Room. The SEC also maintains an website that contains reports, proxy and information statements and other information that registrants file electronically with the SEC, including us. The SEC's website can be found at <http://www.sec.gov>. In addition, we make available on or through our website copies of these reports as soon as reasonably practicable after we electronically file or furnished them to the SEC. Our website can be found at www.interpacediagnostics.com. Our website is not a part of this prospectus.

INFORMATION INCORPORATED BY REFERENCE

We have elected to incorporate certain information by reference into this prospectus. By incorporating by reference, we can disclose important information to you by referring you to other documents we have filed or will file with the SEC. The information incorporated by reference is deemed to be part of this prospectus, except for information incorporated by reference that is superseded by information contained in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any statements in the prospectus or any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents set forth below that we have previously filed with the SEC, except in each case the information contained in such document to the extent "furnished" and not "filed":

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 that we filed with the SEC on March 23, 2018;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018 filed on May 15, 2018;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018 filed on August 9, 2018;
- our Current Reports on Form 8-K filed on March 13, 2018, May 7, 2018, June 14, 2018, and July 31, 2018;
- our definitive proxy statement relating to our 2018 Annual Meeting of Stockholders, which was filed on April 30, 2018; and
- the description of our common stock contained in our Form 8-A that we filed with the SEC on May 13, 1998 pursuant to the Exchange Act and any amendment or report filed for the purpose of further updating such description.

We also incorporate by reference all documents we file in the future pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the sale of all the securities covered by this prospectus (including all such documents filed with the SEC after the date of the initial filing of the Registration Statement that contains this prospectus and prior to effectiveness of the Registration Statement or after such effectiveness), except in each case the information contained in such document to the extent "furnished" and not "filed."

You may obtain copies of these documents on the website maintained by the SEC at <http://www.sec.gov>, or from us without charge (other than exhibits to such documents, unless such exhibits are specifically incorporated by reference into such documents) by calling or writing us at Interpace Diagnostics Group, Inc., Morris Corporate Center 1, Building C, 300 Interpace Parkway, Parsippany, NJ 07054, (855) 776-6419, Attn: Corporate Secretary, or visiting our website at <http://www.interpacediagnostics.com>.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained herein, any prospectus supplement, free writing prospectus or in any other subsequently filed document which also is or deemed to be incorporated by reference herein modifies or supersedes that statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.



[●] Shares of Common Stock

Prospectus Supplement

H.C. Wainwright & Co.

January [●], 2019
