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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from _____to_____

Commission file Number: 000-24249

Interpace Biosciences, Inc.

(Exact name of registrant as specified in its charter)

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

Morris Corporate Center 1, Building C
300 Interpace Parkway, Parsippany, NJ 07054

(Address of principal executive offices and zip code)

(855) 776-6419

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	N/A	N/A

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.01 par value per share

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

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

Large accelerated filer □ Accelerated filer □ Non-accelerated filer ☒ Smaller reporting company ☒
Emerging growth company □

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

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

The aggregate market value of the registrant's common stock, $0.01 par value per share, held by non-affiliates of the registrant on June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was $42,186,849 (based on the closing sales price of the registrant's common stock on that date). Shares of the registrant's common stock held by each officer and director and each person who owns 10% or more of the outstanding common stock of the registrant have been excluded because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 25, 2022, 4,226,422 shares of the registrant's common stock, $0.01 par value per share, were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K will be incorporated by reference from certain portions of the Registrant's definitive proxy statement for the 2021 annual meeting of stockholders, or Proxy Statement, or will be included in an amendment hereto, to be filed within 120 days of the end of the fiscal year ended December 31, 2021. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

Interpace Biosciences, Inc.
Annual Report on Form 10-K

FORWARD LOOKING STATEMENT INFORMATION

This Annual Report on Form 10-K, and the documents incorporated by reference in this document, our press releases and oral statements made from time to time by us or on our behalf, may contain "forward-looking statements" within the meaning of the federal securities laws, including Section 27A of the Securities Act of 1933, as amended (or the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In this context, forward-looking statements are not historical facts and include statements about our plans, objectives, beliefs and expectations. Forward-looking statements include statements preceded by, followed by, or that include the words "believes," "expects," "anticipates," "seeks," "plans," "estimates," "intends," "projects," "targets," "should," "could," "may," "will," "can," "can have," "likely," or the negatives thereof or other comparable words and expressions regarding beliefs, plans, expectations or intentions regarding the future, including risks and uncertainties associated with the coronavirus (COVID-19) pandemic. These forward-looking statements are contained throughout this Form 10-K, including, but not limited to, statements found in Part I – Item 1 – "Business" and Part II – Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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

- the substantial doubt about our ability to continue as a going concern due to our history of operating losses, declining cash position and other liquidity factors, which in the absence of additional short term financing may cause us to cease or scale back operations;

- the effect of the Coronavirus (COVID-19) pandemic which has materially and adversely affected our business and financial results, particularly during portions of 2020, due to the slowdown in demand for our clinical services and pharma services, a reduction in samples received and testing volume and delayed third party collections and other factors and which may continue to have an adverse effect on our future business;

- our expectations of future revenues, expenditures, capital or other funding requirements;

- our reliance on Medicare reimbursement for our clinical services and our being subject to decisions of the Center for Medicare and Medicaid Services ("CMS") regarding reimbursement and pricing of our clinical services which could have a material adverse effect on our business and financial results, which has temporarily had a material adverse effect on our business due to a new billing policy issued by CMS in January 2022 whereby CMS stated they would no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service; while this decision was subsequently reversed in February 2022, the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS;

- our secured lenders have the right to foreclose on substantially all of our assets if we are unable to timely repay our outstanding obligations;

- our dependence on sales and reimbursements from our clinical services for more than 50% of our revenue; the ability to continue to generate sufficient revenue from these and other products and/or solutions that we develop in the future is important for our ability to meet our financial and other targets;

- our revenue recognition is based, in part, on our estimates for future collections and such estimates may prove to be incorrect;

- our ability to finance our business on acceptable terms in the future, which may limit the ability to grow our business, develop and commercialize products and services, develop and commercialize new molecular clinical service solutions and technologies and expand our pharma services offerings;

- our obligations to make royalty and milestone payments to our licensors;
- our dependence on third parties for the supply of some of the materials used in our clinical and pharma services tests;
- the potential adverse impact of current and future laws, licensing requirements and governmental regulations upon our business operations, including but not limited to the evolving U.S. regulatory environment related to laboratory developed tests ("LDTs"), pricing of our tests and services and patient access limitations;
- our reliance on our sales and marketing activities for future business growth and our ability to continue to expand our sales and marketing activities;
- our ability to implement our business strategy; and
- the potential impact of existing and future contingent liabilities on our financial condition.

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

In this Form 10-K, references to "we," "our," "us," "Interpace" and the "Company" refer to Interpace Biosciences, Inc., including consolidated subsidiaries as of December 31, 2021.

PART I

ITEM 1. BUSINESS

Company Overview

We are an emerging leader in enabling precision medicine principally in oncology by offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications through our clinical and pharma services. Through our clinical services, we enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment. Our clinical services provide clinically useful molecular diagnostic tests, bioinformatics and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. Through our pharma services, we develop, commercialize and provide molecular- and biomarker-based tests and services and provide companies with customized solutions for patient stratification and treatment selection through an extensive suite of molecular and biomarker-based testing services, DNA and RNA extraction and customized assay development and trial design consultation. Our pharma services provide pharmacogenomics testing, genotyping, biorepository and other specialized services to the pharmaceutical and biotech industries and advance personalized medicine by partnering with pharmaceutical, academic and technology leaders to effectively integrate pharmacogenomics into drug development and clinical trial programs with the goals of delivering safer, more effective drugs to market more quickly, and improving patient care.

Customer Category	Types of Customers	Nature of Services
Clinical services	● Hospitals ● Physicians ● Cancer Centers ● Clinics ● Commercial laboratories ● Pathology groups	Clinical services provide information on diagnosis, prognosis and predicting treatment outcomes of cancers to guide patient management.
Pharma services	● Pharmaceutical companies ● Biotech companies ● Contract Research Organizations ● Academic Researchers ● Diagnostic companies	Pharma services provide expert-based collaborative solutions, customized assays and high quality services in support of their pharmaceutical and biotechnology clients' therapeutic development programs. By deploying deep scientific and medical expertise, pharma services support all phases of drug development and accelerate their clients' clinical programs.

Our clinical services' customers consist primarily of physicians, hospitals, cancer centers, commercial laboratories, pathology groups and clinics. Our largest customer for ThyGeNEXT® and ThyraMIR® products in 2021 was [Laboratory Corporation of America® or LabCorp]. Our revenue channels include reimbursement by Medicare, Medicare Advantage, Medicaid, and direct client billings (for example, hospitals and clinics), and commercial payers such as Blue Cross Blue Shield, Aetna, Cigna, United Healthcare and others.

We partner with pharmaceutical and biotech companies and clinicians as oncology diagnostic specialists by supporting development and patient care from bench to bedside. Pharmaceutical and biotech companies work with us to provide molecular profiles on clinical trial participants. Similarly, we believe the oncology industry is undergoing a rapid evolution in its approach to diagnostic, prognostic and treatment outcome testing, embracing precision testing and individualized medicine as a means to drive higher standards of patient treatment and disease management. These profiles may help identify biomarker and genomic variations that may be targetable for developing novel personalized therapeutics or that may be responsible for differing responses to existing oncology therapies, thereby increasing the efficiency of trials while lowering costs. We believe tailored and combination therapies can revolutionize oncology care through molecular- and biomarker-based testing services, enabling physicians and researchers to target the factors that make each patient and disease unique. Our pharma services' customers consist primarily of pharmaceutical and biotech companies.

To optimize the operations of laboratory operations within our pharma services, during late 2020 and the first quarter of 2021, we transitioned activities from our Rutherford, NJ facility to our Morrisville, NC facility. We invested several million dollars to facilitate this relocation, including but not limited to the transfer of personnel, expansion of the Morrisville facility and validation of transferred processes. We believe that this investment will result in a reduction in future operating costs. We have also undergone several other cost-cutting initiatives, primarily reductions in headcount, and those costs are categorized as transition expenses as well. It is not certain whether the transition will produce the predicted financial benefits. During Fiscal 2021, the Company experienced a fairly significant decrease in volume within pharma services. The decrease in revenue within pharma services was approximately 32% from the comparable prior year period.

In October 2021, the Company entered into a $7.5 million revolving credit facility with Comerica Bank ("Comerica"). In addition, also in October 2021, the Company entered into an $8.0 million term loan with BroadOak Fund V, L.P. ("BroadOak"). See Part II – Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for more details.

Impact of COVID-19 Pandemic

The COVID-19 pandemic, together with related precautionary measures, continues to impact portions of the regions in which we operate. These regions are attempting to address the COVID-19 pandemic in varying ways, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location.

The continuing impact that the COVID-19 pandemic will have on our operations, including duration, severity and scope, remains highly uncertain and cannot be fully predicted at this time. While we believe we have generally recovered from the adverse impact that the COVID-19 pandemic had on our business during 2020, we believe that the COVID-19 pandemic could continue to adversely impact our results of operations, cash flows and financial condition in the future.

We continue to monitor the COVID-19 pandemic and the guidance that is being provided by relevant federal, state and local public health authorities and may take additional actions based upon their recommendations. It is possible that we may have to make adjustments to our operating plans in reaction to developments that are beyond our control.

Lab closures experienced thus far by the Company have consisted of periodic, temporary work stoppages to clean and disinfect the labs; however, this could change in the future based upon conditions caused by the pandemic. It is also possible that we could experience supply chain shortages if the pandemic worsens and if one or more suppliers is unable to continue to provide us with supplies. For the foreseeable future, however, we do not anticipate supply chain shortages of critical supplies.

We have developed contingency plans and will continue to monitor and update them in order to mitigate pandemic-related, adverse financial impacts upon our business.

Market Overview

Global Molecular Diagnostic Market

The global molecular diagnostics market is estimated to be $11.77 billion (USD) in 2021 and is expected to grow to $18.1 billion (USD) by 2026 with a CAGR of 9.0% between 2021 and 2026, according to Market Data Forecast's Molecular Diagnostics Market report (ID: 10293, published January 2022).

The global esoteric testing market size was valued at $20.2 billion in 2020, and is estimated to reach $66.2 billion by 2030, growing at a CAGR of 12.5% from 2021 to 2030, according to an August 2021 report by Allied Market Research. We believe that the specialty molecular diagnostics market offers significant growth and strong patient value given the substantial opportunity it affords to lower healthcare costs by helping to reduce unnecessary surgeries and ensuring the appropriate frequency of monitoring. We are keenly focused on growing our test volumes, securing additional insurance coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our molecular diagnostic tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. We also believe that BarreGEN® is a potentially significant pipeline product, and we are providing necessary resources to support the development process.

Contract Research Organization Market size was valued at over $43.9 billion in 2020 and is estimated to grow at a 7.8% CAGR between 2021 and 2027. Growing demand for clinical trials in emerging countries coupled with increasing prevalence of chronic diseases is escalating the market growth. The pharma services (clinical research) segment in the contract research organization market accounted for $25.2 billion in 2020 and is projected to showcase an 8% growth rate by 2027.

United States Clinical Oncology Market

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. In 2020, the World Health Organization attributed nearly 10 million deaths globally to cancer, which is about one in six deaths. Within the United States, cancer is the second most common cause of death, exceeded only by heart disease, accounting for nearly one out of every five deaths. Of note, pancreatic cancer is now the third leading cause of cancer deaths in the United States. The Agency for Healthcare Research and Quality estimated that the direct medical treatment costs of cancer in the United States for 2015 were $80.2 billion. In the United States in 2022, it is expected that in total there will be approximately 1.9 million new cancer cases diagnosed, which is the equivalent of approximately 5,205 new cases each day, according to the American Cancer Society. The incidence, deaths and economic loss caused by cancer are staggering. The following table published by The American Cancer Society shows estimated new cases and deaths in 2020 in the United States for selected major cancer types:

Cancer Type	Estimated New Cases	Estimated Deaths
Bladder	81,180	17,100
Breast (Female – Male)	287,858 – 2,710	43,250 – 530
Colon and Rectal (Combined)	151,030	52,580
Kidney (Renal Cell and Renal Pelvis)	79,000	13,920
Leukemia (All Type)	60,650	24,000
Liver and Intrahepatic Bile Duct	41,260	30,520
Lung (Including Bronchus)	236,740	130,180
Melanoma	99,780	7,650
Non-Hodgkin's Lymphoma	80,470	20,250
Pancreatic	62,210	49,830
Prostate	268,490	34,500
Thyroid	43,800	2,230

References

1. American Cancer Society: Cancer Facts and Figures 2022. Atlanta, GA: American Cancer Society, 2022. Also available online. Last accessed February 22, 2022.

United States and International Clinical Trials Market Overview

The United States is currently a world leader in biopharmaceutical research and development and manufacturing. In fiscal year 2021, the National Cancer Institute received a budget of $6.44 billion, an increase of $119 million over fiscal year 2020, to issue grants to support research, with a targeted investment in enhanced and early detection of disease through the analysis of circulating biomarkers using minimally invasive methods, as well as a focused investment in cancer prevention and treatment including research on new vaccines to prevent cancer-causing infections and investigational immuno-oncology drugs and drug combinations. The Pharmaceutical Research and Manufacturers of America (PhRMA) reports that the average cost to develop a drug, including trial failures, can be as high as $2.6 billion and the approval process from development to market may be as long as 15 years. According to the National Cancer Institute, the overall cancer death rate in the United States continues to decline. Life expectancy increases can be attributed to earlier detection, new treatments and oncology medications.

Outside of the United States, particularly in potential target geographies of the European and Asia Pacific ("APAC") regions, growth in the pharmaceuticals and clinical trials market is continuing. Medicines spending in the top five European markets (France, Germany, Italy, Spain, and the UK) is expected to increase at a CAGR of between 3% and 6%, or $51 billion, over the next five years (2022 to 2026), up from $44 billion in the past five years, according to the IQVIA Institute analysis. New brands were the largest driver of growth from 2016 to 2021 and are expected to continue in the next five years (2022 to 2026) but may be hampered by lingering effects of the pandemic on marketing operations and reimbursement decisions. APAC's location provides access to large patient pools within favorable regulatory environments. The CRO market is valued at approximately $7.6 billion as of 2021 and is forecast to reach $11.9 billion by 2025. As a result of ease in regulatory approval, low worker rates, availability of a large patient pool, and the presence of key suppliers, the APAC region is anticipated to see a CAGR growth rate of 12% between 2017 and 2025.

While oncology drugs have the potential to be among the most personalized therapeutics, very few have successfully made it to market. The application of pharmacogenomics to oncology clinical trials enables researchers to better predict differences in drug response, efficacy and toxicity among trial participants, as well as to optimize treatment regimens based on these differences. According to IQVIA, in 2021, more than half (53%) of all pharmaceutical sales in the United States were from specialty drugs, a category of drugs including oncology treatments tailored to patients' genomic profiles. We believe a growing demand for faster development of personalized medicines and more effective clinical trials are growth drivers of this market, and our core expertise is pharmacogenomics, or the study of genetic analysis based on a patient's response to a particular therapy or drug.

Our Strategy

Our primary goal is to become a leader in providing high quality and dependable personalized medicine with exceptional growth. Our strategy is to grow our business both organically as well as by selective partnering, which could potentially include licensing, acquisitions or mergers, to generate positive returns for our shareholders and driving towards cash flow break-even. We expect to not only continue to further develop our existing gastrointestinal and endocrine assays but to also expand our presence in other markets where we have expertise and access. Our existing customer base and broad-based capabilities provide us a unique window not only into our current customers' needs but also permit us to anticipate their future needs.

The key tactics to achieve our goals include:

- Expanding our existing commercial products, especially PancraGEN®, ThyGeNEXT® and ThyraMIR®, focusing on personalized medicine and early intervention related to cancer risk;
- Accelerating the clinical development and commercialization of BarreGEN®, our esophageal cancer risk classifier for Barrett's Esophagus, working with our recently developed Key Opinion Leaders ("KOL's") and expanding clinical studies to seek key reimbursement support while seeking partners to collaborate with us;
- Implementation of automation and focus on improved operating efficiencies in the clinical laboratories to provide consistent superior quality testing and reporting at reduced costs;
- Broadening coverage and reimbursement for our clinical tests including:
    - Initiating and expanding studies to demonstrate that our tests are effective;
    - Meeting standards necessary to be consistent with leading clinical guidelines;
    - Executing by our internal managed care team;
    - Collaborating with KOL's; and
    - Establishing payer relationship and in-network contracts serving our diagnostic customers.
- Targeting synergistic product and service opportunities developed for our clinical customers for use by our pharmaceutical and biotech customers;
- Developing and commercializing other related first-line clinical assays and expanding our service offerings such as PanDNA®, a DNA only version of PancraGEN®, and markers for aggressive thyroid cancer;
- Expanding our commercial sales staff rationally, while supporting our products with high quality data and studies;
- Exploring partnering opportunities to acquire new technologies;
- Expanding our bioinformatics data collected (currently from over 60,000 patients), utilizing registries to improve our assays and leveraging our data with potential collaborators;
- Expanding internationally; and
- Expanding our average contract revenue from pharmaceutical and biotech customers by growing our services and product offerings while providing dependable and timely service and unique solutions.

The reliability of the volume growth from our clinical customers combined with more variable but scalable revenue from our pharmaceutical and biotech customers, we believe, provides the opportunity to expand our services and grow our business. We also believe that the synergistic opportunities of our businesses are important especially in targeted product categories where we have a history of clinical data and sample biorepositories as we expand our roster of pharmaceutical client opportunities. We also believe that our LIM's systems, with the current investments we are making, is already an important tool to support our future growth as we begin to convert data into usable and unique information and insights for our customers' benefit. Our unique commercial infrastructure focused on clinical and pharmaceutical customers is one of our most important assets and we anticipate expanding it in the future with highly trained commercial personnel that have growth potential and can effectively communicate our value proposition to our sophisticated customers. The information and analytics that we have, we believe, will help further differentiate us from our competitors.

Our Service Offerings

Our business is based on demand for molecular- and biomarker-based characterization of cancers from three main sectors: (1) clinical services for physicians, hospitals and clinics, (2) pharma services for biotechnology and pharmaceutical companies, and (3) pharma services for the research community.

Clinicians and oncologists in cancer centers and hospitals seek molecular-based testing since these methods often produce higher value and more accurate cancer diagnostic information than traditional analytical methods. Our proprietary and unique disease-focused or esoteric tests aim to provide actionable information that can guide patient management decisions, potentially resulting in decreased costs.

We continue to pursue the strategy of trying to demonstrate increased value and efficacy with payers who wish to contain costs and academic collaborators seeking to develop new insights and treatments.

Our pharma services are sought by biotechnology and pharmaceutical companies engaged in designing and running clinical trials, from pre-clinical to post market surveillance, for their value and efficacy in oncology and immuno-oncology treatments and therapeutics.

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 clinical services' customers consist primarily of physicians, hospitals and clinics.

Clinical services

Our clinical services business commercializes clinically useful molecular diagnostic tests and molecular pathology services. We commercialize genomic tests and related first line assays principally focused on early detection of patients at high risk of cancer using the latest technology to help personalize medicine and improve patient diagnosis and management. Our tests and services provide mutational analysis of genomic material contained in suspicious cysts, nodules and lesions with the goal of better informing treatment decisions in patients at risk of thyroid, pancreatic, and other cancers. The molecular diagnostic tests we offer enable healthcare providers to better assess cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk, while also helping to identify high risk patients that would benefit from surgical intervention.

Our mission is to provide personalized medicine through genomics-based diagnostics and innovation to advance patient care based on rigorous science. Our laboratories are licensed pursuant to federal law under Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and are accredited by College of American Pathologists ("CAP") and our products are approved by New York State. We are leveraging our licensed and accredited laboratories to refine 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 other cancers. Our customers consist primarily of physicians, hospitals and clinics.

We currently have five commercialized molecular diagnostic tests in the marketplace: PancraGEN®, which is a pancreatic cyst and pancreaticobiliary solid lesion genomic test that helps physicians better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG® platform; PanDNA, a "molecular only" version of PancraGEN® that provides physicians a snapshot of a limited number of factors; ThyGeNEXT®, which is an expanded oncogenic mutation panel that helps identify malignant thyroid nodules; ThyraMIR®, which, in combination with ThyGeNEXT®, assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay. and RespriDx®, which is a genomic test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer and which also utilizes our PathFinderTG® platform.

Gastrointestinal Cancer Products

Our current gastrointestinal integrated pathology risk diagnostic assay, PancraGEN® is based on our PathFinderTG® platform. PathFinderTG® is designed to use advanced clinical algorithms to accurately stratify patients according to risk of pancreatic cancer by assessing panels of DNA abnormalities in patients who have pancreaticobiliary lesions (cysts or solid masses) with potential for cancer. PanDNA is a "molecular only" reporting option for physicians that perform their own integration of first line testing results. PathFinderTG® is supported by our state of the art CLIA certified, and CAP accredited laboratory in Pittsburgh, Pennsylvania. Our Pittsburgh laboratory is our largest clinical laboratory where we process the majority of our oncology related commercial tests; we also support our other gastrointestinal and endocrine commercial activities through this laboratory.

Early detection of pancreatic cancer is crucial. Based on the American Cancer Society Cancer 2022 Cancer Facts and Figures, pancreatic cancer is the third leading cause of cancer deaths in the U.S. (estimated) with an average five year survival rate of 11%. PancraGEN® and PanDNA® are designed to determine risk of malignancy in pancreatic cysts and pancreaticobiliary solid lesions, which are more often than not benign lesions but have potential for developing into cancer. We believe that PancraGEN® is the leader in the market for integrated molecular diagnostic tests for determining risk of pancreaticobiliary malignancy. We currently estimate that the immediate addressable market for PancraGEN® is approximately 115,000 indeterminate pancreaticobiliary lesions annually or approximately $200 million annually based on the current size of the patient population and reimbursement rates. To date, PancraGEN® testing has been used in more than 56,000 clinical cases. The National Pancreatic Cyst Registry study published in Endoscopy in 2015 demonstrated that PancraGEN® more accurately determines the malignant potential of pancreatic cysts than international consensus 2012 imaging criteria, helping to ensure that surgery is reserved for the most appropriate patients. When molecular analysis is not performed, the vast majority of all pancreatic cyst surgeries are performed on cystic lesions that do not harbor malignancy.

The American Gastroenterological Association 2015 Guidelines have cautioned that many pancreatic surgeries have been performed unnecessarily for lesions that will not progress to invasive adenocarcinoma. In addition, the 2016 guidelines published by the American Society of Gastroenterology Endoscopy (ASGE) in Gastrointestinal Endoscopy included a specific recommendation for use of molecular testing in specific circumstances where other types of testing and analysis have not provided sufficient data on which to determine the best course of action for patient treatment. Accordingly, we believe that PancraGEN® provides a highly reliable diagnostic and prognostic option that identifies cancer risk in circumstances where risk of cancer is otherwise uncertain.

Endocrine Cancer Products

We currently market and sell a dual platform endocrine cancer risk diagnostic assay. The incidence of thyroid nodules is on the rise. ThyGeNEXT® is a next generation DNA and RNA sequencing oncogene and mRNA fusion panel that is used to evaluate indeterminate thyroid biopsies. ThyGeNEXT® works synergistically with our second endocrine cancer diagnostic test ThyraMIR®, which is based on measuring the relative expression of ten distinct microRNAs. The combination of ThyGeNEXT® and ThyraMIR® is designed to provide a highly sensitive "rule-in" and "rule-out" test to accurately risk stratify indeterminate thyroid nodules.

We estimate the total market for our endocrine cancer assays is approximately $230 million annually based on the current size of the patient population, estimated numbers of indeterminate biopsies and reimbursement rates. ThyGeNEXT® plus ThyraMIR® is a combination testing platform. The mutational analysis provided by ThyGeNEXT can help inform treatment alone when strong BRAF V600E-like mutations are found. However, reflex to ThyraMIR occurs approximately 85% of the time to provide a greater understanding of malignancy risk and is especially helpful when weaker drivers of malignancy, such as RAS-like mutations, are found.

Endocrinologists and ear, nose and throat ("ENT") specialists evaluate most thyroid nodules for possible cancer by collecting cells through Fine Needle Aspiration ("FNA") that are then analyzed by cytopathologists to determine whether or not a thyroid nodule is cancerous. It is estimated that approximately 20% or well over 100,000 biopsies analyzed annually yield indeterminate results, meaning they cannot be diagnosed as definitely being malignant or benign by cytopathology alone. In the past, guidelines recommended that some patients with indeterminate cytopathology results undergo surgery to remove all or part of their thyroid to obtain an accurate diagnosis by looking directly at the thyroid tissue. According to a study published by Wang, et al. in 2011, in approximately 77% of these cases, the thyroid nodule proved to be benign. Current National Comprehensive Cancer Network ("NCCN") and American Thyroid Association ("ATA") guidelines support use of molecular analysis for nodules with indeterminate cytology results as this testing can prove beneficial to further characterize these lesions and support optimal patient management.

Lung Cancer Product—RespriDx® Test and Metastatic versus Primary Platform

RespriDx® compares the mutational fingerprint of two or more sites of cancer to determine whether the neoplastic deposits are representative of a recurrence (metastasis) of lung cancer or a new primary or independent tumor. The test, which currently provides only nominal revenues, defines the presence or absence of cancer in atypical cytology by comparing the mutational profile with that of known previous cancer. RespriDx® assists in determining the most appropriate course of treatment, whether chemotherapy, surgery, or other modalities.

CLIA Certified and CAP Accredited Laboratories

Our testing is performed in our state of the art Clinical Laboratory Improvement Amendments ("CLIA") certified College of American Pathologists ("CAP") accredited laboratory in Pittsburgh, Pennsylvania. CLIA is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Clinical laboratories must be certified under CLIA in order to perform testing on human specimens, unless they fall within an exception to CLIA certification, such as research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients. CLIA certification is also required to be eligible to bill Federal and State healthcare programs, as well as many private third-party payers, for diagnostic testing and services. In addition, proprietary tests must also be recognized as part of an accredited program under CLIA so that they can be offered in a CLIA-certified laboratory. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. For renewal of CLIA certification, clinical laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of clinical laboratories outside of the renewal process.

Pharma services

We provide data driven solutions for pharmaceutical and biotech companies engaged in clinical trials and focus on providing these clients with oncology specific and non-oncology genetic testing services for phase I-IV clinical trials along with critical support of ancillary services. These ancillary services include: biorepository, clinical trial logistics, clinical trial design, bioinformatics analysis, customized assay development. DNA and RNA extraction and purification, genotyping, gene expression, flow cytometry, cytogenetic and FISH and biomarker analyses. We also seek to apply our expertise in laboratory developed tests to assist in developing and commercializing drug-specific companion diagnostics. We have established business relationships with key instrument manufacturers to provide a multi-omic approach, and to drive acceptance among biopharmaceutical sponsors developing innovative immuno-oncology therapies.

We also utilize our pharma services laboratories to provide clinical trial services to the pharmaceutical and biotech industries to improve the efficiency and economic viability of clinical trials. Our clinical trials services leverage our knowledge of clinical oncology and molecular diagnostics and our laboratories' fully integrated capabilities. We believe our pharma services operates one of only a few laboratories with the capability to combine somatic and germline mutational analyses in clinical trials.

Our pharma services laboratory located in Morrisville, North Carolina has current certificates under CLIA to perform high complexity testing and are accredited by CAP, one of seven CLIA-approved accreditation organizations.

Industry research has shown many promising drugs have produced disappointing results in clinical trials. For example, a 2016 article by the University of Michigan reported that only 1 in 50 cancer drug candidates make it to the clinical market. Given such a high failure rate of oncology drugs, combined with constrained budgets for biotech and pharmaceutical companies, there is a significant need for drug developers to utilize molecular diagnostics to decrease these failure rates. For specific molecular-targeted therapeutics, the identification of appropriate biomarkers indicative of disease type or prognosis may help to optimize clinical trial patient selection and increase trial success rates by helping clinicians identify patients that are most likely to benefit from a therapy based on their individual genomic profile.

From a laboratory infrastructure standpoint, we possess capabilities in histology, immunohistochemistry ("IHC"), flow cytometry, cytogenetics and fluorescent in-situ hybridization ("FISH"), as well as sophisticated molecular analysis techniques, including next generation sequencing. This allows for comprehensive esoteric testing within one lab enterprise, with our CLIA-certified, CAP-accredited laboratory serving as a central hub for specimen tracking. Using this approach, we are able to support demanding clinical trial protocols requiring multiple assays and techniques aimed at capturing data on multiple biomarkers. Our suite of available testing platforms allows for highly customized clinical trial design which is supported by our dedicated group of development scientists and technical personnel.

Through this combination of a variety of testing platforms powered by a team of experienced scientists, we offer a comprehensive approach to clinical trial support. As trial design becomes increasingly complex to cater to more specific drug targets and patient populations, we believe that clinical result generation and reporting through a single-source solution for testing is becoming more valuable than ever. Examples of clinical trial services offered by our pharma services include:

Flow cytometry	Selection of individual antibodies in multiple myeloma, leukemia, lymphomas, and therapy response.
Karyotyping	Genome-wide detection of aberrations at low resolution that have a diagnostic or prognostic significance.
FISH	Fluorescent in-situ hybridization (FISH) probe library for the detection of gene abnormalities in chromosomes indicated in hematological and solid tumors.
Anatomic pathology	Full IHC library with over 180 antibodies available.
Exome sequencing	Sequencing of the protein-encoding genes in a genome.
DNA and RNA sequencing	Sequencing to determine the presence and quantity of RNA or DNA in a specimen.
Next Generation sequencing	Proprietary and custom-designed panels to deep sequence genomic material to identify genetic mutations, substitutions, insertions and deletions, and rearrangements of genetic material.
Cell-free DNA analysis	Multi-gene next generation sequencing panel for lung cancer to detect tumor-derived cell-free DNA obtained from a blood draw.
DNA and RNA microarray	Measures select genomic information for large number of genes simultaneously.
Sanger sequencing	DNA sequencing for validation of next generation sequencing results, and for smaller scale sequencing projects.
Fragment size analysis	Analysis technique where DNA fragments are separated by size and used for mutation detection.
DNA and RNA extraction and purification	Extraction and isolation of DNA and RNA from a wide variety of sample types for immediate testing or for storage.
Biostatistics and Bioinformatics	Design and review of client assays and analysis of datasets.

In March of 2022, ClinicalTrials.gov reported over 80,000 clinical trials that are either preparing or recruiting patients. Molecular- and biomarker-based testing services have been altering the clinical trials landscape by providing biotech and pharmaceutical companies with information about trial subjects' genetic profiles that may be able to inform researchers whether or not a subject will benefit from the trial drug or will experience adverse effects. We believe that streamlined subject selection and stratification and tailored therapies selected to maximally benefit each group of subjects may increase the number of trials that result in approved therapies and make conducting clinical trials more efficient and less costly for biotech and pharmaceutical companies. According to the United States Food and Drug Administration ("FDA"), 2021 produced over 50 new drug approvals and 20% of these drugs were oncology-focused, highlighting the potential value of incorporating genomic information into oncology clinical trial design.

We also provide genetic testing for drug metabolism to aid biotech and pharmaceutical companies identify subjects' likely responses to treatment, allowing these companies to conduct more efficient and safer clinical trials. We believe pharmacogenomics drug metabolism testing helps deliver the promise of personalized medicine by enabling researchers to tailor therapies in development to differences in patients' genomic profiles.

Sales and Marketing

Our sales and marketing efforts consist of both direct and indirect sales channels with the majority of efforts focused on direct sales in the United States as well as a collaborative arrangement with another laboratory services company. In the US, pharma services also execute an indirect channel partner strategy by partnering with clinical research organizations ("CROs") to support demand for unique or esoteric testing, customized data management and individual development of unique biomarkers.

Our commercialization efforts for our clinical services are currently focused on endocrinology, gastroenterology and lung cancers. Communication of our marketing messaging and value proposition is done principally through our two field-based commercial sales teams of approximately 26 representatives and managers. In addition, we employ medical science liaisons or MSLs to respond to clinician inquiries. Additionally, we communicate through print, digital advertising, a web presence, peer-reviewed publications, and trade show exhibits. We believe that our molecular diagnostic tests provide value to payers, physicians and patients by improving patient care and lowering healthcare costs through avoidance of unnecessary surgeries, reducing the morbidity associated with unnecessary surgeries for patients, and providing better diagnostic and prognostic insights to physicians. We support the value propositions of our tests through rigorous science and the accumulation of bioinformatics data that demonstrate clinical and analytical validity as well as clinical utility, and how they actually impact physicians' decisions. We believe our repository of bioinformatics data accumulated in over 37,000 cases using PancraGEN and over 30,000 cases using our thyroid assays is a valuable tool in developing our analytics and potentially an even more valuable tool in the future.

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

Our U.S. pharma services business development and sales professionals have scientific backgrounds in hematology, pathology, and laboratory services, with many years of experience in biopharmaceutical and clinical oncology sales, esoteric laboratory sales from leading biopharmaceutical, pharmaceutical or specialty reference laboratory companies. We currently have a team of 4 business development and sales professionals in the United States. We support our sales force with scientific experts who bring deep domain knowledge in the design and use of our technologies and services.

Our pharma services team also executes an indirect channel partner strategy. As a result of this strategy, the pharma services team conducts project support for sponsors as a partner of such central labs as Covance, ICON Laboratories Inc. and Parexel International Corp. In addition to both direct and indirect sales channels, the pharma services team has formed a partnership with the China-based lab partner Genecast Biotechnology Co., Ltd. or, Genecast. Through our partnership with Genecast, we believe we are able to support our global pharmaceutical and biotechnology clients with their testing needs in the Chinese market.

We also promote our tests and services through marketing channels commonly used by the biopharma and pharmaceutical industries, such as internet, industry meetings and broad-based publication of our scientific and economic data. In addition, we provide easy to access information to our customers over the internet through dedicated websites. Our customers value easily accessible information in order to quickly review patient or study information. We do not, however, market our tests directly to individual patients or consumers.

Clinical Services Reimbursement Coverage

Additional Reimbursement Coverage During 2021

Reimbursement progress is key for our clinical services. We continued to expand the reimbursement of our products in 2021. Specifically, the most significant progress we have made regarding payers in 2021 is as follows:

- In January 2021, we announced an agreement with Blue Cross Blue Shield of Florida under which ThyGeNEXT® and ThyraMIR® tests are now covered in-network services for their 5 million members.

- In February 2021, we announced an agreement with Blue Cross Blue Shield of Illinois that makes ThyGeNEXT® and ThyraMIR® tests covered in-network services for their more than 8 million members in Illinois.

- In April 2021, we announced that Novitas, our Medicare Administrative Contractor, has agreed to recognize the new Proprietary Laboratory Analysis ("PLA") code that specifically identifies ThyGeNEXT® as a distinct test from any other test or service. The new PLA code for ThyGeNEXT® is 0245U and the reimbursement for this code remains $2,919, representing a significant price increase over the prior reimbursement level of $560.

- In May 2021, we announced that eviCore Healthcare ("eviCore"), a wholly owned subsidiary of Cigna, has updated their laboratory management guidelines to include positive coverage for ThyGeNEXT® and ThyraMIR®. This update, which impacts approximately 27 health plans nationwide covering 100 million lives, is effective on July 1, 2021. This means that after the effective date, claims for ThyGeNEXT and ThyraMIR which meet eviCore's criteria for coverage will be considered medically necessary and processed as a covered service.

- In November 2021, CMS announced that it had assigned 0245U for Medicare rate-setting via the gapfill process. Under gapfill, the Medicare payment rate for 0245U will be established by Novitas during CY 2022. Effective January 1, 2023, the Medicare payment rate will be established as the median of the payment amounts established by all Medicare contractors.

Competition

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

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

Specifically, in regard to our thyroid diagnostic tests, Veracyte, Inc., or Veracyte, has a molecular thyroid nodule cancer diagnostic test (Afirma) that is the current market leader and competes with our ThyGeNEXT® and ThyraMir® tests. Quest Diagnostics Incorporated, or Quest, currently offers a diagnostic test similar to the earlier version of our ThyGeNEXT® test and announced an agreement to distribute the Afirma test in partnership with Veracyte. CBLPath, Inc., or CBL, offers ThyroSeq®, a diagnostic test that analyzes genetic alterations using next-generation sequencing. In addition, other thyroid based endocrine competitors include Accelerate Diagnostics, Inc., or other companies we are not aware of. Additionally, in February 2020, we entered into an arrangement to co-market our thyroid test for an additional two years with LabCorp on a reference laboratory basis. We are in the process of negotiating a renewal of the LabCorp contract.

We are currently not aware of any direct competitors to PancraGEN® that integrate clinical, imaging, cytology, and molecular information to stratify patients' risk for malignancy and inform physicians on the best course of action, i.e., surgery or surveillance and surveillance interval length. The University of Pittsburgh Medical Center now offers PancreaSeq®, a Next Generation Sequencing "gene only" panel that focuses on the analysis of mutations in oncogenes and tumor suppressor genes, most of which may help establish the type of pancreatic cyst present and some of which may help establish the presence of malignancy. Some of these related genomic regions are included in PancraGEN®. This laboratory test however does not integrate any additional information to fully characterize a patient's risk for pancreatic cancer. Importantly, there has been no long-term clinical validation or utility studies completed on any gene panel for pancreatic cyst fluid other than that associated with PancraGEN®. PancraGEN® has been validated in multiple studies and peer reviewed publications and has been used in over 45,000 patients. Additionally, we validated and launched a DNA only version of PancraGEN®, known as PanDNA®.

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

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

With respect to pharma services, we also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Precision medicine is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors include public companies such as NeoGenomics, and many private companies.

Research and Development

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

Also, we use reagents for cross site validations and validations of new assays to be used in clinical trials. We may enter into collaborative relationships with research and academic institutions for the development of additional or enhanced tests to further increase the depth and breadth of our test offerings. Where appropriate, we may also enter into licensing agreements with our collaborative partners to both license intellectual property for use in our test panels as well as licensing such intellectual property out.

Our research and development costs are primarily clinical costs and were approximately $1.9 million and $2.8 million in 2021 and 2020, respectively.

We continue to generate and publish clinical evidence related to our key products, including ThyGeNEXT® and ThyraMIR® and PancraGEN® as well as our pipeline product, BarreGEN®.

Clinical Evidence

- The first manuscript reporting the clinical performance of ThyGeNEXT® and ThyraMIR® tests was accepted in July 2020 in the Diagnostic Cytopathology (Lupo M et al. Diagnostic Cytopathology. 2020; DOI: 10.10001/dc.24564.)

Intellectual Property

Patents, trademarks and other proprietary rights are important to us. We generate our own intellectual property portfolio and hold numerous patents and patent applications covering our existing and future products and technologies. As of December 31, 2021, we owned seven issued United States Patents. The U.S. patents are directed to, amongst other things, methods of measuring carcinoembryonic antigen in a biological sample; methods for treating subject with a high risk of disease progression from Barrett's metaplasia to esophageal adenocarcinoma; and methods of treating a subject identified with a papillary thyroid carcinoma. As of December 31, 2021, we owned four issued patents outside of the United States, one each in Australia, Europe (validated in certain European countries), Japan, and Israel. As of December 31, 2021, we owned five pending patent applications in the United States. Provided all maintenance fees and annuities are paid, our issued United States patents expire from 2031 through 2034 and our foreign patents expire in 2027 or 2031, and our pending patent applications, if issued, are expected to expire between 2027 and 2038, absent any disclaimers, adjustments or extensions. On March 29, 2017 we were notified by the European Patent Office that our EP patent # 2772550 for diagnosing thyroid cancer from a sample based upon at least MIR-375 was issued (validated in Spain, France, United Kingdom, Ireland, Italy, Belgium, Switzerland, Germany, and the Netherlands) and, provided all maintenance fees and annuities are paid, expires in 2031. On January 16, 2018, we were notified that an Opposition had been filed against EP patent # 2772550 alleging that the patent is invalid. On February 25, 2019, the European Patent Office Opposition Division issued a decision revoking the patent on grounds that the claims were not supported by a valid basis. On April 25, 2019, we filed a Notice of Appeal challenging the European Patent Office Opposition Division and we are waiting for the appeal to be decided. We continue to believe that the patent is valid. Our patents are directed to certain of the technologies relating to detecting, diagnosing, and classifying thyroid tumors, pancreatic cysts and other forms of gastrointestinal disorders, such as Barrett's esophagus.

On April 9, 2019 the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,255,410, supporting BarreGEN®. Additionally, United States Patent No. 10,444,239 issued on October 15, 2019, for methods measuring carcinoembryonic antigen in a biological sample.

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

On August 13, 2014, we consummated an agreement to acquire certain fully developed thyroid and other tests in development for thyroid cancer, associated intellectual property and a biobank with more than 5,000 patient tissue samples pursuant to an asset purchase agreement, or the Asuragen Asset Purchase Agreement. We paid $8.0 million at closing and paid an additional $0.5 million to Asuragen for certain integral transition service obligations set forth in a transition services agreement, entered into concurrently with the Asuragen Asset Purchase Agreement. We also entered into two license agreements with Asuragen (the Asuragen License Agreement and the CPRIT License Agreement) relating to our ability to sell the fully developed diagnostic tests and other tests in development for thyroid cancer. Under the Asuragen License Agreement, we owed a $500,000 milestone payment, all of which was paid in installments throughout 2016 and paid in full as of January 13, 2017. We are further obligated to pay royalties on the future net sales of tests based on the miR*Inform*® pancreas platform, if developed, on the future net sales of tests based on the miR*Inform*® thyroid platform (i.e., ThyGeNEXT®) and potentially on certain other thyroid diagnostics tests. We rely on Asuragen as our sole supplier for certain components of our endocrine cancer diagnostic tests pursuant to our supply agreement with them.

In October 2014, we acquired RedPath Integrated Pathology Inc. (RedPath) which included its pancreatic and gastrointestinal assets. Additionally, we have a broad and growing trademark portfolio. We have secured trademark registrations for the marks AccuCEA® (or TM), PancraGEN®, PanDNA®, BarreGEN® and miR*Inform*® in the United States, and miR*Inform*® with the World Intellectual Property Organization. In July 2019, in connection with the acquisition of the pharma services business of Cancer Genetics we acquired certain know-how.

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

Raw Material and Suppliers

We procure reagents, equipment and other materials that we use to perform our tests from sole suppliers. We also purchase components used in our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. Our most significant suppliers for reagents and supplies include Thermo Fisher Scientific, Illumina, Inc., Qiagen, Asuragen, and F. Hoffmann-La Roche AG. While we have developed alternate sourcing strategies for most of these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to perform the tests and for our collection kits, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in test processing could occur, we may not be able to deliver patient reports and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available. If our test volume decreases or we switch suppliers, we may hold excess inventory with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new test, we may experience supply issues as we ramp test volume.

Government Regulations and Industry Guidelines

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

Regulations over Our Clinical Laboratories

The conduct and provision of our clinical services and pharma services are regulated under the Clinical Laboratory Improvements Amendments ("CLIA"). CLIA requires us to maintain Federal certification. CLIA imposes requirements relating to test processes, personnel qualifications, facilities and equipment, recordkeeping, quality assurance and participation in proficiency testing. CLIA compliance and certification are also a condition for participation by clinical laboratories in the Medicare Program and for eligibility to bill for services provided to governmental healthcare program beneficiaries. As a condition of CLIA certification, our laboratories are subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is typically conducted by a State agency, or, if the laboratory is accredited, a CMS-approved accreditation organization. Sanctions for failure to meet these certification, accreditation and licensure requirements include suspension, revocation or limitation of a laboratory's CLIA certification, accreditation or license, which is necessary to conduct business, cancellation or suspension of the laboratory's ability to receive Medicare or Medicaid reimbursement, as well as imposition of plans to correct deficiencies, injunctive actions and civil monetary and criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could harm our business. In addition to CLIA requirements, we participate in the accreditation program of the College of American Pathologists ("CAP"). Under CMS requirements, accreditation by CAP is sufficient to satisfy the requirements of CLIA.

In addition to CLIA certification, we are required to hold state licenses in certain states. Some state licensing requirements differ from federal regulation and may be stricter. CLIA does not preempt state laws that are more stringent. If we were to lose our CLIA certification, CAP Accreditation, or required state licenses for our laboratories, whether as a result of revocation, suspension or limitation, we would no longer be able to provide our services, which would have a material adverse effect on our business, financial condition and results of operations.

Our laboratories are also subject to licensing and regulation under Federal, State and local laws relating to hazard communication and employee right-to-know regulations, and the safety and health of laboratory employees. Additionally, our laboratories are subject to applicable Federal and State laws and regulations and licensing requirements relating to the handling, storage and disposal of hazardous waste and laboratory specimens, including the regulations of the Environmental Protection Agency, the Department of Transportation, and the National Fire Protection Agency. The regulations of the United States Department of Transportation, Public Health Service and Postal Service apply to the surface and air transportation of laboratory specimens. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of hazardous waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

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

Potential U.S. Food and Drug Administration Regulation of Laboratory Developed Tests ("LDTs")

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

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

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

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

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

In March 2017, members of Congress posted a discussion draft of "The Diagnostics Accuracy and Innovation Act" (DAIA). The discussion draft included language that, if enacted, would have established a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. In March 2020, members of Congress introduced "The Verifying Accurate, Leading-edge IVCT Development (VALID) Act"; this bill was re-introduced in substantially similar form in June 2021. Pursuant to VALID, a risk-based approach would be used to regulate IVCTs while grandfathering many existing 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 certain 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 if it is reasonable possible that such tests will cause serious adverse health consequences (among other criteria). 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. It is unclear when, or if, the VALID Act will become law.

Healthcare, Fraud, Abuse and Anti-Kickback Laws

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

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

In addition to the Anti-Kickback Statute, the U.S. enacted the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). EKRA is an all-payer anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. The term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to $200,000, up to 10 years in prison, or both, per violation. As drafted, EKRA prohibits incentive compensation to sales employees, a practice that is common in the industry.

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

We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and state equivalents. These restrictions generally prohibit us from billing a patient or Medicare for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition. The government has also claimed in FCA litigation that the Stark Law applies to Medicaid claims. Some states have also enacted state Stark Law equivalents that can apply to that state's Medicaid plan and/or commercial payors.

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

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $26,125 for each service arising out of the prohibited referral;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $174,172 against parties that enter into a scheme to circumvent the Stark Law's prohibition.

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

Additionally, the Federal Civil Monetary Penalties Law prohibits, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

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

HIPAA, Fraud and Privacy Regulations

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

HIPAA, along with the Health Information Technology for Economic and Clinical Health Act (HITECH) and the various regulations promulgated thereunder, also establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by certain healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities," as well as individuals or entities to the extent they function as a business associate of a covered entity. The regulations promulgated under HIPAA govern: the Privacy of Individually Identifiable Health Information, restricting the use and disclosure of certain individually identifiable health information and establishing certain rights of individuals who are the subject of such information (45 C.F.R. §§ 164.500, et seq.); Administrative Requirements for electronic transactions, establishing standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures (45 C.F.R. §§ 162.100, et seq.); Security Standards for the Protection of Electronic Protected Health Information, requiring covered entities to implement and maintain certain security measures to safeguard certain electronic health information (45 C.F.R. §§ 164.302, et seq.); and Breach Notification, requiring covered entities and their business associates to provide certain notifications following a breach of unsecured protected health information (PHI) (45 C.F.R. §§ 164.400, et seq.). As a covered entity, and also in our capacity as a business associate to certain of our customers, we are subject to these standards. We may also be liable for violations of HIPAA by any individual or entity, which may include a business associate, that is acting as our agent under the federal common law of agency. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards entails significant costs for us and limits our performance of functions or activities that involve collecting, receiving, maintaining, transmitting, using, or disclosing PHI. Our failure to comply with HIPAA, HITECH, and their implementing regulations could lead to enforcement action that could have an adverse effect on our business. If we or our operations are found to be in violation of HIPAA, HITECH, or their respective implementing regulations, we may be subject to potentially significant penalties, including civil and criminal penalties, damages and fines, and may incur damage to our reputation.

In addition to Federal regulations issued under HIPAA and HITECH, many States and foreign jurisdictions have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent laws as HIPAA and HITECH do not supersede State laws to the extent such State laws are broader in scope, impose more stringent requirements for PHI, or give individuals more rights with respect to their PHI. If we fail to comply with applicable State or foreign laws, rules, or regulations, we could be subject to additional sanctions or other liabilities under those laws, rules, and regulations.

Federal and State Consumer Protection Laws

The Federal Trade Commission, or FTC, is an independent U.S. law enforcement agency charged with protecting consumers and enhancing competition across broad sectors of the economy. In 2022, the FTC has said that it will be evaluating new data privacy regulations, which, if adopted, could impact our operations. The FTC's authority with respect to data privacy and security comes from Section 5 of the FTC Act. The FTC uses its broad grant of authority to regulate data privacy and security, using its powers to investigate and bring lawsuits. Where appropriate, the FTC can seek a variety of remedies, such as but not limited to requiring the implementation of comprehensive privacy and security programs, biennial assessments by independent experts, monetary redress to consumers, and provision of robust notice and choice mechanisms to consumers.

In addition to the FTC Act, many U.S. states have unfair and deceptive acts and practices statutes, known as UDAP statutes, that are substantively similar to the FTC Act and have been applied in the privacy and data security context. These UDAP statutes vary in substance and strength from state to state. Many have broad prohibitions against unfair and deceptive acts and practices. These statutes generally allow for private rights of action, and are enforced by the states' Attorneys General.

California, Virginia, and Colorado have adopted comprehensive consumer privacy laws that are in effect or will take effect within the next 12 to 18 months, and regulate how certain for-profit businesses collect, use, and disclose the personal information of consumers who reside in those respective states. Among other things, these laws confer to their consumers the right to: receive notice of information collection and use practices; access, delete, correct, or transfer personal information and opt out of the "sale" of their personal information. These laws also require companies to adopt reasonable measures to safeguard the personal information that we collect and regulate categories of "sensitive" data such as information associated with minors, citizenship, and other personal data for which these state laws have designated special protection. These laws do not, however, apply to personal information that constitutes PHI under HIPAA, HIPAA-regulated entities to the extent that the entity maintains patient information in the same manner as PHI, and de-identified data as defined under HIPAA. As a result, we do not or likely will not have compliance obligations with respect to most testing and patient information we collect and process. However, we are required to comply with these consumer privacy laws insofar as we collect other categories of California, Virginia and Colorado consumers' personal information. These laws are generally enforced by the respective state Attorney General. California's law also includes a private right of action for certain data breaches.

Dozens of other states in the United States are currently considering similar, consumer data privacy laws, which could impact our operations if enacted.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or PPACA (also known as the Affordable Care Act), as amended by the Health Care and Education Reconciliation Act, a sweeping law intended to broaden access to health insurance and coverage for patients, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, coordinate and promote research on comparative clinical effectiveness of different technologies and procedures, and impose additional health policy reforms. PPACA, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on pricing and implemented changes which significantly affect the pharmaceutical, medical device and clinical laboratory industries. There have been legislative and administrative actions to make changes to PPACA, including repeal and replacement of certain provisions.

The PPACA has also been subject to challenges in the courts however, the U.S. Supreme Court upheld the law in 2021.

Further changes to the PPACA remain possible, although the new Administration under President Biden has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden has used executive orders to undo changes to the PPACA made by the Trump administration and indicated he would advocate for legislation to build on the PPACA. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the PPACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Third Party Coverage and Reimbursement for our Clinical Services

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

We generally bill third-party payers and individual patients for testing services on a test-by-test basis. Third-party payers include Medicare, private insurance companies, institutional direct clients and Medicaid, each of which has different billing requirements. Medicare reimbursement programs are complex and often ambiguous, and are continuously being evaluated and modified by CMS. Our ability to receive timely reimbursements from third-party payers is dependent on our ability to submit accurate and complete billing statements, and/or correct and complete missing and incorrect billing information. Missing and incorrect information on reimbursement submissions slows down the billing process and increases the aging of accounts receivable. We must bill Medicare directly for tests performed for Medicare patients and must accept Medicare's fee schedule for the covered tests as payment in full. State Medicaid programs are generally prohibited from paying more than the Medicare fee schedule. Through February 2021, we were contracted with XIFIN, Inc. ("XIFIN"), a healthcare billing services management company, to work with our in-house staff and help manage our third-party billing. In early March 2021, we expanded our relationship with XIFIN to deploy XIFIN's revenue cycle management solution enterprise-wide to support all of our diagnostics testing services. During January 2022, the Company became aware that CMS issued a new billing policy whereby CMS would no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service. In February 2022, the Company announced that this billing policy determination by CMS had been changed retroactively to January 1, 2022. As a result, the Company will continue billing for both tests according to its LCD as originally set by Novitas.

Some billing arrangements require us to bill multiple payers, and there are several other factors that complicate billing (e.g., disparity in coverage and information requirements among various payers; and incomplete or inaccurate billing information provided by ordering physicians). Since 2018 several private payers implemented pre-authorization requirements for molecular and genetic testing, including Anthem Blue Cross Blue Shield and United Healthcare, as well as various lab benefit companies such as American Imaging Management, Inc., or AIM, and Beacon Lab Benefits Solutions, or Beacon. In addition, more commercial payers are contracting with and delegating risk for lab services costs to lab benefits management companies (e.g. eviCore healthcare, AIM, and Beacon). This requires us to go through their technology assessment process to secure coverage and obtain a contract as an in-network lab provider for our services. We incur additional costs as a result of our participation in Medicare and Medicaid programs because diagnostic testing services are subject to complex, stringent and frequently ambiguous federal and state laws and regulations, including those relating to coverage, billing and reimbursement. Additionally, auditing for compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further cost and complexity to the billing process. Further, our billing systems require significant technology investment and, as a result of marketplace demands, we need to continually invest in our billing systems. Changes in laws and regulations could further complicate our billing and increase our billing expense. CMS establishes procedures and continuously evaluates and implements changes to the reimbursement process and requirements for coverage.

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

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

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

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

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

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

The Medicare Part B program contains fee schedule payment methodologies for clinical testing services performed for covered patients, including a national ceiling on the amount that carriers could pay under their local Medicare clinical testing fee schedules. Historically, the Medicare Clinical Laboratory Fee Schedule, or CLFS, has been subject to local variations in pricing. In April 2014, President Obama signed the Protecting Access to Medicare Act of 2014, or PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, CLFS rates are based upon the weighted median of private payor rates reported for each type of laboratory test. PAMA requires laboratories that receive a majority of their Medicare revenue from payments made under the CLFS and the Physician Fee Schedule, and at least $12,500 in CLFS revenue during the six month data collection period to report private payor data collected from such 6-month period (January 1 through June 30 in the applicable year) to CMS between January 1 through March 31 of the following year. CMS posted the first new Medicare CLFS rates (based on weighted median private payer rates) in November 2017 and the new rates became effective on January 1, 2018. CMS published final rules implementing these changes in 2016 and 2018. The result of the PAMA calculations was an increase in our reimbursement rate for ThyGenX® of approximately 40% for our Medicare volume. However, on July 26, 2018, we received a coding update from CMS, which changed the billable procedure code (CPT) for ThyGeNEXT®. This code change resulted in a reduction of the fee schedule for payments to us. We have recently presented clinical data to CMS adding additional markers to the panel that we run that increase our gene families above 50. If approved, reimbursement for the new panel will exceed the previously approved rate. There can be no assurances that our request will be successful and that the rate will be escalated.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, as amended by the Protecting Medicare and American Farmers from Sequester Cuts Act, revised payment reductions and the data reporting schedule for CDLTs that are not ADLTs. Under these laws, the next data reporting period is January 1, 2023 through March 31, 2023, and will be based upon the data collected during the January 1, 2019 to June 30, 2019 period. 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 2023 through 2025. Payments will not be reduced for 2021 or 2022 for CDLTs.

Under the revised Medicare Clinical Laboratory Fee Schedule, reimbursement for clinical laboratory testing was reduced for most tests in 2018, 2019, and 2020. PAMA calls for further revisions of the Medicare Clinical Laboratory Fee Schedule for years after 2021, based on future surveys of market rates.

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

Historically, most Medicare and Medicaid beneficiaries were covered under the traditional Medicare and Medicaid programs administered by the federal government. Reimbursement from traditional Medicare and Medicaid programs represented approximately 43% of our consolidated net revenues during 2020. Over the last several years, the federal government has continued to expand its contracts with private health insurance plans for Medicare beneficiaries and has encouraged such beneficiaries to switch from the traditional programs to the private programs, called “Medicare Advantage” programs. There has been growth of health insurance providers offering Medicare Advantage programs and of beneficiary enrollment in these programs. Commercial health plans that might not cover one or all of our tests for their commercially insured members are required to follow the Novitas LCD coverage policy for their Medicare Advantage members. To the extent we maintain the LCD coverage policies with Novitas for our products, any shift of members from traditional Medicare to Medicare Advantage plans doesn’t represent a risk of lost revenue. In recent years, in an effort to control costs, states also have mandated that Medicaid beneficiaries enroll in private managed care arrangements.

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

In December 2019, our Medicare Administrative Contractor (MAC) issued a new draft local coverage determination (LCD) for our ThyGeNEXT® test, representing an increase of approximately $2,400 per assay over previous reimbursement coverage. This increase in reimbursement rates reflects the expansion of the ThyGeNEXT® panel to aid in identifying the appropriate patients for surgery. Final approval is expected during the first half of 2020. Additionally, in February 2020, the CMS modified the reimbursement for ThyraMIR® retroactively to January 1, 2020. This determination increases the Medicare reimbursement for ThyraMIR® from approximately $1,800 to $3,000 reflecting a re-evaluation of the technical and clinical performance of the test relative to other molecular tests in the market and their respective prices.

In January 2022, the Company announced that CMS issued a new billing policy whereby CMS will no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service. On February 28, 2022, the Company announced that the National Correct Coding Initiative (NCCI) program issued a response on behalf of CMS stating that the January 2022 billing policy reimbursement change for ThyGeNEXT® (0245U) and ThyraMIR® (0018U) tests has been retroactively reversed to January 1, 2022. CMS is currently reimbursing the Company for one of its two thyroid tests, and has agreed to retroactively reimburse for the second test once they have completed their internal administrative adjustments. We have been notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 will be completed beginning July 1, 2022. As of the date of this filing, the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS.

Reporting Segments

We operate under one segment which is the business of developing and selling diagnostic clinical and pharma services.

Employees

As of February 28, 2022, we had approximately 147 full time employees and 147 total employees. We are not party to a collective bargaining agreement with any labor union.

Corporate Information

We were originally incorporated in New Jersey in 1986 and began commercial operations as PDI, Inc., a contract sales organization or CSO in 1987. In connection with PDI, Inc.'s initial public offering, it reincorporated in Delaware in 1998. In 2015 the CSO business and assets were sold, and we operated our molecular diagnostics business as Interpace Diagnostics Group, Inc. (IDXG). On July 15, 2019, we acquired the pharma services business from the secured creditors of CGI and Gentris, LLC, a wholly owned subsidiary of CGI and conduct that business as Interpace Pharma Solutions, Inc. We conduct our business through our wholly-owned subsidiaries, Interpace Diagnostics, LLC, which was formed in Delaware in 2013, Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007, and Interpace Pharma Solutions Inc. (formerly known as Interpace BioPharma, Inc.), which was formed in Delaware in 2019. On November 12, 2019, we changed the name of Interpace Diagnostics Group, Inc. to Interpace Biosciences, Inc. and that of our newly-formed subsidiary, Interpace BioPharma, Inc. to Interpace Pharma Solutions, Inc. 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.

Business Development

Series B Investment by 1315 Capital and Ampersand

On January 10, 2020, we entered into a Securities Purchase and Exchange Agreement (the "Securities Purchase and Exchange Agreement") with 1315 Capital II, L.P., a Delaware limited partnership ("1315 Capital"), and Ampersand 2018 Limited Partnership ("Ampersand" and together with 1315 Capital, the "Investors") pursuant to which we sold to the Investors, in a private placement pursuant to Regulation D and Section 4(a)(2) under the Securities Act, an aggregate of $20,000,000 in Series B Preferred Stock, at an issuance price per share of $1,000. Pursuant to the Securities Purchase and Exchange Agreement, 1315 Capital purchased 19,000 shares of Series B Preferred Stock at an aggregate purchase price of $19,000,000 and Ampersand purchased 1,000 shares of Series B Preferred Stock at an aggregate purchase price of $1,000,000.

In addition, we exchanged $27,000,000 of the Company's existing Series A Preferred Stock held by Ampersand, represented by 270 shares of Series A Preferred Stock, which represented all of the Company's issued and outstanding Series A Preferred Stock, for 27,000 newly created shares of Series B Preferred Stock (such shares of Series B Preferred Stock, the "Exchange Shares" and such transaction, the "Exchange"). Following the Exchange, no shares of Series A Preferred Stock remain designated, authorized, issued or outstanding. Under the terms of the Securities Purchase and Exchange Agreement, Ampersand also agreed to waive all dividends and weighted-average anti-dilution adjustments accrued to date on the Series A Preferred Stock.

For so long as each of Ampersand and 1315 Capital holds at least sixty percent (60%) of the Series B Preferred Stock issued to it on January 15, 2020, such Investor will be entitled to elect two directors to the Board, provided that one of the directors qualifies as an "independent director" under Rule 5605(a)(2) of the listing rules of the Nasdaq Stock Market (or any successor rule or similar rule promulgated by another exchange on which the Company's securities are then listed or designated) ("Independent Director"). However, if at any time such Investor holds less than sixty percent (60%), but at least forty percent (40%), of the Series B Preferred Stock issued to them on January 15, 2020, such Investor would only be entitled to elect one director to the Board. Any director elected pursuant to the terms of the Certificate of Designation may be removed without cause by, and only by, the affirmative vote of the holders of Series B Preferred Stock. A vacancy in any directorship filled by the holders of Series B Preferred Stock may be filled only by vote or written consent in lieu of a meeting of such holders of Series B Preferred Stock or by any remaining director or directors elected by such holders of Series B Preferred Stock.

The Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Certificate of Designation") provides that each share of Series B Preferred Stock is convertible, at any time and from time to time, at the option of the holder into a number of shares of our common stock equal to dividing the amount equal to the greater of the stated value of $1,000 of such Series B Preferred Stock, plus any dividends declared but unpaid thereon, or such amount per share as would have been payable had each such share been converted into our common stock immediately prior to a liquidation, by sixty cents ($0.60) (as adjusted to $6.00 following effectuation of the Reverse Stock Split in January 2020 and subject to further adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares). The aggregate number of shares of our common stock that may be issued through conversion of the currently outstanding Series B Preferred Stock is 78,333,334 shares (as adjusted to 7,833,334 shares following effectuation of the Reverse Stock Split and subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares). On any matter presented to our stockholders for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series B Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of our common stock into which the shares of Series B Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the Certificate of Designation, holders of Series B Preferred Stock will vote together with the holders of common stock as a single class and on an as-converted to common stock basis.

The Series B Preferred Stock entitles the holders thereof to certain protective provisions. In particular, for so long as any shares of Series B Preferred Stock are outstanding, the written consent of the holders of at least seventy five percent (75%) of the then outstanding shares of Series B Preferred Stock (voting as a single class) is required for us to amend, waive, alter or repeal the preferences, rights, privileges or powers of the holders of the Series B Preferred Stock, amend, alter or repeal any provision of the Certificate of Designation in a manner adverse to the holders of the Series B Preferred Stock, authorize, create or issue any equity securities senior to or pari passu with the Series B Preferred Stock, or increase or decrease the number of directors constituting the Board. Moreover, for so long as thirty percent (30%) of the Series B Preferred Stock outstanding as of January 15, 2020 remains outstanding (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares, including the Reverse Stock Split effected in January 2020), the written consent of the holders representing at least seventy-five percent (75%) of the of the outstanding shares of Series B Preferred Stock (voting as a single class) is required for us to: (A) authorize, create or issue any debt securities for borrowed money or funded debt (1) pursuant to which we issue shares, warrants or any other convertible security, or (2) in excess of $4,500,000 initially, with such amount to be increased in connection with an aggregate consolidated revenue milestone, but excluding certain specified permitted transactions; (B) merge with or acquire all or substantially all of the assets of one or more other companies or entities with a value in excess of $20,000,000, to be increased in connection with an aggregate consolidated revenue milestone; (C) materially change our business; (D) consummate any Liquidation (as defined in the Certificate of Designation); (E) transfer material intellectual property rights other than in the ordinary course of business; (F) declare or pay any cash dividend or make any cash distribution on any of our equity interests other than the Series B Preferred Stock; (G) repurchase or redeem any shares of our capital stock, except for the redemption of the Series B Preferred Stock pursuant to the terms of the Certificate of Designation, or repurchases of our common stock under agreements previously approved by the Board with employees, consultants, advisors or others who performed services for us in connection with the cessation of such employment or service; (H) incur any additional individual debt, indebtedness for borrowed money or other additional liabilities pursuant to we issue shares, warrants or any other convertible security, or incur any individual debt, indebtedness for borrowed money or other liabilities pursuant to which we do not issue shares, warrants or any other convertible security exceeding, in each case, $4,500,000 initially, with such amount to be increased in connection with an aggregate consolidated revenue milestone, but excluding certain specified permitted transactions; (I) change any of our accounting methods, except for those changes required by GAAP or applicable regulatory agencies or authorities; or (J) conduct a public offering of common stock registered with the SEC, including any at-the-market offering of our common stock.

During April 2020, the Company applied for various federal stimulus loans, grants and advances made available under Title 1 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, including a loan request under the Small Business Administration (SBA) Paycheck Protection Program (PPP). In connection with the Company's application for the PPP loan, both Ampersand and 1315 Capital consented to, and agreed to vote their shares of Series B Preferred Stock in favor of any "Fundamental Action" taken by the Company as determined by the Company's Board of Directors. "Fundamental Actions" include the Company's ability to a) authorize, create or issue any debt securities for borrowed money or funded debt; b) merge with or acquire all or substantially all of the assets of one or more other companies or entities with a value in excess of $20 million; c) transfer, by sale, exclusive license or otherwise, material intellectual property rights of the Company or any of its direct or indirect subsidiaries, other than those accomplished in the ordinary course of business; d) declare or pay any cash dividend or make any cash distribution on any equity interests of the Company other than the Series B Shares; e) incur any additional individual debt, indebtedness for borrowed money or other additional liabilities; and f) change any accounting methods or practices of the Company, except for those changes required by GAAP or applicable regulatory agencies or authorities. Subsequently, the Company and Ampersand agreed that Ampersand no longer was required to vote its shares of Series B Preferred Stock in favor of any "Fundamental Action" taken by the Company as determined by the Company's Board of Directors.

Reverse Stock Split

At a Special Meeting of Stockholders held on December 13, 2019, our stockholders authorized our Board, in its discretion, to amend our certificate of incorporation, as amended, to effect a reverse split of our outstanding common stock at a ratio between one-for-five (1:5) and one-for-fifteen (1:15), with such final ratio to be determined by the Board following the special meeting (the "**Reverse Stock Split**"). On January 14, 2020, the Board determined to set the Reverse Stock Split ratio at one-for-ten (1:10) and approved the final form of the certificate of amendment to our certificate of incorporation to effectuate the Reverse Stock Split, which was filed with the Secretary of State of the State of Delaware on January 14, 2020. The Reverse Stock Split became effective in accordance with the terms of the certificate of amendment at 12:01a.m. Eastern Time on Wednesday, January 15, 2020, at which time every ten (10) shares of common stock issued and outstanding automatically combined into one (1) share of issued and outstanding common stock, without any change in the par value per share. Fractional shares were not issued as a result of the Reverse Stock Split. Instead, any fractional shares of our common stock that would have otherwise resulted from the Reverse Stock Split were rounded up to the nearest whole share.

The Reverse Stock Split resulted in a proportionate adjustment to the per share exercise price and the number of shares of common stock issuable upon the exercise of our outstanding stock options and warrants, as well as the number of shares of common stock eligible for issuance under the Interpace Biosciences, Inc. 2019 Equity Incentive Plan and the Interpace Biosciences, Inc. Employee Stock Purchase Plan.

Except as otherwise indicated, all share and per share information herein gives effect to the Reverse Stock Split.

Available Information

We maintain an internet website at www.interpace.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports are available free of charge through the "Investor Relations" portion of our website, as soon as reasonably practicable after they are filed with the SEC. The content contained in, or that can be accessed through, our website is not incorporated into this Form 10-K.

ITEM 1A. RISK FACTORS

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

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks:

- Our operating history of net losses, negative working capital and insufficient cash flows, and lack of liquidity to pay our current obligations raise doubts about our ability to continue as a going concern.
- The COVID-19 global pandemic may continue to materially and adversely impact our business, financial condition and results of operations.
- We have and may continue to experience intangible asset or other long-lived asset impairment charges.
- We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Due to how we recognize revenue, our quarterly revenue and operating results are likely to fluctuate.
- A deterioration in the collectability of our accounts receivable could have a material adverse effect on our business, financial condition and results of operations.
- We depend on sales and reimbursements from our clinical services for more than 50% of our revenue, and we will need to generate sufficient revenue from these and other products and/or solutions that we develop or acquire to grow our business.
- Two private equity firms and their affiliates' control, on an as-converted basis, an aggregate of 65% of our outstanding shares of common stock through their holdings of our Series B Preferred Stock, and this concentration of ownership along with their authority for designation rights for a majority of our directors and their right to approve certain of our actions has a substantial influence on our decisions.
- Our secured lenders have the right to foreclose on substantially all of our assets if we are unable to timely repay our outstanding obligations.
- Billing for our clinical services tests is complex, and we must dedicate substantial time and resources to the billing process to be paid for our clinical services tests.
- We depend on a few payers for a significant portion of our revenue for our clinical services, and if one or more significant payers, including CMS, stops providing reimbursement or decreases the amount of reimbursement for our tests, or if we are unable to successfully negotiate additional reimbursement contracts for our clinical services tests, our revenue could decline and our commercial success could be compromised. Our reliance on Medicare reimbursement for our clinical services and our being subject to decisions of the Center for Medicare and Medicaid Services ("CMS") regarding reimbursement and pricing of our clinical services which could have a material adverse effect on our business and financial results, which has temporarily had a material adverse effect on our business due to a new billing policy issued by CMS in January 2022 whereby CMS stated they would no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service; while this decision was subsequently reversed in February 2022, the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS;

- We rely on third-parties to process and transmit claims to payers for our clinical services, and any delay in processing or transmitting could have an adverse effect on our revenue and financial condition.
- We may experience a decline in demand for our clinical services tests and/or our pharma services products, which may result in a reduction in revenue.
- If we are unable to increase sales of our clinical services and the tests and services in our pharma services, we may be unable to achieve profitability.
- Our profitability will be impaired by our obligations to make royalty and milestone payments to our licensors for our clinical services tests.
- We depend on third parties for the supply of some of the materials used in our clinical and pharma services tests, and we may not be able to find replacements or transition to alternative suppliers in a timely manner.
- The markets that our clinical services and pharma services operate in is competitive, and our ability to compete successfully in this market depends on a variety of reasons, including our ability to keep up with rapid technological, medical, and scientific changes or our ability to enter into new clinical study collaborations. If we are unable to compete successfully in the markets our clinical services and pharma services operate in, we may be unable to increase or sustain our revenue or achieve profitability.
- If the FDA changes its enforcement policy as to laboratory developed tests (LDTs) or disagrees with our position that our clinical services 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 clinical services and/or incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and comply with applicable post-market requirements.
- A failure to comply with federal and state laws and regulations, including but not limited to those laws related to billing practices, fraud, abuse, and payer regulations, could result in our being excluded from participation in Medicare, Medicaid or other governmental payer programs and/or significant monetary fines, and additionally may decrease our revenues and adversely affect our results of operations and financial condition for our clinical services.
- We may not realize all of the anticipated benefits of the acquisition of our pharma services or those benefits may take longer to realize than expected.
- If we are unable to successfully utilize, integrate, and/or promote our pharma services in the market, we may be unable to generate sufficient revenue to sustain our pharma services.
- If we fail to perform our pharma services in accordance with contractual and regulatory requirements, and ethical considerations, we could be subject to significant costs, legal liabilities and could experience a decline in revenue.
- The loss of members of our senior management team or our inability to attract and retain key personnel could adversely affect 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.
- Legislation reforming the U.S. healthcare system may have a material adverse effect on our financial condition and operations.

- 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 risks associated with penny stock classification could affect the marketability of the Company's common stock and stockholders could find it difficult to sell their shares.

- We believe the delisting of our common stock from Nasdaq and trading on OTCQX® has adversely affected trading in our common stock and our ability to seek financing.

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

Risks Related to our Business

There are substantial doubts about our ability to continue as a going concern due to our operating history of net losses, negative working capital and insufficient cash flows, and lack of liquidity to pay our current obligations and if we are unable to continue our business, our shares may have little or no value.

Our ability to become a profitable operating company is dependent upon our ability to generate revenues and/or obtain financing adequate to support our cost structure. We do not currently have enough cash on hand to meet our obligations over the next twelve months, and we cannot provide our stockholders any assurance that we will be able to raise sufficient funding from the generation of revenue, the sale of our common stock, or through financing to sustain us over the next twelve months.

For the fiscal year ended December 31, 2021, we had an operating loss of $14.0 million. As of December 31, 2021, we had cash and cash equivalents of $3.1 million and current liabilities of $15.7 million. The Company must fund its operating deficit until a sustainable level of revenue is achieved. These factors have raised substantial doubts about our ability to continue as a going concern. We may need to attempt to raise additional equity capital by selling shares of common stock or other dilutive or non-dilutive means, if necessary. However, the doubts raised, relating to our ability to continue as a going concern, may make investing in our securities an unattractive investment for potential investors. These factors, among others, may make it difficult to raise any additional capital.

Our results of operations have been adversely affected and, in the future, could be materially adversely impacted by the coronavirus (COVID-19) pandemic.

The world is currently suffering a COVID-19 pandemic which has resulted in governments around the world implementing stringent measures to help control the spread of the virus, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. The continuing impact that the COVID-19 pandemic will have on our operations, including duration, severity and scope, remains highly uncertain and cannot be fully predicted at this time. Such impact is a function of the scope of any new virus mutations and outbreaks, the nature of government public health guidelines and the public's adherence to those guidelines, the rate of individuals becoming fully vaccinated, the public's adherence to guidelines to receive booster shots, the success of business and economic recovery as the pandemic recedes, unemployment levels, the extent to which new shutdowns may be needed and the impact of any further government economic relief on the U.S. economy. In particular, the continued spread of the coronavirus globally is adversely affecting global economies and financial markets which has materially and adversely impacted our operations including, without limitation, the functioning of our laboratories, the availability of supplies including reagents, the progress and data collection of our pharma services, demand for our services and travel, customer demand and employee health and availability. Further, the impact of the COVID-19 pandemic in part caused us to reevaluate the carrying charge of our intangible assets and led us to restate certain of our financial statements to record impairment charges and amortization expense. While we believe we have generally recovered from the adverse impact that the COVID-19 pandemic had on our business during 2020, we believe that the COVID-19 pandemic could continue to adversely impact our results of operations, cash flows and financial condition in the future.

The ongoing military conflict between Russia and Ukraine has caused geopolitical instability, economic uncertainty, financial markets volatility and capital markets disruption. Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the U.S. Russia's invasion, the responses of countries and political bodies to Russia's actions, the larger overarching tensions, and Ukraine's military response and the potential for wider conflict have resulted in financial market volatility and capital markets disruption, potentially increasing in magnitude, and could have severe adverse effects on regional and global economic markets and international relations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial.

Following Russia's actions, various countries, including the U.S., Canada and the United Kingdom, as well as the European Union, issued broad-ranging economic sanctions against Russia. Such sanctions included, among other things, a prohibition on doing business with certain Russian companies, officials and oligarchs; a commitment by certain countries and the European Union to remove selected Russian banks from the Society for Worldwide Interbank Financial Telecommunications (SWIFT) electronic banking network that connects banks globally; a ban on Russian oil and gas imports to the U.S.; and restrictive measures to prevent the Russian Central Bank from undermining the impact of the sanctions. The current sanctions (and potential further sanctions in response to continued Russian military activity) and other actions may have adverse effects on regional and global economic markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds and increasing the volatility of our stock price. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results.

Actions that we have taken to restructure our business to strengthen the Company's profile, enhance shareholder values, and increase revenue growth may not be as effective as anticipated.

During Fiscal 2020 and 2021, we implemented certain restructuring and reprioritization plans to strengthen the Company's profile, enhance shareholder values, and increase revenue growth, by engaging in actions that included, but were not limited to, corporate reprioritization efforts and implementation of various cost saving measures. These plans included the transition of pharma activities from the Rutherford, NJ facility to our Morrisville, NC facility in order to optimize the operations of laboratory operations within our pharma services. We invested several million dollars to facilitate this relocation which was completed in March 2021, including but not limited to the transfer of personnel, expansion of the Morrisville facility and validation of transferred processes. While we expect to realize cost-saving benefits from these initiatives, these actions may not be successful and may not bring the cost saving benefits that we anticipate.

We have a history of operating losses, and our clinical and pharma services have generated limited revenue. We expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.

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 (i) continue to devote resources to increase adoption of, and reimbursement for, our clinical services tests and assays and to use our bioinformatics data to develop and enhance our clinical services products and services, (ii) leverage and invest in our pharma services to expand and enhance our pharma services and (iii) develop and acquire additional products and services. However, our business may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could have a material adverse effect on our business, financial condition and results of operations, as well as cause the market price of our common stock to decline.

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 has had and would have a negative and unexpected impact on our net worth.

In January 2021, we filed restated financial statements contained in the Company's Annual Report on Form 10-K for the years ended December 31, 2014 through 2019 as well as the financial statements contained in the Quarterly Reports on Form 10-Q for each quarterly period within those fiscal years as well as the quarterly periods ended March 31, 2020 and June 30, 2020. Such restatements reflected a non-cash impairment charge and amortization expense related to our Barrett's intangible asset of approximately $18 million.

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

We began commercial sales of our molecular diagnostic tests in late 2014. On July 15, 2019, we acquired the pharma services business. We conduct our business through our wholly-owned subsidiaries, Interpace Diagnostics, LLC, which was formed in Delaware in 2013, Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007, and Interpace BioPharma, Inc., which was formed in Delaware in 2019. On November 12, 2019 we changed the name of Interpace Diagnostics Group, Inc. to Interpace Biosciences, Inc. and that of our newly-formed subsidiary, Interpace BioPharma, Inc. to Interpace Pharma Solutions, Inc. 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.

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

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

- uncertainty of cash collections which could impact or affect net realizable values of sales of our tests and services;
- inability of one or more of our laboratories to perform tests;
- progress or lack of progress in developing and commercializing tests and services;
- favorable or unfavorable decisions about our tests or services or reimbursement rates from government regulators, insurances companies, customers, or other third party payers;
- the commencement, delay, cancellation or completion of sales and marketing programs;
- 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;
- changes in our relationships with key collaborators, suppliers, customers and third parties;
- 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. 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.

We depend on sales and reimbursements from our clinical services for more than 50% of our revenue, and we will need to generate sufficient revenue from these and other products and/or solutions that we develop or acquire to grow our business.

More than 50% of our revenue is derived from our clinical services. We have molecular diagnostics tests and complimentary service extensions that are in development, but there can be no assurance that we will be able to successfully commercialize or sufficiently increase revenues from those tests. If we are unable to increase sales of our molecular diagnostic tests, expand reimbursement for these tests, or successfully develop and commercialize other molecular diagnostic tests, our revenue and our ability to achieve and sustain profitability would be impaired, and this could have a material adverse effect on our business, financial condition and results of operations, and the market price of our common stock could decline.

We rely on third-parties to process and transmit claims to payers for our clinical services, and any delay in processing or transmitting could have an adverse effect on our revenue and financial condition.

We rely on third-parties to provide overall processing of claims and to transmit actual claims to payers based on specific payer billing formats. In 2019, we transitioned to a new third-party processor and there can be no assurance that we will not experience interruptions or collection delays with our future billings, an occurrence of which may adversely impact our revenue and financial condition. If claims for our clinical services are not submitted to payers on a timely basis, or if we are again required to switch to a different third-party processor to handle claim submissions, we may experience delays in our ability to process claims and receive payment from payers, which could have a material adverse effect on our business, financial condition and results of operations.

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

We adopted Financial Accounting Standards Board ("FASB") ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)" (or "ASC 606") effective January 1, 2018. As of this date, all revenue is recognized on the accrual basis, based upon actual collection histories for tests and services and respective payers or payer groups. Due to this change in accounting and the estimations required under ASC 606, our quarterly revenue and operating results are likely to fluctuate. As we recognize revenue from payers under ASC 606, we may subsequently determine that certain judgments underlying estimated reimbursement change, or that the 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. We experienced an adjustment in our estimate for variable consideration under ASC 606 during the fourth quarter of 2019 which resulted in a $5.2 million reduction in revenue recognized year to date; however there have been no such adjustments since then.

As a result, comparing our operating results on a period-to-period basis may be difficult due to fluctuations resulting from the estimation process under ASC 606 and such comparisons 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.

A deterioration in the collectability of our accounts receivable could have a material adverse effect on our business, financial condition and results of operations.

Collection of accounts receivable from third-party payers and clients is critical to our operating performance. Our primary collection risks are (i) the risk of overestimating our net revenue at the time of billing, which may result in us receiving less than the recorded receivable, (ii) the risk of non-payment as a result of denied claims, (iii) in certain states, the risk that clients will fail to remit insurance payments to us when the commercial insurance company pays out-of-network claims directly to the client and (iv) resource and capacity constraints that may prevent us from handling the volume of billing and collection issues in a timely manner. Additionally, our ability to hire and retain experienced personnel affects our ability to bill and collect accounts in a timely manner. We routinely review accounts receivable balances in conjunction with these factors and other economic conditions that might ultimately affect the collectability of the client accounts and factor them into our estimation of collectability as warranted. Significant changes in business operations, payer mix or economic conditions, including changes resulting from legislation or other health reform efforts (including to repeal or significantly change the Affordable Care Act), could affect our collection of accounts receivable, cash flows and results of operations. In addition, increased client concentration in states that permit commercial insurance companies to pay out-of-network claims directly to the client instead of the provider, could adversely affect our collection of receivables. Unexpected changes in reimbursement rates by third-party payers could have a material adverse effect on our business, financial condition and results of operations.

Our business is substantially dependent on third-party reimbursement. Any change in the overall health care reimbursement system may adversely impact our business.

Our revenues are substantially dependent on third-party reimbursement. We are paid directly by private insurers and governmental agencies, often on a fixed fee basis. If the average fees allowable by private insurers or governmental agencies were reduced, the negative impact on revenues could have a material effect on our business, financial condition, results of operations and cash flows. Also, if amounts owed to us by payors are reduced or not paid on a timely basis, we may be required to increase our concessions and/or decrease our revenues. Changes to the health care reimbursement system that favor other technologies or treatment regimens and reduce our reimbursements may adversely affect our ability to market our services profitably. Overall, such dependency and potential changes could materially and adversely affect our business, financial condition, results of operations and cash flows.

Our inability to finance our business on acceptable terms in the future may limit our ability to develop and commercialize products and services and grow our business.

Our business is not currently operating on a cash flow breakeven or positive basis, 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. On January 7, 2021, we entered into promissory notes ("Notes") with our two private equity investors in the aggregate amount of $5 million with a maturity date of June 30, 2021 which were secured by all of our assets. In October 2021, the Company entered into a $7.5 million revolving credit facility with Comerica Bank ("Comerica"). In addition, also in October 2021, the Company entered into an $8.0 million term loan with BroadOak Fund V, L.P. ("BroadOak"), the proceeds of which were used to repay in full at their maturity the Notes extended by our two private equity investors. The BroadOak loan agreement contains affirmative and negative restrictive covenants, including restrictions on certain mergers, acquisitions, investments and encumbrances which could adversely affect our ability to conduct our business. The BroadOak loan agreement also contains customary events of default. The Comerica loan agreement contains affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the Comerica loan agreement. These restrictive covenants, which include restrictions on certain mergers, acquisitions, investments, encumbrances, etc., could adversely affect our ability to conduct our business. The Comerica loan agreement also contains financial covenants requiring specified minimum liquidity and minimum revenue thresholds and also contains customary events of default.

We will need additional funding to repay the Comerica and BroadOak borrowings as well as to continue operations. Additional funding may not be available to us on acceptable terms, or at all. If we seek to raise funds by issuing additional equity securities, dilution to our stockholders could result. Any public offering of equity securities must be approved by the holders of our Series B Preferred Stock who are our private equity investors. In addition, we are currently ineligible to use a Form S-3 shelf registration statement. If we are unable to timely repay the Comerica and BroadOak borrowings when due, Comerica and BroadOak will have the right to foreclose on our assets (BroadOak being subordinated to Comerica). 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.

If we are unable to timely repay our outstanding obligations, our secured lenders will have the right to foreclose on our assets.

In October 2021, the Company entered into a $7.5 million revolving credit facility with Comerica and an $8.0 million term loan with BroadOak, which are secured by all of our assets. We will need additional funding to repay these outstanding obligations as well as to continue operations. Additional funding may not be available to us on acceptable terms, or at all. If we are unable to timely repay these outstanding obligations, our secured lenders will have the right to foreclose on substantially all of our assets.

Risks Related to our Preferred Stock

We have issued and may issue additional preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue up to five million shares of preferred stock in one or more series. Our Board may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue additional preferred stock, it could affect stockholder rights or reduce the market value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party. We have designated, issued and sold an aggregate of 47,000 outstanding shares of Series B Preferred Stock.

Two private equity firms and their affiliate's control, on an as-converted basis, an aggregate of 65% of our outstanding shares of common stock through their holdings of our Series B Preferred Stock, and this concentration of ownership along with their authority for designation rights for a majority of our directors and their right to approve certain of our actions has a substantial influence on our decisions.

Ampersand holds 28,000 shares of our Series B Preferred Stock and 1315 Capital holds 19,000 shares of our Series B Preferred Stock. Accordingly, on an as converted basis, Ampersand and its affiliates beneficially own 38.7% of the Company's outstanding common stock of 4,217,063 and 1315 Capital and its affiliates beneficially own 26.3%. The conversion and sale by such holders of one or more large blocks of our common stock could have a negative impact on the market price of our common stock.

These stockholders, acting together, have control over the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. Holders of Series B Preferred Stock were granted director designation rights over a majority of our Board. Accordingly, these stockholders, acting together, have significant influence over our management and affairs. This concentration of ownership might harm the market price of our common stock by delaying, deterring or preventing a change in control, making some transactions more difficult or impossible to complete without the support of these shareholders, regardless of the impact of this transaction on our other shareholders. Such ownership interests could effectively deter a third party from making an offer to buy us, which might involve a premium over our current stock price or other benefits for our stockholders, or otherwise prevent changes in the control or management. For example, this concentration of ownership may have the effect of impeding a merger, consolidation, takeover or other business combination involving us or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The holders of our Series B Preferred Stock have preferential rights that may be adverse to holders of our common stock.

The holders of our Series B Preferred Stock have preferential rights with respect to distributions upon a liquidation of the Company, including certain business combinations or sales of assets deemed to be a liquidation. Accordingly, no distributions upon liquidation may be made to the holders of common stock until the holders of the Series B Preferred Stock have been paid their liquidation preference. As a result, it is possible that, on a liquidation event and depending on the price thereof, all amounts available for the holders of equity of the Company would be paid to the holders of Series B Preferred Stock, and that the holders of common stock would not receive any payment. In addition, the holders of Series B Preferred Stock have the right to approve certain actions of the Company.

In April 2020, 1315 Capital consented to, and agreed to vote (by proxy or otherwise) their Series B Preferred Stock in favor of any "Fundamental Action" taken by the Company as determined by the Company's Board of Directors. "Fundamental Actions" include the Company's ability to a) authorize, create or issue any debt securities for borrowed money or funded debt; b) merge with or acquire all or substantially all of the assets of one or more other companies or entities with a value in excess of $20 million; c) transfer, by sale, exclusive license or otherwise, material intellectual property rights of the Company or any of its direct or indirect subsidiaries, other than those accomplished in the ordinary course of business; d) declare or pay any cash dividend or make any cash distribution on any equity interests of the Company other than the Series B Shares; e) incur any additional individual debt, indebtedness for borrowed money or other additional liabilities; and f) change any accounting methods or practices of the Company, except for those changes required by GAAP or applicable regulatory agencies or authorities.

Risks Related to our Clinical Services

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

Billing for clinical 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 clinical services, 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;
- changes in billing policy reimbursement by CMS;
- 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;
- the resources required to manage the billing and claims appeals process including those of our billing service providers;
- our inability to bill timely and accurate requisitions and process denials efficiently may result in delayed collections and reduced reimbursement rates; and
- the overall performance and effectiveness of our billing service providers.

As we grow and introduce new clinical services 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 from our clinical services. 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 solutions, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We depend on a few payers for a significant portion of our revenue for our clinical services, and if one or more significant payers, including CMS, stops providing reimbursement or decreases the amount of reimbursement for our tests, or if we are unable to successfully negotiate additional reimbursement contracts for our clinical services tests, our revenue could decline and our commercial success could be compromised.

Revenue for clinical services tests performed on patients covered by Medicare was approximately 54% of our revenue for the fiscal year ended December 31, 2021. The percentage of our revenue derived from significant payers for our clinical services tests is expected to fluctuate from period to period as our revenue increases, as additional payers provide reimbursement for such tests, and in the event that one or more payers were to stop reimbursing for our clinical services tests or change their reimbursement amounts.

In January 2022, the Company announced that CMS issued a new billing policy whereby CMS will no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service. On February 28, 2022, the Company announced that the National Correct Coding Initiative (NCCI) program issued a response on behalf of CMS stating that the January 2022 billing policy reimbursement change for ThyGeNEXT® (0245U) and ThyraMIR® (0018U) tests has been retroactively reversed to January 1, 2022. CMS is currently reimbursing the Company for one of its two thyroid tests, and has agreed to retroactively reimburse for the second test once they have completed their internal administrative adjustments. We have been notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 will be completed beginning July 1, 2022. As of the date of this filing, the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS.

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

Our PancraGEN®, ThyraMIR® and ThyGeNEXT® tests are reimbursed by Medicare based on applicable CPT codes. RespriDx® is currently only covered by the Medicare Advantage program and our BarreGEN® assay is not reimbursed at all. Any future reductions from the current reimbursement rates for our clinical services tests 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 clinical services 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 for our clinical services tests.

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

Physicians may generally not order our clinical services 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 clinical services 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 for our clinical services tests.

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 for our clinical services tests could be harmed and this could have a material adverse effect on our business, financial condition and results of operations.

We may experience a reduction in revenue if physicians decide not to order our clinical services tests.

If we are unable to create or maintain sufficient demand for our clinical services 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 clinical services tests in order to change clinical practices through clinical trials, published papers, presentations at scientific conferences and one-on-one education by our commercial sales force, which are costly and time-consuming. In addition, our ability to obtain and maintain adequate reimbursement from third-party payers for our clinical services tests 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. Moreover, 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 from our clinical services tests and achieve profitability, which could have a material adverse effect on our business, financial condition and results of operations.

We may experience a reduction in revenue if patients decide not to use our clinical services tests.

Some patients may decide not to use our clinical services tests due to price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. Many insurers seek to shift more of the cost of healthcare to patients in the form of higher deductibles, co-payments, or premiums. In addition, the economic environment in the United States may result in the loss of healthcare coverage. Implementation of provisions of PPACA provided coverage for patients, particularly in the individual market, who were previously either uninsured or faced high premiums. However, premiums for many of the plans participating in the exchanges established as part of this legislation have increased and some health plans have chosen to drop out of these networks in specific markets or the program altogether. In 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. Overall, 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 clinical services 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 for our clinical services tests if they meet the criteria for participation.

If our clinical services tests 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 in part 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 in our clinical services tests.

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

In connection with our acquisition of certain assets of Asuragen in 2014, we currently license certain patents and know-how from Asuragen relating to (i) miR*Inform*® thyroid and pancreas cancer diagnostic tests and other tests in development for thyroid cancer (the "Asuragen License Agreement"), and (ii) the sale of diagnostic devices and the performance of certain services relating to thyroid cancer (the "CPRIT License Agreement"). Pursuant to the Asuragen License Agreement and the CPRIT License Agreement, we are obligated to make certain royalty and milestone payments to Asuragen and the Cancer Prevention & Research Institute of Texas, or CPRIT. Under the Asuragen License Agreement, we are obligated to pay royalties on the future net sales of tests utilizing the miR*Inform*® thyroid platform (i.e., ThyGeNEXT®), potentially on certain other thyroid diagnostics tests and potentially on other tests in development for thyroid cancer. A similar obligation exists if we elect to launch any molecular tests utilizing the miR*Inform*® pancreas platform. We are also required by the CPRIT License Agreement with Asuragen to make certain related royalty payments to CPRIT.

When performing the ThyraMIR® test, we use products supplied by Exiqon A/S (now a part of Qiagen), subject to a license agreement with Exiqon A/S. The license agreement obligates us to pay royalties on the future net sales of our assays that utilize licensed patents and know-how obtained from Exiqon A/S. Our profitability will be impaired by our obligations to make royalty payments to our licensors. Although we believe, under such circumstances, that the increase in revenue will exceed the corresponding royalty payments, our obligations to our licensors could have a material adverse effect on our business, financial condition and results of operations if we are unable to manage our operating costs and expenses at profitable levels.

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

Under the CPRIT License Agreement, we are obligated to pay 5% of net sales on sales of certain diagnostic devices and the performance of services relating to thyroid cancer that incorporate technology developed and funded under an agreement between Asuragen and the Cancer Prevention and Research Institute of Texas, subject to a maximum deduction of 3.5% for royalties paid to third parties. Both of the Asuragen License Agreement and the CPRIT License Agreement continue until terminated by (i) mutual agreement of the parties or (ii) either party in the event of a material breach of the respective agreement by the other party.

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 technology would end. To the extent such licensed technology 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 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 technology licensed to us under these license agreements, and to the extent such 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 NGS-based thyroid and pancreatic cancer molecular diagnostic tests and other tests in development for thyroid cancer, and the sale of molecular diagnostic tests and the performance of certain services relating to thyroid cancer.

Under the agreement, neither party will be held responsible for a default or breach for failure or delay in performing its obligations when such failure or delay is caused by or results from events beyond reasonable control of the non-performing party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics or pandemics, quarantines war, acts of war, etc.

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 molecular diagnostic test, helping to assure there is appropriate reimbursement. We will need to conduct additional studies for our molecular 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 rely on sole suppliers for some of the materials used in our tests and services, and we may not be able to find replacements or transition to alternative suppliers in a timely manner.

We rely on sole suppliers for certain materials that we use to perform our tests and services, including Asuragen, for our endocrine cancer diagnostic tests pursuant to our supply agreement with them. We also purchase reagents used in our tests and services 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 tests and services, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing and services could occur. Any such interruption may directly impact our revenue and cause us to incur higher costs. In particular, the continued spread of the coronavirus globally could materially and adversely impact our operations including without limitation our supply chain, which may have a material and adverse effect on our business, financial condition and results of operations.

We may experience problems in scaling our operations, or delays or reagent and supply shortages for our tests and services 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 tests and services, 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 tests and services fluctuate, we could incur additional costs associated with either expediting or postponing delivery of those materials or reagents.

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

As demand for our tests and services grow, 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 tests and services. 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 and services 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.

Developing new 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 tests, assays, services and solutions under development.

Developing new tests, services and solutions will require us to devote considerable resources to research and development, which we may not be in a position to do. We may face challenges obtaining sufficient numbers of samples to validate a newly acquired or developed test or service. In order to develop and commercialize new tests and services, 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 tests and services; and
- build and maintain the commercial infrastructure to market and sell new tests and services.

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 test, service 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, service or solution. 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 test, service or solution which could harm our business. In addition, competitors may develop and commercialize new competing tests, services and solutions 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 are unable to develop or acquire tests, services and solutions to keep pace with rapid technological, medical and scientific change, our operating results and competitive position in the market 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 clinical services and pharma services 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 tests, services and solutions or to demonstrate the applicability of our tests and services 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 related to our tests and services, 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 the FDA changes its enforcement policy as to LDTs or disagrees with our position that our clinical services 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 clinical services 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 clinical services 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. Most 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 July 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 unless subject to continued enforcement discretion. 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 January 13, 2017, the FDA released a discussion paper on LDTs outlining a possible, substantially-revised risk-based approach for FDA and Centers for Medicare & Medicaid Services, or CMS, oversight of LDTs. According to the 2017 discussion paper, most 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 many 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. The evidence of the analytical and clinical validity of all LDTs would be made publicly available. LDTs would be 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, members of Congress posted a discussion draft of "The Diagnostics Accuracy and Innovation Act" (DAIA). The discussion draft included language that, if enacted, would have established a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. In 2020, members of Congress introduced "The Verifying Accurate, Leading-edge IVCT Development (VALID) Act"; this bill was re-introduced in substantially similar form in June 2021. If enacted, VALID would create a risk-based approach to regulate IVCTs while grandfathering many existing IVCTs. The new regulatory framework will include quality control and post-market reporting requirements. 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 certain 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 if it is reasonably possible that such tests will cause serious adverse health consequences (among other criteria). We cannot predict whether this bill will become law or the ultimate impact of its passage, or other legislative or regulatory changes, 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 pre-certification or approval before continuing to market such tests in the U.S. We may not be able to obtain such pre-certifications or 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.

If we are required to submit applications for our currently-marketed clinical services 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 clinical services, 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 clinical services 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 clinical services 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 clinical services and results of operations.

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

The marketing, sale and use of our tests and services could lead to product liability claims if someone were to allege that the test or service 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.

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

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

Risks Related to our Pharma Services

We may not realize all of the anticipated benefits of the acquisition of our pharma services business or those benefits may take longer to realize than expected. We may also encounter significant unexpected difficulties in integrating the pharma services business.

Our ability to realize the anticipated benefits of the acquisition of the pharma services business depends, to a large extent, on our ability to integrate it successfully. The combination and integration of two independent operations is a complex, costly and time-consuming process. As a result, we have been required and are continuing to devote significant management attention and resources to integrating the business practices and operations of our pharma services with our clinical services practices and operations. The integration process, which includes moving laboratory locations, may disrupt the operations and, if implemented ineffectively or if impacted by unforeseen negative economic or market conditions or other factors, we may not realize the full anticipated benefits of the acquisition. Our failure to meet the challenges involved in integrating the two operations to realize the anticipated benefits of such acquisition could cause an interruption of, or a loss of momentum in, our activities and could adversely affect our results of operations.

In addition, the overall integration of the operations may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention. The difficulties of combining the operations include but are not limited to:

- diversion of management's attention from the management of daily operations to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from combining our pharma services with our clinical services operations;
- difficulties entering new markets or new laboratory or data management services where we have no or limited direct prior experience;

- difficulties in the integration of operations and systems;
- difficulties in the assimilation of employees and in the retention of key employees;
- difficulties in retaining employees who may be vital to the integration of departments, information technology systems, including accounting systems, technologies, books and records, and procedures, and maintaining uniform standards, such as internal accounting controls, procedures, and policies;
- difficulties in the assimilation of different corporate cultures and business practices;
- difficulties in managing the expanded operations of a significantly larger and more complex company;
- potential deterioration in the sales and revenues of the tests and services of our pharma services;
- costs and expenses associated with any undisclosed or potential liabilities;
- successfully managing relationships with our new strategic partners, suppliers and customer base;
- challenges in maintaining existing, and establishing new business relationships; and
- challenges as a result of the COVID-19 pandemic.

Many of these factors are outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact the business, financial condition and our results of operations. In addition, even if the operations of our clinical services operations and our pharma services are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, cost savings or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all.

Furthermore, additional unanticipated costs which may be incurred in the continuing integration of operations or unanticipated increases in expenses unrelated to the acquisition of our pharma services may offset the expected benefits from the acquisition of our pharma services. In addition, our acquisition of the pharma services business has resulted in the incurrence of additional amortization expenses related to intangible assets, which could have a material adverse effect on the Company's financial condition, operating results, and cash flow. Further, the acquisition of the pharma services business resulted in the Company recording significant goodwill and other assets, and we may be required to incur impairment charges, which could adversely affect our consolidated financial position and results of operations. Since the acquisition, we have also undergone several cost-cutting initiatives with our pharma services business, including reductions in headcount. Further, during Fiscal 2021, the Company experienced a fairly significant decrease in volume within pharma services. The decrease in revenue within pharma services was approximately 32% from the comparable prior year period. Such revenue headwinds may continue in future periods. As such, all of these factors could decrease or delay the expected accretive effect of the pharma services business acquisition and negatively impact our business, financial condition and results of operations. As a result, we cannot be certain that the integration process and resulting combined operations will result in the realization of the full benefits anticipated from the acquisition.

If we are unable to increase sales of the tests and services in our pharma services or to successfully develop and commercialize other proprietary tests in our pharma services, we may be unable to achieve profitability.

Our pharma services provide pharmaceutical and biotech companies, universities and contract research organizations performing clinical trials with lab testing services for patient stratification and treatment selection through an extensive suite of molecular- and biomarker-based testing services, DNA- and RNA- extraction and customized assay development and trial design consultation. It is unclear whether we will be able to maintain and grow the number of customers who will avail themselves of our tests and services, or how regular a flow of business we will be able to obtain from existing customers. If we are unable to increase sales of our tests and services or to successfully develop, validate and commercialize other diagnostic tests and services, our pharma services may not produce sufficient revenues to become profitable.

If pharmaceutical and biotech companies, universities and contract research organizations performing clinical trials decide not to use our diagnostic tests and services, we may be unable to generate sufficient revenue to sustain our pharma services.

To generate demand for our pharma services, we need to educate pharmaceutical and biotech companies, universities and contract research organizations performing clinical trials on the utility of our tests and services to improve the outcomes of clinical trials for new oncology drugs and more rapidly advance targeted therapies through the clinical development process through published papers, presentations at scientific conferences and one-on-one education sessions by members of our sales force. We may need to hire additional commercial, scientific, technical and other personnel to support this process. If we cannot convince pharmaceutical and biotech companies, universities and contract research organizations performing clinical trials to order our diagnostic tests and services or other future tests and services we develop, we will likely be unable to create demand for our tests and services in sufficient volume for us to achieve sustained profitability of our pharma services.

As a result of our pharma services, our quarterly operating results may be subject to significant fluctuations and may be difficult to forecast.

The nature of the services of our pharma services is that they tend to come in relatively large projects but episodically, rather than providing steady sources of revenues. The timing, size and duration of our contracts with our customers depend on the size, pace and duration of such customer's clinical trial, over which we have no control and sometimes limited visibility. In addition, our expense levels are based, in part, on expectation of future revenue levels. A shortfall in expected revenue could, therefore, result in a disproportionate decrease in our net income. As a result, our quarterly operating results may be subject to significant fluctuations and may be difficult to forecast.

If we fail to perform our pharma services in accordance with contractual and regulatory requirements, and ethical considerations, we could be subject to significant costs or liability.

Through our pharma services offerings, we contract with pharmaceutical and biotech companies, universities and contract research organizations performing clinical trials to perform lab testing services for patient stratification and treatment selection through an extensive suite of molecular- and biomarker-based testing services, DNA- and RNA- extraction and customized assay development and trial design consultation. Such services are complex and subject to contractual requirements, regulatory standards and ethical considerations. If we fail to perform our services in accordance with these requirements, standards, and considerations regulatory authorities may take action against us or our customers. Such actions may include failure of such regulatory authority to grant marketing approval of our customers' products, imposition of holds or delays, suspension or withdrawal of clearances or approvals, rejection of data collected, laboratory license revocation, product recalls, operational restrictions, civil or criminal penalties or prosecutions, damages or fines. Any such action could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our Operations

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

As a small company with less than 200 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 financial officer, and others in key management positions. During January and February 2021, we experienced turnover in our chief executive officer and chief financial officer positions. The efforts of these persons will be critical to us as we continue to grow our clinical services and develop and/or acquire additional molecular diagnostic tests, and increase or maintain pharma services tests and service revenue or to successfully develop and commercialize other pharma services proprietary tests and services. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy. In addition, our commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel, and we may have to pay higher salaries to attract and retain qualified personnel. We may also be at a disadvantage in recruiting and retaining key personnel as our small size, limited resources, and limited liquidity may be viewed as providing a less stable environment, with fewer opportunities than would be the case at one of our larger competitors. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our clinical laboratory and commercialization.

If we lose the support of key opinion leaders or KOL's, it may limit our revenue growth from our tests or services and our 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 existing products and services or other products and services 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 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.

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

Although we have been selling commercial products since 2014, genomic diagnostics and pharma services are new areas of science, and we continue to focus and refine our efforts to sell, market and receive reimbursement for our clinical service products and to leverage our bioinformatics data. We may not be able to market, sell, or distribute our existing products or services or other products or services 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 services 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 leverage our data and to compete effectively will depend in part on our ability to manage this potential future growth effectively, without compromising quality.

If our 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 clinical services tests on a direct basis and operating our pharma services, and leveraging our bioinformatics data and our limited history makes forecasting difficult.

If our 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 and pharma services. If we fail to establish our clinical services tests and pharma services in the marketplace, it could have a negative effect on our ability to sell subsequent products or services and hinder the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our clinical services products, and no prior history operating our pharma services before our acquisition of pharma services in 2019. Our ability to produce product quantities that meet customer demand is dependent upon our ability to forecast accurately and plan production accordingly.

If we are unable to compete successfully in the markets our clinical services and pharma services operate in, 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 and to conduct clinical trials. 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 clinical services tests in order to impact clinical practices. In addition, we face competition from other companies that offer diagnostic tests. Specifically, in regard to our thyroid diagnostic tests, Veracyte has thyroid nodule cancer diagnostic tests which are currently on the market that compete with our ThyGeNEXT® and ThyraMIR® tests. Quest currently offers Veracyte's tests via a co-marketing agreement, and CBL is offering a diagnostic test performed via the University of Pittsburgh Medical Center (UPMC) that analyzes genetic alterations using next-generation sequencing mutation panel for pancreatic cysts. While we do not believe we currently have significant direct competition for PancraGEN® in the gastrointestinal market, technology such as a next-generation sequencing mutation panel could in the future lead to increased competition.

It is also possible that we face future competition from laboratory developed tests, or LDTs, developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, we may be subject to competition as a result of the new, unforeseen technologies that can be developed by our competitors in the gastrointestinal and endocrine cancer molecular diagnostic testing space. To compete successfully, we must be able to demonstrate, among other things, that our test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our tests. Since our clinical services 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 clinical services 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 clinical services 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 clinical services tests and other products and services, we will likely face many of these same competitive risks that we do currently.

With respect to our pharma services, we also face competition from companies that currently offer or are developing products to profile genes, gene expression or protein biomarkers in various cancers. Precision medicine is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results superior to the results we are able to achieve with the tests we develop. Our competitors for our pharma services include public companies such as NeoGenomics and many private companies.

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

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

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

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

The laboratories and equipment we use to perform our tests and services would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, power outages, and health epidemics or pandemics, including the outbreak of Coronavirus (COVID-19), which may render it difficult or impossible for us to perform our testing or services for some period of time or to receive and store samples. The inability to perform our tests or services for even a short period of time, including due to disruption in staffing, supplies, distribution, or transport or temporary closures related to an outbreak of disease such as COVID-19, 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. In addition, COVID-19 has materially and adversely impacted our operations particularly during portions of 2020. Further continued spread of COVID-19 globally and resulting travel and other restrictions that may be imposed could negatively impact our ability to obtain raw materials needed for manufacture of our clinical services testing, our ability to provide testing and our pharma services to patients, our financial condition and our results of operation. The extent to which COVID-19 and global efforts to contain its spread will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the COVID-19 outbreak.

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 PHI, personally identifiable information such as genetic information or credit card information about patients or other individuals, and our proprietary business and financial information. We must comply with the HIPAA and HITECH privacy, security, and breach notification regulations with respect to PHI in our capacity as a covered entity and business associate, and with consumer protection and consumer privacy laws that apply to our processing of this sensitive data, which may increase our operational costs. Furthermore, the privacy, security, and breach notification regulations implemented under HIPAA and HITECH as well as other federal and state consumer protection and consumer privacy laws and regulations that may apply to us provide for significant fines and other penalties, including potential civil and criminal fines and penalties, for non-compliance. We face a number of risks relative to our protection of, and our service providers' protection of, this critical information, other personally identifiable information, and our proprietary business and financial information, including loss of access, fraudulent modifications, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. If such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, modified without our knowledge, lost or stolen. In 2017, we discovered malware installed on certain servers. After an internal investigation, we do not believe that any PHI or other sensitive data on the affected servers was accessed or compromised. We removed the malware, and enhanced our cybersecurity procedures.

Additionally, we engage third-party contractors who, insofar as they are our business associates, are contractually and legally obligated to safeguard and maintain the confidentiality of any PHI that they create, receive, maintain, transmit, use, or disclose on our behalf. Unauthorized persons may be able to gain access to PHI stored by such third-party contractors, including in their 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 HIPAA and HITECH and their implementing regulations do not expressly provide for a private right of damages, they permit state attorneys general to bring civil actions and obtain damages on behalf of state residents for violations, and enjoin further violations, of the privacy and security regulations implemented under HIPAA. 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, or 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 or other data protection laws in the United States are often uncertain, contradictory and in flux, particularly as more states enact comprehensive consumer privacy laws. It is possible that these various 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.

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

We are a small company with less than 200 employees. We may increase the number of employees in the future depending on the progress and growth of our business. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our future financial performance and our ability to sell or promote our existing tests and services and develop and commercialize new tests and services 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.

Risks Related to Regulation within our Markets

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 any disease, or impairment of, or the assessment of the health of, human beings. 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 Pittsburgh, Pennsylvania laboratory. Pennsylvania law requires that we maintain a license, and establish standards for the day-to-day operation of our clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, our Pittsburgh laboratory is required to be licensed by certain states, including California, Maryland, New York and Rhode Island. New York law requires us to obtain test-specific approval before offering our tests as LDT. California, 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, Maryland, New York or Rhode Island. 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 clinical services and pharma services, 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 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 (if Pennsylvania) or cease testing specimens from those States (if California, New York, Maryland, or Rhode Island), which could have a material adverse effect on our business, financial condition and results of operations. New molecular diagnostic tests and pharma services we may develop may be subject to new requirements by governmental bodies, including state governments, and we may not be able to offer our new molecular diagnostic tests or pharma services in such jurisdictions until such requirements are met.

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. For example, PPACA includes 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 or service, 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; however, the U.S. Supreme Court upheld the law in 2021.

President Biden has used executive orders to undo certain changes to the PPACA made by the Trump administration and has indicated it will advocate for legislation to build on the PPACA. It is unknown what form any such changes or any law would take, and how or whether it may affect our business in the future. We expect that changes or additions to the PPACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

For example, Medicare payment rates have been – and in the future, will continue to be, to varying extents, subject to sequestration. 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.

In April 2014, President Obama signed the Protecting Access to Medicare Act, or PAMA, which included a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, CLFS payment rates are based upon the weighted median of private payor rates for each type of laboratory test. To calculate these rates, PAMA requires CLIA-certified laboratories that receive a majority of their Medicare revenue from payments made under the CLFS and the Physician Fee Schedule, and receive at least $12,500 in CLFS revenue, within the 6-month reporting period, to report private payor rates and volumes for their tests with specific CPT codes based on final payments made during a 6-month period of data collection (from January 1 through June 30 of the applicable year). For most laboratory tests, the CLFS is updated every three years, but rates are updated annually for Advanced Diagnostic Laboratory Tests, or ADLTs. The first private payor rate-based CLFS was based on data collected from January 1 through June 30, 2016, and, following an initial, one-year delay became effective on January 1, 2018. CMS published final rules implementing these changes in 2016 and 2018.

Under the revised Medicare Clinical Laboratory Fee Schedule, reimbursement for clinical laboratory testing was reduced for most tests in 2018, 2019, and 2020. PAMA (as revised) calls for further revisions of the Medicare Clinical Laboratory Fee Schedule for years after 2022, based on future surveys of market rates. Further reductions in reimbursement may result from such revisions.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, as amended by the Protecting Medicare and American Farmers from Sequester Cuts Act, revised payment reductions and the data reporting schedule for CDLTs that are not ADLTs. Under these laws, the next data reporting period is January 1, 2023 through March 31, 2023, and will be based upon the data collected during the January 1, 2019 to June 30, 2019 period. 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 2023 through 2025. Payments will not be reduced for 2021 or 2022 for CDLTs.

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. There is additional uncertainty in light of the current Presidential administration. 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.

Complying with numerous statutes and regulations pertaining to our clinical and pharma services 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 operations. 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;
- CLIA and state licensing requirements;
- Manufacturing and promotion laws;
- Medicare and Medicaid billing and payment regulations applicable to clinical laboratories;
- The Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which prohibits the solicitation, receipt, payment or offer of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers;
- The Federal Anti-Kickback Statute (and state equivalents), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program;
- The Federal physician self-referral law, commonly referred to as the "Stark Law," (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- HIPAA, which established comprehensive federal standards with respect to the privacy and security of PHI 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 FTC Act and various state consumer privacy laws, which require regulated entities to take reasonable steps to safeguard the personal information of consumers, minimize its use and provide consumers with certain rights as to their personal data such as the right to correct or delete their personal information;
- 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 CMS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- Other federal and state fraud and abuse laws, prohibitions on self-referral and kickbacks, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, transparency, reporting, and disclosure requirements, which may extend to services reimbursable by any third-party payer, including private insurers;

- The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

- The Protecting Access to Medicare Act of 2014, which requires us to report private payer rates and test volumes for specific CPT codes on a triennial basis and imposes penalties for failures to report, omissions, or misrepresentations;

- The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier; and

- State laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving coinsurance, co-payments, deductibles, and other amounts owed by patients, and billing a State Medicaid program at a price that is higher than what is charged to other payers.

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

The growth of our business may increase the potential of violating these laws, regulations or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Violations of federal or state regulations may incur investigation or enforcement action by the FDA, Department of Justice, State agencies, or other legal authorities, and may result in substantial civil, criminal, or other sanctions. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to civil and criminal penalties, damages and fines, we could be required to refund payments received by us, we could face possible exclusion from Medicare, Medicaid and other federal or state healthcare programs and we could even be required to cease our operations. Any of the foregoing consequences could have a material adverse effect on our business, financial condition and results of operations.

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

We retain healthcare practitioners as key opinion leaders providing consultation in various aspects of our business, maintain a sales force, and contract for marketing services. These arrangements, like any arrangement that includes compensation to a healthcare provider or potential referral source, may trigger federal or state anti-kickback, Stark Law liability, and False Claims Act liability. There are no guarantees that the federal or state governments will find that these arrangements are designed properly or that they do not trigger liability under federal and state laws. Under existing laws, all arrangements must be commercially reasonable and compensation must be fair market value. These terms require some subjective analysis. Safe harbors in the anti-kickback laws do not necessarily equate to exceptions in the Stark Law, and there is no guarantee that the government will agree with our payment practices with respect to the relationships between our laboratories and the healthcare providers, sales force members, or other parties. A failure to comply with Federal and State laws and regulations pertaining to our payment practices could result in substantial penalties and adversely affect our business, financial condition and results of operations.

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

In 2018, the U.S. enacted the Eliminating Kickbacks in Recovery Act, or EKRA, as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). EKRA is an all-payer anti-kickback law that makes it a criminal offense to pay any remuneration to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory. Although it appears that EKRA was intended to reach patient brokering and similar arrangements to induce patronage of substance use recovery and treatment, the language in EKRA is broadly written. The term "laboratory" is defined broadly and without reference to any connection to substance use disorder treatment. EKRA is a criminal statute and violations can result in fines of up to $200,000, up to 10 years in prison, or both, per violation. As drafted, EKRA prohibits incentive compensation to sales employees, a practice that is common in the industry.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, potentially including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, 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 tests or services 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. Additional changes may be forthcoming in light of the current Presidential administration.

Risks Relating To Our Intellectual Property

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

We rely on patent protection as well as trademark, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technology. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. While we apply for patents covering our products and technologies and uses thereof, we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in relevant jurisdictions. Others could seek to design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. On January 16, 2018, we were notified that an Opposition had been filed against EP patent #2772550 alleging that the patent is invalid. On February 25, 2019, the European Patent Office Opposition Division issued a decision revoking the patent on grounds that the claims were not supported by a valid basis. On April 25, 2019, we filed a Notice of Appeal challenging the European Patent Office Opposition Division and we are waiting for the appeal to be decided. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation, such as oppositions or post-grant reviews can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

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

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

As is the case with other companies operating in our industry, our success is somewhat dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents of molecular diagnostics tests, like our molecular diagnostic tests in our PancraGEN® and miR*Inform*® platforms (including ThyGeNEXT®), involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. From time-to-time the U.S. Supreme Court, other Federal courts, the U.S. Congress or the United States Patent and Trademark Office, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation.

The U.S. Supreme Court later reversed that decision in *Bilski v. Kappos*, finding that the "machine-or-transformation" test is not the only test for determining patent eligibility. The Court, however, declined to specify how and when processes are patentable. On March 30, 2012, in the case *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the U.S. Supreme Court reversed the Federal Circuit's application of Bilski and invalidated a patent focused on a process for identifying a proper dosage for an existing therapeutic because the patent claim embodied a law of nature. On July 3, 2012, the USPTO released a memorandum entitled "2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature," with guidelines for determining patentability of diagnostic or other processes in line with the Mayo decision. On June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. The Supreme Court did not address the patentability of any innovative method claims involving the manipulation of isolated genes. On March 4, 2014, the USPTO released a memorandum entitled "2014 Procedure for Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products." This memorandum provides guidelines for the USPTO's new examination procedure for subject matter eligibility under 35 U.S.C. § 101 for claims embracing natural products or natural principles.

On June 12, 2015, the Federal Circuit issued a decision in *Ariosa v. Sequenom* holding that a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female were unpatentable as directed to a naturally occurring phenomenon. On July 30, 2015, the USPTO released a Federal Register Notice entitled, "July 2015 Update on Subject Matter Eligibility," This Notice updated the USPTO guidelines for the USPTO's procedure for subject matter eligibility under 35 U.S.C. § 101 for claims embracing natural products or natural principles phenomenon. On May 4, 2016, the USPTO released life science examples that were intended to be used in conjunction with the USPTO guidance on subject matter eligibility. Although the guidelines and examples do not have the force of law, patent examiners have been instructed to follow them. On February 6, 2019, the Federal Circuit for Court of Appeals issued a decision in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, which relied on the decisions from Mayo and Ariosa, to find a claim directed to a method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase not eligible for patenting under 35 U.S.C. § 101. What constitutes a law of nature and a sufficient inventive concept continues to remain uncertain, and it is possible that certain aspects of diagnostic tests will continue to be considered natural laws and, therefore, ineligible for patent protection.

Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending or issued claims will be patentable or upheld as valid as a result of such evolving standards. In addition, patents we own or license that issued before these recent cases may be subject to challenge in court or before the USPTO in view of these current legal standards. Accordingly, the evolving interpretation and application of patent laws in the United States governing the eligibility of diagnostics for patent protection may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. Changes in either the patent laws or in interpretations and application of patent laws may also diminish the value of our existing intellectual property or intellectual property that we continue to develop. We cannot predict the breadth of claims that may be allowed or enforceable in our patents or in third-party patents.

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

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

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

Other Risks Related to our Business

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

We have incurred net losses since 2015 and may never achieve or sustain profitability. As of the fiscal year ended December 31, 2021, we had U.S. federal and state net operating losses, or NOLs, of approximately $118.6 million and $56.3 million respectively. Subject to the final two sentences of this paragraph, the federal and state NOL carryforwards will begin to expire, if not utilized, beginning in 2028 for certain states. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of Federal taxable income.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. We may be limited in the portion of NOL and tax credit carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes. Sections 382 and 383 of Internal Revenue Code of 1986, or the Code, limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The limitation could prevent us from using some or all of our NOLs and tax credits, as it places a formula limit of how much of our NOL and tax credit carryforwards we would be permitted to use in a tax year. The amount of the annual limitation, if any, will be determined based on the value of our company immediately prior to an ownership change. During the periods 2017 through 2019, the company experienced greater than 50% changes in ownership and as a result, NOLs attributable to the pre-ownership change are subject to a substantial annual limitation under Section 382 of the Code due to the ownership changes. The Company has adjusted their NOL carryforwards to address the impact of the Section 382 ownership changes. Federal Net Operating Losses of $71.2 million are subject to annual limitation as of the ownership changes for ownership changes. The remaining $47.4 million of NOLs incurred post July 15, 2019 are not subject to any annual limitation and can be carried forward indefinitely. Subsequent ownership changes may further affect the limitation in future years. In the event we have undergone or will undergo an ownership change under Section 382 of the Code, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may become subject to these limitations, which could potentially result in increased future tax liability to us.

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

New income, sales and use or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws and regulations could be interpreted, modified or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs for past amounts deemed to be due. New laws, or laws that are changed, modified or newly interpreted or applied, also could increase our compliance, operating and other costs, as well as the costs of our products. For example, the Tax Cuts and Jobs Act of 2017 enacted many significant changes to the U.S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current or a future presidential administration. In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses, and other deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense.

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 testing, service or solution 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. The holders of our Series B Preferred Stock have the right to approve any public offering. 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 or pharma services 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 or 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, epidemics, pandemics including COVID-19, malicious attacks by computer viruses or hackers, power loss, failure of computer systems, Internet, telecommunications or data networks. In 2017, we discovered malware installed on certain clinical services servers. We do not believe that any data on the affected servers was accessed or compromised. We removed the malware, and enhanced our cybersecurity procedures. Additionally, our clinical services and pharma services are largely dependent on our partially internally developed and partially purchased Laboratory Information Management Systems 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.

Risks Related To Our Common Stock Price

The price and trading volume of our common stock may be highly 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 2021, our common stock traded at a low of $2.98 and a high of $10.51. During 2020, our common stock traded at a low of $2.57 and a high of $11.00. Volatility in our stock price or trading volume may be in response to various factors, some of which may be beyond our control. In addition to the other factors discussed or incorporated by reference herein, factors that may cause fluctuations in our stock price or trading volume, include, among others:

- general volatility in the trading markets;
- the impact of the delisting of our common stock from Nasdaq and listing on the OTCQX;
- adverse research and development results;
- significant fluctuations in our quarterly operating results;
- significant changes in our cash and cash equivalent reserves;
- our liquidity and ability to obtain additional capital, including the market's reaction to any announced capital-raising transactions;
- market assessments of any announced strategic transaction, including the likelihood that it would be completed and the timing for completion;
- potential negative market reaction to the terms or volume of any issuance of shares of our common stock, preferred stock or other securities to new investors, pursuant to strategic or capital-raising transactions or to employees, directors or other service providers;
- sales of substantial amounts of our common stock, or the perception that substantial amounts of our common stock may be sold, by stockholders in the public market;
- 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;
- statements or changes in opinions, ratings or earnings estimates made, or the failure to make, by brokerage firms or industry analysts relating to the markets in which we operate or expect to operate; and
- general market and economic conditions.

The issuance of additional shares of our common stock in any future offerings could be dilutive to stockholders.

The issuance of additional shares of our common stock in any future offerings could be dilutive to stockholders. In order to raise additional capital, such securities may be at prices that are not the same as the price per share in previous offerings. We cannot assure investors 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 previous offerings, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. 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 (including our Series B Preferred Stock), and those options, warrants or other securities are exercised, converted or exchanged, stockholders may experience further dilution.

The delisting of our common stock from Nasdaq and subsequent trading on OTCQX® has adversely affected our common stock and business and financial condition.

On February 25, 2020, our common stock was delisted from the Nasdaq Capital Market ("Nasdaq") and commenced trading on the OTCQX® Best Market tier of the OTC Markets Group Inc. (the "OTCQX"), an electronic quotation service operated by OTC Markets Group Inc.

Trading in stock quoted on the OTCQX is often thin, volatile, and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with the issuer's operations, results or business prospects. The availability of buyers and sellers represented by this volatility could lead to a market price for our Common Stock that is unrelated to operating performance. Moreover, the OTCQX is not a stock exchange, and trading of securities quoted on the OTCQX is often more volatile than the trading of securities listed on a stock exchange like Nasdaq or the New York Stock Exchange. The OTCQX quotation system may provide less liquidity than Nasdaq.

Prices for securities traded solely on the OTCQX quotation system may be difficult to obtain, and holders of our common stock may be unable to resell their shares at or near their original acquisition price or at any price. Further, our delisting from Nasdaq and commencement of trading on the OTCQX has and may continue to have negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, the loss of federal preemption of state securities laws, greater difficulty in raising capital through the public or private sale of equity securities, deterring broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, a loss of current or future coverage by certain sell-side analysts, deterring certain institutions and persons from investing in our securities at all and a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

The risks associated with penny stock classification could affect the marketability of the Company's common stock and stockholders could find it difficult to sell their shares.

If the Company's shares of Common Stock do not maintain a trading price of $5.00 or more per share, the Company's common stock will be subject to "penny stock" rules as defined in Exchange Act Rule 3a51-1. The SEC adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Transaction costs associated with purchases and sales of penny stocks are likely to be higher than those for other securities. Penny stocks generally are equity securities with a price of less than $5.00.

The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation.

In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from such rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for the Company's common stock and stockholders may find it more difficult to sell their shares.

Risks Relating to Being a Public Company

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

As a public company, we are incurring significant legal, accounting and other expenses. In addition to being required to comply with certain requirements of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), we are required to comply with certain requirements of the Dodd Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will continue to need to divert attention from operational and other business matters to devote substantial time to these public company requirements.

For example, in 2020, our Audit Committee conducted an independent investigation in accordance with Section 10A of the Exchange Act into complaints of certain employment and billing and compliance matters and concluded that the allegations made in the complaints were unsubstantiated and that there was no evidence of any illegal acts. The completion of the investigation caused us to be late in filing our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

We also recently spent considerable management time in connection with our restatement of previously issued financial statements contained in our Annual Reports on Form 10-K for the years ended December 31, 2014 through 2019 as well as the financial statements contained in the Quarterly Reports on Form 10-Q for each quarterly period within those fiscal years as well as the quarterly periods ended March 31, 2020 and June 30, 2020. This was due to evaluating and recording an impairment charge and amortization expense relating to our BarreGen asset, as disclosed in Item 9A of our Report on Form 10-K for the fiscal year 2021.

Further, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. In addition, if we lose our status as a "smaller reporting company," we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. Our compliance with Section 404 of the Sarbanes-Oxley Act, as applicable, requires us to incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to continue to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

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

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

Risks Relating to Our Corporate Structure and Our Common Stock

We have a substantial number of authorized shares of common and preferred stock 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 December 31, 2021, we had 95,771,831 shares of common stock and 4,953,000 shares of preferred stock available for issuance. As of December 31, 2021, we have reserved 961,450 shares of our common stock for issuance under our 2019 Equity Incentive Plan and 25,715 shares of our common stock for issuance under our Employee Stock Purchase Plan and 602,077 additional shares available for future grants of awards under our 2019 Equity Incentive Plan as well as warrants for 1,404,648 shares of our common stock outstanding at prices ranging from $9.40 to $46.90 per warrant share. As of December 31, 2021, the aggregate number of shares of common stock that may be issued through conversion of all of the outstanding Series B Preferred Stock is 7,833,334. Provided that we have a sufficient number of unreserved authorized capital stock available, we may seek financing that could result in the issuance of additional shares of our capital stock and/or rights to acquire additional shares of our capital stock. We may also make acquisitions that result in issuances of additional shares of our capital stock. Those additional issuances of capital stock could result in substantial dilution of our existing stockholders. Furthermore, the book value per share of our common stock may be reduced. This reduction would occur if the exercise price of any issued warrants, the conversion price of any convertible notes or the conversion ratio of any issued preferred stock is lower than the book value per share of our common stock at the time of such exercise or conversion. Additionally, new investors in any subsequent issuances of our securities could gain rights, preferences and privileges senior to those of holders of common stock.

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

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 without separate shareholder approval. 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 are subject to, and may be adversely affected by, the rights of holders of our Series B Preferred Stock as well as 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. We are prohibited from paying dividends on our common stock without the approval of the holders of the Series B Preferred Stock for so long as 30% of the Series B Preferred Stock outstanding as of January 15, 2020 remains outstanding. We presently intend to retain all earnings for our operations. As a result, capital appreciation, if any, of our common stock will be an investor's sole source of gain for the foreseeable future.

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Parsippany, New Jersey where we lease approximately 6,000 square feet. The lease runs through September 2022. Our diagnostic laboratory facility is located in Pittsburgh, Pennsylvania where we lease approximately 21,400 square feet. Our Pittsburgh, Pennsylvania lease runs through June 30, 2023. Our pharma services laboratory facilities are located in Research Triangle Park (RTP) in Morrisville, North Carolina where we lease approximately 24,900 square feet. The Morrisville lease runs through May 2030.

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

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Effective February 25, 2021, our common stock was delisted from The Nasdaq Capital Market and began trading on the OTCQX Best Market under the symbol "IDXG." OTCQX Best Market quotations reflect inter-dealer prices and may not necessarily represent actual transactions.

Reverse Stock Split

On January 15, 2020, we effected a one-for-ten reverse split of our issued and outstanding shares of our common stock. At the effective time of the reverse split, every 10 shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock, without any change in the par value per share. Our common stock began trading on a reverse stock split-adjusted basis on January 15, 2020.

Holders of Record

We had 197 stockholders of record as of February 28, 2022. Not reflected in the number of stockholders of record are persons who beneficially own shares of common stock held in nominee or street name.

Dividends

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

ITEM 6. [RESERVED]

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

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

Company Overview

We are an emerging leader in enabling precision medicine principally in oncology by offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications through our clinical and pharma services. Through our clinical services, we enable physicians to personalize the clinical management of each individual patient by providing genomic information to better diagnose, monitor and inform cancer treatment. Our clinical services provide clinically useful molecular diagnostic tests, bioinformatics and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. Through our pharma services, we develop, commercialize and provide molecular- and biomarker-based tests and services and provide companies with customized solutions for patient stratification and treatment selection through an extensive suite of molecular and biomarker-based testing services, DNA- and RNA- extraction and customized assay development and trial design consultation. Our pharma services provide pharmacogenomics testing, genotyping, biorepository and other specialized services to the pharmaceutical and biotech industries and advance personalized medicine by partnering with pharmaceutical, academic and technology leaders to effectively integrate pharmacogenomics into drug development and clinical trial programs with the goals of delivering safer, more effective drugs to market more quickly, and improving patient care.

Impact of COVID-19 pandemic

The COVID-19 pandemic, together with related precautionary measures, continues to impact portions of the regions in which we operate. These regions are attempting to address the COVID-19 pandemic in varying ways, including stay-at-home orders, temporarily closing businesses, restricting gatherings, restricting travel, and mandating social distancing and face coverings. The level and nature of the disruption caused by COVID-19 is unpredictable, may be cyclical and long-lasting and may vary from location to location.

The continuing impact that the COVID-19 pandemic will have on our operations, including duration, severity and scope, remains highly uncertain and cannot be fully predicted at this time. While we believe we have generally recovered from the adverse impact that the COVID-19 pandemic had on our business during 2020, we believe that the COVID-19 pandemic could continue to adversely impact our results of operations, cash flows and financial condition in the future.

We continue to monitor the COVID-19 pandemic and the guidance that is being provided by relevant federal, state and local public health authorities and may take additional actions based upon their recommendations. It is possible that we may have to make adjustments to our operating plans in reaction to developments that are beyond our control.

Lab closures experienced thus far by the Company have consisted of periodic, temporary work stoppages to clean and disinfect the labs; however, this could change in the future based upon conditions caused by the pandemic. It is also possible that we could experience supply chain shortages if the pandemic worsens and if one or more suppliers is unable to continue to provide us with supplies. For the foreseeable future, however, we do not anticipate supply chain shortages of critical supplies.

We have developed contingency plans and will continue to monitor and update them in order to mitigate pandemic-related, adverse financial impacts upon our business.

Clinical services

Our clinical services provide clinically useful molecular diagnostic tests, bioinformatics and pathology services for evaluating cancer risk by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. We develop and commercialize genomic tests and related first line assays principally focused on early detection of patients with indeterminate biopsies and at high risk of cancer using the latest technology to help personalized medicine and improve patient diagnosis and management. Our tests and services provide mutational analysis of genomic material contained in suspicious cysts, nodules and lesions with the goal of better informing treatment decisions in patients at risk of thyroid, pancreatic, and other cancers. The laboratory developed molecular diagnostic tests we offer are designed to enable healthcare providers to better assess cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk. We currently have five commercialized molecular diagnostic tests in the marketplace: PancraGEN®, which is a pancreatic cyst and pancreaticobiliary solid lesion genomic test for the diagnosis and prognosis of pancreatic cancer; PanDNA, a "molecular only" version of PancraGEN® that provides physicians a snapshot of a limited number of factors enabling physicians to better assess risk of pancreaticobiliary cancers using our proprietary PathFinderTG® platform; ThyGeNEXT®, which is an expanded oncogenic mutation panel that helps identify malignant thyroid nodules; ThyraMIR®, which assesses thyroid nodules for risk of malignancy utilizing a proprietary microRNA gene expression assay; and RespriDx®, which is a genomic test that helps physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer and which also utilizes our PathFinderTG® platform to compare the genomic fingerprint of two or more sites of lung cancer. In addition, BarreGEN®, a molecular based assay that helps resolve the risk of progression of Barrett's Esophagus to esophageal cancer, is currently in a clinical evaluation program (CEP) whereby we gather information from physicians using BarreGEN® to assist us in gathering clinical evidence relative to the safety and performance of the test. We currently have a multicenter study underway to further assess the ability of BarreGEN® to accurately predict progression to high grade dysplasia or cancer and to assist us in positioning our product for full launch, partnering, and potentially supporting reimbursement with payers.

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

We leverage our 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 $11.77 billion (USD) in 2021 and is expected to grow to $18.1 billion (USD) by 2026 with a CAGR of 9.0% between 2021 and 2026, according to Market Data Forecast's Molecular Diagnostics Market report (ID: 10293, published January 2022).

We believe that the molecular diagnostics market offers significant growth and strong patient value given the substantial opportunity it affords to lower healthcare costs by helping to reduce unnecessary surgeries and ensuring the appropriate frequency of monitoring. We are keenly focused on growing our test volumes, securing additional insurance coverage and reimbursement, maintaining and growing our current reimbursement and supporting revenue growth for our molecular diagnostic tests, introducing related first line product and service extensions, as well as expanding our business by developing and promoting synergistic products in our markets. We also believe that BarreGEN® is a potentially significant pipeline product, and we are providing necessary resources to accelerate our development process. Further, we believe BarreGEN® is synergistic with our capabilities in the gastrointestinal market, which is one of the sectors in which we operate.

In January 2022, we announced that CMS issued a new billing policy whereby CMS will no longer reimburse for the use of our ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service. On February 28, 2022, we announced that the National Correct Coding Initiative (NCCI) program issued a response on behalf of CMS stating that the January 2022 billing policy reimbursement change for ThyGeNEXT® (0245U) and ThyraMIR® (0018U) tests has been retroactively reversed to January 1, 2022. CMS is currently reimbursing the Company for one of its two thyroid tests, and has agreed to retroactively reimburse for the second test once they have completed their internal administrative adjustments. We have been notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 will be completed beginning July 1, 2022. As of the date of this filing, we have not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS.

Pharma services

Our pharma services provide pharmacogenomics testing, genotyping, biorepository and other specialized services to the pharmaceutical and biotech industries. Laboratory and testing services are performed for pharmaceutical and biotech companies engaged in clinical trials and focuses on providing these clients with oncology specific and non-oncology genetic testing services for phase I-IV clinical trials along with critical support of ancillary services. These services include: biorepository, clinical trial logistics, clinical trial design, bioinformatics analysis, customized assay development, DNA and RNA extraction and purification, genotyping, gene expression and biomarker analyses. We also seek to apply our expertise in laboratory developed tests to assist in developing and commercializing drug-specific companion diagnostics. We have established business relationships with key instrument manufacturers to support their platforms in the market, and to drive acceptance among biopharmaceutical sponsors developing innovative immuno-oncology therapies.

Molecular- and biomarker-based testing services have been altering the clinical trials landscape by providing biotech and pharmaceutical companies with information about trial subjects' genetic profiles that may be able to inform researchers whether or not a subject will benefit from the trial drug or will experience adverse effects. Streamlined subject selection and stratification, and tailored therapies selected to maximally benefit each group of subjects may increase the number of trials that result in approved therapies and make conducting clinical trials more efficient and less costly for biotech and pharmaceutical companies. In 2021, over 50 new drugs were approved by the FDA, and 20% of these drugs were oncology-focused, highlighting the potential value of incorporating genomic information into oncology clinical trial design.

In addition to the tests and services provided to our pharma customers, we custom develop Next Generation Sequencing (NGS) panels for our customers focused on pharmacogenomics and oncology.

We also utilize our laboratories to provide clinical trial services to the pharmaceutical and biotech industries to improve the efficiency and economic viability of clinical trials. Our clinical trials services leverage our knowledge of clinical oncology and molecular diagnostics and our laboratories' fully integrated capabilities. We believe our laboratory is one of a few with the capability to combine somatic and germline mutational analyses in clinical trials. We operate through a CLIA certificated and CAP accredited laboratory located in Morrisville, North Carolina.

Our laboratory possesses capabilities in histology, immunohistochemistry (IHC), flow cytometry, cytogenetics and fluorescent in-situ hybridization (FISH), as well as sophisticated molecular analysis techniques, including next generation sequencing. This allows for comprehensive customized testing within one lab enterprise, with our CAP-accredited biorepository laboratory serving as a central hub for specimen tracking. Using this approach, we are able to support demanding clinical trial protocols requiring multiple assays and techniques aimed at capturing data on multiple biomarkers. Our suite of available testing platforms allows for highly customized clinical trial design which is supported by our dedicated group of development scientists and technical personnel.

We also provide genetic testing for drug metabolism to aid biotech and pharmaceutical companies identify subjects' likely responses to treatment, allowing these companies to conduct more efficient and safer clinical trials. We believe pharmacogenomics drug metabolism testing helps deliver the promise of personalized medicine by enabling researchers to tailor therapies in development to differences in patients' genomic profiles.

Transition costs

To optimize the operations of laboratory operations within our pharma services, we transitioned activities from the Rutherford, NJ facility to our Morrisville, NC facility. We invested several million dollars to facilitate this relocation which was completed in March 2021, including but not limited to the transfer of personnel, expansion of the Morrisville facility and validation of transferred processes. We believe that this investment will result in a reduction in future operating costs; however, it is not certain whether we will fully realize the anticipated savings. We have also undergone several other cost-cutting initiatives, primarily reductions in headcount, and those costs are categorized as transition expenses as well.

Nasdaq Delisting

On February 16, 2021, the Company received a delisting determination letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") stating that the Staff had determined to delist the Company's common stock from Nasdaq due to the Company's failure to regain compliance with the Nasdaq Capital Market's minimum $2,500,000 stockholders' equity requirement for continued listing as set forth in Nasdaq Listing Rule 5550(b) (the "Rule") and the Company's failure to timely execute its plan to regain compliance under the Rule.

Nasdaq commenced with delisting the Company's common stock from the Nasdaq Capital Market and, suspended trading in the Company's common stock effective at the open of business on February 25, 2021.

On February 24, 2021, the Company was approved to have its common stock quoted on the OTCQX® Best Market tier of the OTC Markets Group Inc. (the "OTCQX"), an electronic quotation service operated by OTC Markets Group Inc. The trading of the Company's common stock commenced on OTCQX at the open of business on February 25, 2021 under the trading symbol IDXG.

DESCRIPTION OF REPORTING SEGMENTS

We operate under one segment which is the business of developing and selling diagnostic clinical and pharma services.

CRITICAL ACCOUNTING POLICIES

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

Revenue and Cost of Revenue

The Company's revenue is primarily generated from the performance of its proprietary molecular diagnostic tests for its clinical customers and its DNA-based testing services in support of clinical trials for its pharma services customers. The Company's performance obligation is fulfilled upon completion, review and release of test results and subsequent billing to the third-party payer, hospital or service provider, or biopharma companies.

Revenue Recognition

ASC 606 Revenue Recognition

Clinical services derive its revenues from the performance of its proprietary assays or tests. The Company's performance obligation is fulfilled upon completion, review and release of test results to the customer. The Company subsequently bills third-party payers or direct-bill payers for the tests performed. Revenue is recognized based on the estimated transaction price or net realizable value ("NRV"), which is determined based on historical collection rates by each payer category for each proprietary test offered by the Company. To the extent the transaction price includes variable consideration, for all third party and direct-bill payers and proprietary tests, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience.

For our clinical services, we regularly review the ultimate amounts received from the third-party and direct-bill payers and related estimated reimbursement rates and adjust the NRV's and related contractual allowances accordingly. If actual collections and related NRV's vary significantly from our estimates, we adjust the estimates of contractual allowances, which would affect net revenue in the period such variances become known.

For our pharma services customers, performance obligations are satisfied at a point in time as the Company processes samples delivered by the customer. Project level activities, including study setup and project management, are satisfied over the life of the contract. Revenues are recognized at a point in time when the test results or other deliverables are reported to the customer.

Leases

The Company determines if an arrangement contains a lease in whole or in part at the inception of the contract. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term while lease liabilities represent our obligation to make lease payments arising from the lease. All leases with terms greater than twelve months result in the recognition of a ROU asset and a liability at the lease commencement date based on the present value of the lease payments over the lease term. Unless a lease provides all of the information required to determine the implicit interest rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of the lease payments. We use the implicit interest rate in the lease when readily determinable.

Our lease terms include all non-cancelable periods and may include options to extend (or to not terminate) the lease when it is reasonably certain that we will exercise that option. Leases with terms of twelve months or less at the commencement date are expensed on a straight-line basis over the lease term and do not result in the recognition of an asset or liability. See Note 8, *Leases*.

Long-Lived Assets, including Finite-Lived Intangible Assets

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

As a result of overall economic conditions related to the coronavirus pandemic, the impact of the coronavirus pandemic on the Company's financial results, and the decrease in the price of the Company's common stock noted during the third quarter of fiscal 2020, the Company performed an internal review of its long-lived assets. Due to an extended delay in the launch of the Company's Barrett's test, the Company believes there was a triggering event in Fiscal 2016. The Company applied the required procedures under ASC 360 and assessed the estimated future cash flows related to the Barrett's intangible asset on an undiscounted basis. It was determined that the carrying value of the asset was in excess of the undiscounted cash flows as of December 31, 2016. As a result, the Company performed a formal valuation of the asset on a discounted basis in order to measure the related impairment. Additionally, the Company concluded that amortization of both the Barrett's intangible asset and its Thyroid intangible assets should have commenced upon acquisition of those assets as opposed to the Company's previously disclosed policy of beginning asset amortization when the product was launched and generating revenue.

Contingencies

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

Income Taxes

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

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

We operate in multiple tax jurisdictions and provide taxes in each jurisdiction where we conduct business and are subject to taxation. The breadth of our operations and the complexity of the various tax laws require assessments of uncertainties and judgments in estimating the ultimate taxes we will pay. The final taxes paid are dependent upon many factors, including negotiations with taxing authorities in various jurisdictions, outcomes of tax litigation and resolution of proposed assessments arising from federal and state audits. We have established estimated liabilities for uncertain federal and state income tax positions. Uncertain tax positions are recognized in the financial statements when it is more likely than not (for example, a likelihood of more than fifty percent) that a position taken or expected to be taken in a tax return would be sustained upon examination by tax authorities that have full knowledge of all relevant information. A recognized tax position is then measured as the largest amount of benefit that is greater than fifty percent likely to be realized upon ultimate settlement. We adjust our accruals for unrecognized tax benefits as facts and circumstances change, such as the progress of a tax audit. We believe that any potential audit adjustments will not have a material adverse effect on our financial condition or liquidity. However, any adjustments made may be material to our consolidated results of operations or cash flows for a reporting period. Penalties and interest, if incurred, would be recorded as a component of current income tax expense.

Significant judgment is also required in evaluating the need for and magnitude of appropriate valuation allowances against deferred tax assets. We currently have significant deferred tax assets resulting from net operating loss carryforwards and deductible temporary differences. The realization of these assets is dependent on generating future taxable income. We perform an analysis quarterly to determine whether the expected future income will more likely than not be sufficient to realize the deferred tax assets. Our recent operating results and projections of future income weighed heavily in our overall assessment. The existing and forecasted levels of pretax earnings for financial reporting purposes are not sufficient to generate future taxable income and realize our deferred tax assets and, as a result, we established a full federal and state valuation allowance for the net deferred tax assets at December 31, 2021 and 2020, as we determined that it was more likely than not that these assets would not be realized.

The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL, and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as similar state tax provisions. The amount of the annual limitation, if any, will be determined based on the value of our company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. Additionally, U.S. tax laws limit the time during which these carry forwards may be applied against future taxes, therefore, we may not be able to take full advantage of these carry forwards for federal income tax purposes. . During 2021, the Company completed a 382 assessment of the available NOLs under Section 382 and determined that the Company underwent an ownership change on September 30, 2017 and July 15, 2019, and as a result, NOLs attributable to the pre-ownership change are subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to the multiple ownership changes. The Company has adjusted their NOL carryforwards to address the impact of the 382 ownership change.

Stock Compensation Costs

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

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

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

CONSOLIDATED RESULTS OF OPERATIONS

The following table sets forth the selected statements of operations data ($ in thousands) as a percentage of revenue for the periods indicated. The trends illustrated in this table may not be indicative of future operating results.

	Years Ended December 31,			
	2021	2021	2020	2020
Revenue, net	$ 41,314	100.0%	$ 32,398	100.0%
Cost of revenue	23,369	56.6%	21,673	66.9%
Gross profit	17,945	43.4%	10,725	33.1%
Operating expenses:				
Sales and marketing	10,067	24.4%	9,254	28.6%
Research and development	1,882	4.6%	2,795	8.6%
General and administrative	13,669	33.1%	18,192	56.2%
Transition expense	2,585	6.3%	2,578	8.0%
Loss on DiamiR transaction	13	0.0%	-	0.0%
Acquisition related amortization expense	4,064	9.8%	4,461	13.8%
Change in fair value of contingent consideration	(338)	-0.8%	(489)	-1.5%
Total operating expenses	31,942	77.3%	36,791	113.6%
Operating loss	(13,997)	-33.9%	(26,066)	-80.5%
Interest accretion expense	(496)	-1.2%	(549)	-1.7%
Related party interest	(424)	-1.0%	-	0.0%
Other (expense) income, net	(496)	-1.2%	467	1.4%
Loss from continuing operations before tax	(15,413)	-37.3%	(26,148)	-80.7%
(Benefit) provision for income taxes	(667)	-1.6%	53	0.2%
Loss from continuing operations	(14,746)	-35.7%	(26,201)	-80.9%
Loss from discontinued operations, net of tax	(197)	-0.5%	(250)	-0.8%
Net loss	$ (14,943)	-36.2%	$ (26,451)	-81.6%

Revenue, net

Consolidated revenue for the year ended December 31, 2021 increased by $8.9 million, or 28%, to $41.3 million, compared to $32.4 million for the year ended December 31, 2020. The increase in net revenue was driven by increased reimbursement rates and increased clinical services volume as the year ended December 31, 2020 was impacted by the pandemic. This increase was partially offset by a fairly significant decrease in volume within pharma services. The decrease in revenue within pharma services was approximately 32% from the comparable prior year period.

Cost of revenue

Consolidated cost of revenue for the year ended December 31, 2021 increased by $1.7 million, or 8%, to $23.4 million, compared to $21.7 million for the year ended December 31, 2020. This increase is primarily attributed to the increased volume associated with the clinical services business.

Gross Profit

Consolidated gross profit for the year ended December 31, 2021 increased $7.2 million, or 67%, to $17.9 million, compared to $10.7 million for the year ended December 31, 2020. The increase can be attributed to increased reimbursement rates as well as the change in the gross profit mix.

Sales and marketing expense

Consolidated sales and marketing expense was $10.1 million for the year ended December 31, 2021, as compared to $9.3 million for the year ended December 31, 2020. As a percentage of revenue, sales and marketing expense decreased to 24% from 29% in the comparable prior year period due to the higher revenue for the year ended December 31, 2021.

Research and development

Research and development expense was $1.9 million for the year ended December 31, 2021 and $2.8 million for the year ended December 31, 2020 due to lower professional services and employee costs. As a percentage of revenue, research and development expense decreased to 5% from 9% in the comparable prior year period.

General and administrative

General and administrative expense for the year ended December 31, 2021 was $13.7 million as compared to $18.2 million for the year ended December 31, 2020. The decrease can be primarily attributed to the closing of the Rutherford, NJ office as well as employee and consulting costs associated with the closure. The year ended December 31, 2020 also included approximately $1.1 million in executive severance costs. As a percentage of net revenue, general and administrative expense was 33% for the year ended December 31, 2021 as compared to 56% for the year ended December 31, 2020.

Transition expense

Transition expense was approximately $2.6 million for the year ended December 31, 2021 and $2.6 million for the year ended December 31, 2020. These expenses are primarily related to the Rutherford, NJ lab closing and subsequent move to North Carolina, as well as other cost-saving initiatives, primarily reductions in headcount and the implementation of a new laboratory information system.

Loss on DiamiR transaction

During the year ended December 31, 2021 there was a loss of $0.01 million on the disposition of New Haven, CT laboratory to DiamiR in April 2021.

Acquisition related amortization expense

During the years ended December 31, 2021 and December 31, 2020, we recorded amortization expense of approximately $4.1 million and $4.5 million, respectively, which is related to intangible assets associated with our acquisitions.

Change in fair value of contingent consideration

During the year ended December 31, 2021, there was a $0.3 million decrease in the contingent consideration liability. During the year ended December 31, 2020, there was a $0.5 million decrease in the contingent consideration liability related thereto.

Operating loss

There were consolidated operating losses from continuing operations of $14.0 million and $26.1 million during the years ended December 31, 2021 and 2020, respectively.

(Benefit) provision for income taxes

The income tax benefit was approximately $0.7 million for the year ended December 31, 2021 and which primarily pertained to the Company's sale of NOLs of approximately $0.7 million under the State of New Jersey's Technology Business Tax Certificate Transfer Program. Income tax expense of $0.1 million for the year ended December 31, 2020 was primarily driven by minimum state and local taxes.

Loss from discontinued operations, net of tax

We had a loss from discontinued operations of $0.2 million for the year ended December 31, 2021 as compared to a loss from discontinued operations of $0.3 million for the year ended December 31, 2020.

Non-GAAP Financial Measures

In addition to the United States generally accepted accounting principles, or GAAP, results provided throughout this document, we have provided certain non-GAAP financial measures to help evaluate the results of our performance. We believe that these non-GAAP financial measures, when presented in conjunction with comparable GAAP financial measures, are useful to both management and investors in analyzing our ongoing business and operating performance. We believe that providing the non-GAAP information to investors, in addition to the GAAP presentation, allows investors to view our financial results in the way that management views financial results.

In this 10-K, we discuss Adjusted EBITDA, a non-GAAP financial measure. Adjusted EBITDA is a metric used by management to measure cash flow of the ongoing business. Adjusted EBITDA is defined as income or loss from continuing operations, plus depreciation and amortization, acquisition related expenses, transition expenses, non-cash stock based compensation, interest and taxes, and other non-cash expenses including asset impairment costs, bad debt expense, loss on extinguishment of debt, goodwill impairment and change in fair value of contingent consideration, and warrant liability. The table below includes a reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure.

Reconciliation of Adjusted EBITDA (Unaudited)
($ in thousands)

	Years Ended December 31,	
	2021	**2020**
Loss from continuing operations (GAAP Basis)	$ (14,746)	$ (26,201)
Bad debt (recovery) expense	(140)	585
Loss on DiamiR transaction	13	-
Receipt of HHS stimulus grant	-	(650)
Transition expenses	2,585	2,578
Legal and professional services	-	495
Depreciation and amortization	5,374	5,501
Stock-based compensation	1,368	2,242
Taxes (benefit)/expense	(667)	53
Interest accretion expense	496	549
Financing interest and related costs	950	-
Mark to market on warrant liability	50	(61)
Change in fair value of note payable	(58)	-
Change in fair value of contingent consideration	(338)	(489)
Adjusted EBITDA	$ (5,113)	$ (15,398)

LIQUIDITY AND CAPITAL RESOURCES

For the fiscal year ended December 31, 2021, we had an operating loss of $14.0 million. As of December 31, 2021, we had cash, cash equivalents and restricted cash of $3.3 million, total current assets of $12.2 million and current liabilities of $15.7 million. As of March 18, 2022, we had approximately $2.7 million of cash on hand, excluding restricted cash.

During the year ended December 31, 2021, net cash used in operating activities was $8.7 million. The main component of cash used in operating activities was our net loss of $14.9 million which was partially offset by non-cash depreciation, amortization and stock compensation expenses of $6.6 million. During the year ended December 31, 2020, net cash used in operating activities was $14.0 million. The main component of cash used in operating activities was our net loss of $26.5 million which was partially offset by non-cash expenses of $7.7 million.

For the year ended December 31, 2021, cash provided from financing activities was $9.0 million, of which $7.7 million were the net proceeds from the BroadOak loan and $1.5 million borrowed under our line of credit. See Note 13, *Notes Payable,* for more details. For the year ended December 31, 2020, cash provided from financing activities was $16.6 million, $19.2 million which resulted from the issuance of preferred stock in January 2020 and $0.4 million from sales of Common Stock, partially offset by the repayment of $3.0 million of borrowed funds under our now terminated revolving line of credit with Silicon Valley Bank.

For the year ended December 31, 2021, cash used in investing activities was $0.4 million, primarily related to the purchase of lab equipment. For the year ended December 31, 2020, cash used in investing activities was $1.6 million, primarily related to capital expenditures associated with the moving of our Rutherford, New Jersey lab to North Carolina.

On January 7, 2021, the Company entered into secured promissory notes in the amount of $3 million and $2 million with Ampersand and 1315 Capital, respectively. See Note 13, *Notes Payable* of the notes to the financial statements. On May 10, 2021, the Company amended the Ampersand Note to increase the principal amount to $4.5 million and amended the 1315 Capital Note to increase the principal amount to $3.0 million. The maturity dates of the Notes were the earlier of (a) June 30, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Notes. On June 24, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) August 31, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On June 25, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner. On August 31, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) September 30, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On August 31, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner.

On September 29, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) October 31, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On September 29, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner.

In October 2021, the Company and its subsidiaries entered into a Loan and Security Agreement (the "Comerica Loan Agreement") with Comerica Bank ("Comerica"), providing for a revolving credit facility of up to $7,500,000 (the "Credit Facility"). The Company may use the proceeds of the Credit Facility for working capital and other general corporate purposes.

The amount that may be borrowed under the Credit Facility is the lower of (i) the revolving limit of $7,500,000 (the "Revolving Line") and (ii) 80% of the Company's eligible accounts receivable plus an applicable non-formula amount consisting of $2,000,000 of additional availability at close not based upon the Company's eligible accounts receivable, with such additional availability reducing by $250,000 per quarter beginning with the quarter ending June 30, 2022. Borrowings on the Credit Facility are limited to $5,000,000 until 80% of the Company's and its subsidiaries' customers are paying into a collection account or segregated governmental account with Comerica. The Revolving Line can also include, at the Company's option, credit card services with a sublimit of $300,000. Borrowings on the Revolving Line are subject to an interest rate equal to prime plus 0.50%, with prime being the greater of (x) Comerica's stated prime rate or (y) the sum of (A) the daily adjusting LIBOR rate plus (B) 2.5% per annum. The Company is also required to pay an unused facility fee quarterly in arrears in an amount equal to 0.25% per annum on the average unused but available portion of the Revolving Line for such quarter. See Note 19, *Line of Credit*, for more details. Comerica has a first priority security interest in substantially all of the Company's and its subsidiaries' assets.

In addition, also in October 2021, the Company entered into a Loan and Security Agreement (the "BroadOak Loan Agreement") with BroadOak, providing for a term loan in the aggregate principal amount of $8,000,000 (the "Term Loan"). Funding of the Term Loan took place on November 1, 2021. The Term Loan matures upon the earlier of (i) October 31, 2024 or (ii) the occurrence of a change in control, and bears interest at the rate of 9% per annum. The Term Loan is secured by a security interest in substantially all of the Company's and its subsidiaries' assets and is subordinate to the Company's recently established $7,500,000 revolving credit facility with Comerica Bank. The Term Loan has an origination fee of 3% of the Term Loan amount, and a terminal payment equal to (i) 15% of the original principal amount of the Term Loan if the change of control occurs on or prior to the first anniversary of the funding of the Term Loan, (ii) 20% of the original principal amount of the Term Loan if the change of control occurs after the first anniversary but on or prior to the second anniversary of the funding of the Term Loan and (iii) 30% of the original principal amount of the Term Loan if the change of control occurs after the second anniversary of the funding of the Term Loan, or if the Term Loan is repaid on its maturity date. Upon receipt of the term loan, the proceeds were used to repay in full at their maturity the notes extended by Ampersand and 1315 Capital discussed above. See Note 13, *Notes Payable,* for more details. As of the date of this Report, the Company currently anticipates that current cash and cash equivalents and availability on the revolving credit facility with Comerica will be sufficient to meet its anticipated operating cash requirements through at least the end of the first quarter of fiscal 2023.

The BroadOak Loan Agreement contains affirmative and negative restrictive covenants, including restrictions on certain mergers, acquisitions, investments and encumbrances which could adversely affect our ability to conduct our business. The BroadOak Loan Agreement also contains customary events of default. The Comerica Loan Agreement contains affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the Comerica loan agreement. These restrictive covenants, which include restrictions on certain mergers, acquisitions, investments, encumbrances, etc., could adversely affect our ability to conduct our business. The Comerica Loan Agreement also contains financial covenants requiring specified minimum liquidity and minimum revenue thresholds and also contains customary events of default. However, if we are unable to meet the financial covenants under the Comerica Loan Agreement, the revolving line of credit and notes payable will become due and payable immediately.

As of December 31, 2021, contractual obligations with terms exceeding one year and estimated minimum future rental payments required by non-cancelable operating leases with initial or remaining lease terms exceeding one year are as follows:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Operating lease obligations	$ 5,085	$ 1,295	$ 1,464	$ 816	$ 1,510
Total	$ 5,085	$ 1,295	$ 1,464	$ 816	$ 1,510

Although the Company is targeting to achieve adjusted EBITDA and cash flow breakeven during Fiscal 2022, we may not generate positive cash flows from operations for the year ending December 31, 2022. We intend to meet our ongoing capital needs by using our available cash and availability under the Comerica Loan Agreement, as well as through revenue growth and margin improvement; collection of accounts receivable; containment of costs; and the potential use of other financing options.

The Company is exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources in order to provide additional liquidity and expand the business through acquisitions or other strategic transactions. With the Company's delisting from Nasdaq in February 2021, its ability to raise additional capital on terms acceptable to the Company may be adversely impacted. In January 2022, the Company's registration statement for a rights offering become effective. The rights offering was subsequently terminated in January 2022. There can be no assurance that the Company will be successful in obtaining such funding on terms acceptable to the Company or at all.

As of the date of this Report, the Company currently anticipates that current cash and cash equivalents will be insufficient to meet its anticipated cash requirements through the next twelve months. These factors raise substantial doubt about the Company's ability to continue as a going concern.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2021, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information relating to directors and executive officers of the registrant that is responsive to Item 10 of this Annual Report on Form 10-K will be included in an amendment hereto or will be included in our Proxy Statement for our 2022 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 11. EXECUTIVE COMPENSATION

Information relating to executive compensation of the registrant that is responsive to Item 11 of this Annual Report on Form 10-K will be included in an amendment hereto or will be included in our Proxy Statement for our 2022 annual meeting of stockholders, and such information is incorporated by reference herein.

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

Information relating to security ownership of certain beneficial owners and management of the registrant that is responsive to Item 12 of this Annual Report on Form 10-K will be included in an amendment hereto or will be included in our Proxy Statement for our 2022 annual meeting of stockholders and such information is incorporated by reference herein.

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

Information relating to certain relationships and related transactions of the registrant that is responsive to Item 13 of this Annual Report on Form 10-K will be included in an amendment hereto or will be included in our Proxy Statement for our 2022 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information relating to principal accounting fees and services of the registrant that is responsive to Item 14 of this Annual Report on Form 10-K will be included in an amendment hereto or will be included in our Proxy Statement for our 2022 annual meeting of stockholders and such information is incorporated by reference herein.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

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

Schedule II: Valuation and Qualifying Accounts

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

(3) Exhibits

Exhibit No.	Description
2.1	Asset Purchase Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to Exhibit 2.2 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014.
2.2	Asset Purchase Agreement, dated as of October 30, 2015, by and between Publicis Touchpoint Solutions, Inc. and PDI, Inc., incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed with the SEC on November 2, 2015.
2.3	Asset Purchase Agreement by and among the Company and Diamir Biosciences Corp. dated March 16, 2021,incorporated by reference to Exhibit 2.1 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 11, 2021.
3.1+	Conformed version of Certificate of Incorporation of Interpace Biosciences, Inc., as amended by the Certificate of Amendment, effective January 15, 2020, and the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, filed January 17, 2020, incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
3.2	Amended and Restated Bylaws of Interpace Biosciences, Inc., incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed with the SEC on November 14, 2019.
4.1	Description of Securities, incorporated by reference to Exhibit 4.1 of the Company's Annual Report on Form 10-K, filed with the SEC on April 1, 2021.
4.2	Specimen Certificate Representing the Common Stock, incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-3 (File No. 333-227728), filed with the SEC on October 5, 2018.
4.3	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on January 20, 2017.
4.4	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K, as amended, filed with the SEC on March 24, 2017.
4.5	Form of PreFunded Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2017.
4.6	Form of Underwriters' Warrants, incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2017.
4.7	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2017.
4.8	Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 12, 2017.
4.9	Loan and Security Agreement, dated November 13, 2018, by and among Silicon Valley Bank, Interpace Diagnostics Group, Inc., Interpace Diagnostics Corporation, and Interpace Diagnostics, LLC, incorporated by reference to Exhibit 4.9 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
4.10	Form of Underwriter Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on January 29, 2019.
4.11	Subordinated Seller Note of Interpace BioPharma, Inc., dated July 15, 2019, in favor of Cancer Genetics, Inc., incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed with the SEC on July 19, 2019.
10.1*	Amended and Restated 2004 Stock Award and Incentive Plan, incorporated by reference to Annex A of the Company's definitive proxy statement, filed with the SEC on August 14, 2017.
10.2*	Form of Restricted Stock Unit Agreement for Employees, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018.

Exhibit No.	Description
10.3*	Form of Restricted Stock Unit Agreement for Directors, incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018.
10.4*	Form of Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018.
10.5*	Form of Incentive Stock Option Agreement, incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, filed with the SEC on May 15, 2018.
10.6*	Interpace Diagnostics Group, Inc. 2019 Equity Incentive Plan, incorporated by reference to Exhibit 4.1 of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 14, 2019.
10.7*	Amendment to the Interpace Biosciences, Inc. 2019 Equity Incentive Plan, incorporated by reference to Exhibit 10.8 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on June 26, 2020.
10.8*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2019 Equity Incentive Plan, incorporated by reference to Exhibit 4.3 of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 14, 2019.
10.9*	Form of Interpace Biosciences, Inc. 2019 Equity Incentive Plan Restricted Stock Unit And Restricted Stock Unit Agreement, incorporated by reference to Exhibit 10.9 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on June 26, 2020.
10.10*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2019 Equity Incentive Plan, incorporated by reference to Exhibit 4.4 of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 14, 2019.
10.11*	Interpace Diagnostics Group, Inc. Employee Stock Purchase Plan, incorporated by reference to Exhibit 4.2 of the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 14, 2019.
10.12*	Employment agreement entered into May 10, 2021, effective February 1, 2021, between Thomas Freeburg and the Company, incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 11, 2021.
10.15*	Severance agreement and General Release, dated January 31, 2021, by and between the Company and Fred Knechtel, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on February 4, 2021.
10.16*	Incentive Stock Option Agreement between Interpace Diagnostics Group, Inc. and Jack E. Stover, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 20, 2016.
10.17*	Amended and Restated Employment Agreement dated December 5, 2018, between the Company and Jack E. Stover, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on December 11, 2018.
10.18*	First Amendment to Amended and Restated Employment Agreement, dated January 29, 2020, by and between Interpace Biosciences, Inc. and Jack E. Stover, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed with the SEC on January 31, 2020.
10.20*	Employment Agreement, dated November 23, 2020, between Thomas W. Burnell and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on November 25, 2020.
10.21*	Separation and Consulting Agreement and General Release, dated November 23, 2020, between Jack E. Stover and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on November 25, 2020.
10.22*	Form of Indemnification Agreement by and between Interpace Diagnostics Group, Inc. and its directors and executive officers, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on August 8, 2016.
10.23*	Form of Indemnification Agreement by and between Interpace Biosciences, Inc. and Indemnitee, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on January 17, 2020.
10.24	License Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to Exhibit 10.31 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014.

Exhibit No.	Description
10.25	CPRIT License Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to Exhibit 10.32 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014.
10.26	Supply Agreement, dated August 13, 2014, by and between Interpace Diagnostics, LLC and Asuragen, Inc., incorporated by reference to Exhibit 10.33 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014.
10.27	Guaranty, dated August 13, 2014 by the Company in favor of Asuragen, Inc., incorporated by reference to Exhibit 10.34 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 5, 2014.
10.28	Morris Corporate Center Lease, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 5, 2009.
10.29	First Amendment to Lease, dated May 24, 2017, by and between Brookwood MC Investors, LLC, Brookwood MC II, LLC, and the Company, incorporated by reference to Exhibit 10.52 of the Company's Registration Statement on Form S-1 (333-218140), as amended, filed with the SEC on June 13, 2017.
10.39	Lease Agreement, dated March 31, 2017, by and between Saddle Lane Realty, LLC and the Company, incorporated by reference to Exhibit 10.53 of the Company's Registration Statement on Form S-1 (333-218140), as amended on June 13, 2017.
10.40	First Amendment, dated September 26, 2017, by and between Saddle Lane Realty, LLC and Interpace Diagnostics Corporation, incorporated by reference to Exhibit 10.36 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time
10.41	Amendment No. 2 to Lease, dated March 15, 2018, between Saddle Lane Realty, LLC and Interpace Diagnostics Corporation, incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 23, 2018.
10.42	Form of Securities Purchase Agreement, dated January 20, 2017, by and between Interpace Diagnostics Group, Inc. and certain purchasers named therein, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on January 20, 2017.
10.43	Warrant Agency Agreement, dated June 21, 2017, by and between Interpace Diagnostics Group, Inc. and American Stock Transfer & Trust Company, LLC, incorporated by reference to Exhibit 1.2 of the Company's Current Report on Form 8-K, filed with the SEC on June 21, 2017.

Exhibit No.	Description
10.44	Form of Warrant Exercise Agreement dated October 12, 2017, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 12, 2017.
10.45	Securities Purchase Agreement, dated July 15, 2019, by and between Interpace Diagnostics Group, Inc. and Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on July 19, 2019.
10.46	Transition Services Agreement, dated July 15, 2019, by and between Interpace BioPharma, Inc. and Cancer Genetics, Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on July 19, 2019.
10.47	Form of Voting Agreement, incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K, filed with the SEC on July 19, 2019.
10.50	Consent to Assignment, dated July 19, 2019, by and among Meadows Landmark LLC, Cancer Genetics, Inc., and Interpace BioPharma, Inc, incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.51	Lease Agreement, dated June 12, 2004, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.47 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.52	Letter Amendment, dated October 21, 2004, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.48 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.53	Second Amendment to Lease, dated June 17, 2005, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.49 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.54	Third Amendment to Lease, dated May 25, 2006, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.50 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.55	Fourth Amendment to Lease, dated December 20, 2007, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.51 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.56	Fifth Amendment to Lease, dated June 15, 2009, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.52 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.

Exhibit No.	Description
10.57	Sixth Amendment to Lease, dated June 3, 2010, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.53 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.58	Seventh Amendment to Lease, dated October 26, 2010, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.54 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.59	Eighth Amendment to Lease, dated July 27, 2011, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.55 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.60	Ninth Amendment to Lease, dated November 7, 2012, by and between Southport Business Park Limited Partnership and Gentris Corporation, incorporated by reference to Exhibit 10.56 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.61	Tenth Amendment to Lease, dated July 15, 2014, by and among Southport Business Park Limited Partnership, Gentris Corporation, and Gentris, LLC, incorporated by reference to Exhibit 10.57 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.62	Eleventh Amendment to Lease, effective as of June 1, 2020, by and between Southport Business Park Limited Partnership and Interpace Pharma Solutions, Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on June 9, 2020.
10.63	Assignment of Lease, dated July 15, 2019, by and between Cancer Genetics, Inc. and Interpace BioPharma, Inc., incorporated by reference to Exhibit 10.58 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.64	Guaranty of Lease, dated July 15, 2019, by and between Interpace Diagnostics Group, Inc. and Southport Business Park Limited Partnership, incorporated by reference to Exhibit 10.59 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
10.65	Equity Distribution Agreement, dated September 20, 2019, by and between Interpace Diagnostics Group, Inc. and Oppenheimer & Co. Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on September 20, 2019.
10.66	Securities Purchase and Exchange Agreement, dated January 10, 2020, by and among Interpace Biosciences, Inc., 1315 Capital II, L.P. and Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on January 14, 2020.
10.67	Amended and Restated Investor Rights Agreement, dated as of January 15, 2020, by and among Interpace Biosciences, Inc., 1315 Capital II, L.P. and Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on January 17, 2020.
10.68	Support Agreement, dated April 7, 2020, by and between Ampersand 2018 Limited Partnership and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.1 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on October 19, 2020.
10.69	Termination Agreement, dated July 9, 2020, by and between Ampersand 2018 Limited Partnership and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.3 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on October 19, 2020.
10.70	Support Agreement, dated April 2, 2020, by and between 1315 Capital II, L.P. and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on October 19, 2020.
10.71	First Loan Modification Agreement, dated March 18, 2019, by and among Silicon Valley Bank, Interpace Diagnostics Group, Inc. (n/k/a Interpace Biosciences, Inc.), Interpace Diagnostics Corporation, and Interpace Diagnostics, LLC, incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020, filed with the SEC on October 19, 2020.

Exhibit No.	Description
10.72	Joinder and Second Loan Modification Agreement, dated October 19, 2020, by and among the Company, Interpace Diagnostics Corporation, Interpace Diagnostics, LLC, Interpace Pharma Solutions, Inc. and Silicon Valley Bank, incorporated by reference to Exhibit 4.3 of the Company's Current Report on Form 8-K, filed with the SEC on October 23, 2020.
10.73	Promissory Note entered into between the Company and Ampersand 2018 Limited Partnership, dated January 7, 2021,incorporated by reference to Exhibit 10.3 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 11, 2021.
10.74	Promissory Note entered into between the Company and 1315 Capital II, L.P, dated January 7, 2021, incorporated by reference to Exhibit 10.4 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 11, 2021.
10.75	Security Agreement entered into between the Company and Ampersand 2018 Limited Partnership, dated January 7, 2021, incorporated by reference to Exhibit 10.5 of the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 11, 2021.
10.76	Amendment to Secured Promissory Note dated May 10, 2021 with Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 10.1 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 11, 2021.
10.77	Amendment to Secured Promissory Note dated May 10, 2021 with1315 Capital II, L.P., incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 11, 2021.
10.78	Amendment to Security Agreement dated May 10, 2021 by and between Ampersand 2018 Limited Partnership and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.3 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021, filed with the SEC on August 11, 2021.
10.79	Second Amendment to Secured Promissory Note dated June 24, 2021 with Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K, filed with the SEC on June 29, 2021.
10.80	Second Amendment to Secured Promissory Note dated June 25, 2021 with 1315 Capital II, L.P., incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K, filed with the SEC on June 29, 2021.
10.81	Third Amendment to Secured Promissory Note dated August 31, 2021 with Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K, filed with the SEC on August 31, 2021.
10.82	Third Amendment to Secured Promissory Note dated August 31, 2021 with 1315 Capital II, L.P., incorporated by reference to Exhibit 99.2 of the Company's Current Report on Form 8-K, filed with the SEC on August 31, 2021.
10.83	Fourth Amendment to Secured Promissory Note dated September 29, 2021 with Ampersand 2018 Limited Partnership, incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 1, 2021.
10.84	Fourth Amendment to Secured Promissory Note dated September 29, 2021 with 1315 Capital II, L.P., incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on October 1, 2021.
10.85	Loan and Security Agreement by and between Comerica Bank, Interpace Biosciences, Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and Interpace Pharma Solutions, Inc., dated October 13, 2021, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 19, 2021.
10.86	Subordination Agreement by and between Ampersand 2018 Limited Partnership, 1315 Capital II, L.P., Comerica Bank Interpace Biosciences, Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and Interpace Pharma Solutions, Inc., dated October 13, 2021, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on October 19, 2021.
10.87	Loan and Security Agreement by and between BroadOak Fund V, L.P., Interpace Biosciences, Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and Interpace Pharma Solutions, Inc., dated October 29, 2021, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on November 3, 2021.

Exhibit No.	Description
10.88	First Amendment to Loan and Security Agreement by and between Comerica Bank, Interpace Biosciences, Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and Interpace Pharma Solutions, Inc., dated November 1, 2021, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on November 3, 2021.
10.89	Subordination and Intercreditor Agreement by and between Comerica Bank, BroadOak Fund V, L.P., Interpace Biosciences, Inc., Interpace Diagnostics Corporation, Interpace Diagnostics, LLC and Interpace Pharma Solutions, Inc., dated as of November 1, 2021, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed with the SEC on November 3, 2021.
21.1	Subsidiaries of the Registrant, incorporated by reference to Exhibit 21.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
23.1	Consent of BDO USA, LLP, filed herewith.
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.

* Denotes compensatory plan, compensation arrangement or management contract.

ITEM 16. Form 10-K Summary

The Company has opted to not provide a summary.

SIGNATURES

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

INTERPACE BIOSCIENCES, INC.

Date: March 31, 2022

/s/ Thomas W. Burnell
Thomas W. Burnell
President and Chief Executive Officer

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

Name	Title	Date
/s/ Thomas W. Burnell Thomas W. Burnell	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2022
/s/ Thomas Freeburg Thomas Freeburg	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 31, 2022
/s/ Stephen J. Sullivan Stephen J. Sullivan	Director	March 31, 2022
/s/ Joseph Keegan Joseph Keegan	Director	March 31, 2022
/s/ Vijay Aggarwal Vijay Aggarwal	Director	March 31, 2022
/s/ Robert Gorman Robert Gorman	Chairman of the Board of Directors	March 31, 2022
/s/ Edward Chan Edward Chan	Director	March 31, 2022
/s/ Fortunato Ron Rocca Fortunato Ron Rocca	Director	March 31, 2022

Interpace Biosciences, Inc.
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and Financial Statement Schedules

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Interpace Biosciences, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2021, and the related notes and schedules (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has suffered operating losses, has negative operating cash flows and is dependent upon its ability to generate profitable operations in the future and/or obtain additional financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition

As described in Note 1 of the consolidated financial statements, the Company's clinical services derive revenue from the performance of its proprietary assays or tests. The Company's performance obligation is fulfilled upon the completion, review and release of test results to the customer. The Company subsequently bills third-party payers or direct-bill payers for the tests performed. Revenue is recognized based on the estimated transaction price or net realizable value ("NRV"), which is determined based on historical collection rates by each payer category for each proprietary test offered by the Company. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience.

We identified revenue recognition related to the measurement of the Company's clinical services revenue recognized for each specified test based on an estimated transaction price or NRV as a critical audit matter. The principal considerations for our determination included the following: (i) the judgment applied by management based on historical collection rates, (ii) the estimation of the amount of variable consideration using the expected value method based on historical experience, and (iii) the expected collection for each test, as the estimate is affected by assumptions in payor behavior such as changes in payor mix, payor collections, current customer contractual requirements, and experience with ultimate collection from the third-party payors Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skill or knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the consistency and reasonableness of management's judgments and estimates of variable consideration utilizing the expected value method based on its historical experience in its calculation of net realizable value.

- Comparing the significant assumptions and inputs used by management to the Company's fee schedule, third-party payor collection trends, and assessing the historical accuracy of the cash collections used in the Company's revenue models and assessing the completeness of adjustments to estimates of future cash collections as a result of significant subsequent contract amendments, changes in collection trends and changes in payor behavior.

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

/s/ BDO USA, LLP

Woodbridge, New Jersey
March 31, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,064	$ 2,772
Restricted cash	250	600
Accounts receivable, net of allowance for doubtful accounts of $72 and $275, respectively	6,158	8,028
Other current assets	2,694	2,722
Total current assets	12,166	14,122
Property and equipment, net	6,349	7,349
Other intangible assets, net	7,287	11,351
Goodwill	8,433	8,433
Operating lease right of use assets	4,032	4,384
Other long-term assets	160	42
Total assets	$ 38,427	$ 45,681
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 2,694	$ 4,511
Accrued salary and bonus	3,024	3,161
Other accrued expenses	9,198	9,795
Current liabilities from discontinued operations	766	766
Total current liabilities	15,682	18,233
Contingent consideration	1,383	1,818
Operating lease liabilities, net of current portion	3,154	3,540
Line of credit	1,500	-
Note payable at fair value	7,942	-
Other long-term liabilities	4,648	4,637
Total liabilities	34,309	28,228
Commitments and contingencies (Note 11)		
Preferred stock, $.01 par value; 5,000,000 shares authorized, 47,000 Series B issued and outstanding	46,536	46,536
Stockholders' deficit:		
Common stock, $.01 par value; 100,000,000 shares authorized; 4,228,169 and 4,075,257 shares issued, respectively; 4,195,412 and 4,055,593 shares outstanding, respectively	403	402
Additional paid-in capital	186,106	184,404
Accumulated deficit	(227,059)	(212,116)
Treasury stock, at cost (32,757 and 19,664 shares, respectively)	(1,868)	(1,773)
Total stockholders' deficit	(42,418)	(29,083)
Total liabilities and stockholders' deficit	$ (8,109)	$ (855)
Total liabilities, preferred stock and stockholders' deficit	$ 38,427	$ 45,681

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

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except for per share data)

	For The Years Ended December 31,	
	2021	**2020**
Revenue, net	$ 41,314	$ 32,398
Cost of revenue (excluding amortization of $4,064 and $4,461, respectively)	23,369	21,673
Gross profit	17,945	10,725
Operating expenses:		
Sales and marketing	10,067	9,254
Research and development	1,882	2,795
General and administrative	13,669	18,192
Transition expense	2,585	2,578
Loss on DiamiR transaction	13	-
Acquisition related amortization expense	4,064	4,461
Change in fair value of contingent consideration	(338)	(489)
Total operating expenses	31,942	36,791
Operating loss	(13,997)	(26,066)
Interest accretion expense	(496)	(549)
Related party interest	(424)	-
Other (expense) income, net	(496)	467
Loss from continuing operations before tax	(15,413)	(26,148)
(Benefit) provision for income taxes	(667)	53
Loss from continuing operations	(14,746)	(26,201)
Loss from discontinued operations, net of tax	(197)	(250)
Net loss	(14,943)	(26,451)
Less adjustment for preferred stock deemed dividend	-	(3,033)
Net loss attributable to common stockholders	$ (14,943)	$ (29,484)
Basic and diluted loss per share of common stock:		
From continuing operations	$ (3.57)	$ (7.26)
From discontinued operations	(0.04)	(0.06)
Net loss per basic and diluted share of common stock	$ (3.61)	$ (7.32)
Weighted average number of common shares and common share equivalents outstanding:		
Basic	4,135	4,029
Diluted	4,135	4,029

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

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands)

	For The Year Ended December 31, 2021		For The Year Ended December 31, 2020	
	Shares	**Amount**	**Shares**	**Amount**
Common stock:				
Balance at January 1	4,075	$ 402	3,932	$ 393
Common stock issued	9	-	37	1
Restricted stock issued	12	-	6	-
Common stock issued through market sales	-	-	80	8
Common stock issued through ESPP	36	-	-	-
Balance at March 31	4,132	402	4,055	402
Common stock issued	10	-	-	-
Balance at June 30	4,142	402	4,055	402
Common stock issued	13	-	5	-
Common stock issued through ESPP	39	1	-	-
Balance at September 30	4,194	403	4,060	402
Common stock issued	34	-	15	-
Balance at December 31	4,228	403	4,075	402
Treasury stock:				
Balance at January 1	20	(1,773)	12	(1,721)
Treasury stock purchased	-	-	-	-
Balance at March 31	20	(1,773)	12	(1,721)
Treasury stock purchased	-	-	7	(49)
Balance at June 30	20	(1,773)	19	(1,770)
Treasury stock purchased	-	-	-	-
Balance at September 30	20	(1,773)	19	(1,770)
Treasury stock purchased	13	(95)	1	(3)
Balance at December 31	33	(1,868)	20	(1,773)
Additional paid-in capital:				
Balance at January 1		184,404		182,514
Common stock issued		108		-
Extinguishment of Series A Shares		-		(828)
Beneficial Conversion Feature in connection with Series B Issuance		-		2,205
Amortization of Beneficial Conversion Feature		-		(2,205)
Common stock issued through market sales		-		476
Stock-based compensation expense		286		418
Balance at March 31		184,798		182,580
Stock-based compensation expense		551		400
Balance at June 30		185,349		182,980
Common stock issued		226		-
Stock-based compensation expense		477		563
Balance at September 30		186,052		183,543
Common stock issued through market sales, net of expenses		-		-
Stock-based compensation expense		54		861
Balance at December 31		186,106		184,404
Accumulated deficit:				
Balance at January 1		(212,116)		(185,665)
Net loss		(4,207)		(6,494)
Adoption of ASC 842		-		-
Balance at March 31		(216,323)		(192,159)
Net loss		(3,446)		(5,580)
Balance at June 30		(219,769)		(197,739)
Net loss		(3,561)		(6,234)
Balance at September 30		(223,330)		(203,973)
Net loss		(3,729)		(8,143)
Balance at December 31		(227,059)		(212,116)
Total stockholders' deficit		$ (42,418)		$ (29,083)

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

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

	For The Years Ended December 31,	
	2021	**2020**
Cash Flows From Operating Activities		
Net loss	$ (14,943)	$ (26,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,374	5,501
Interest accretion expense	496	549
Bad debt (recovery) expense	(140)	585
Reversal of 2019 bonus accrual	-	(1,156)
Mark to market on warrants	50	(61)
Amortization of deferred financing fees	122	-
Accrued interest - note payable	120	-
Note payable fees	312	-
Stock-based compensation	1,255	2,187
ESPP expense	113	55
Change in fair value of note payable	(58)	-
Deferred income taxes	38	37
Loss on DiamiR transaction	13	-
Change in fair value of contingent consideration	(338)	(489)
Asset impairment	-	37
Other gains and expenses, net	(2)	-
Other changes in operating assets and liabilities:		
Decrease in accounts receivable	2,148	1,725
Decrease in other current assets	28	241
Increase in other long-term assets	(118)	-
Decrease in accounts payable	(1,817)	(198)
(Decrease) increase in accrued salaries and bonus	(137)	1,976
(Decrease) increase in accrued liabilities	(1,086)	1,395
(Decrease) increase in long-term liabilities	(149)	88
Net cash used in operating activities	(8,719)	(13,979)
Cash Flows From Investing Activity		
Purchase of property and equipment	(354)	(1,575)
Sale of property and equipment	39	-
Net cash used in investing activities	(315)	(1,575)
Cash Flows From Financing Activities		
Issuance of common stock, net of expenses	335	434
Issuance of Series B preferred stock, net of expenses	-	19,223
Loan proceeds - related parties	7,500	-
Loan proceeds - BroadOak	8,000	-
Loan expenses - BroadOak	(312)	-
Payment of related party note and related interest	(7,924)	-
Financing fees - related party	(123)	-
Borrowings (payments) on Line of Credit	1,500	(3,000)
Cash paid for repurchase of restricted shares	-	(52)
Net cash provided by financing activities	8,976	16,605
Net (decrease) increase in cash, cash equivalents and restricted cash	(58)	1,051
Cash, cash equivalents and restricted cash – beginning	3,372	2,321
Cash, cash equivalents and restricted cash – ending	$ 3,314	$ 3,372

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

1. Nature of Business and Significant Accounting Policies

Nature of Business

Interpace Biosciences, Inc. ("Interpace" or the "Company") enables personalized medicine, offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications and pharma services. The Company provides molecular diagnostics, bioinformatics and pathology services for evaluation of risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. The Company also provides pharmacogenomics testing, genotyping, biorepository and other specialized services to the pharmaceutical and biotech industries. The Company advances personalized medicine by partnering with pharmaceutical, academic, and technology leaders to effectively integrate pharmacogenomics into their drug development and clinical trial programs.

Principles of Consolidation

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

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

The Company has one reporting segment: the Company's clinical and pharma services business. The Company's current reporting segment structure is reflective of the way the Company's management views the business, makes operating decisions and assesses performance. This structure allows investors to better understand Company performance, better assess prospects for future cash flows, and make more informed decisions about the Company.

Accounting Estimates

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

Reverse stock split

On January 15, 2020, the Company effected a one-for-ten reverse split of its issued and outstanding shares of its common stock (the "Reverse Stock Split"). Every 10 shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock, without any change in the par value per share. The Company's issued and outstanding stock decreased from 39,323,701 to 3,932,370 and 39,205,895 to 3,920,589 at December 31, 2019. All information related to common stock, stock options, restricted stock units, warrants and earnings per share have been retroactively adjusted to give effect to the reverse stock split for all periods presented.

Cash and Cash Equivalents

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

Accounts Receivable, Net

The Company's accounts receivables represent unconditional rights to consideration and are generated using its proprietary tests and pharma services. The Company's clinical services are fulfilled upon completion of the test, review and release of the test results. In conjunction with fulfilling these services, the Company bills the third-party payer or direct-bill payer. Contractual adjustments represent the difference between the list prices and the reimbursement rates set by third party payers, including Medicare, commercial payers, and amounts billed to direct-bill payers. Specific accounts may be written off after several appeals, which in some cases may take longer than twelve months. Pharma services represent, primarily, the performance of laboratory tests in support of clinical trials for pharma services customers. The Company bills these services directly to the customer.

Other current assets

Other current assets consisted of the following as of December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Lab supply inventory	$ 1,786	$ 2,052
Prepaid expenses	800	625
Other	108	45
Total other current assets	$ 2,694	$ 2,722

Property and Equipment, net

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

Software Costs

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

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

See Note 6, *Property and Equipment*, for further information.

Long-Lived Assets, including Finite-Lived Intangible Assets

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

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

As a result of overall economic conditions related to the coronavirus pandemic, the impact of the coronavirus pandemic on the Company's financial results, and the decrease in the price of the Company's common stock noted during the third quarter of fiscal 2020, the Company performed an internal review of its long-lived assets. Due to an extended delay in the launch of the Company's Barrett's test, the Company believes there was a triggering event in Fiscal 2016. The Company applied the required procedures under ASC 360 and assessed the estimated future cash flows related to the Barrett's intangible asset on an undiscounted basis. It was determined that the carrying value of the asset was in excess of the undiscounted cash flows as of December 31, 2016. As a result, the Company performed a formal valuation of the asset on a discounted basis in order to measure the related impairment.

Contingencies

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

Revenue Recognition

Our clinical services derive its revenues from the performance of its proprietary assays or tests. The Company's performance obligation is fulfilled upon the completion, review and release of test results to the customer. The Company subsequently bills third-party payers or direct-bill payers for the tests performed. Revenue is recognized based on the estimated transaction price or NRV, which is determined based on historical collection rates by each payer category for each proprietary test offered by the Company. To the extent the transaction price includes variable consideration, for all third party and direct-bill payers and proprietary tests, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience.

For our clinical services, we regularly review the ultimate amounts received from the third-party and direct-bill payers and related estimated reimbursement rates and adjust the NRV's and related contractual allowances accordingly. If actual collections and related NRV's vary significantly from our estimates, we will adjust the estimates of contractual allowances, which would affect net revenue in the period such variances become known.

For our pharma services, project level activities, including study setup and project management, are satisfied over the life of the contract. Revenues are recognized at a point in time when the test results or other deliverables are reported to the customer.

The Company elected the practical expedient to expense contract costs as incurred related to clinical services because the contract term is less than one year. Contract costs for pharma services were not significant.

Deferred Revenue

For our pharma services, project level fee revenue is recognized as deferred revenue and recorded at fair value. It represents payments received in advance of services rendered and is recognized ratably over the life of the contract.

Cost of revenue

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

Stock-Based Compensation

The compensation cost associated with the granting of stock-based awards is based on the grant date fair value of the stock award. The Company recognizes the compensation cost, net of estimated forfeitures, over the shorter of the vesting period or the period from the grant date to the date when retirement eligibility is achieved. Forfeitures are initially estimated based on historical information and subsequently updated over the life of the awards to ultimately reflect actual forfeitures. As a result, changes in forfeiture activity can influence the amount of stock compensation cost recognized from period to period. The Company primarily uses the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards is made on the date of grant and is affected by the Company's stock price as well as assumptions made regarding a number of complex and subjective variables. These assumptions include: expected stock price volatility over the term of the awards; actual and projected employee stock option exercise behaviors; the risk-free interest rate; and expected dividend yield. The fair value of restricted stock units, or RSUs, and restricted shares is equal to the closing stock price on the date of grant. In 2020, the Company issued performance-based options and RSUs based on achieving stock price or certain other financial metrics. These require the Company to assess the likelihood of achieving certain performance milestones on a quarterly basis. In these instances, the Company has the initial valuation model prepared by an outside expert.

See Note 15, *Stock-Based Compensation,* for further information.

Treasury Stock

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

Leases

The Company determines if an arrangement contains a lease in whole or in part at the inception of the contract. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term while lease liabilities represent our obligation to make lease payments arising from the lease. All leases with terms greater than twelve months result in the recognition of a ROU asset and a liability at the lease commencement date based on the present value of the lease payments over the lease term. Unless a lease provides all of the information required to determine the implicit interest rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of the lease payments. We use the implicit interest rate in the lease when readily determinable.

Our lease terms include all non-cancelable periods and may include options to extend (or to not terminate) the lease when it is reasonably certain that we will exercise that option. Leases with terms of twelve months or less at the commencement date are expensed on a straight-line basis over the lease term and do not result in the recognition of an asset or liability. See Note 8, *Leases*.

Income taxes

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

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

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

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

Income (Loss) per Share

Basic earnings per common share are computed by dividing net income by the weighted average number of shares outstanding during the year including any unvested share-based payment awards that contain nonforfeitable rights to dividends. Diluted earnings per common share are computed by dividing net income by the sum of the weighted average number of shares outstanding and dilutive common shares under the treasury method. Unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid), are participating securities and are included in the computation of earnings per share pursuant to the two-class method. As a result of the losses incurred in both 2021 and 2020, the potentially dilutive common shares have been excluded from the earnings per share computation for these periods because its inclusion would have been anti-dilutive. Additionally, preferred shares have been excluded in the denominator of the earnings per share computation, on an if-converted basis, as such shares would have been anti-dilutive.

2. Recent Accounting Standards

Recently Adopted Accounting Guidance

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"). ASU 2019-12 will simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendment was effective for annual periods beginning after December 15, 2020.

The Company adopted this pronouncement on January 1, 2021 and the impact was not material to the Company's Consolidated Financial Statements.

Accounting Pronouncements Pending Adoption

In February 2020, the FASB issued ASU 2020-02, Financial Instruments-Credit Losses (Topic 326) and Leases (Topic 842) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02, Leases (Topic 842) which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on results of operations. The Company is in the process of determining the effects adoption will have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40), ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The ASU2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company does not expect this will have any impact on its unaudited consolidated financial statements.

3. Going Concern

The accompanying consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Accordingly, the accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty.

For the fiscal year ended December 31, 2021, we had an operating loss of $14.0 million. As of December 31, 2021, we had cash, cash equivalents and restricted cash of $3.3 million, total current assets of $12.2 million and current liabilities of $15.7 million. As of March 18, 2022, we had approximately $2.7 million of cash on hand, excluding restricted cash.

In January 2022, the Company announced that CMS issued a new billing policy whereby CMS will no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service. On February 28, 2022, the Company announced that the National Correct Coding Initiative (NCCI) program issued a response on behalf of CMS stating that the January 2022 billing policy reimbursement change for ThyGeNEXT® (0245U) and ThyraMIR® (0018U) tests has been retroactively reversed to January 1, 2022. CMS is currently reimbursing the Company for one of its two thyroid tests, and has agreed to retroactively reimburse for the second test once they have completed their internal administrative adjustments. We have been notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 will be completed beginning July 1, 2022. As of the date of this filing, the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS. As of the date of this Report, the Company currently anticipates that current cash and cash equivalents will be insufficient to meet its anticipated cash requirements through the next twelve months. These factors raise substantial doubt about the Company's ability to continue as a going concern.

On January 7, 2021, the Company entered into secured promissory notes in the amount of $3 million and $2 million with Ampersand ("Ampersand Note") and 1315 Capital ("1315 Capital Note"), respectively. See Note 13, *Notes Payable,* of the notes to the financial statements. On May 10, 2021, the Company amended the Ampersand Note to increase the principal amount to $4.5 million and amended the 1315 Capital Note to increase the principal amount to $3.0 million. The maturity dates of the Notes were the earlier of (a) June 30, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Notes. On June 24, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) August 31, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On June 25, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner. On August 31, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) September 30, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On August 31, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner.

On September 29, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) October 31, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On September 29, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner.

In October 2021, the Company entered into a $7.5 million revolving credit facility with Comerica. See Note 19, *Revolving Line of Credit*, for more details. In addition, also in October 2021, the Company entered into the $8.0 million BroadOak Term Loan, the proceeds of which were used to repay in full at their maturity the notes extended by Ampersand and 1315 Capital discussed above. See Note 13, *Notes Payable,* for more details.

Although the Company is targeting to achieve adjusted EBITDA and cash flow breakeven during Fiscal 2022, we may not generate positive cash flows from operations for the year ending December 31, 2022. We intend to meet our ongoing capital needs by using our available cash and availability under the Comerica Loan Agreement, as well as through revenue growth and margin improvement; collection of accounts receivable; containment of costs; and the potential use of other financing options. However, if we are unable to meet the financial covenants under the Comerica Loan Agreement, the revolving line of credit and notes payable will become due and payable immediately.

The Company is exploring various dilutive and non-dilutive sources of funding, including equity and debt financings, strategic alliances, business development and other sources in order to provide additional liquidity and expand the business through acquisitions or other strategic transactions. With the Company's delisting from Nasdaq in February 2021, its ability to raise additional capital on terms acceptable to the Company may be adversely impacted. There can be no assurance that the Company will be successful in obtaining such funding on terms acceptable to the Company. In January 2022, the Company's registration statement for a rights offering become effective. The rights offering was subsequently terminated in January 2022.

4. Discontinued Operations

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

The components of liabilities classified as discontinued operations relate to Commercial Services and consist of the following as of December 31, 2021 and December 31, 2020:

	December 31, 2021	December 31, 2020
Accrued liabilities	$ 766	$ 766
Current liabilities from discontinued operations	766	766
Total liabilities	$ 766	$ 766

The table below presents the significant components of CSO, Group DCA's, Pharmakon's and TVG's results included within loss from discontinued operations, net of tax in the consolidated statements of operations for the years ended December 31, 2021 and 2020.

	Years Ended December 31,	
	2021	2020
Income from discontinued operations, before tax	$ -	$ -
Income tax expense	197	250
Loss from discontinued operations, net of tax	$ (197)	$ (250)

5. Fair Value Measurements

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

Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2: Valuations for assets and liabilities traded in less active dealer or broker markets. Valuations are obtained from third-party pricing services for identical or similar assets or liabilities.

Level 3: Valuations for assets and liabilities include certain unobservable inputs in the assumptions and projections used in determining the fair value assigned to such assets or liabilities.

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

	As of December 31, 2021		Fair Value Measurements As of December 31, 2021		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen	$ 1,871	$ 1,871	$ -	$ -	$ 1,871
Other accrued expenses:					
Warrant liability	71	71	-	-	71
Note payable:					
BroadOak loan	7,942	7,942	-	-	7,942
	$ 9,884	$ 9,884	$ -	$ -	$ 9,884

	As of December 31, 2020		Fair Value Measurements As of December 31, 2020		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen	$ 2,216	$ 2,216	$ -	$ -	$ 2,216
Other long-term liabilities:					
Warrant liability	21	21	-	-	21
	$ 2,237	$ 2,237	$ -	$ -	$ 2,237

In connection with the acquisition of certain assets from Asuragen, the Company recorded contingent consideration related to contingent payments and other revenue-based payments. The Company determined the fair value of the contingent consideration based on a probability-weighted income approach derived from revenue estimates. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement.

In connection with the BroadOak loan, the Company records the loan at fair value. The fair value of the loan is determined by a probability-weighted approach regarding the loan's change in control feature. See Note 13, *Notes Payable,* for more details. The fair value measurement is based on the estimated probability of a change in control and thus represents a Level 3 measurement.

	December 31, 2020	Loan Received	Payments	Accretion/ Interest Accrued	Adjustment to Fair Value/ Mark to Market	December 31, 2021
Asuragen	$ 2,216		$ (503)	$ 496	$ (338)	$ 1,871
Underwriters Warrants	21		-	-	50	71
BroadOak Loan	-	8,000	-	-	(58)	7,942
	$ 2,237	$ 8,000	$ (503)	$ 496	$ (346)	$ 9,884

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

6. Property and Equipment

Property and equipment consisted of the following as of December 31, 2021 and 2020:

	December 31,	
	2021	2020
Furniture and fixtures	$ 339	$ 339
Lab and office equipment	7,837	7,536
Computer equipment	331	339
Internal-use software	1,572	1,572
Leasehold improvements	506	505
Property and equipment	10,585	10,291
Less accumulated depreciation and amortization	(4,236)	(2,942)
Net property and equipment	$ 6,349	$ 7,349

Depreciation and amortization expense from continuing operations was approximately $1.2 million and $0.8 million for the years ended December 31, 2021 and 2020, respectively. There was internal-use software amortization expense included in depreciation and amortization expense in 2021 of approximately $0.3 million. As of December 31, 2021, capitalized external-use software was fully amortized.

7. Goodwill and Other Intangible Assets

Goodwill is attributable to the acquisition of the Biopharma business from CGI in July 2019. The carrying value of the intangible assets acquired was $15.6 million, with goodwill of approximately $8.3 million and identifiable intangible assets of approximately $7.3 million. The goodwill balance at December 31, 2021 was $8.4 million. The net carrying value of the identifiable intangible assets as of December 31, 2021 and December 31, 2020 is as follows:

	Life (Years)	As of December 31, 2021 Carrying Amount	As of December 31, 2020 Carrying Amount
Asuragen acquisition:			
Thyroid	9	$ 8,519	$ 8,519
RedPath acquisition:			
Pancreas test	7	16,141	16,141
Barrett's test	9	6,682	6,682
BioPharma acquisition:			
Trademarks	10	1,600	1,600
Customer relationships	8	5,700	5,700
CLIA Lab	2.3	$ 609	$ 609
Total		$ 39,251	$ 39,251
Accumulated Amortization		$ (31,964)	$ (27,900)
Net Carrying Value		$ 7,287	$ 11,351

The following table displays a roll forward of the carrying amount of goodwill from January 1, 2020 to December 31, 2021:

	Carrying Amount
Balance as of January 1, 2020	$ 8,433
Adjustments	-
Balance as of December 31, 2020	$ 8,433
Adjustments	-
Balance as of December 31, 2021	$ 8,433

Amortization expense was approximately $4.1 million and $4.5 million for the years ended December 31, 2021 and 2020, respectively. Estimated amortization expense for the next five years is as follows:

2022	2023	2024	2025	2026
$ 2,143	$ 1,734	$ 873	$ 873	$ 873

8. Leases

Finance lease assets are included in fixed assets, net of accumulated depreciation.

The table below presents the lease-related assets and liabilities recorded in the Condensed Consolidated Balance Sheet:

	Classification on the Balance Sheet	December 31, 2021
Assets		
Financing lease assets	Property and equipment, net	$ 636
Operating lease assets	Operating lease right of use assets	4,032
Total lease assets		$ 4,668
Liabilities		
Current		
Financing lease liabilities	Other accrued expenses	$ 79
Operating lease liabilities	Other accrued expenses	1,041
Total current lease liabilities		$ 1,120
Noncurrent		
Financing lease liabilities	Other long-term liabilities	59
Operating lease liabilities	Operating lease liabilities, net of current portion	3,154
Total long-term lease liabilities		3,213
Total lease liabilities		$ 4,333

The weighted average remaining lease term for the Company's operating leases was 6.4 years as of December 31, 2021 and 7.1 years as of December 31, 2020 and the weighted average discount rate for those leases was 6.5% and 6.0% as of December 31, 2021 and December 31, 2020, respectively. The Company's operating lease expenses are recorded within "Cost of revenue" and "General and administrative expenses."

The table below reconciles the undiscounted cash flows to the lease liabilities recorded on the Company's Consolidated Balance Sheet as of December 31, 2021:

	Operating Leases	Financing Leases
2022	$ 1,295	$ 86
2023	897	60
2024	567	-
2025	402	-
2026-2030	1,924	
Total minimum lease payments	5,085	146
Less: amount of lease payments representing effects of discounting	890	8
Present value of future minimum lease payments	4,195	138
Less: current obligations under leases	1,041	79
Long-term lease obligations	$ 3,154	$ 59

9. Retirement Plans

The Company offers an employee 401(k) saving plan. Under the Interpace Biosciences, Inc. 401(k) Plan, employees may contribute up to 50% of their pre- or post-tax base compensation. The Company currently offers a safe harbor matching contribution equal to 100% of the first 3% of the participant's contributed base salary plus 50% of the participant's base salary contributed exceeding 3% but not more than 5%. Participants are not allowed to invest any of their 401(k) funds in the Company's common stock. The Company's total contribution expense from continuing operations related to the 401(k) plan for the years ended December 31, 2021 and December 31, 2020 was approximately $0.3 million and $0.4 million, respectively.

10. Accrued Expenses and Other Long-Term Liabilities

Other accrued expenses consisted of the following as of December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Accrued royalties	$ 3,890	$ 2,710
Contingent consideration	488	398
Upfront Medicare payment	-	2,066
Operating lease liability	1,041	1,027
Financing lease liability	79	177
Deferred revenue	40	54
Interest payable	120	-
Warrant liability	71	-
Accrued sales and marketing - diagnostics	47	51
Accrued lab costs - diagnostics	228	161
Accrued professional fees	932	854
Taxes payable	245	334
Unclaimed property	565	565
All others	1,452	1,398
Total other accrued expenses	$ 9,198	$ 9,795

Other long-term liabilities consisted of the following as of December 31, 2021 and 2020:

	December 31, 2021	December 31, 2020
Warrant liability	$ -	$ 21
Uncertain tax positions	4,577	4,342
Deferred revenue	13	136
Other	58	138
Total other long-term liabilities	$ 4,648	$ 4,637

11. Commitments and Contingencies

The Company leases facilities and certain equipment under agreements classified as operating leases, which expire at various dates through May 2030. Substantially all of the property leases provide for increases based upon use of utilities and landlord's operating expenses as well as pre-defined rent escalations. Total expense from continuing operations under these agreements for the years ended December 31, 2021 and 2020 was approximately $1.2 million and $2.1 million, respectively.

As of December 31, 2021, contractual obligations with terms exceeding one year and estimated minimum future rental payments required by non-cancelable operating leases with initial or remaining lease terms exceeding one year are as follows:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	After 5 Years
Operating lease obligations	$ 5,085	$ 1,295	$ 1,464	$ 816	$ 1,510
Total	$ 5,085	$ 1,295	$ 1,464	$ 816	$ 1,510

Litigation

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

The Company could also be held liable for errors and omissions of its employees in connection with the services it performs that are outside the scope of any indemnity or insurance policy. The Company could be materially adversely affected if it were required to pay damages or incur defense costs in connection with a claim that is outside the scope of an indemnification agreement; if the indemnity, although applicable, is not performed in accordance with its terms; or if the Company's liability exceeds the amount of applicable insurance or indemnity.

12. Equity

Preferred Stock Issuance: Securities Purchase and Exchange Agreement

On January 10, 2020, the Company entered into a Securities Purchase and Exchange Agreement (the "Securities Purchase and Exchange Agreement") with 1315 Capital and Ampersand (collectively, the "Investors") pursuant to which the Company agreed to sell to the Investors an aggregate of $20.0 million in Series B Preferred Stock of the Company, at an issuance price per share of $1,000. Pursuant to the Securities Purchase and Exchange Agreement, 1315 Capital agreed to purchase 19,000 shares of Series B Preferred Stock at an aggregate purchase price of $19.0 million and Ampersand agreed to purchase 1,000 shares of Series B Preferred Stock at an aggregate purchase price of $1.0 million.

In addition, the Company agreed to exchange $27.0 million of the Company's existing Series A convertible preferred stock, par value $0.01 per share, held by Ampersand (the "Series A Preferred Stock"), represented by 270 shares of Series A Preferred Stock with a stated value of $100,000 per share, which represents all of the Company's issued and outstanding Series A Preferred Stock, for 27,000 newly issued shares of Series B Preferred Stock (such shares of Series B Preferred Stock, the "Exchange Shares" and such transaction, the "Exchange"). Following the Exchange, no shares of Series A Preferred Stock remained designated, authorized, issued or outstanding. The Series B Preferred Stock has a conversion price of $6.00 as compared to a conversion price of $8.00 on the Series A Preferred Stock, but did not include certain rights applicable to the Series A Preferred Stock, including a six-percent (6%) dividend and a conversion price adjustment for any failure by the Company to achieve a revenue target of $34.0 million in 2020 related to its clinical services or a weighted-average anti-dilution adjustment. Under the terms of the Securities Purchase and Exchange Agreement, Ampersand also agreed to waive all dividends and weighted-average anti-dilution adjustments accrued to date on the Series A Preferred Stock.

A convertible financial instrument includes a beneficial conversion feature if its conversion price is lower than the Company's stock price at the commitment date. The Company determined that the sale of the Series B Preferred resulted in a beneficial conversion feature with an intrinsic value of $2.2 million, which the Company recorded as a reduction to additional paid-in capital upon the sale of the Series B Preferred stock. The Company calculated the intrinsic value of the beneficial conversion feature as the difference between the estimated fair value of the Common Stock on January 15, 2020 of $6.79 per share and the effective conversion price per share of $6.00 multiplied by the number of shares of common stock issuable upon conversion. The Company fully amortized the beneficial conversion feature during the three months ended March 31, 2020 in accordance with GAAP. The beneficial conversion feature resulted in an increase in the loss attributable to common shareholders for the three months ended March 31, 2020 in the Condensed Consolidated Statement of Operations, as it represented a deemed dividend to the preferred shareholders.

In April 2020, the Company entered into support agreements with each of the Series B Investors, pursuant to which Ampersand and 1315 Capital, respectively, consented to, and agreed to vote (by proxy or otherwise), all shares of Series B Preferred Stock registered in its name or beneficially owned by it and/or over which it exercises voting control as of the date of the Support Agreement and any other shares of Series B Preferred Stock legally or beneficially held or acquired by such Series B Investor after the date of the Support Agreement or over which it exercises voting control, in favor of any Fundamental Action desired to be taken by the Company as determined by the Board. For purposes of each Support Agreement, "Fundamental Action" means any action proposed to be taken by the Company and set forth in Section 4(d)(i), 4(d)(ii), 4(d)(v), 4(d)(vi), 4(d)(viii) or 4(d)(ix) of the Certificate of Designation of Series B Preferred Stock or Section 8.5.1.1, 8.5.1.2, 8.5.1.5, 8.5.1.6, 8.5.1.8 or 8.5.1.9 of the Amended and Restated Investor Rights Agreement. The support agreement between the Company and Ampersand was terminated by mutual agreement on July 9, 2020; however, the support agreement entered into with 1315 Capital remains in effect. During October 2021, Ampersand and 1315 Capital provided consent to the Company to enter into the Comerica Loan Agreement and the BroadOak Term Loan.

As of December 31, 2021 and 2020, there were 47,000 Series B issued and outstanding shares of preferred stock, respectively.

13. Notes Payable

BroadOak Loan and Repayment of Promissory Notes

On October 29, 2021, the Company and its subsidiaries entered into a Loan and Security Agreement (the "BroadOak Loan Agreement") with BroadOak, providing for a term loan in the aggregate principal amount of $8,000,000 (the "Term Loan"). Funding of the Term Loan took place on November 1, 2021. The Term Loan matures upon the earlier of (i) October 31, 2024 or (ii) the occurrence of a change in control, and bears interest at the rate of 9% per annum. The Term Loan is secured by a security interest in substantially all of the Company's and its subsidiaries' assets and is subordinate to the Company's recently established $7,500,000 revolving credit facility with Comerica Bank. The Term Loan has an origination fee of 3% of the Term Loan amount, and a terminal payment equal to (i) 15% of the original principal amount of the Term Loan if the change of control occurs on or prior to the first anniversary of the funding of the Term Loan, (ii) 20% of the original principal amount of the Term Loan if the change of control occurs after the first anniversary but on or prior to the second anniversary of the funding of the Term Loan and (iii) 30% of the original principal amount of the Term Loan if the change of control occurs after the second anniversary of the funding of the Term Loan, or if the Term Loan is repaid on its maturity date.

The BroadOak Loan Agreement contains affirmative and negative restrictive covenants that are applicable from and after the date of the Term Loan advance. These restrictive covenants, which include restrictions on certain mergers, acquisitions, investments, encumbrances, etc., could adversely affect our ability to conduct our business. The BroadOak Loan Agreement also contains customary events of default.

In connection with the BroadOak Loan Agreement, the Company and its subsidiaries entered into that certain First Amendment to Loan and Security Agreement and Consent with Comerica, dated as of November 1, 2021 (the "Comerica Amendment"), pursuant to which Comerica consented to the Company's and its subsidiaries' entry into the BroadOak Loan Agreement, and amended that certain Loan and Security Agreement among Comerica, the Company and its subsidiaries (the "Comerica Loan Agreement") to, among other things, permit the indebtedness, liens and encumbrances contemplated by the BroadOak Loan Agreement.

As a condition for BroadOak to extend the Term Loan to the Company and its subsidiaries, the Company's existing creditor, Comerica, and BroadOak entered into that certain Subordination and Intercreditor Agreement, dated as of November 1, 2021, pursuant to which BroadOak agreed to subordinate all of the indebtedness and obligations of the Company and its subsidiaries owing to BroadOak to all of the indebtedness and obligations of the Company and its subsidiaries owing to Comerica (the "Intercreditor Agreement"). BroadOak further agreed to subordinate all of its respective security interests in assets or property of the Company and its subsidiaries to Comerica's security interests in such assets or property. The Intercreditor Agreement provides that it is solely for the benefit of BroadOak and Comerica and is not for the benefit of the Company or any of its subsidiaries.

The Company concluded that the Note met the definition of a "recognized financial liability" which is an acceptable financial instrument eligible for the fair value option under ASC 825-10-15-4, and did not meet the definition of any of the financial instruments listed within ASC 825-10-15-5 that are not eligible for the fair value option. The Note is not convertible and does not have any component recorded to shareholders' equity. Accordingly, the Company elected the fair value option for the Note.

Secured Promissory Notes – Related Parties

On January 7, 2021, the Company entered into promissory notes with Ampersand, in the amount of $3 million, and 1315 Capital, in the amount of $2 million, respectively (together, the "Notes") and a related security agreement (the "Security Agreement").

Ampersand holds 28,000 shares of the Company's Series B Convertible Preferred Stock, which are convertible from time to time into an aggregate of 4,666,666 shares of our Common Stock, and 1315 Capital holds 19,000 shares of the Company Series B Convertible Preferred Stock, which are convertible from time to time into an aggregate of 3,166,668 shares of our Common Stock. On an as-converted basis, such shares would represent approximately 38.7% and 26.3% of our fully-diluted shares of Common Stock, respectively. In addition, pursuant to the terms of the Series B Convertible Preferred Stock certificate of designation and an amended and restated investor rights agreement among the Company and Ampersand and 1315 Capital, they each have the right to (1) approve certain of our actions, including our borrowing of money and any public offering of securities, and (2) designate two directors to our Board of Directors; provided, that certain of such rights held by 1315 Capital have been delegated pursuant to the related Support Agreement (See Note 12, *Equity*). As a result, the Company considers the Notes and Security Agreement to be a related party transaction.

The rate of interest on the Notes was equal to eight percent (8.0%) per annum and their maturity date was the earlier of (a) June 30, 2021 and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Notes. No interest payments were due on the Notes until their maturity date. All payments on the Notes were pari passu.

On May 10, 2021, (i) the Company and Ampersand amended the Ampersand Note to increase its principal amount to $4.5 million, (ii) the Company and 1315 Capital amended the 1315 Capital Note to increase its principal amount to $3.0 million and (iii) the Company and Ampersand amended the Security Agreement to include the new total principal amount of the Notes of $7.5 million. The maturity date of the Notes remained the earlier of June 30, 2021 and the date on which all amounts become due upon the occurrence of any event of default and the interest rate remained 8%, and except with respect to their respective principal amounts, the terms of the Notes and the Security Agreement were otherwise unchanged.

On June 24, 2021, August 31, 2021, and September 29, 2021, the Company and Ampersand amended the Ampersand Note to change its maturity date to the earlier of (a) August 31, 2021, September 30, 2021, and October 31, 2021, respectively and (b) the date on which all amounts become due upon the occurrence of any event of default as defined in the Ampersand Note. On June 25, 2021, August 31, 2021, and September 29, 2021, the Company and 1315 Capital amended the 1315 Capital Note to change its maturity date in a similar manner. Except with respect to their respective maturity dates, the terms of the Notes are otherwise unchanged. The Security Agreement remained in full force and effect, and was not amended in connection with the amendments to the Notes.

In the case of the amendments, the Company reviewed the changes in accordance with ASC 470 and determined they should be treated as modifications.

The Notes contained certain negative covenants which prevented the Company from issuing any debt securities pursuant to which the Company issues shares, warrants or any other convertible security in the same transaction or a series of related transactions, except that Company may incur or enter into any capitalized and operating leases in the ordinary course of business consistent with past practice, or borrowed money or funded debt in an amount not to exceed $4.5 million (the "Debt Threshold") that is subordinated to the Notes on terms acceptable to Ampersand and 1315 Capital; provided, that if the aggregate consolidated revenue recognized by the Company as reported on Form 10-K as filed with the SEC for any fiscal year ending after January 10, 2020 exceeds $45 million, the Debt Threshold for the following fiscal year shall increase to an amount equal to: (x) ten percent (10%); multiplied by (y) the consolidated revenue as reported by the Company on Form 10-K as filed with the SEC for the previous fiscal year.

The Company used the proceeds of the BroadOak Term Loan discussed above to repay in full at their maturity all outstanding indebtedness under the promissory notes with Ampersand, dated January 7, 2021 and as last amended on September 29, 2021, in the amount of $4.5 million, and 1315 Capital, dated January 7, 2021 and as last amended on September 29, 2021, in the amount of $3 million, respectively. The Company, Ampersand, and 1315 Capital also terminated a related security agreement.

14. Warrants

Warrants outstanding and warrant activity for the year ended December 31, 2021 are as follows:

Description	Classification	Exercise Price	Expiration Date	Warrants Issued	Balance December 31, 2020	Warrants Cancelled/ Expired	Balance December 31, 2021
Private Placement Warrants, issued January 25, 2017	Equity	$ 46.90	June 2022	85,500	85,500	-	85,500
RedPath Warrants, issued March 22, 2017	Equity	$ 46.90	September 2022	10,000	10,000	-	10,000
Underwriters Warrants, issued June 21, 2017	Liability	$ 13.20	December 2022	57,500	53,500	-	53,500
Base & Overallotment Warrants, issued June 21, 2017	Equity	$ 12.50	June 2022	1,437,500	870,214	-	870,214
Warrants issued October 12, 2017	Equity	$ 18.00	April 2022	320,000	320,000	-	320,000
Underwriters Warrants, issued January 25, 2019	Equity	$ 9.40	January 2022	65,434	65,434	-	65,434
				1,975,934	1,404,648	-	1,404,648

The weighted average exercise price of the warrants is $15.97 and the weighted average remaining contractual life is approximately 0.4 years.

15. Stock-Based Compensation

The Company's stock-incentive program is a long-term retention program that is intended to attract, retain and provide incentives for talented employees, officers and directors, and to align stockholder and employee interests. Currently, the Company is able to grant options, stock appreciation rights ("SARs") and restricted shares from the Interpace Biosciences, Inc. 2019 Equity Incentive Plan. No new grants may be made under the Company's prior stock incentive plan, the Interpace Diagnostics Group, Inc. (now known as Interpace Biosciences, Inc.) Amended and Restated 2004 Stock Award and Incentive Plan (the "2004 Plan"). Unless earlier terminated by action of the Company's board of directors, the 2004 Plan will remain in effect until such time as no stock remains available for delivery and the Company has no further rights or obligations under the 2004 Plan with respect to outstanding awards thereunder.

Historically, stock options have been granted with an exercise price equal to the market value of the common stock on the date of grant, expire 10 years from the date they are granted, and generally vested over a one to three-year period for employees and members of the Board. Upon exercise, new shares will be issued by the Company. The restricted shares and restricted stock units ("RSUs") granted to employees generally have a three-year graded vesting period and are subject to accelerated vesting and forfeiture under certain circumstances. Restricted shares and RSUs granted to Board members generally have a three-year graded vesting period and are subject to accelerated vesting and forfeiture under certain circumstances.

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

The Company began an employee stock purchase plan in 2020 and recognized approximately $0.1 million and $0.04 million in expense related to that plan for the years ended December 31, 2021 and 2020, respectively.

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

The following table provides the weighted average assumptions used in determining the fair value of the stock options granted during the years ended December 31, 2021 and December 31, 2020.

	December 31, 2021	December 31, 2020
Risk-free interest rate	0.79%	0.75%
Expected life	6.0 years	6.5 years
Expected volatility	134.73%	123.71%
Dividend yield	-	-

The weighted-average fair value of stock options granted during the year ended December 31, 2021 was estimated to be $4.64. The weighted-average fair value of stock options granted during the year ended December 31, 2020 was estimated to be $5.36. There were 13,042 options exercised in 2021. There were no options exercised in 2020. Historically, shares issued upon the exercise of options have been new shares and have not come from treasury shares.

Stock-based compensation for the years ended December 31, 2021 and 2020 is as follows:

	2021	2020
RSUs and restricted stock	$ 433	$ 176
Performance-based awards	107	265
Common stock awards	-	116
Options	715	1,630
Total stock-based compensation expense	$ 1,255	$ 2,187

A summary of stock option activity for the year ended December 31, 2021, and changes during such year, is presented below:

	Shares	Weighted-Average Grant Price	Weighted-Average Remaining Contractual Period (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	848,819	$ 8.76	8.59	$ -
Granted	347,500	6.00	9.21	-
Exercised	(13,042)	9.45		
Forfeited or expired	(550,766)	9.15		-
Outstanding at December 31, 2021	632,511	6.89	8.40	-
Exercisable at December 31, 2021	206,732	9.14	7.53	-
Vested and expected to vest	537,520	7.15	8.36	-

A summary of the status of the Company's non-vested options for the year ended December 31, 2021, and changes during such year, is presented below:

	Shares	Weighted-Average Grant Date Fair Value
Nonvested at January 1, 2021	487,318	$ 5.81
Granted	347,500	4.64
Vested	(127,696)	6.54
Forfeited	(284,646)	5.72
Nonvested at December 31, 2021	422,476	$ 4.78

The aggregate fair value of options vested during the years ended December 31, 2021 and 2020 was $0.8 million and $1.5 million, respectively. The weighted-average grant date fair value of options vested during the year ended December 31, 2020 was $7.34.

A summary of the Company's non-vested shares of restricted stock and restricted stock units for the year ended December 31, 2021, and changes during such year, is presented below:

	Shares	Weighted-Average Grant Date Fair Value	Average Remaining Vesting Period (in years)	Aggregate Intrinsic Value
Nonvested at January 1, 2021	239,457	$ 10.00	1.75	$ 1,348,781
Granted	207,438	5.46	-	-
Vested	(65,577)	4.65	-	-
Forfeited	(52,379)	5.23	-	-
Nonvested at December 31, 2021	328,939	$ 3.67	1.34	$ 2,467,043

The aggregate fair value of restricted stock units vested during each of the years ended December 31, 2021 and 2020 was $0.3 million and $0.4 million, respectively.

As of December 31, 2021, there was approximately $2.0 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and restricted stock units.

16. Revenue Sources

The Company's clinical services customers consist primarily of physicians, hospitals and clinics. Its revenue channels include Medicare, Medicare Advantage, Medicaid, Client Billings (hospitals, etc.), and commercial payers. The following sets forth the net revenue generated by revenue channel accounted for more than 10% of the Company's revenue from continuing operations during the years ended December 31, 2021 and 2020, respectively. For the years ended December 31, 2021 and December 31, 2020, revenue from Medicare was approximately 54% and 50% of total revenue, respectively.

	Years Ended December 31,	
Customer	2021	2020
Medicare	$ 17,778	$ 10,186
Medicare Advantage	$ 5,859	$ 3,566
Commercial Payors	$ 5,555	$ 4,136
Client Billings	$ 3,752	$ 2,582

17. Income Taxes

The benefit from income taxes on continuing operations for the years ended December 31, 2021 and 2020 is comprised of the following:

	2021	**2020**
Current:		
Federal	$ -	$ -
State	(705)	16
Total current	(705)	16
Deferred:		
Federal	24	23
State	14	14
Total deferred	38	37
(Benefit) provision from income taxes	$ (667)	$ 53

The Company performs an analysis each year to determine whether the expected future income will more likely than not be sufficient to realize the deferred tax assets. The Company's recent operating results and projections of future income weighed heavily in the Company's overall assessment. As a result of this analysis, the Company continues to maintain a full valuation allowance against its federal and state net deferred tax assets at December 31, 2021 as the Company believes that it is more likely than not that these assets will not be realized. In the current year, the company maintains a full valuation allowance in consolidation and no separate company deferred tax liability recorded will be recorded.

The tax effects of significant items comprising the Company's deferred tax assets and (liabilities) as of December 31, 2021 and 2020 are as follows:

	2021	2020
Deferred tax assets:		
Federal net operating loss carryforwards	$ 24,923	$ 17,015
State net operating loss carryforwards	3,498	2,953
Compensation	1,844	1,492
Allowances and reserves	585	436
Intangible assets	571	292
State taxes	942	900
Credit carryforward	2	229
163(j) interest	1,047	745
Leases	41	54
Deferred revenue	95	95
Valuation allowance	(33,170)	(23,684)
	378	527
Deferred tax liability:		
Property and equipment	(471)	(582)
Deferred tax liability-net valuation allowance	$ (93)	$ (55)

The Company's deferred tax asset and deferred tax liabilities are included within *Other long-term liabilities*, respectively, within the consolidated balance sheet as of December 31, 2021 and 2020. Federal tax attribute carryforwards at December 31, 2021, consist primarily of approximately $118.6 million of federal net operating losses. In addition, the Company has approximately $56.3 million of state net operating losses carryforwards post 382 ownership change. The utilization of the federal carryforwards as an available offset to future taxable income is subject to limitations under federal income tax laws. Under current federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of Federal Taxable Income, and current state net operating losses not utilized begin to expire this year.

The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL, and tax credit carry forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, as well as similar state tax provisions. The amount of the annual limitation, if any, will be determined based on the value of our company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. Additionally, U.S. tax laws limit the time during which these carry forwards may be applied against future taxes, therefore, we may not be able to take full advantage of these carry forwards for federal income tax purposes. During 2021, the Company completed a 382 assessment of the available NOLs under Section 382 and determined that the Company underwent an ownership change on March 30, 2017 and July 15, 2019 and as a result, NOLs attributable to the pre-ownership change are subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to the multiple ownership changes. The Company has adjusted their NOL carryforwards to address the impact of the 382 ownership change. Federal Net Operating Losses of $71.2 million are subject to annual limitation as of the ownership changes for ownership changes. The remaining $47.4M of NOLs incurred post July 15, 2019 are not subject to any annual limitation and can be carried forward indefinitely.

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

	2021	2020
Federal statutory rate	21.0%	21.0%
State income tax rate, net of Federal tax benefit	4.2%	4.0%
Meals and entertainment	(0.1%)	(0.1%)
Valuation allowance	(25.3)%	(25.0%)
Naked credit	(0.2%)	(0.1%)
NJ NOL credit sale	4.7%	0.0%
Effective tax rate	4.3%	(0.2%)

The following table summarizes the change in uncertain tax benefit reserves for the two years ended December 31, 2020:

	Unrecognized Tax Benefits
Balance of unrecognized benefits as of January 1, 2020	$ 877
Additions for tax positions of prior years	-
Balance as of January 1, 2021	$ 877
Additions for tax positions of prior years	-
Balance as of December 31, 2021	$ 877

As of December 31, 2021 and 2020, the total amount of gross unrecognized tax benefits was $0.9 million and $0.9 million, respectively. The total amount of unrecognized tax benefits that, if recognized, would affect the effective tax rate as of December 31, 2021 and 2020 was $0.9 million and $0.9 million, respectively.

The Company recognized interest and penalties of $0.2 million and $0.3 million, respectively, related to uncertain tax positions in income tax expense during each of the years ended December 31, 2021 and 2020. At December 31, 2021 and 2020, accrued interest and penalties, net were $3.6 million and $3.4 million, respectively, and included in the *Other long-term liabilities* in the consolidated balance sheets.

The Company and its subsidiaries file a U.S. Federal consolidated income tax return and consolidated and separate income tax returns in numerous states and local tax jurisdictions. The following tax years remain subject to examination as of December 31, 2021:

Jurisdiction	Tax Years
Federal	2017 – 2021
State and Local	2016 – 2021

To the extent there was a failure to file a tax return in a previous year; the statute of limitation will not begin until the return is filed. There were no examinations in process by the Internal Revenue Service as of December 31, 2021.

18. Basic and Diluted Net Loss per Share

A reconciliation of the number of shares used in the calculation of basic and diluted earnings per share for the years ended December 31, 2021 and 2020 are as follows (rounded to thousands):

	Years Ended December 31,	
	2021	2020
Basic weighted average number of common shares	4,135	4,029
Potential dilutive effect of stock-based awards	-	-
Diluted weighted average number of common shares	4,135	4,029

The Company's Series B Preferred Stock, on an as converted basis of 7,833,334 shares and the following outstanding stock-based awards and warrants were excluded from the computation of the effect of dilutive securities on loss per share for the following periods as they would have been anti-dilutive (rounded to thousands):

	Years Ended December 31,	
	2021	2020
Options	632	849
Restricted stock units (RSUs)	329	238
Warrants	1,405	1,405
	2,366	2,492

19. Revolving Line of Credit

On October 13, 2021, the Company and its subsidiaries entered into a Loan and Security Agreement (the "Comerica Loan Agreement") with Comerica Bank ("Comerica"), providing for a revolving credit facility of up to $7,500,000 (the "Credit Facility"). The Company may use the proceeds of the Credit Facility for working capital and other general corporate purposes.

The amount that may be borrowed under the Credit Facility is the lower of (i) the revolving limit of $7,500,000 (the "Revolving Line") and (ii) 80% of the Company's eligible accounts receivable plus an applicable non-formula amount consisting of $2,000,000 of additional availability at close not based upon the Company's eligible accounts receivable, with such additional availability reducing by $250,000 per quarter beginning with the quarter ending June 30, 2022. Borrowings on the Credit Facility are limited to $5,000,000 until 80% of the Company's and its subsidiaries' customers are paying into a collection account or segregated governmental account with Comerica. The Revolving Line can also include, at the Company's option, credit card services with a sublimit of $300,000. Borrowings on the Revolving Line are subject to an interest rate equal to prime plus 0.50%, with prime being the greater of (x) Comerica's stated prime rate or (y) the sum of (A) the daily adjusting LIBOR rate plus (B) 2.5% per annum. The Company is also required to pay an unused facility fee quarterly in arrears in an amount equal to 0.25% per annum on the average unused but available portion of the Revolving Line for such quarter.

The Credit Facility matures on September 30, 2023, and is secured by a first priority lien on substantially all of the assets of the Company and its subsidiaries. As of December 31, 2021, the balance of the revolving line was $1.5 million.

The Comerica Loan Agreement contains affirmative and negative restrictive covenants that are applicable whether or not any amounts are outstanding under the Comerica Loan Agreement. These restrictive covenants, which include restrictions on certain mergers, acquisitions, investments, encumbrances, etc., could adversely affect our ability to conduct our business. The Comerica Loan Agreement also contains financial covenants requiring specified minimum liquidity and minimum revenue thresholds and also contains customary events of default.

As a condition for Comerica to extend the Credit Facility to the Company and its subsidiaries, the Company's existing creditors, Ampersand and 1315 Capital (the "Existing Creditors"), entered into that certain Subordination Agreement, dated as of October 13, 2021, pursuant to which each Existing Creditor agreed to subordinate all of the indebtedness and obligations of the Company and its subsidiaries owing to such Existing Creditor to all of the indebtedness and obligations of the Company and its subsidiaries owing to Comerica (the "Subordination Agreement"). Each Existing Creditor further agreed to subordinate all of its respective security interests in assets or property of the Company and its subsidiaries to Comerica's security interests in such assets or property. The Subordination Agreement provides that it is solely for the benefit of Comerica and each of the Existing Creditors and is not for the benefit of the Company or any of its subsidiaries.

Revolving Line of Credit – Silicon Valley Bank

On November 13, 2018 the Company, Interpace Diagnostics Corporation, and Interpace Diagnostics, LLC entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), which provided for up to $4.0 million of debt financing consisting of a term loan of up to $850,000 and a revolving line of credit based on its outstanding accounts receivable (the "Revolving Line") of up to $3.75 million. As of December 31, 2020, the balance of the Revolving Line with SVB was zero.

On January 5, 2021, the Company terminated the SVB Loan Agreement in accordance with the terms of the agreement. In connection with the termination, SVB waived its right to any termination fees and released its security interest in the assets of the Company.

20. Transition Expenses

These expenses are primarily related to the Rutherford, NJ lab closing and subsequent move to North Carolina, as well as other cost-saving initiatives, primarily reductions in headcount as well as certain legal expenses. The following is a roll forward of the transition expenses liabilities:

	Personnel	Facilities/ Infrastructure	Legal	Total
Balance at December 31, 2020	$ 885	$ 269	$ -	$ 1,154
Transition expenses	1,044	1,036	505	2,585
Payments	(1,929)	(1,305)	(505)	(3,739)
Balance at December 31, 2021	$ -	$ -	$ -	$ -

21. Supplemental Cash Flow Information

Supplemental Disclosure of Other Cash Flow Information
(in thousands)

Cash paid for taxes	$	369	$	218
Cash paid for interest	$	424	$	60

Supplemental Disclosures of Non Cash Activities
(in thousands)

	Years Ended December 31,			
		2021		2020
Operating				
Taxes accrued for repurchase of restricted shares	$	95	$	-
Investing				
Preferred Stock Deemed Dividend	$	-	$	3,033
Investment in DiamiR		248		-
Financing				
Accrued financing costs	$	-	$	31

22. Subsequent Events

Centers for Medicare & Medicaid Services (CMS) Billing Policy Notice & Rights Offering

On January 28, 2022, the Company announced that the Centers for Medicare & Medicaid Services (CMS) issued a new billing policy whereby CMS would no longer reimburse for the use of the Company's ThyGeNEXT® and ThyraMIR® tests when billed together by the same provider/supplier for the same beneficiary on the same date of service and that the Company was terminating its previously announced rights offering and the mutual termination of the standby purchase agreement with 3K Limited Partnership. The CMS billing policy decision was subsequently reversed in February 2022, however the Company has not yet realized the full cash collection benefit of current and retroactive Thyroid testing and such cash collections may be temporarily reduced or delayed until we resolved the matter with CMS.

INTERPACE BIOSCIENCES, INC.
VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 2021 AND 2020
($ in thousands)

Description	Balance at Beginning of Period	Additions (Reductions) Charged to Operations	(1) Deductions Other	Balance at end of Period
2020				
Allowance for doubtful accounts	$ 25	-	250	$ 275
Allowance for doubtful notes	$ 869	-	-	$ 869
Tax valuation allowance	$ 17,027	-	6,657	$ 23,684
2021				
Allowance for doubtful accounts	$ 275	-	(203)	$ 72
Allowance for doubtful notes	$ 869	-	-	$ 869
Tax valuation allowance	$ 23,684	-	9,486	$ 33,170

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Interpace Biosciences, Inc.
Parsippany, New Jersey

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-207263 and 333-227728) and Form S-8 (Nos. 333-61231, 333-60512, 333-177969, 333-201070, 333-214260, 333-252574 and 333-234284) of Interpace Biosciences, Inc. of our report dated March 31, 2022, relating to the consolidated financial statements and schedule, which appear in this Annual Report on Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/BDO USA, LLP

Woodbridge, New Jersey
March 31, 2022

Exhibit 31.1

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

I, Thomas W. Burnell, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2021 of Interpace Biosciences, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

/s/ Thomas W. Burnell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Thomas Freeburg, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2021 of Interpace Biosciences, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

/s/ Thomas Freeburg
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Interpace Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas W. Burnell, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2022

/s/ Thomas W. Burnell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Interpace Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Freeburg, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2022

/s/ Thomas Freeburg
Chief Financial Officer
(Principal Financial Officer)