

**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, 2022

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

(State or other jurisdiction of
incorporation or organization)

22-2919486

(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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was \$11,565,729 (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 17, 2023, 4,311,414 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 2023 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, 2022. 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

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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:

- we have a history of operating losses and our clinical services have generated limited revenue;
- we expect to incur net losses for the foreseeable future and we may never achieve or sustain profitability;
- the effect of the Coronavirus (COVID-19) pandemic which in the past has materially and adversely affected our business and financial results;
- 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;
- our ability to continue to perform, bill and receive reimbursement for our PancreGEN molecular test under the existing local coverage determination (“LCD”), given that such LCD is currently under review by Novitas Solutions, Inc. (“Novitas”), the Company’s Medicare administrative contractor;
- 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 all of our revenue;
- the ability to continue to generate sufficient revenue from our clinical service products 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 which may prove to be incorrect with the changes in reimbursement rates for ThyGeNEXT[®] by Medicare causing us to revise our net realizable values (“NRV’s”) which will reduce revenues in future periods;

- 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;
- 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 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 being subject to the controlling interests of our two private equity investors who control, on an as-converted basis, an aggregate of 64.5% 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;
- geopolitical and other economic and political conditions or events (such as the war in Ukraine);
- 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, 2022.

PART I

ITEM 1. BUSINESS

Company Overview

We are a company that 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. 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.

Customer Category	Types of Customers	Nature of Services
Clinical services	<ul style="list-style-type: none"> ● 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.

Our clinical services' customers consist primarily of physicians, hospitals, cancer centers, commercial laboratories, pathology groups and clinics. Our largest customer for ThyGeNEXT[®] and ThyraMIR[®]v2 products in 2022 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.

Strategic Disposition of Pharma Business

On August 31, 2022, Interpace Biosciences, Inc. ("Interpace" or the "Company") and Interpace Pharma Solutions, Inc. (the "Subsidiary") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Flagship Biosciences, Inc. (the "Purchaser") pursuant to which the Purchaser agreed to (i) acquire substantially all of the assets of the Subsidiary used in Subsidiary's business of complex molecular analysis for the early diagnosis and treatment of cancer and supporting the development of targeted therapeutics (the "Business") and (ii) assume and pay certain liabilities related to the purchased assets as set forth in the Purchase Agreement (collectively, the "Transaction"). The Transaction closed on August 31, 2022.

As consideration for the Transaction, under the Purchase Agreement, the Company received a total purchase price of approximately \$6.2 million after working capital and other adjustments (\$0.5 million of which was deposited into escrow), subject to the assumption by the Purchaser of certain specified liabilities. In addition, subject to the terms and conditions set forth in the Purchase Agreement, Purchaser was obligated to pay the Company an earnout of up to \$2.0 million based on revenue for the period beginning September 1, 2021 and ending August 31, 2022. The Company received an earnout payment of approximately \$1.0 million in September 2022 which is the fully settled amount and there will be no further earnout payments in the future.

The Purchase Agreement includes a one-year commitment of the Company not to compete with the Business, recruit or hire any former employees of the Subsidiary who accept employment with the Purchaser in connection with the Transaction, or divert or attempt to divert from Purchaser any business to be performed from any of the contracts or agreements with customers as set forth in the Purchase Agreement. The Purchase Agreement also contains customary representations and warranties, post-closing covenants and mutual indemnification obligations for, among other things, any inaccuracy or breach of any representation or warranty and any breach or non-fulfillment of any covenant.

In connection with the Transaction, on August 31, 2022, the Company, the Subsidiary and the Purchaser entered into a Shared Services Agreement (the "Shared Services Agreement") pursuant to which Interpace agreed to provide, or cause its affiliates to provide, to the Purchaser certain services set forth in the Shared Services Agreement on a transitional basis and subject to the terms and conditions set forth in the Shared Services Agreement (the "Services"). As consideration for the Services provided by the Company, the Purchaser is paying the Company the amounts specified for each Service as set forth in the Shared Services Agreement. The Company's obligations to provide the Services will terminate with respect to each Service as set forth in the Shared Services Agreement.

The Purchaser is identified as a related party of the Company and is an affiliate of both Ampersand 2018 Limited Partnership ("Ampersand"), a private equity investor in the Company, and BroadOak Fund V, L.P. ("BroadOak"), a secured lender to the Company. Ampersand and BroadOak have each provided equity financing to the Purchaser, collectively own a majority of the Purchaser's outstanding equity securities and are represented on its Board of Directors.

The Company is using the remaining net proceeds of the Transaction to fund its future business activities and for general working capital purposes. As a result of the sale, the gain on sale and all operations from the Subsidiary have been classified as discontinued operations for all periods presented.

Continuing Impact of COVID-19 Pandemic

Beginning in the first quarter of 2021, there has been a trend in many parts of the world of increasing availability and administration of vaccines against COVID-19, as well as an easing of restrictions on social, business, travel and government activities and functions. On the other hand, infection rates and regulations continue to fluctuate in various regions and there are ongoing global impacts resulting from the pandemic, including challenges and increases in costs for logistics and supply chains. We have also previously been affected by temporary laboratory closures, employment and compensation adjustments and impediments to administrative activities. 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.

In addition, we have experienced and are experiencing varying levels of inflation resulting in part from various supply chain disruptions, increased shipping and transportation costs, increased raw material and labor costs and other disruptions caused by the COVID-19 pandemic and general global economic conditions.

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. At this time, the Biden Administration does not plan to renew the COVID-19 national and public health emergencies when they expire on May 11, which has been extended every 90 days since they were established in 2020. This decision, therefore, appears to represent a de-escalation in the way the government treats the pandemic, as well as a perception that most people have either been vaccinated or have recovered from a COVID-19 infection (or both). Despite this anticipated change in policy, COVID-19 is still with us and as the virus continues to reproduce and mutate, the Administration's policy may need be adjusted. In any event, it is likely that we will still need to make adjustments to our operating plans in reaction to developments that are beyond our control.

Impact of the ongoing military conflict between Russia and Ukraine.

In February 2022, Russian military forces invaded Ukraine, and although the length, impact, and outcome of the ongoing war in Ukraine is highly unpredictable, this war has led, and could continue to lead, to significant market and other disruptions, including instability in financial markets, supply chain interruptions, political and social instability, and increases in cyberattacks, intellectual property theft, and espionage. We are actively monitoring the situation in Ukraine and assessing its impact on our business.

We have no way to predict the progress or outcome of the war in Ukraine or its impacts in Ukraine, Russia, or Belarus as the war, and any resulting government reactions, are rapidly developing and beyond our control. The extent and duration of the war, sanctions, and resulting market disruptions could be significant and could potentially have a substantial impact on the global economy and our business for an unknown period of time. Any of the above-mentioned factors could materially adversely affect our business, financial condition, and results of operations. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

Market Overview

Global Molecular Diagnostic Market

The global molecular diagnostics market is estimated to be \$23.2 billion (USD) in 2022 and is expected to grow to \$30.2 billion (USD) by 2027 with a Compound Annual Growth rate or CAGR of 5.4% between 2022 and 2027, according to Markets and Markets's Molecular Diagnostics Market report (Report Code: MD 2521, published May 2022).

The global esoteric testing market is projected to reach 36.3 billion (USD) by 2026, growing at a CAGR of 11.6% from 2022 to 2026 (Markets and Markets, Esoteric Testing Market report published June 2021, Report Code: MD 5930). 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; supporting revenue growth for our molecular diagnostic tests; introducing related first-line product and service extensions; and 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 continuing to provide necessary resources to support the development process.

United States Clinical Oncology Market

Despite many advances in the treatment of cancer, it remains one of the greatest areas of unmet medical need. According to estimates from the International Agency for Research on Cancer (IARC), by 2040 it is expected that there will be 16.3 million cancer deaths worldwide simply due to the growth and aging of the global population. Within the United States, cancer is the second most common cause of death, exceeded only by heart disease. In 2022, it is expected that there will be 1.9 million new cancer cases and almost 610,000 cancer-related deaths, or about 1,670 deaths each day. In the United States, while pancreatic cancer represents only about 3% of all new cancer cases, it is the third leading cause of cancer death. The incidence, deaths and economic loss caused by cancer are staggering. Cancer-attributed medical care costs in the United States are substantial and projected to increase dramatically by 2030 to an estimated \$246 billion (USD). The following table taken from Common Cancer Types, originally published by the National Cancer Institute (Updated: May 10, 2022) shows estimated new cases and deaths in 2022 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

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 PancaGEN[®], 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.
- Developing and commercializing other related first-line clinical assays and expanding our service offerings such as PanDNA[®], a DNA only version of PancaGEN[®], 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; and
- Expanding our bioinformatics data collected (currently from over 60,000 patients), utilizing registries to improve our assays and leveraging our data with potential collaborators.

Our Service Offerings

Our business is based on demand for molecular- and biomarker-based characterization of cancers from one main sector: clinical services for physicians, hospitals and clinics.

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.

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 risk-stratification 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 surgery or surveillance treatment decisions in patients suspected of thyroid, pancreatic, and other cancers. The molecular diagnostic tests we offer enable healthcare providers to stratify cancer risk, helping to avoid unnecessary surgical treatment in patients at low risk, while also helping to identify patients that would benefit from surgical intervention.

Our mission is to assist healthcare providers in the diagnosis, triage, and treatment of patients through advanced diagnostics. Our laboratory is 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 laboratory 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: PancaGEN[®], a pancreatic cyst and pancreaticobiliary solid lesion genomic test that helps physicians better risk-stratify pancreaticobiliary cancers using our proprietary PathFinderTG[®] platform and full integration of clinical factors; PanDNA[®], an alternate reporting option of the PathFinderTG platform, that provides physicians the “molecular only” information provided within PancaGEN; ThyGeNEXT[®], an expanded oncogenic mutation panel that helps “rule-in” and “rule-out” malignancy in thyroid nodules; ThyraMIR[®], used in combination with ThyGeNEXT[®], which further stratifies thyroid nodules for malignancy risk utilizing a proprietary microRNA gene expression assay; and RespriDx[®] a genomic test that also utilizes our PathFinderTG[®] platform, to help physicians differentiate metastatic or recurrent lung cancer from the presence of newly formed primary lung cancer.

Gastrointestinal Cancer Products

Our current diagnostic assay, PancaGEN[®], is a reporting option of our proprietary PathFinderTG[®] platform. This platform is designed to use advanced clinical algorithms to accurately risk-stratify patients suspected of having pancreatic cancer by assessing panels of DNA abnormalities in patients who have pancreaticobiliary lesions (cysts or solid masses). PanDNA[®] is a “molecular only” reporting option of PathFinderTG[®] and is used by physicians who prefer to perform their own integration of first-line testing results to stratify pancreatic cancer risk.

Based on the American Cancer Society Cancer 2023 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 12%. PancaGEN[®] and PanDNA[®] are designed to determine the risk of malignancy in pancreatic cysts and pancreaticobiliary solid lesions, which have potential for developing into cancer. We believe that PancaGEN[®] 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 PancaGEN[®] is approximately 124,000 indeterminate pancreaticobiliary lesions annually or approximately \$200 million annually based on the current size of the patient population and reimbursement rates. To date, PancaGEN[®] testing has been used in more than 64,000 clinical cases. The National Pancreatic Cyst Registry study published in *Endoscopy* in 2015 demonstrated that PancaGEN[®] more accurately determined the malignancy potential of pancreatic cysts than international consensus 2012 imaging criteria, helping to ensure that surgery is reserved for the most appropriate patients. This is important because pancreatic surgery is high-risk surgery with over 40% postoperative morbidity rates and 0%–15% postoperative mortality rates. (Ahola, et al, March 2020, doi.org/10.1177/1457496919900411) 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 PancreaGEN[®] provides a highly reliable diagnostic and prognostic option that can accurately stratify cancer risk in circumstances where risk of cancer is otherwise uncertain.

Endocrine Cancer Products

We currently market and sell a combination testing platform that can inform cancer risk in indeterminate thyroid nodules—those that are not clearly malignant or benign by cytology. ThyGeNEXT[®] is a next generation DNA and RNA sequencing oncogene and mRNA fusion panel. The markers within the ThyGeNEXT[®] oncogene panel provide clinical utility by informing diagnosis, prognosis, and targeted treatment guidance aligned to FDA-approved therapies for *RET*, *NTRK*, and other markers found within the panel. ThyGeNEXT[®] works with our second endocrine cancer diagnostic test, ThyraMIR[®]v2, an assay that measures the relative expression of eleven distinct microRNAs. The combined analysis of the ThyGeNEXT[®] and ThyraMIR[®]v2 test results provides highly accurate “rule-in” and “rule-out” malignancy risk guidance.

We estimate the total market for our endocrine (thyroid) cancer assays is approximately \$221 million (USD) annually based on the current size of the patient population, estimated numbers of indeterminate biopsies and reimbursement rates. The mutational analysis provided by ThyGeNEXT[®] can help inform treatment alone when strong driver *BRAF* V600E-like mutations are found. However, reflex to ThyraMIR[®]v2 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, ear, nose and throat (“ENT”), and other specialists evaluate 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 25% 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 practice and guidelines, such as those from the National Comprehensive Cancer Network (“NCCN”) and American Thyroid Association (“ATA”), support use of molecular analysis for nodules with indeterminate cytology results as this testing can prove beneficial to further characterize these lesions and help 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 Laboratory

Our testing is performed in our state of the art 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.

Sales and Marketing

Our sales and marketing efforts consist of both direct and indirect sales channels with the efforts focused in the United States. We also have collaborative arrangements with other laboratory services companies.

Our commercialization efforts for our clinical services are currently focused on endocrine (thyroid), gastroenterologic (pancreatic) and lung cancers. Communication of our marketing messaging and value propositions is accomplished through multiple channels, including two field-based commercial sales teams of approximately 32 representatives and managers. In addition, we employ medical science liaisons (MSLs)—therapeutic specialists with advanced scientific training to aid in communicating complex scientific and medical information to leading physicians. Other channels of communication include print, digital advertising, social media, 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 that supports the analytical and clinical validity as well as clinical utility of our tests. We believe our repository of bioinformatics data accumulated from our testing is a valuable tool in developing and refining our analytics while also potentially being an even more valuable tool in the future.

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

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[®]v2 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.

We are currently not aware of any direct competitors to PancreGEN[®] 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 PancreGEN[®]. 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 PancreGEN[®]. PancreGEN[®] 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 PancreGEN[®], 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.

Research and Development

We conduct 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 \$0.7 million and \$1.5 million in 2022 and 2021, respectively.

We continue to generate and publish clinical evidence related to our key products, including ThyGeNEXT[®] and ThyraMIR[®]v2 and PancreGEN[®] 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: 10.1001/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, 2022, 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, 2022, we owned three issued patents outside of the United States, one each in Australia, Japan, and Israel. As of December 31, 2022, we owned two 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, our foreign patents expire in 2031, and our pending patent applications, if issued, are expected to expire between 2027 and 2038, absent any disclaimers, adjustments or extensions. 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.

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[®]v2, 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 miRInform[®] pancreas platform, if developed, on the future net sales of tests based on the miRInform[®] thyroid platform (i.e., ThyGeNEXT[®]) and potentially on certain other thyroid diagnostics tests.

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

We 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 Inc., Illumina, Inc., Qiagen N.V., 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 lab supplies 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 Laboratory

The conduct and provision of our services are regulated under the CLIA. CLIA requires us to maintain Federal certification. CLIA imposes requirements relating to test processes, personnel qualifications, facilities and equipment, recordkeeping, quality assurance and participation in proficiency testing. CLIA compliance and certification are also a condition for participation by clinical laboratories in the Medicare Program and for eligibility to bill for services provided to governmental healthcare program beneficiaries. As a condition of CLIA certification, our laboratory is subject to survey and inspection every other year, in addition to being subject to additional random inspections. The biennial survey is typically conducted by a State agency, or, if the laboratory is accredited, a CMS-approved accreditation organization. Potential 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. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our tests and the results of our operations.

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 impose additional or different requirements. 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 laboratory, 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 laboratory is 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 laboratory is 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”)

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 framework, and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests,” which described how FDA would implement a proposed notification process applicable to LDT manufacturers, including adverse event reporting.

On January 13, 2017, the FDA released a discussion paper on LDTs which outlined a substantially-revised approach for regulating 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 regulatory approaches proposed over the past decade, FDA continues to exercise enforcement discretion over most LDTs. If FDA ceases to exercise enforcement discretion over LDTs, failure to comply with applicable requirements could result in warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity.

Regulatory and legislative proposals have been introduced alongside FDA’s regulatory proposals. 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 forms over the years, and, most recently in December 2022, as part of the as part of the Food and Drug Omnibus Reform Act of 2022 (“FDORA”). Under the most recent version of the VALID Act, a risk-based approach would be used to regulate IVCTs while grandfathering many existing IVCTs. Each test will be classified as high-risk, moderate-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, IVCTs falling within the scope of a certification order 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.

While the VALID Act was not ultimately included in the version of FDORA that was incorporated into the Consolidated Appropriations Act, 2023, it may be re-introduced in the future. In the absence of legislative action, some have speculated that the FDA may attempt to regulate LDTs on their own (e.g., via notice and comment rulemaking), which is likely to continue to be met with resistance by certain sections of industry. We cannot predict if this (or any other bill) will be enacted in its current (or any other) form and cannot quantify the effect of such proposals on our business.

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 does not clearly protect incentive compensation to sales employees, a practice that is common in the industry. The government has not issued or proposed regulations or other guidance interpreting EKRA.

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. Penalties under the federal False Claims Act can include up to three times the damages sustained by the federal program and up to about \$12,000 and \$26,000 per claim (these per-claim penalties are adjusted for inflation from time to time). Further, numerous states have enacted state false claims acts that apply to state government programs. 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 \$27,750 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 \$185,009 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 aimed 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 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 perform health care operations functions as a "business associate" for or on behalf of a covered entity. The regulations promulgated under HIPAA governing covered entities and business associates include the following subparts: "Privacy of Individually Identifiable Health Information", which establishes conditions for the permissible use and disclosure of certain individually identifiable health information by covered entities and establishes certain rights of individuals who are the subject of such information (45 C.F.R. §§ 164.500, et seq.); "Administrative Requirements", which establishes electronic 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", which requires covered entities and their business associates to implement and maintain certain security measures to safeguard certain electronic health information (45 C.F.R. §§ 164.302, et seq.); and "Breach Notification", which requires covered entities and their business associates to provide certain notifications to affected individuals, HHS and relevant media outlets 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 requires us to follow specific policies and procedures when we use and disclose individually identifiable health information. If we 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. Such enforcement actions could have an adverse effect on our business.

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 individually identifiable health information, or give individuals more rights with respect to their individually identifiable health information. 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 Biden Administration 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. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

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 approved Clinical Diagnostic Laboratory Tests (“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 45% of our consolidated net revenues during 2022. 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 laboratory is that it does not meet the definition of an “Applicable Manufacturer” under the “Sunshine Act” section of PPACA and therefore is 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 no remaining outstanding collections regarding this matter and is fully up to date with CMS. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

Reporting Segments

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

Employees

As of February 28, 2023, we had approximately 94 full time employees and 94 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). We conduct our business through our wholly-owned subsidiaries, Interpace Diagnostics, LLC, which was formed in Delaware in 2013 and Interpace Diagnostics Corporation (formerly known as RedPath Integrated Pathology, Inc.), which was formed in Delaware in 2007. On November 12, 2019, we changed the name of Interpace Diagnostics Group, Inc. to Interpace Biosciences, 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 (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 six dollars (\$6.00) (subject to 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 7,833,334 shares (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.

The holders of our Series B Preferred Stock have preferential rights with respect to distributions upon a liquidation or sale 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 (including a sale of the Company) 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.

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.

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:

- We face substantial risks 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 results of operations have been adversely affected and, in the future, could be materially adversely impacted by the COVID-19 virus.
- The war between Russia and Ukraine could materially adversely affect our business, results of operations, and financial condition.
- We have a history of operating losses, and our clinical services have generated limited revenue. We may continue to incur net losses for the foreseeable future and may never achieve or sustain profitability.
- Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity.
- We depend on sales and reimbursements from our clinical services for all 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.
- 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.
- 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.
- If we are unable to timely repay our outstanding obligations, our secured lenders will have the right to foreclose on our assets.
- Two private equity firms and their affiliates' control, on an as-converted basis, an aggregate of 64.5% of our outstanding shares of common stock through their holdings of our Series B Preferred Stock, which has a liquidation preference in the event of a sale of the Company, 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.
- 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.

- We may experience a reduction in revenue if physicians or patients decide not to order 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.
- 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.
- 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.
- 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 are unable to compete successfully in the markets our clinical services operate in, we may be unable to increase or sustain our revenue or achieve profitability.
- 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.
- A failure to comply with federal and state laws and regulations pertaining to our payment practices could result in substantial penalties.
- 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 delisting of our common stock from Nasdaq and subsequent trading on OTCQX[®] has adversely affected our common stock and business and financial condition.
- 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 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

We face substantial risks 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.

For the fiscal year ended December 31, 2022, we had an operating loss from continuing operations of \$3.6 million. As of December 31, 2022, we had cash and cash equivalents of \$4.8 million and current liabilities of \$14.3 million. The Company must fund its operating deficit until a sustainable level of revenue is achieved. 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, investing in our securities may be 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 COVID-19 virus.

The continuing impact that the COVID-19 virus 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. The coronavirus may continue to spread globally, adversely affecting global economies and financial markets, has and may materially and adversely impact our operations including, without limitation, the functioning of our laboratory, the availability of supplies including reagents, demand for our services and travel, customer demand and employee health and availability. 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 virus could continue to adversely impact our results of operations, cash flows and financial condition in the future. At this time, the Biden Administration does not plan to renew the COVID-19 national and public health emergencies when they expire on May 11, which has been extended every 90 days since they were established in 2020. This decision, therefore, appears to represent a de-escalation in the way the government treats the pandemic, as well as a perception that most people have either been vaccinated or have recovered from a COVID-19 infection (or both). Despite this anticipated change in policy, COVID-19 is still with us and as the virus continues to reproduce and mutate, the Administration's policy may need be adjusted. In any event, it is likely that we will still need to make adjustments to our operating plans in reaction to developments that are beyond our control.

The war between Russia and Ukraine could materially adversely affect our business, results of operations, and financial condition.

In February 2022, Russian military forces invaded Ukraine, and although the length, impact, and outcome of the ongoing war in Ukraine is highly unpredictable, this war has led, and could continue to lead, to significant market and other disruptions, including instability in financial markets, supply chain interruptions, political and social instability, and increases in cyberattacks, intellectual property theft, and espionage. We are actively monitoring the situation in Ukraine and assessing its impact on our business.

We have no way to predict the progress or outcome of the war in Ukraine or its impacts in Ukraine, Russia, or Belarus as the war, and any resulting government reactions, are rapidly developing and beyond our control. The extent and duration of the war, sanctions, and resulting market disruptions could be significant and could potentially have a substantial impact on the global economy and our business for an unknown period of time. Any of the above-mentioned factors could materially adversely affect our business, financial condition, and results of operations. Any such disruptions may also magnify the impact of other risks described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

Adverse developments affecting financial institutions, companies in the financial services industry or the financial services industry generally, including those we do business with, could adversely affect our operations and liquidity.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver.

Our access to our cash and cash equivalents and our ability to access bank financing in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire or take down financing on acceptable terms or at all. Any material decline in available funding or our ability to access our cash and cash equivalents or our ability to access bank financing could adversely impact our ability to meet our operating expenses and result in breaches of our contractual obligations which could have material adverse impacts on our operations and liquidity.

We have a history of operating losses, and our clinical services have generated limited revenue. We may continue 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 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, and (ii) develop and acquire additional products and services. However, our business may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could have a material adverse effect on our business, financial condition and results of operations, as well as cause the market price of our common stock to decline.

Our 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 our laboratory 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, insurance 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 all 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.

All of our revenue is derived from our clinical services business. 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. 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”) ASC 606 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.

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. In May 2022, the Company issued a Convertible Note to BroadOak, pursuant to which BroadOak funded a term loan in the aggregate principal amount of \$2 million. In August 2022, the Convertible Note was converted into a subordinated term loan and was added to the outstanding BroadOak loan balance discussed above.

We will need additional funding to repay the Comerica and BroadOak borrowings, which have maturity dates of September 2023 and October 2024, respectively, 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 and have maturity dates of September 2023 and October 2024, respectively. In May 2022, the Company issued a Convertible Note to BroadOak, pursuant to which BroadOak funded a term loan in the aggregate principal amount of \$2 million. In August 2022, the Convertible Note was converted into a subordinated term loan and was added to the outstanding BroadOak loan balance discussed above. 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 64.5% 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 38.4% of the Company's outstanding common stock of 4,311,414 shares and 1315 Capital and its affiliates beneficially own 26.1%. 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 or sale 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 (including a sale of the Company) 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 45% of our revenue for the fiscal year ended December 31, 2022. 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[®]v2 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[®]v2 (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 no remaining outstanding collections regarding this matter and is fully up to date with CMS. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

Novitas has been and is the current regional MAC that handles claims processing for Medicare services with jurisdiction for PancreGEN[®], ThyGeNEXT[®], ThyraMIR[®]v2, 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. If Novitas restricts coverage for PancreGEN[®], our liquidity could be negatively impacted beginning in Fiscal 2023.

Our PancreGEN[®], ThyraMIR[®]v2 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 PancreGEN[®], ThyGeNEXT[®], ThyraMIR[®]v2 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 PancreGEN[®], ThyGeNEXT[®] and ThyraMIR[®]v2 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 laboratory 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) miRInform[®] 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 miRInform[®] thyroid platform (i.e., ThyGeNEXT[®]), potentially on certain other thyroid diagnostics tests and potentially on other tests in development for thyroid cancer. A similar obligation exists if we elect to launch any molecular tests utilizing the miRInform[®] pancreas platform. We are also required by the CPRIT License Agreement with Asuragen to make certain related royalty payments to CPRIT.

When performing the ThyraMIR[®]v2 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 for our endocrine cancer diagnostic tests. 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 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 offered as LDTs are currently subject to enforcement discretion by the FDA. LDTs are defined by FDA as IVDs that are intended for clinical use and are designed, manufactured, and used within a single CLIA-certified, high-complexity clinical laboratory.

Given the history of attempts by FDA and Congress to regulate LDTs over the past decade, there is substantial uncertainty concerning whether FDA's enforcement discretion policy will continue.

If we are required to submit applications to FDA for our currently-marketed clinical 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 warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. Any other regulatory or legislative proposals that would increase general FDA oversight of clinical laboratories or 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 and state licenses, which permit 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 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 100 employees, the success of our business depends largely on the skills, experience and performance of members of our senior management team, including our chief executive officer, and others in key management positions. In September 2022 our chief financial officer entered into a Severance and Consulting Agreement and General Release whereby he would continue to act as the principal financial officer for up to six (6) months from the date of termination. 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. 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.

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

Although we have been selling commercial products since 2014, genomic diagnostics is a relatively new area 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 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. If we fail to establish our clinical services tests 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. 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 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, Inc. ("Veracyte") has thyroid nodule cancer diagnostic tests which are currently on the market that compete with our ThyGeNEXT[®] and ThyraMIR[®]v2 tests. Quest Diagnostics Inc. currently offers Veracyte's tests via a co-marketing agreement, and CBLPath, Inc. is offering a diagnostic test performed via the University of Pittsburgh Medical Center (UPMC) that analyzes genetic alterations using next-generation sequencing mutation panel for pancreatic cysts. While we do not believe we currently have significant direct competition for PancreaGEN[®] 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.

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 our laboratory or if it becomes inoperable for any other reason, we will be unable to perform our testing and our business will be harmed.

The laboratory 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 or reimposed could negatively impact our ability to obtain raw materials needed for manufacture of our clinical services testing, our ability to provide testing to patients, our financial condition and our results of operations. 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. At this time, the Biden Administration does not plan to renew the COVID-19 national and public health emergencies when they expire on May 11, which has been extended every 90 days since they were established in 2020. This decision, therefore, appears to represent a de-escalation in the way the government treats the pandemic, as well as a perception that most people have either been vaccinated or have recovered from a COVID-19 infection (or both). Despite this anticipated change in policy, COVID-19 is still with us and as the virus continues to reproduce and mutate, the Administration's policy may need to be adjusted. In any event, it is likely that we will still need to make adjustments to our operating plans in reaction to developments that are beyond our control.

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 100 employees. We may increase the number of employees in the future depending on the progress and growth of our business. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our future financial performance and our ability to sell or promote our existing 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 laboratory. 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 laboratory, whether as a result of revocation, suspension or limitation, we would no longer be able to perform our current clinical 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 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 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 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 laboratory 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 PancreGEN[®] and miRInform[®] platforms (including ThyGeNEXT[®]), involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. From time-to-time the U.S. Supreme Court, other Federal courts, the U.S. Congress or the United States Patent and Trademark Office, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation.

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

On June 12, 2015, the Federal Circuit issued a decision in *Ariosa v. Sequenom* holding that a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female were unpatentable as directed to a naturally occurring phenomenon. On July 30, 2015, the USPTO released a Federal Register Notice entitled, “July 2015 Update on Subject Matter Eligibility.” This Notice updated the USPTO guidelines for the USPTO’s procedure for subject matter eligibility under 35 U.S.C. § 101 for claims embracing natural products or natural principles phenomenon. On May 4, 2016, the USPTO released life science examples that were intended to be used in conjunction with the USPTO guidance on subject matter eligibility. Although the guidelines and examples do not have the force of law, patent examiners have been instructed to follow them. On February 6, 2019, the Federal Circuit for Court of Appeals issued a decision in *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, which relied on the decisions 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, 2022, we had U.S. federal and state net operating losses, or NOLs, of approximately \$127.2 million and \$59.5 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 \$56.0 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;
- 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 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 2022, our common stock traded at a low of \$0.51 and a high of \$8.69. During 2021, our common stock traded at a low of \$2.98 and a high of \$10.51. 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.

On January 5, 2023, we received notice from the OTCQX indicating that the Company’s market capitalization has been below the required \$5 million for 30 consecutive calendar days preceding the date of such notice, and that the Company no longer meets the standards for continued qualification for the OTCQX U.S. tier under the OTCQX Rules for U.S. Companies section 3.2.b.2. The Company has been provided 180 calendar days from the date of such notice, or until July 3, 2023, to maintain a market capitalization of \$5 million for ten consecutive trading days. If the Company cannot meet this requirement, its common stock will be removed from the OTCQX. In such event, the Company may be eligible for the OTCQB market.

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 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, 2022, we had 95,632,170 shares of common stock and 4,953,000 shares of preferred stock available for issuance. As of December 31, 2022, we have reserved 776,849 shares of our common stock for issuance under our 2019 Equity Incentive Plan and 1,000,007 shares of our common stock for issuance under our Employee Stock Purchase Plan and 1,672,746 additional shares available for future grants of awards under our 2019 Equity Incentive Plan. As of December 31, 2022, 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. Our Parsippany, New Jersey lease runs through November 2023. 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, 2028.

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 "IDYG." OTCQX Best Market quotations reflect inter-dealer prices and may not necessarily represent actual transactions.

Holders of Record

We had 197 stockholders of record as of February 28, 2023. 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 a fully integrated commercial company that 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. 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.

Strategic Disposition of Pharma Business

On August 31, 2022, the Company and Interpace Pharma Solutions, Inc. (the "Subsidiary") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Flagship Biosciences, Inc. (the "Purchaser") pursuant to which the Purchaser agreed to (i) acquire substantially all of the assets of the Subsidiary used in Subsidiary's business of complex molecular analysis for the early diagnosis and treatment of cancer and supporting the development of targeted therapeutics (the "Business") and (ii) assume and pay certain liabilities related to the purchased assets as set forth in the Purchase Agreement (collectively, the "Transaction"). The Transaction closed on August 31, 2022.

As consideration for the Transaction, under the Purchase Agreement, the Company received a total purchase price of approximately \$6.2 million after working capital and other adjustments (\$0.5 million of which was deposited into escrow), subject to the assumption by the Purchaser of certain specified liabilities. In addition, subject to the terms and conditions set forth in the Purchase Agreement, Purchaser was obligated to pay the Company an earnout of up to \$2.0 million based on revenue for the period beginning September 1, 2021 and ending August 31, 2022. The Company received an earnout payment of approximately \$1.0 million in September 2022 which is the fully settled amount and there will be no further earnout payments in the future.

The Purchase Agreement includes a one-year commitment of the Company not to compete with the Business, recruit or hire any former employees of the Subsidiary who accept employment with the Purchaser in connection with the Transaction, or divert or attempt to divert from Purchaser any business to be performed from any of the contracts or agreements with customers as set forth in the Purchase Agreement. The Purchase Agreement also contains customary representations and warranties, post-closing covenants and mutual indemnification obligations for, among other things, any inaccuracy or breach of any representation or warranty and any breach or non-fulfillment of any covenant.

In connection with the Transaction, on August 31, 2022, the Company, the Subsidiary and the Purchaser entered into a Shared Services Agreement (the "Shared Services Agreement") pursuant to which the Company agreed to provide, or cause its affiliates to provide, to the Purchaser certain services set forth in the Shared Services Agreement on a transitional basis and subject to the terms and conditions set forth in the Shared Services Agreement (the "Services"). As consideration for the Services provided by the Company, the Purchaser is paying the Company the amounts specified for each Service as set forth in the Shared Services Agreement. The Company's obligations to provide the Services will terminate with respect to each Service as set forth in the Shared Services Agreement.

The Purchaser is identified as a related party of the Company and is as an affiliate of both Ampersand 2018 Limited Partnership ("Ampersand"), a private equity investor in the Company, and BroadOak Fund V, L.P. ("BroadOak"), a secured lender to the Company. Ampersand and BroadOak have each provided equity financing to the Purchaser, collectively own a majority of the Purchaser's outstanding equity securities and are represented on its Board of Directors.

The Company is using the remaining net proceeds of the Transaction to fund its future business activities and for general working capital purposes. As a result of the sale, the gain on sale and all operations from the Subsidiary have been classified as discontinued operations for all periods presented.

Impact of Our Reliance on CMS and Novitas

In January 2022, 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. However, 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. In May 2022, the Company was notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 would be completed beginning July 1, 2022. However, on June 9, 2022, the Company was notified that Novitas re-priced ThyGeNEXT[®] (0245U) from \$2,919 to \$806.59 retroactively effective to January 1, 2022. On July 20, 2022, the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel affirmed a gapfill price of \$806.59. As a result of the ThyGeNEXT[®] pricing change, the Company reduced its NRV rates for ThyGeNEXT[®] Medicare billing to reflect the \$806.59 pricing for tests performed during the second quarter of 2022. In addition, in order to reflect the retroactive pricing change to January 1, 2022, the Company recorded an NRV adjustment of \$0.7 million during the second quarter of 2022 to reduce revenue recorded during the first quarter of 2022. The Company estimated the ThyGeNEXT[®] pricing change would negatively impact Fiscal 2022 revenue by approximately \$5.0 million. During July 2022, the Company began implementing cost-savings initiatives including a reduction in headcount and incidental expenses and a freeze on all non-essential travel and hiring. In August 2022, the Company sold its pharma business. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

Further, along with many laboratories, we may be affected by the Proposed Local Coverage Determination ("LCD") DL39365, which was posted on June 9, 2022 with comments extended to September 6, 2022 due to changes made to the related draft and is currently under consideration by our local Medicare Administrative Contractor, Novitas. If finalized, this Proposed LCD, which governs "Genetic Testing for Oncology," could impact the existing LCD for one of our molecular tests, PancaGEN[®]. If Novitas restricts coverage for PancaGEN[®], our liquidity could be negatively impacted beginning in Fiscal 2023.

Impact of COVID-19 Pandemic

Beginning in the first quarter of 2021, there has been a trend in many parts of the world of increasing availability and administration of vaccines against COVID-19, as well as an easing of restrictions on social, business, travel and government activities and functions. On the other hand, infection rates and regulations continue to fluctuate in various regions and there are ongoing global impacts resulting from the pandemic, including challenges and increases in costs for logistics and supply chains. We have also previously been affected by temporary laboratory closures, employment and compensation adjustments and impediments to administrative activities. 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.

In addition, we have experienced and are experiencing varying levels of inflation resulting in part from various supply chain disruptions, increased shipping and transportation costs, increased raw material and labor costs and other disruptions caused by the COVID-19 pandemic and general global economic conditions.

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.

At this time, the Biden Administration does not plan to renew the COVID-19 national and public health emergencies when they expire on May 11, which has been extended every 90 days since they were established in 2020. This decision, therefore, appears to represent a de-escalation in the way the government treats the pandemic, as well as a perception that most people have either been vaccinated or have recovered from a COVID-19 infection (or both). Despite this anticipated change in policy, COVID-19 is still with us and as the virus continues to reproduce and mutate, the Administration's policy may need to be adjusted.

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.

Impact of the ongoing military conflict between Russia and Ukraine.

In February 2022, Russian military forces invaded Ukraine, and although the length, impact, and outcome of the ongoing war in Ukraine is highly unpredictable, this war has led, and could continue to lead, to significant market and other disruptions, including instability in financial markets, supply chain interruptions, political and social instability, and increases in cyberattacks, intellectual property theft, and espionage. We are actively monitoring the situation in Ukraine and assessing its impact on our business.

We have no way to predict the progress or outcome of the war in Ukraine or its impacts in Ukraine, Russia, or Belarus as the war, and any resulting government reactions, are rapidly developing and beyond our control. The extent and duration of the war, sanctions, and resulting market disruptions could be significant and could potentially have a substantial impact on the global economy and our business for an unknown period of time. Any of the above-mentioned factors could materially adversely affect our business, financial condition, and results of operations. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

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: PancreGEN[®], 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 PancreGEN[®] 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[®]v2, 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 laboratory is licensed pursuant to federal law under CLIA and are accredited by CAP and New York State.

We leverage our laboratory 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 \$23.2 billion (USD) in 2022 and is expected to grow to \$30.2 billion (USD) by 2027 with a CAGR of 5.4% between 2022 and 2027, according to Markets and Markets's Molecular Diagnostics Market report (Report Code: MD 2521, published May 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[®]v2 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[®]v2 (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 no remaining outstanding collections regarding this matter and are fully up to date with CMS. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

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.

OTCQX

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.

On January 5, 2023, we received notice from the OTCQX indicating that the Company's market capitalization has stayed below the required \$5 million for 30 consecutive calendar days preceding the date of such notice, and that the Company no longer meets the standards for continued qualification for the OTCQX U.S. tier under the OTCQX Rules for U.S. Companies section 3.2.b.2. The Company is provided 180 calendar days from the date of such notice, or until July 3, 2023, to maintain a market capitalization of \$5 million for ten consecutive trading days. If the Company cannot meet this requirement, its common stock will be removed from the OTCQX to the OTCQB.

DESCRIPTION OF REPORTING SEGMENTS

We operate under one segment which is the business of developing and selling diagnostic clinical 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. Prior to the disposition of our Pharma business in August 2022, we also generated revenue from 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.

Revenue Recognition

ASC 606 Revenue Recognition

Clinical services derive their revenues from the performance of their 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.

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.

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, 2022 and 2021, 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 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 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,			
	2022	2022	2021	2021
		% to revenue		% to revenue
Revenue, net	\$ 31,838	100.0%	\$ 33,117	100.0%
Cost of revenue	13,607	42.7%	14,314	43.2%
Gross profit	18,231	57.3%	18,803	56.8%
Operating expenses:				
Sales and marketing	9,125	28.7%	9,177	27.7%
Research and development	703	2.2%	1,493	4.5%
General and administrative	10,973	34.5%	10,705	32.3%
Transition expense	-	0.0%	897	2.7%
Loss on DiamiR transaction	-	0.0%	13	0.0%
Acquisition related amortization expense	1,270	4.0%	3,192	9.6%
Change in fair value of contingent consideration	(223)	-0.7%	(338)	-1.0%
Total operating expenses	21,848	68.6%	25,139	75.9%
Operating loss	(3,617)	-11.4%	(6,336)	-19.1%
Interest accretion expense	(158)	-0.5%	(496)	-1.5%
Related party interest	-	0.0%	(424)	-1.3%
Note payable interest	(850)	-2.7%	(120)	-0.4%
Other expense, net	(1,211)	-3.8%	(366)	-1.1%
Loss from continuing operations before tax	(5,836)	-18.3%	(7,742)	-23.4%
Provision (benefit) for income taxes	29	0.1%	(705)	-2.1%
Loss from continuing operations	(5,865)	-18.4%	(7,037)	-21.2%
Loss from discontinued operations, net of tax	(16,093)	-50.5%	(7,906)	-23.9%
Net loss	\$ (21,958)	-69.0%	\$ (14,943)	-45.1%

Revenue, net

Consolidated revenue for the year ended December 31, 2022 decreased by \$1.3 million, or 4%, to \$31.8 million, compared to \$33.1 million for the year ended December 31, 2021. The decrease in net revenue was largely driven by the NRV adjustment related to the Medicare pricing change on ThyGeNEXT[®] discussed in “Impact of Our Reliance on CMS and Novartis” above.

Cost of revenue

Consolidated cost of revenue for the year ended December 31, 2022 decreased by \$0.7 million, or 5%, to \$13.6 million, compared to \$14.3 million for the year ended December 31, 2021. This decrease was primarily driven by lower employee costs.

Gross Profit

Consolidated gross profit for the year ended December 31, 2022 decreased \$0.6 million, or 3%, to \$18.2 million, compared to \$18.8 million for the year ended December 31, 2021. The decrease can be attributed to the decrease in revenue.

Sales and marketing expense

Sales and marketing expense was \$9.1 million for the year ended December 31, 2022 and \$9.2 million for the year ended December 31, 2021. As a percentage of revenue, sales and marketing expense increased to 29% from 28% in the comparable prior year period due to the lower revenue for the year ended December 31, 2022.

Research and development

Research and development expense was \$0.7 million for the year ended December 31, 2022 and \$1.5 million for the year ended December 31, 2021 due to lower professional services and employee costs. As a percentage of revenue, research and development expense decreased to 2% for the year ended December 31, 2022 from 5% in the comparable prior year period.

General and administrative

General and administrative expense for the year ended December 31, 2022 was \$11.0 million as compared to \$10.7 million for the year ended December 31, 2021. The increase can be primarily attributed to an increase in employee compensation costs and an increase in professional fees. As a percentage of net revenue, general and administrative expense was 34% for the year ended December 31, 2022 as compared to 32% for the year ended December 31, 2021.

Transition expense

Transition expense was approximately \$0.9 million for the year ended December 31, 2021. In 2021, these expenses were related to one-time legal expenses and employee severance costs.

Loss on DiamiR transaction

During the year ended December 31, 2021, there was a loss of \$13,000 on the disposition of the New Haven, CT laboratory to DiamiR in April 2021.

Acquisition related amortization expense

During the years ended December 31, 2022 and December 31, 2021, we recorded amortization expense of approximately \$1.3 million and \$3.2 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, 2022, there was a \$0.2 million decrease in the contingent consideration liability. During the year ended December 31, 2021, there was a \$0.3 million decrease in the contingent consideration liability related thereto.

Operating loss

There were consolidated operating losses from continuing operations of \$3.6 million and \$6.3 million during the years ended December 31, 2022 and 2021, respectively. The decrease in operating loss was primarily attributable to the decrease in acquisition related amortization expense.

Other expense, net

During the years ended December 31, 2022 and December 31, 2021, there were other expenses, net of approximately \$1.2 million and \$0.4 million, respectively. The increase was primarily related to the \$1.2 million in fair value adjustments recorded on the note payable.

Provision (benefit) for income taxes

Income tax expense of \$29,000 for the year ended December 31, 2022 was primarily driven by minimum state and local taxes. The income tax benefit was approximately \$0.7 million for the year ended December 31, 2021 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.

Loss from discontinued operations, net of tax

We had a loss from discontinued operations of \$16.1 million for the year ended December 31, 2022 as compared to a loss from discontinued operations of \$7.9 million for the year ended December 31, 2021. The increased loss for the year ended December 31, 2022 was primarily attributed to the impairment of goodwill and intangible assets associated with the disposition of the Pharma business in August 2022.

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, non-cash stock based compensation, interest and taxes, and other non-cash expenses including asset impairment costs, goodwill impairment, change in fair value of contingent consideration, change in fair value of notes payable, 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,	
	2022	2021
Loss from continuing operations (GAAP Basis)	\$ (5,865)	\$ (7,037)
Loss on DiamiR transaction	-	13
Depreciation and amortization	1,429	3,469
Stock-based compensation	1,237	1,145
Taxes expense/(benefit)	29	(705)
Interest accretion expense	158	496
Financing interest and related costs	850	950
Mark to market on warrant liability	(71)	50
Change in fair value of note payable	1,224	(58)
Change in fair value of contingent consideration	(223)	(338)
Adjusted EBITDA	<u>\$ (1,232)</u>	<u>\$ (2,015)</u>

LIQUIDITY AND CAPITAL RESOURCES

In October 2021, we entered into the Comerica Loan Agreement with Comerica, providing for a revolving credit facility of up to \$7,500,000 (the “Credit Facility”). The Company is using 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 18, *Revolving Line of Credit*, for more details. Comerica has a first priority security interest in substantially all of the Company’s and its subsidiaries’ assets. As of March 17, 2023 the Company owed \$2.3 million on the line of credit and had approximately \$1.5 million available to borrow on the line.

In addition, also in October 2021, the Company entered into 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 \$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 14, *Notes Payable*, for more details. In May 2022, the Company issued a Convertible Note to BroadOak, pursuant to which BroadOak funded a term loan in the aggregate principal amount of \$2.0 million. See Note 14, *Notes Payable*, for more details.

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.

In January 2022, the Company's registration statement for a rights offering filed with the Securities and Exchange Commission (SEC) became effective; however, the rights offering was subsequently terminated later in January 2022 when the Company announced that the Centers for Medicare & Medicaid Services, or 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. In May 2022, the Company was notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 would be completed beginning July 1, 2022. However, on June 9, 2022, the Company was notified that Novitas re-priced ThyGeNEXT[®] (0245U) from \$2,919 to \$806.59 retroactively effective to January 1, 2022. On July 20, 2022 the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel affirmed a gapfill price for ThyGeNEXT[®] of \$806.59. As a result of the ThyGeNEXT[®] pricing change, the Company reduced its net realizable value, or NRV rates for ThyGeNEXT[®] Medicare billing to reflect the \$806.59 pricing for tests performed during the second quarter of 2022. In addition, in order to reflect the retroactive pricing change to January 1, 2022, the Company recorded an NRV adjustment of \$0.7 million during the second quarter of 2022 to reduce revenue recorded during the first quarter of 2022. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

On August 31, 2022, the Company closed on the sale of its Pharma Solutions business for a total sale price of \$6.2 million after a post-closing working capital adjustment. In addition, we received the earnout payment of \$1,043,000. See Note 4, *Discontinued Operations*.

For the year ended December 31, 2022, we had an operating loss from continuing operations of \$3.6 million. As of year ended December 31, 2022, we had cash and cash equivalents of \$4.8 million, total current assets of \$12.2 million, net of restricted cash, and current liabilities of \$14.3 million. As of March 17, 2023, we had approximately \$5.7 million of cash on hand, net of restricted cash.

During the year ended December 31, 2022, net cash used in operating activities was \$7.7 million. The main component of cash used in operating activities was our net loss of \$22.0 million, partially offset by depreciation and amortization expense of \$2.6 million and non-cash impairment charges of \$12.4 million. 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, 2022, net cash provided from investing activities was \$6.2 million, which primarily pertained to the net proceeds received from the sale of our Pharma Solutions business unit. During the year ended December 31, 2021, net cash used in investing activities was \$0.3 million, primarily related to the purchase of lab equipment.

For the year ended December 31, 2022, cash provided from financing activities was \$3.0 million, of which \$1.0 million was from the drawdown on the Revolving Line and \$2.0 million was the Convertible Debt agreement entered into with BroadOak. See Note 14, *Notes Payable*, for more details. 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 14, *Notes Payable*, for more details.

We did 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 targeted margin improvement; collection of accounts receivable; containment of costs; and the potential use of other financing options and other strategic alternatives. 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 continues to explore various strategic alternatives, 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. With the Company's delisting of its common stock from Nasdaq in February 2021, its ability to raise additional capital on terms acceptable to the Company has been adversely impacted. There can be no assurance that the Company will be successful in obtaining such funding on terms acceptable to the Company.

Further, along with many laboratories, we may be affected by the Proposed Local Coverage Determination ("LCD") DL39365, which was posted on June 9, 2022 and is currently under consideration by our local Medicare Administrative Contractor, Novitas. If finalized, this Proposed LCD, which governs "Genetic Testing for Oncology," could impact the existing LCD for one of our molecular tests, PancraGEN[®]. If Novitas restricts coverage for PancraGEN[®], our liquidity could be negatively impacted beginning in Fiscal 2023.

As of December 31, 2022, 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	\$ 3,232	\$ 832	\$ 1,025	\$ 1,100	\$ 275
Total	<u>\$ 3,232</u>	<u>\$ 832</u>	<u>\$ 1,025</u>	<u>\$ 1,100</u>	<u>\$ 275</u>

With the proceeds received from the sale of the Pharma Solutions business, as well as the expected improvement in future operating cash flows associated with the disposition, as of the date of this filing, the Company anticipates that current cash and cash equivalents and forecasted cash receipts will be sufficient to meet its anticipated cash requirements through the next twelve months.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and the financial statement schedule specified by this Item 8, together with the reports thereon of EisnerAmper LLP and 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, 2022. 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, 2022, 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, 2022, 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 fourth quarter of the fiscal year ended December 31, 2022 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 2023 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 2023 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 2023 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 2023 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 2023 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.
2.4	Asset Purchase Agreement, dated August 31, 2022 by and among Interpace Biosciences, Inc., Interpace Pharma Solutions, Inc. and Flagship Biosciences, Inc., incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed with the SEC on September 7, 2022.
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.
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*	<u>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.</u>
10.4*	<u>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.</u>
10.5*	<u>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.</u>
10.6*	<u>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.</u>
10.7*	<u>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.</u>
10.8*	<u>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.</u>
10.9*	<u>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.</u>
10.10*	<u>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.</u>
10.11*	<u>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.</u>
10.12*	<u>Severance and Consulting Agreement and General Release, dated September 30, 2022, by and between Interpace Biosciences, Inc. and Thomas Freeburg, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 4, 2022.</u>
10.13*	<u>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.</u>
10.14*	<u>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.</u>
10.15*	<u>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.</u>
10.16*	<u>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.</u>
10.17*	<u>Robert Gorman Letter Agreement dated April 16, 2020, by and between Interpace Biosciences, Inc. and Robert Gorman, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q, filed with the SEC on August 15, 2022.</u>
10.18*	<u>Agreement, dated January 21, 2022, between Dr. Vijay Aggarwal 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 January 27, 2022.</u>
10.19	<u>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.</u>

Exhibit No.	Description
10.20	<u>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.</u>
10.21	<u>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.</u>
10.22	<u>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.</u>
10.23	<u>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.</u>
10.24	<u>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.</u>
10.25	<u>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.</u>
10.26	<u>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.</u>
10.27	<u>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.</u>
10.28	<u>Fourth Lease Amendment (the "Amendment") by and between Interpace Biosciences, Inc. and Saddle Lane Realty, LLC, dated as of October 31, 2022, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 4, 2022.</u>
10.29	<u>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.</u>
10.30	<u>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.</u>
10.31	<u>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.</u>
10.32	<u>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.</u>
10.33	<u>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.</u>
10.34	<u>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.</u>
10.35	<u>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.</u>
10.36	<u>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.</u>

Exhibit No.	Description
10.37	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.
10.38	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.
10.39	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.
10.40	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.
10.41	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.
10.42	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.
10.43	Shared Services Agreement, dated August 31, 2022 by and among Interpace Biosciences, Inc., Interpace Pharma Solutions, Inc. and Flagship Biosciences, Inc., incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 7, 2022.
10.44*	Amendment to the Interpace Biosciences, Inc. 2019 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on November 15, 2022.
10.45*	Amendment to the Interpace Biosciences, Inc. Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed with the SEC on November 15, 2022.
16.1	Letter from BDO USA, LP dated April 13, 2022, incorporated by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K, filed with the SEC on April 14, 2022.
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.
23.2	Consent of EisnerAmper, 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, furnished 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, furnished herewith.
101 INS	Inline XBRL Instance Document
101 SCH	Inline XBRL Taxonomy Extension Schema Document
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)
*	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 27, 2023

/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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Thomas W. Burnell</u> Thomas W. Burnell	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2023
<u>/s/ Thomas Freeburg</u> Thomas Freeburg	Principal Financial Officer (Principal Financial and Accounting Officer)	March 27, 2023
<u>/s/ Stephen J. Sullivan</u> Stephen J. Sullivan	Director	March 27, 2023
<u>/s/ Joseph Keegan</u> Joseph Keegan	Director	March 27, 2023
<u>/s/ Vijay Aggarwal</u> Vijay Aggarwal	Director	March 27, 2023
<u>/s/ Robert Gorman</u> Robert Gorman	Chairman of the Board of Directors	March 27, 2023
<u>/s/ Edward Chan</u> Edward Chan	Director	March 27, 2023
<u>/s/ Fortunato Ron Rocca</u> Fortunato Ron Rocca	Director	March 27, 2023

Interpace Biosciences, Inc.
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and Financial Statement Schedules

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Interpace Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Interpace Biosciences, Inc. and Subsidiaries (the “Company”) as of December 31, 2022, and the related consolidated statements of operations, stockholders’ deficit, and cash flows for the year then ended, and the related notes and the financial statement schedule identified in item 15 (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s 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 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 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 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 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 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the 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.

Variable Consideration in Revenue

As described in Note 1 to 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, 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 the estimation of the variable consideration as a critical audit matter due to the significant judgement and estimation required by management in their assessment. This led to a high degree of auditor subjectivity and significant audit effort was required in performing our procedures and evaluating audit evidence relating to estimates and assumptions made by management.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our procedures included, among other things, (i) obtaining an understanding of management’s process and evaluating the design of controls related to revenue recognition; (ii) assessing the reasonableness of management’s estimates of variable consideration utilizing the expected value method based on its historical experience; (iii) comparing the Company’s estimates of variable consideration to the history of cash ultimately received from its payors; and (iv) testing the historical accuracy of cash collections used in the Company’s assumptions relating to variable consideration.

/s/ EisnerAmper LLP

We have served as the Company’s auditor since 2022.

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 27, 2023

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 sheet of Interpace Biosciences, Inc. and Subsidiaries (the "Company") as of December 31, 2021, the related consolidated statements of operations, stockholders' deficit, and cash flows for the year 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 the results of its operations and its cash flows for 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 audit. 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 audit 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 audit 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 audit 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 audit 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 audit provide a reasonable basis for our opinion.

We have served as the Company's auditor from 2012 to 2022.

/s/ BDO USA, LLP

Woodbridge, New Jersey
March 31, 2022 Except for Note 4 as to which the date is March 27, 2023

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

	<u>December 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,828	\$ 2,672
Restricted cash	-	250
Accounts receivable	5,032	4,672
Other current assets	2,294	1,479
Current assets of discontinued operations	-	3,093
Total current assets	<u>12,154</u>	<u>12,166</u>
Property and equipment, net	480	317
Other intangible assets, net	861	2,132
Operating lease right of use assets	2,439	1,284
Other long-term assets	45	141
Long-term assets of discontinued operations	-	22,387
Total assets	<u>\$ 15,979</u>	<u>\$ 38,427</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,050	\$ 1,374
Accrued salary and bonus	1,456	2,689
Other accrued expenses	8,419	8,462
Line of credit - current	2,500	-
Current liabilities of discontinued operations	858	3,157
Total current liabilities	<u>14,283</u>	<u>15,682</u>
Contingent consideration	518	1,383
Operating lease liabilities, net of current portion	1,848	520
Line of credit	-	1,500
Note payable at fair value	11,165	7,942
Other long-term liabilities	4,701	4,577
Long-term liabilities of discontinued operations	-	2,705
Total liabilities	<u>32,515</u>	<u>34,309</u>
Commitments and contingencies (Note 11)		
Redeemable preferred stock, \$.01 par value; 5,000,000 shares authorized, 47,000 shares Series B issued and outstanding	46,536	46,536
Stockholders' deficit:		
Common stock, \$.01 par value; 100,000,000 shares authorized; 4,367,830 and 4,228,169 shares issued, respectively; 4,296,710 and 4,195,412 shares outstanding, respectively	405	403
Additional paid-in capital	187,516	186,106
Accumulated deficit	(249,017)	(227,059)
Treasury stock, at cost (71,120 and 32,757 shares, respectively)	(1,976)	(1,868)
Total stockholders' deficit	<u>(63,072)</u>	<u>(42,418)</u>
Total liabilities and stockholders' deficit	<u>(30,557)</u>	<u>(8,109)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 15,979</u>	<u>\$ 38,427</u>

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,	
	2022	2021
Revenue, net	\$ 31,838	\$ 33,117
Cost of revenue	13,607	14,314
Gross profit	18,231	18,803
Operating expenses:		
Sales and marketing	9,125	9,177
Research and development	703	1,493
General and administrative	10,973	10,705
Transition expense	-	897
Loss on DiamiR transaction	-	13
Acquisition related amortization expense	1,270	3,192
Change in fair value of contingent consideration	(223)	(338)
Total operating expenses	21,848	25,139
Operating loss from continuing operations	(3,617)	(6,336)
Interest accretion expense	(158)	(496)
Related party interest	-	(424)
Note payable interest	(850)	(120)
Other expense, net	(1,211)	(366)
Loss from continuing operations before tax	(5,836)	(7,742)
Provision (benefit) for income taxes	29	(705)
Loss from continuing operations	(5,865)	(7,037)
Loss from discontinued operations, net of tax	(16,093)	(7,906)
Net loss	\$ (21,958)	\$ (14,943)
Basic and diluted loss per share of common stock:		
From continuing operations	\$ (1.38)	\$ (1.70)
From discontinued operations	(3.80)	(1.91)
Net loss per basic and diluted share of common stock	\$ (5.18)	\$ (3.61)
Weighted average number of common shares and common share equivalents outstanding:		
Basic	4,238	4,135
Diluted	4,238	4,135

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

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

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -December 31, 2020	<u>4,075,257</u>	<u>\$ 402</u>	<u>19,664</u>	<u>\$ (1,773)</u>	<u>\$ 184,404</u>	<u>\$ (212,116)</u>	<u>\$ (29,083)</u>
Issuance of common stock	152,912	1	-	-	334	-	335
Treasury stock purchased	-	-	13,093	(95)	-	-	(95)
Stock-based compensation expense	-	-	-	-	1,368	-	1,368
Net loss	-	-	-	-	-	(14,943)	(14,943)
Balance -December 31, 2021	<u>4,228,169</u>	<u>\$ 403</u>	<u>32,757</u>	<u>\$ (1,868)</u>	<u>\$ 186,106</u>	<u>\$ (227,059)</u>	<u>\$ (42,418)</u>
Issuance of common stock	139,652	2	-	-	106	-	108
Treasury stock purchased	-	-	38,363	(108)	-	-	(108)
Exercise of warrants	9	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	1,304	-	1,304
Net loss	-	-	-	-	-	(21,958)	(21,958)
Balance -December 31, 2022	<u>4,367,830</u>	<u>\$ 405</u>	<u>71,120</u>	<u>\$ (1,976)</u>	<u>\$ 187,516</u>	<u>\$ (249,017)</u>	<u>\$ (63,072)</u>

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,	
	2022	2021
Cash Flows From Operating Activities		
Net loss	\$ (21,958)	\$ (14,943)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,560	5,374
Interest accretion expense	158	496
Bad debt recovery	-	(140)
Goodwill impairment	8,433	-
Intangible asset impairment	3,964	-
Amortization of deferred financing fees	60	122
Interest - note payable	-	120
Note payable fees	-	312
Stock-based compensation	1,258	1,255
ESPP expense	46	113
Change in fair value of note payable	1,223	(58)
Deferred income taxes	(93)	38
Change in fair value of contingent consideration	(223)	(338)
Other gains and expenses, net	(71)	61
Other changes in operating assets and liabilities:		
Accounts receivable	(133)	2,148
Other current assets	(216)	28
Other long-term assets	34	(118)
Accounts payable	(735)	(1,817)
Accrued salaries and bonus	(1,421)	(137)
Accrued liabilities	(749)	(1,086)
Long-term liabilities	171	(149)
Net cash used in operating activities	<u>(7,692)</u>	<u>(8,719)</u>
Cash Flows From Investing Activity		
Proceeds from sale of Interpace Pharma Solutions, net	6,528	-
Purchase of property and equipment	(322)	(354)
Sale of property and equipment	-	39
Net cash provided by (used in) investing activities	<u>6,206</u>	<u>(315)</u>
Cash Flows From Financing Activities		
Issuance of common stock, net of expenses	108	335
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)
Proceeds from convertible debt issuance	2,000	-
Borrowings on line of credit	1,000	1,500
Cash paid for repurchase of restricted shares	(108)	-
Net cash provided by financing activities	<u>3,000</u>	<u>8,976</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	1,514	(58)
Cash, cash equivalents and restricted cash from continuing operations– beginning	2,922	1,236
Cash, cash equivalents and restricted cash from discontinued operations– beginning	392	2,136
Cash, cash equivalents and restricted cash – beginning	<u>\$ 3,314</u>	<u>\$ 3,372</u>
Cash, cash equivalents and restricted cash from continuing operations– ending	\$ 4,828	\$ 2,922
Cash, cash equivalents and restricted cash from discontinued operations– ending	-	392
Cash, cash equivalents and restricted cash – ending	<u>\$ 4,828</u>	<u>\$ 3,314</u>

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”) is a company that 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 develops and commercializes 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.

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, and Interpace Diagnostics, LLC.

Discontinued operations include the Company’s wholly-owned subsidiaries: Group DCA, LLC (“Group DCA”), InServe Support Solutions (Pharmakon), TVG, Inc. (TVG, dissolved December 31, 2014) its Commercial Services (“CSO”) business unit and its Interpace Pharma Solutions business (“Pharma Solutions”) which was sold on August 31, 2022. All significant intercompany balances and transactions have been eliminated in consolidation.

The Company has one reporting segment: the Company’s clinical 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, notes payable, allowances for doubtful accounts and notes, revenue recognition, unrecognized tax benefits, and asset impairments involving other intangible assets. The Company periodically reviews these matters and reflects changes in estimates as appropriate. Actual results could materially differ from those estimates.

Cash and Cash Equivalents

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

Accounts Receivable, Net

The Company’s accounts receivables represent unconditional rights to consideration and are generated using its proprietary tests. 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. The opening accounts receivable balance as of January 1, 2021 was \$4.4 million.

Other current assets

Other current assets consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Lab supplies	\$ 1,224	\$ 825
Prepaid expenses	390	584
Funds in escrow	500	-
Other	180	70
Total other current assets	<u>\$ 2,294</u>	<u>\$ 1,479</u>

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 one to five years. Repairs and maintenance are charged to expense as incurred. Upon disposition, the asset and related accumulated depreciation and amortization are removed from the related accounts and any gains or losses are reflected in operations.

Software Costs

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

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 related asset group, an impairment loss is recognized by reducing the recorded value of the asset group to its fair value. This analysis requires estimates of the amount and timing of projected cash flows and, where applicable, judgments associated with, among other factors, the appropriate discount rate. Such estimates are critical in determining whether any impairment charge should be recorded and the amount of such charge if an impairment loss is deemed to be necessary.

Contingencies

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

Revenue Recognition

We derive our revenues from the performance of 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. Under Accounting Standards Codification 606, revenue is recognized based on the estimated transaction price or net realizable value, 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.

We regularly review the ultimate amounts received from the third-party and direct-bill payers and related estimated reimbursement rates and adjust the net realizable values ("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 affects net revenue in the period such variances become known. The Company recorded an NRV adjustment of \$0.7 million as a reduction of revenue during the second quarter of 2022 to record the impact on revenue recorded during the first quarter of 2022. See Note 3, *Going Concern*, for more details.

Financing and Payment

For non-Medicare claims, our payment terms vary by payer category. Payment terms for direct-payers in our clinical services are typically thirty days and in our pharma services, up to sixty days. Commercial third-party-payers are required to respond to a claim within a time period established by their respective state regulations, generally between thirty to sixty days. However, payment for commercial third-party claims may be subject to a denial and appeal process, which could take up to two years in some instances where multiple appeals are submitted. The Company generally appeals all denials from commercial third-party payers. We bill Medicare directly for tests performed for Medicare patients and must accept Medicare's fee schedule for the covered tests as payment in full.

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 was assisted in the initial valuation model by a third party valuation professional.

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.

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 annual tax 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 basis and financial reporting basis 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 2022 and 2021, 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

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 are effective for the Company beginning January 1, 2023. 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 does not expect this will have a material impact 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 ASU 2020-06 amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted. The Company does not expect this will have any impact on its consolidated financial statements.

3. Going Concern

In October 2021, the Company entered into a \$7.5 million revolving credit facility with Comerica Incorporated (“Comerica”)(the “Comerica Loan Agreement”). See Note 19, *Revolving Line of Credit*, for more details. Also in October 2021, the Company entered into an \$8.0 million term loan with BroadOak Fund V, L.P. (“BroadOak”)(the “BroadOak Term Loan”), the proceeds of which were used to repay in full at their maturity the existing secured promissory note with Ampersand Capital Partners (“Ampersand”) (the “Ampersand Note”) and 1315 Capital II, L.P (“1315 Capital”)(the “1315 Capital Note”). In May 2022, the Company entered into a Subordinated Convertible Promissory Note agreement with BroadOak for an additional \$2.0 million (the “Convertible Note”), which was converted into a subordinated term loan and was added to the outstanding BroadOak Term Loan balance. See Note 13, *Notes Payable*, for more details.

In January 2022, the Company’s registration statement for a rights offering filed with the Securities and Exchange Commission (SEC) became effective; however, the rights offering was subsequently terminated later in January 2022 when the Company announced that the Centers for Medicare & Medicaid Services, or 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. However, 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. In May 2022, the Company was notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 would be completed beginning July 1, 2022. However, on June 9, 2022, the Company was notified that Novitas re-priced ThyGeNEXT[®] (0245U) from \$2,919 to \$806.59 retroactively effective to January 1, 2022. On July 20, 2022 the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel affirmed a gapfill price for ThyGeNEXT[®] of \$806.59. As a result of the ThyGeNEXT[®] pricing change, the Company reduced its net realizable value, or NRV rates, for ThyGeNEXT[®] Medicare billing to reflect the \$806.59 pricing for tests performed during the second quarter of 2022. In addition, in order to reflect the retroactive pricing change to January 1, 2022, the Company recorded an NRV adjustment of \$0.7 million during the second quarter of 2022 to reduce revenue recorded during the first quarter of 2022. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

Further, along with many laboratories, the Company may be affected by the Proposed Local Coverage Determination (“LCD”) DL39365, which was posted on June 9, 2022 and is currently under consideration by our local Medicare Administrative Contractor, Novitas. If finalized, this Proposed LCD, which governs “Genetic Testing for Oncology,” could impact the existing LCD for one of our molecular tests, PancreGEN[®]. If Novitas restricts coverage for PancreGEN[®], the Company’s liquidity could be negatively impacted beginning in Fiscal 2023.

On August 31, 2022, the Company closed on the sale of its Pharma Solutions business for a total purchase price of \$6,560,000 after adjustments. In addition, we received the earnout payment of \$1,043,000. See Note 4, *Discontinued Operations*.

For the year ended December 31, 2022, the Company had an operating loss from continuing operations of \$3.6 million. As of December 31, 2022, the Company had cash and cash equivalents of \$4.8 million, total current assets of \$12.2 million and current liabilities of \$14.3 million. As of March 17, 2023, the Company had approximately \$5.7 million of cash on hand, excluding restricted cash.

The Company may not generate positive cash flows from operations for the year ending December 31, 2023. The Company intends to meet its ongoing capital needs by using its available cash and availability under the Comerica Loan Agreement, as well as through targeted margin improvement; collection of accounts receivable; containment of costs; and the potential use of other financing options and other strategic alternatives. However, if the Company is 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 March 27, 2023, the Company had \$1.5 million available under the Loan Agreement.

The Company continues to explore various strategic alternatives, 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. With the delisting of its common stock from Nasdaq in February 2021, the Company's ability to raise additional capital on terms acceptable to it has been adversely impacted. There can be no assurance that the Company will be successful in obtaining such funding on terms acceptable to it.

The Company's consolidated financial statements assumes the Company will continue as a going concern. Its ability to continue as a going concern depends on having working capital for vendor payments, meeting short-term obligations on other accrued liabilities, and amongst other requirements, making interest payments on its debt obligations. Without positive operating margins and sufficient working capital and the ability to meet its debt obligations, our business will be jeopardized and we may not be able to continue in our current structure, if at all. Under these circumstances, the Company would likely have to consider other options, such as selling assets, raising additional debt or equity capital, cutting costs or otherwise reducing our cash requirements, or negotiating with our creditors to restructure our applicable obligations. With the proceeds received from the sale of the Pharma Solutions business, as well as the expected improvement in future operating cash flows associated with the disposition, as of the date of this filing, the Company anticipates that current cash and cash equivalents and forecasted cash receipts will be sufficient to meet its anticipated cash requirements through the next twelve months.

4. Discontinued Operations

On August 31, 2022, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Flagship Biosciences, Inc. (the "Purchaser") pursuant to which the Purchaser agreed to (i) acquire substantially all of the assets of Interpace Pharma Solutions, Inc. used in its business of complex molecular analysis for the early diagnosis and treatment of cancer and supporting the development of targeted therapeutics (the "Business") and (ii) assume and pay certain liabilities related to the purchased assets (collectively, the "Transaction"). The Transaction closed on August 31, 2022.

As consideration for the Transaction, Interpace received a total sale price of approximately \$6.2 million after working capital and other adjustments (\$0.5 million of which has been deposited into escrow). In addition, the Purchaser paid the Company an earnout of approximately \$1.0 million based on revenue for the period beginning September 1, 2021 and ending August 31, 2022.

The Purchase Agreement includes a one-year commitment of Interpace not to compete with the Business, recruit or hire any former employees of the Subsidiary who accept employment with the Purchaser in connection with the Transaction, or divert or attempt to divert from Purchaser any business to be performed from any of the contracts or agreements with customers as set forth in the Purchase Agreement. The Purchase Agreement also contains customary representations and warranties, post-closing covenants and mutual indemnification obligations for, among other things, any inaccuracy or breach of any representation or warranty and any breach or non-fulfillment of any covenant.

In connection with the Transaction, on August 31, 2022, Interpace and Purchaser entered into a Shared Services Agreement (the "Shared Services Agreement") pursuant to which Interpace agreed to provide, or cause its affiliates to provide, to the Purchaser certain services set forth in the Shared Services Agreement on a transitional basis and subject to the terms and conditions set forth in the Shared Services Agreement (the "Services"). As consideration for the Services provided by Interpace, Purchaser will pay Interpace the amounts specified for each Service as set forth in the Shared Services Agreement. The Company's obligations to provide the Services will terminate with respect to each Service as set forth in the Shared Services Agreement.

The Purchaser is identified as a related party as an affiliate of Ampersand and an affiliate of BroadOak and have each provided equity financing to the Purchaser. Collectively, they own a majority of the Purchaser's outstanding equity securities and are represented on its Board of Directors.

The Company intends to use the remaining net proceeds to fund its future business activities and for general working capital purposes. As a result of the sale, the gain on sale and all operations from Interpace Pharma Solutions have been classified as discontinued operations for all periods presented.

A reconciliation of the accounting for the Company's Pharma Solutions business is as follows:

	<u>Gain on Sale</u>
Purchase price	\$ 7,000
Earnout received	1,043
Working capital adjustment, net	(766)
Less: transaction costs	(307)
Total net consideration	<u>\$ 6,970</u>
Assets and liabilities disposed of, net ⁽¹⁾	(6,970)
Gain on sale	<u>\$ -</u>

- (1) includes goodwill and intangible assets written down prior to the Transaction. The goodwill write-down was approximately \$8.4 million and the write-down of intangible assets was approximately \$3.8 million.

The components of assets and liabilities classified as discontinued operations consist of the following as of December 31, 2022 and December 31, 2021:

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Accounts receivable, net	\$ -	\$ 1,486
Other	-	1,607
Current assets of discontinued operations	-	3,093
Property and equipment, net	-	6,032
Other intangible assets, net	-	5,155
Goodwill	-	8,433
Other	-	2,767
Long-term assets of discontinued operations	-	22,387
Total assets	<u>\$ -</u>	<u>\$ 25,480</u>
Accounts payable	-	1,320
Accrued salary and bonus	92	335
Other ⁽¹⁾	766	1,502
Current liabilities of discontinued operations	858	3,157
Operating lease liabilities, net of current portion	-	2,634
Other	-	71
Long-term liabilities of discontinued operations	-	2,705
Total liabilities	<u>\$ 858</u>	<u>\$ 5,862</u>

- (1) Includes \$766 of liabilities related to the former Commercial Services business unit.

The table below presents the significant components of its former Pharma Solutions business unit's results included within loss from discontinued operations, net of tax in the consolidated statements of operations for the years ended December 31, 2022 and 2021.

	For The Years Ended	
	December 31,	
	2022	2021
Revenue, net	\$ 5,678	\$ 8,197
Loss from discontinued operations	(15,968)	(7,671)
Gain (loss) on sale of Pharma Solutions	-	-
Income tax expense	125	235
Loss from discontinued operations, net of tax	\$ (16,093)	\$ (7,906)

The income tax expense for the years ended December 31, 2022 and December 31, 2021 primarily pertained to the interest accrued on uncertain tax position liabilities.

Cash used from discontinued operations, operating activities, for the year ended December 31, 2022 was approximately \$2.8 million. There was cash provided by discontinued operations, investing activities, for the year ended December 31, 2022 of \$6.5 million which pertained to the net proceeds received from the Pharma Solutions sale. Cash used from discontinued operations, operating activities, for the year ended December 31, 2021 was approximately \$4.9 million. There was cash used from discontinued operations, investing activities, for the year ended December 31, 2021 of \$0.1 million. Depreciation and amortization expense within discontinued operations for the years ended December 31, 2022 and December 31, 2021 was \$1.1 million and \$1.8 million, respectively.

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, 2022		Fair Value Measurements As of December 31, 2022		
	Carrying Amount	Fair Value	Level 1 (unaudited)	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen ⁽¹⁾	\$ 1,088	\$ 1,088	\$ -	\$ -	\$ 1,088
Other accrued expenses:					
Warrant liability ⁽²⁾	-	-	-	-	-
Note payable:					
BroadOak loan	10,000	11,165	-	-	11,165
	<u>\$ 11,088</u>	<u>\$ 12,253</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 12,253</u>

	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	8,000	7,942	-	-	7,942
	<u>\$ 9,942</u>	<u>\$ 9,884</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 9,884</u>

(1)(2) See Note 10, *Accrued Expenses and Long-Term Liabilities*

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.

The Company records the BroadOak 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.

	<u>December 31, 2021</u>	<u>Issued</u>	<u>Reclassified</u>	<u>Transferred to Accrued Expenses</u>	<u>Accretion/ Interest Accrued</u>	<u>Adjustment to Fair Value/ Mark to Market</u>	<u>December 31, 2022</u>
Asuragen	\$ 1,871	\$ -	\$ -	\$ (718)	\$ 158	\$ (223)	\$ 1,088
Underwriters Warrants	71	-	-	-	-	(71)	-
BroadOak loans	7,942	-	2,000	-	-	1,223	11,165
BroadOak Convertible Note	-	2,000	(2,000)	-	-	-	-
	<u>\$ 9,884</u>	<u>\$ 2,000</u>	<u>\$ -</u>	<u>\$ (718)</u>	<u>\$ 158</u>	<u>\$ 929</u>	<u>\$ 12,253</u>

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, 2022 and 2021:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Furniture and fixtures	\$ 69	\$ 62
Lab and office equipment	2,243	1,944
Computer equipment	233	217
Internal-use software	139	139
Leasehold improvements	175	175
Property and equipment	2,859	2,537
Less accumulated depreciation and amortization	(2,379)	(2,220)
Net property and equipment	<u>\$ 480</u>	<u>\$ 317</u>

Depreciation and amortization expense from continuing operations was approximately \$0.2 million and \$0.3 million for the years ended December 31, 2022 and 2021, respectively. There was zero internal-use software amortization expense included in depreciation and amortization expense in 2022.

7. Goodwill and Other Intangible Assets

The net carrying value of the identifiable intangible assets from all acquisitions within continuing operations as of December 31, 2022 and December 31, 2021 are as follows:

	Life (Years)	As of December 31, 2022 Carrying Amount	As of December 31, 2021 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
CLIA Lab	2.3	609	609
Total		\$ 31,951	\$ 31,951
Accumulated Amortization		(31,090)	(29,819)
Net Carrying Value		\$ 861	\$ 2,132

Amortization expense from continuing operations was approximately \$1.3 million and \$3.2 million for the years ended December 31, 2022 and 2021, respectively. The remaining amortization expense of \$0.9 million will be amortized in 2023.

8. Leases

The Company leases facilities and certain equipment under agreements classified as operating leases, which expire at various dates through June 2028. 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, 2022 and 2021 was approximately \$0.9 million and \$0.7 million, respectively.

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

	Classification on the Balance Sheet	December 31, 2022	December 31, 2021
Assets			
Operating lease assets	Operating lease right of use assets	2,439	1,284
Total lease assets		\$ 2,439	\$ 1,284
Liabilities			
Current			
Operating lease liabilities	Other accrued expenses	578	762
Total current lease liabilities		\$ 578	\$ 762
Noncurrent			
Operating lease liabilities	Operating lease liabilities, net of current portion	1,848	520
Total long-term lease liabilities		1,848	520
Total lease liabilities		\$ 2,426	\$ 1,282

The weighted average remaining lease term for the Company's operating leases was 5.0 years as of December 31, 2022 and 6.4 years as of December 31, 2021 and the weighted average discount rate for those leases was 11.7% and 6.5% as of December 31, 2022 and December 31, 2021, 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, 2022:

	Operating Leases
2023	\$ 832
2024	575
2025	450
2026	550
2027-2028	825
Total minimum lease payments	<u>3,232</u>
Less: amount of lease payments representing effects of discounting	<u>806</u>
Present value of future minimum lease payments	2,426
Less: current obligations under leases	<u>578</u>
Long-term lease obligations	<u>\$ 1,848</u>

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, 2022 and December 31, 2021 was approximately \$0.3 million and \$0.2 million, respectively.

10. Accrued Expenses and Other Long-Term Liabilities

Other accrued expenses consisted of the following as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Accrued royalties	\$ 4,909	\$ 3,890
Contingent consideration	569	488
Operating lease liability	578	762
Interest payable	-	120
Warrant liability	-	71
Accrued sales and marketing - diagnostics	40	47
Accrued lab costs - diagnostics	167	228
Accrued professional fees	641	932
Taxes payable	262	222
Unclaimed property	565	565
All others	688	1,137
Total other accrued expenses	<u>\$ 8,419</u>	<u>\$ 8,462</u>

Other long-term liabilities consisted of uncertain tax positions as of December 31, 2022 and 2021.

11. Commitments and Contingencies

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. Mezzanine Equity

Redeemable Preferred Stock

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.

Voting

On any matter presented to the stockholders of the Company 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 the Company's 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 of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (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.

Director Designation Rights

The Certificate of Designation also provides each Investor with the following director designation rights: for so long such Investor holds at least sixty percent (60%) of the Series B Preferred Stock issued to it on the Issuance Date (as defined therein), such Investor will be entitled to elect two directors to the Company's Board of Directors (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 the Issuance Date, 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.

Conversion

The Certificate of Designation provides that from and after the Issuance Date and subject to the terms of the Certificate of Designation, 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 Common Stock equal to dividing the amount equal to the greater of the Stated Value 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 Common Stock immediately prior to a liquidation, by six dollars (\$6.00) (subject to adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares). The aggregate number of shares of Common Stock that may be issued through conversion of all of the New Investment Shares and Exchange Shares is 7,833,334 shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares).

Mandatory Conversion

If the Company consummates the sale of shares of Common Stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act pursuant to which the price of the Common Stock in such offering is at least equal to twelve dollars (\$12.00) (subject to adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares) and such offering does not include warrants (or any other convertible security) and results in at least \$25,000,000.00 in proceeds, net of the underwriting discount and commissions, to the Company, and the Common Stock continues to be listed for trading on the Nasdaq Capital Market or another exchange, all outstanding shares of Series B Preferred Stock will automatically be converted into shares of Common Stock, at the then effective Series B Conversion Ratio (as defined in the Certificate of Designation).

Liquidation

Upon any voluntary or involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation (as defined in the Certificate of Designation) (a "Liquidation"), the holders of shares of Series B Preferred Stock then outstanding will be entitled to be paid out of the assets of the Company available for distribution to its stockholders (on a pari passu basis with the holders of any class or series of preferred stock ranking on liquidation on a parity with the Series B Preferred Stock), and before any payment will be made to the holders of Common Stock or any other class or series of preferred stock ranking on liquidation junior to the Series B Preferred Stock by reason of their ownership thereof, an amount per share of Series B Preferred Stock equal to the greater of (i) the Stated Value of such share of Series B Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had each such share been converted into Common Stock immediately prior to such Liquidation.

As of December 31, 2022 and December 31, 2021, there were 47,000 Series B issued and outstanding shares of preferred stock which on an as converted basis are equal to 7,833,334 shares of common stock.

13. Notes Payable

BroadOak Loan

On October 29, 2021, the Company and its subsidiaries entered into the BroadOak Loan Agreement, 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 \$7,500,000 revolving credit facility with Comerica Bank. See Note 18 *Revolving Line of Credit*. The Term Loan had 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.

BroadOak Convertible Note

On May 5, 2022, the Company issued a Convertible Note to BroadOak, pursuant to which BroadOak funded an aggregate principal amount of \$2 million (the “Convertible Debt”).

The Convertible Note was to be converted into shares of common stock of the Company in connection with, and upon the consummation of, a private placement transaction pursuant to which the Company would issue common stock to certain investors, and such conversion would be subject to the same terms and conditions (including purchase price per share) applicable to the purchase of common stock of the Company by such investors. Since the private placement transaction was not consummated by August 5, 2022 (the “Maturity Date”), the Convertible Note was converted into an additional term loan advance under the Company’s existing BroadOak Loan Agreement on the Maturity Date. The Convertible Debt bore interest at a fixed rate of 9.0% per annum and was unsecured. There were no scheduled amortization payments prior to the Maturity Date. The Convertible Note contained customary representations and warranties and customary events of default.

The Company entered into a) a consent letter (the “Comerica Consent”) with Comerica, pursuant to which Comerica consented to the issuance of the Convertible Note, the incurrence of the Convertible Debt and the conversion of the Convertible Debt into common stock of the Company or an additional term loan advance under the BroadOak Loan Agreement.

Related Party Secured Promissory Note

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. 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. The Company used the proceeds of the BroadOak Term Loan discussed above to repay in full all outstanding indebtedness under the promissory notes with Ampersand, in the amount of \$4.5 million, and 1315 Capital, in the amount of \$3 million.

14. Warrants

Warrants outstanding and warrant activity for the year ended December 31, 2022 are as follows:

<u>Description</u>	<u>Classification</u>	<u>Exercise Price</u>	<u>Expiration Date</u>	<u>Warrants Issued</u>	<u>Balance December 31, 2021</u>	<u>Warrants Exercised</u>	<u>Warrants Cancelled/Expired</u>	<u>Balance December 31, 2022</u>
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	(9)	(870,205)	-
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)	-
				<u>1,975,934</u>	<u>1,404,648</u>	<u>(9)</u>	<u>(1,404,639)</u>	<u>-</u>

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 estimates 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 \$46,000 and \$0.1 million in expense related to that plan for the years ended December 31, 2022 and 2021, respectively. The Company suspended its plan in July 2022 as there were no shares available in the original authorized shares pool. In November 2022, the shareholders approved an increase to the pool of an additional one million shares.

As of December 31, 2022, we have reserved 776,849 shares of our common stock for issuance under our 2019 Equity Incentive Plan and 1,000,007 shares of our common stock for issuance under our Employee Stock Purchase Plan and 1,672,746 additional shares available for future grants of awards under our 2019 Equity Incentive Plan.

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, 2022 and December 31, 2021:

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Risk-free interest rate	1.75%	0.79%
Expected life	6.0 years	6.0 years
Expected volatility	129.88%	134.73%
Dividend yield	-	-

The weighted-average fair value of stock options granted during the year ended December 31, 2022 was estimated to be \$4.50. The weighted-average fair value of stock options granted during the year ended December 31, 2021 was estimated to be \$4.64. There were no options exercised in 2022. There were 13,042 options exercised in 2021.

Stock-based compensation from continuing operations for the years ended December 31, 2022 and 2021 is as follows:

	<u>2022</u>	<u>2021</u>
RSUs and restricted stock	\$ 498	\$ 370
Performance-based awards	71	107
Options	622	555
Total stock-based compensation expense	<u>\$ 1,191</u>	<u>\$ 1,032</u>

A summary of stock option activity for the year ended December 31, 2022, 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, 2022	632,511	\$ 6.89	8.40	\$ -
Granted	41,000	5.03	9.01	-
Forfeited or expired	(145,667)	7.91	-	-
Outstanding at December 31, 2022	<u>527,844</u>	6.46	7.57	-
Exercisable at December 31, 2022	270,080	7.39	7.16	-
Vested and expected to vest	518,511	6.47	7.55	-

A summary of the change in of the Company's non-vested options for the year ended December 31, 2022 is presented below:

	Shares	Weighted-Average Grant Date Fair Value
Nonvested at January 1, 2022	422,476	\$ 4.78
Granted	41,000	4.50
Vested	(142,709)	5.02
Forfeited	(63,003)	4.69
Nonvested at December 31, 2022	<u>257,764</u>	\$ 4.63

The aggregate fair value of options vested during the years ended December 31, 2022 and 2021 was \$0.7 million and \$0.8 million, respectively. The weighted-average grant date fair value of options vested during the year ended December 31, 2021 was \$6.54.

A summary of the Company's non-vested shares of restricted stock and restricted stock units for the year ended December 31, 2022, 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, 2022	328,939	\$ 3.67	1.34	\$ 2,467,043
Granted	74,000	6.18	-	-
Vested	(113,932)	4.88	-	-
Forfeited	(40,002)	6.15	-	-
Nonvested at December 31, 2022	<u>249,005</u>	\$ 3.47	0.98	\$ 258,965

The aggregate fair value of restricted stock units vested during each of the years ended December 31, 2022 and 2021 was \$0.6 million and \$0.3 million, respectively.

As of December 31, 2022, there was approximately \$0.9 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and restricted stock units which will be expensed over the next three years.

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 accounting for more than 10% of the Company's revenue from continuing operations during the years ended December 31, 2022 and 2021, respectively. For the years ended December 31, 2022 and December 31, 2021, revenue from Medicare was approximately 45% and 54% of total revenue, respectively.

Customer	Years Ended December 31,	
	2022	2021
Medicare	\$ 14,413	\$ 17,778
Medicare Advantage	\$ 4,384	\$ 5,859
Commercial Payors	\$ 7,154	\$ 5,555
Client Billings	\$ 5,679	\$ 3,752

17. Income Taxes

The provision (benefit) from income taxes on continuing operations for the years ended December 31, 2022 and 2021 is comprised of the following:

	2022	2021
Current:		
Federal	\$ -	\$ -
State	29	(705)
Total current	29	(705)
Deferred:		
Federal	-	-
State	-	-
Total deferred	-	-
Provision (benefit) from income taxes	\$ 29	\$ (705)

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, 2022 as the Company believes that it is more likely than not that these assets will not be realized.

The tax effects of significant items comprising the Company's deferred tax assets and (liabilities) as of December 31, 2022 and 2021 are as follows:

	2022	2021
Deferred tax assets:		
Federal net operating loss carryforwards	\$ 26,713	\$ 24,923
State net operating loss carryforwards	3,639	3,498
Compensation	2,059	1,844
Allowances and reserves	395	585
Intangible assets	3,584	571
State taxes	987	942
Credit carryforward	1	2
163(j) interest	1,279	1,047
Leases	(3)	41
Deferred revenue	94	95
Capitalized 174	158	-
Valuation allowance	(38,256)	(33,170)
	650	378
Deferred tax liability:		
Property and equipment	(650)	(471)
Deferred tax liability-net valuation allowance	\$ -	\$ (93)

The Company's deferred tax asset and deferred tax liabilities are included within *Other long-term liabilities*, within the consolidated balance sheet as of December 31, 2022 and 2021. Federal tax attribute carryforwards at December 31, 2022, consist primarily of approximately \$127.2 million of federal net operating losses. In addition, the Company has approximately \$59.1 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 \$56.0 million 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:

	<u>2022</u>	<u>2021</u>
Federal statutory rate	21.0%	21.0%
State income tax rate, net of Federal tax benefit	3.6%	4.3%
Meals and entertainment	(0.4)%	(0.2)%
Valuation allowance	(24.7)%	(25.4)%
NJ NOL credit sale	0.0%	9.4%
Effective tax rate	<u>(0.5)%</u>	<u>9.1%</u>

The following table summarizes the change in uncertain tax benefit reserves for the two years ended December 31, 2022:

	<u>Unrecognized Tax Benefits</u>
Balance of unrecognized benefits as of January 1, 2021	\$ 877
Additions for tax positions of prior years	-
Balance as of January 1, 2022	<u>\$ 877</u>
Additions for tax positions of prior years	-
Balance as of December 31, 2022	<u>\$ 877</u>

As of December 31, 2022 and 2021, 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, 2022 and 2021 was \$0.9 million and \$0.9 million, respectively.

The Company recognized interest and penalties of \$0.2 million and \$0.2 million, respectively, related to uncertain tax positions in income tax expense during each of the years ended December 31, 2022 and 2021. At December 31, 2022 and 2021, accrued interest and penalties, net were \$3.8 million and \$3.6 million, respectively, and are 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, 2022:

<u>Jurisdiction</u>	<u>Tax Years</u>
Federal	2019 – 2022
State and Local	2018 – 2022

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, 2022.

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, 2022 and 2021 are as follows (rounded to thousands):

	Years Ended December 31,	
	2022	2021
Basic weighted average number of common shares	4,238	4,135
Potential dilutive effect of stock-based awards	-	-
Diluted weighted average number of common shares	4,238	4,135

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,	
	2022	2021
Options	528	632
Restricted stock units (RSUs)	249	329
Warrants	-	1,405
	777	2,366

19. Revolving Line of Credit

On October 13, 2021, the Company and its subsidiaries entered into the Comerica Loan Agreement with 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, 2022, the balance of the revolving line was \$2.5 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, which the Company was in compliance with as of December 31, 2022, and also contains customary events of default. In April 2022, Comerica waived certain covenants specifically relating to the Company receiving financial statements with a going concern comment or qualification. In April 2022 and August 2022, Comerica waived certain covenants specifically relating to failure to maintain bank accounts outside of Comerica in an aggregate amount not to exceed \$0.5 million during the transition period. Additionally, in August 2022, Comerica waived certain covenants relating to failure to segregate collections made from government account debtors from collections made from all other account debtors and customers.

As a condition for Comerica to extend the Credit Facility to the Company, the Company’s existing creditors, Ampersand and 1315 Capital (the “Existing Creditors”), entered into a 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 owing to such Existing Creditor to all of the indebtedness and obligations of the Company 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 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.

20. Supplemental Cash Flow Information

Supplemental Disclosure of Other Cash Flow Information
(in thousands)

Cash paid for taxes	\$	251	\$	369
Cash paid for interest	\$	971	\$	424

Supplemental Disclosures of Non Cash Activities
(in thousands)

	Years Ended	
	December 31,	
	2022	2021
Taxes accrued for repurchase of restricted shares	\$ -	\$ 95
Investment in DiamiR	-	248
Conversion of convertible debt into notes payable	2,000	-

INTERPACE BIOSCIENCES, INC.
VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 2022 AND 2021
(\$ in thousands)

Description	Balance at Beginning of Period	Additions (Reductions) Charged to Operations	(1) Deductions Other	Balance at end of Period
2021				
Allowance for doubtful accounts	\$ 72	-	-	\$ 72
Allowance for doubtful notes	\$ 869	-	-	\$ 869
Tax valuation allowance	\$ 23,684	-	9,486	\$ 33,170
2022				
Allowance for doubtful accounts	\$ 72	-	(72)	\$ -
Allowance for doubtful notes	\$ 869	-	-	\$ 869
Tax valuation allowance	\$ 33,170	-	5,086	\$ 38,256

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

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-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, except for Note 4 as to which the date is March 27, 2023 relating to the consolidated financial statements and schedule as of December 31, 2021 and for the year then ended, which appear in this Annual Report on this Form 10K. 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 27, 2023

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Interpace Biosciences, Inc. on Form S-8 (Nos. 333-61231, 333-60512, 333-177969, 333-201070, 333-214260, 333-252574 and 333-234284) of our report dated March 27, 2023, on our audit of the financial statements as of December 31, 2022 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 27, 2023.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 27, 2023

**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, 2022 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 27, 2023

/s/ Thomas W. Burnell

Chief Executive Officer
(Principal Executive Officer)

**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, 2022 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 27, 2023

/s/ Thomas Freeburg
(Principal Financial Officer)

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

In connection with the Annual Report of Interpace Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 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 27, 2023

/s/ Thomas W. Burnell

Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report of Interpace Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas Freeburg, as Principal 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 27, 2023

/s/ Thomas Freeburg

(Principal Financial Officer)
