

**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, 2024

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.)

**Waterview Plaza, Suite 310
2001 Route 46, 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, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was \$3,999,609 (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 21, 2025, 4,423,093 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 2024 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, 2024. 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.

EXPLANATORY NOTE

Restatement Background

As described in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on March 6, 2025, during the preparation of the Company's consolidated financial statements for the year ended December 31, 2024, the Company determined that it should not have been accruing royalty expense with respect to certain royalty agreements and therefore certain of its royalty accruals from 2016-2023 should be reversed. As a result of this the Company's previously issued financial statements described below were materially misstated in prior periods.

As a result of the above, the Company determined that its previously issued financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2023 should no longer be relied upon. Further, the Company's unaudited condensed consolidated financial statements included in the Quarterly Reports on Form 10-Q for the quarterly periods within the year ended December 31, 2023 (the "2023 Quarterly Reports"), as well as the unaudited condensed consolidated financial statements included in the Quarterly Reports on Form 10-Q for the quarterly periods within the year ended December 31, 2024 (the "2024 Quarterly Reports") should also no longer be relied upon.

Internal Control Considerations

Management has determined that the Company's ineffective internal control over financial reporting as it pertained to the royalty agreements and resulting material weakness was attributed to a lack of an existing control whereby the accounting team was not aware that the Company's revenue sources, ThyraMIR and ThyGeNEXT, did not utilize the technology covered under the royalty agreements. See Item 9A, Controls and Procedures, for additional information related to this material weakness in internal control over financial reporting and the related remediation.

Restatement of Previously Issued Consolidated Financial Statements

This Annual Report on Form 10-K for the year ended December 31, 2024 includes consolidated financial statements as of and for the years ended December 31, 2024 and 2023, as well as the relevant unaudited interim financial information for the quarters in the years ended December 31, 2024 and 2023. The Company has restated certain information within this Annual Report on Form 10-K, including the consolidated financial statements as of and for the year ended December 31, 2023, and the relevant unaudited interim financial information for the quarterly periods in 2023 and 2024. In addition to the restatement errors described above, the Company has corrected certain items that were concluded as immaterial, individually and in the aggregate, to the consolidated financial statements for the year ended December 31, 2023 and the quarters within the years ended December 31, 2023 and December 31, 2024.

See Note 2 to our Consolidated Financial Statements included within Part II, Item 8 contained in this Annual Report on Form 10-K for additional information related to the 2023 Consolidated Financial Statements restatement including descriptions of the errors and the impact to our consolidated financial statements. Please also see Note 22 to our Consolidated Financial Statements included within Part II, Item 8 contained in this Annual Report for our restatement of unaudited interim condensed consolidated financial statements for 2023 and 2024. See also Part II Item 7 contained in this Annual Report for our restatement of Management's Discussion and Analysis of our previously issued financial information as of and for the year ended December 31, 2023. As a result of the restatement, it was determined that the Company's disclosure controls and procedures were not effective as of December 31, 2024 and December 31, 2023, and that the Company had identified material weaknesses in its internal controls over financial reporting, as referenced in Item 9A.

Reliance on Prior Consolidated Financial Statements

The Company has not amended and does not plan to amend its previously filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for the periods affected by the restatement for the yearly and quarterly periods –spanning fiscal years 2016 to 2023. The information that has been previously filed or otherwise reported for these periods is superseded by the information in this Form 10-K. Accordingly, the consolidated financial statements and related financial information contained in such previously filed or furnished reports should no longer be relied upon.

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. These forward-looking statements are contained throughout this Form 10-K, including, but not limited to, statements found in Part I – Item 1 – “Business” and Part II – Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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

- our 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 long-term under the existing local coverage determination (“LCD”) after April 24, 2025;
- our secured lender has 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 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 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 84% of our outstanding shares of common stock through their holdings of our Series C Preferred Stock, and this concentration of ownership may have a substantial influence on our decisions;

- the delisting of our common stock from Nasdaq has adversely affected and may continue to adversely affect our common stock and business and financial condition;
- our ability to remediate the material weakness identified in our internal control over financial reporting as of December 31, 2024
- our determination to restate prior period consolidated financial statements and its impact on investor confidence and reputational issues;
- 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 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, 2024.

PART I

ITEM 1. BUSINESS

Company Overview

We are a company that provides esoteric molecular diagnostic testing, and pathology services to aid physicians in their evaluation of cancer risk in patients with indeterminate biopsies and a perceived high risk of cancer from clinical features. We develop and commercialize genomic tests and related first-line assays that can personalize medicine to help improve patient diagnosis and management.

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 that help guide patient management decisions by providing information on the diagnosis and prognosis of indeterminate specimens. Guidance on genetic marker-related pharmaceutical treatment options, when available, is also provided.

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 2024 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.

Market Overview

Global Molecular Diagnostic Market

The global esoteric molecular diagnostics market, valued at \$29.9 billion (USD) in 2023 and is expected to grow to \$48.3 billion (USD) by 2029 with a Compound Annual Growth rate or CAGR of 8.5% between 2023 and 2029, according to MarketsandMarkets™ (Report Code: MD5930, published June 2024).

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 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. The American Cancer Society annually estimates new cancer cases and deaths within the United States. In 2025, there will be an estimated 2,041,910 new cancer cases and 618,120 cancer deaths, corresponding to ~1,700 deaths per day. The cancer burden is also shifting from older to younger adults and from men to women. Additionally, while cancer is the second most common cause of death in the United States, exceeded only by heart disease, it is the leading cause of death among men aged 60-79 years of age and women aged 40-79 years of age.

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, 2024) shows estimated new cases and deaths in 2024 in the United States for selected major cancer types:

Cancer Type	Estimated New Cases	Estimated Deaths
Bladder	83,190	16,840
Breast (Female – Male)	310,720-2,790	42,250-530
Colon and Rectal (Combined)	152,810	53,010
Kidney (Renal Cell and Renal Pelvis)	81,610	14,390
Leukemia (All Type)	62,770	23,670
Liver and Intrahepatic Bile Duct	41,630	29,840
Lung (Including Bronchus)	234,580	125,070
Melanoma	100,640	8,290
Non-Hodgkin's Lymphoma	80,620	20,140
Pancreatic	66,440	51,750
Prostate	299,010	35,250
Thyroid	44,020	2,170

Our Strategy

Our primary goal is to drive exceptional growth while becoming a leader in providing high-quality and dependable personalized medicine. Our strategy is to grow our business organically and by selectively partnering—which could potentially include licensing, acquisitions or mergers, to generate positive returns for our shareholders. 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. Given the potential loss of PancreGEN® reimbursement, we will adapt our strategy to mitigate the impact and continue to drive growth.

The key tactics to achieve our goals include:

- Expanding awareness and use of our existing commercial products, especially ThyGeNEXT[®] and ThyraMIR[®]v2 through omnichannel marketing programs;
- Continuing the clinical development and commercialization of BarreGEN[®], our esophageal cancer risk classifier for Barrett’s Esophagus, and accelerating and further expanding clinical studies for our inline assays;
- 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:
 - Continuing support of an internal managed care team;
 - Utilizing Key Opinion Leaders to educate on the validity and utility of our testing services; and
 - Establishing payer relationships and in-network contracts serving our diagnostic customers.
- 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 understanding and utilization of our bioinformatics data to improve our assays and elevate scientific understanding of the genetic drivers of cancer progression and aggressiveness.

Additionally, we will focus on diversifying our product portfolio and exploring new revenue streams. This includes investing in research and development to bring innovative diagnostic solutions to market and strengthening our relationships with commercial payers to ensure broader coverage for our tests.

Our Service Offerings

Our business is based on the increasing clinician demand for molecular- and biomarker-based characterization of cancers to help inform patient management decisions.

Molecular-based testing often produces higher value and more accurate cancer diagnostic information than traditional clinical assessments and non-genetic diagnostic methods. Our proprietary and unique disease-focused 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 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 pancreatic, thyroid 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 increased surveillance or 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: PancreGEN[®], 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 PancreGEN; ThyGeNEXT[®], an oncogenic mutation panel that helps “rule-in” and “rule-out” malignancy in thyroid nodules; ThyraMIR[®]v2, used in combination with ThyGeNEXT[®], which further stratifies thyroid nodules for malignancy risk utilizing a proprietary microRNA gene expression classifier; 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, PancreGEN[®], 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 2025 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 13%. PancreGEN[®] and PanDNA[®] assess the risk of malignancy in pancreatic cysts and pancreaticobiliary solid lesions, which have potential for developing into cancer. We believe that PancreGEN[®] 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 PancreGEN[®] is approximately 124,000 mucinous indeterminate pancreaticobiliary lesions annually or approximately \$200 million annually based on the current size of the patient population and reimbursement rates. To date, PancreGEN[®] testing has been used in over 80,000 clinical cases. The National Pancreatic Cyst Registry study published in *Endoscopy* in 2015 demonstrated that PancreGEN[®] 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.

Most recently, the International Association of Pancreatology (IAP) reviewed and revised their guidelines with a main objective being to update their patient management algorithm. These revised guidelines indicate that molecular markers can be used when the diagnosis of a pancreatic cyst is unclear and will alter surveillance. Additionally, the guidelines further indicate that molecular markers, such as the ones found within PancreGEN[®], can be useful in identifying the presence of high-grade dysplasia and invasive carcinoma. (*Pancreatology*. 2023 Dec 28: S1424-3903(23)01883-5. doi: 10.1016/j.pan.2023.12.009). Accordingly, we believe that PancreGEN[®] provides a highly reliable diagnostic and prognostic option that can accurately stratify cancer risk in circumstances where risk of cancer is otherwise uncertain.

As described below, on January 9, 2025, the Company announced the new LCD established non-coverage for its PancraGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancraGEN[®] testing after February 7, 2025. On January 27, 2025, the Company announced that CMS had directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. For more information, please see Part I – **Item 1 – “Business – Government Regulations and Industry Guidelines - Third Party Coverage and Reimbursement for our Clinical Services – Novitas LCD for PancraGEN.”**

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 unique microRNA-based endocrine cancer diagnostic test, ThyraMIR[®]v2. This assay measures the expression of eleven distinct microRNAs. The combined analysis of the ThyGeNEXT[®] and ThyraMIR[®]v2 test results provides very narrow malignancy risk ranges to help guide patient management decision-making.

We estimate the total market for our endocrine (thyroid) cancer assays is approximately \$300 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.

We believe that our Endocrine Cancer Products franchise for indeterminant thyroid nodules, ThyGeNEXT[®] + ThyraMIR[®]v2, is quite strong and provides a solid foundation for continued growth and profitability should there be any change to existing test-specific local coverage determinations for other Interpace testing services.

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.

Our testing is performed in our state-of-the-art CLIA certified and 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 efforts focused predominantly in the United States. We also have collaborative arrangements with other laboratory services companies.

Our commercialization efforts for our clinical services are mainly focused on endocrine (thyroid), and gastroenterologic (pancreatic) cancers. Communication of our marketing messaging and value propositions is accomplished through multiple channels, including two field-based commercial sales teams of approximately 40 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 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.

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 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 or local institution-created tests to diagnose gastrointestinal and endocrine cancers. 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 distributes the Afirma test in partnership with Veracyte. Sonic, Inc., or Sonic, offers ThyroSeq[®], a diagnostic test that analyzes genetic alterations using next-generation sequencing.

We are currently not aware of any direct competitors to PancaGEN[®] that fully 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 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 PancaGEN[®]. This competitive laboratory test also does not follow current physician patient management decision-making which includes the integration of clinical features 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 PancaGEN[®]. PancaGEN[®] has been validated in multiple studies and peer reviewed publications and has been used in over 80,000 patients with up to approximately ~8 years of patient follow-up information.

Given the size of the Barrett's Esophagus market, there are companies who are either in the process of developing assays and LDTs to identify the condition or who have started to commercialize diagnostic tests, such as the methylated biomarker test currently being marketed by Lucid Diagnostics. We anticipate that this space will become increasingly competitive as new diagnostic tests come to market in the future.

It is also possible that we face future competition from other laboratory-developed tests (LDT's), developed by commercial laboratories or by other diagnostic companies utilizing different technologies in the gastrointestinal and endocrine cancer molecular diagnostic tests space.

Research and Development

We continue to generate and publish clinical evidence mainly related to our key products, including ThyGeNEXT[®] and ThyraMIR[®]v2 and PancaGEN[®].

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.

As part of our growth strategy, 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 \$0.6 million in 2024 and 2023, respectively.

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, 2024, we owned nine 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, 2024, we owned four issued patents outside of the United States, one each in Australia, Canada, Japan, and Israel. As of December 31, 2024, 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.

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), PancreGEN[®], 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 the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), the Food and Drug Administration (“FDA”) has claimed regulatory authority over 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. On April 29, 2024, however, the FDA published a final rule on LDTs, in which the FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories running LDTs will be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements, as well as requirements for maintenance of complaint files under the FDA’s quality systems regulation (QSR). In Phase 2 (effective May 6, 2026), clinical laboratories will be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for the remaining QSR requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories will be required to comply with all remaining applicable QSR requirements. In Phase 4 (effective November 6, 2027), clinical laboratories will be required to comply with premarket review requirements for high-risk tests (i.e., tests subject to the premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories will be required to comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to the de novo or 510(k) requirement).

Under the final rule, several types of tests will be eligible for some degree of continued enforcement discretion. For example, LDTs approved by the New York State Department of Health will be exempt from premarket review requirements but will remain subject to the requirements of Phases 1 through 3. Similarly, LDTs first marketed prior to May 6, 2024 that are not subsequently modified, or are modified only in certain limited ways, will be exempt from the premarket review and most quality systems requirements, but will remain subject to the requirements of Phases 1 and 2. The FDA notes, however, that it retains discretion to pursue enforcement action for violations of the Federal Food, Drug and Cosmetic Act at any time and intends to do so when appropriate. The FDA further explains that it may update any of the enforcement discretion policies set forth in the final rule as circumstances warrant or if the circumstances that inform those policies change, consistent with the FDA’s good guidance practices.

To the extent the FDA ultimately regulates certain LDTs, our LDTs may be subject to certain additional regulatory requirements. Complying with the FDA’s requirements can be expensive, time-consuming, and subject us to significant or unanticipated delays. Insofar as we may be required to obtain premarket clearance or approval to perform or continue performing an LDT, we cannot assure you that we will be able to obtain such authorization. Even if we obtain regulatory clearance or approval where required, such authorization may not be for the intended uses that we believe are commercially attractive or are critical to the commercial success of our tests. As a result, the application of the FDA’s requirements to our tests could materially and adversely affect our business, financial condition, and results of operations.

Failure to comply with applicable requirements could result in a range of enforcement actions 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.

Legislative proposals have also been introduced that, if enacted, would potentially supersede the final rule. In March 2017, members of Congress posted a discussion draft of “The Diagnostics Accuracy and Innovation Act”. 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 has been re-introduced in substantially similar forms over the years, and, most recently in March 2023. Under the most recent version of the VALID Act, a risk-based approach would be used to regulate IVCTs while grandfathering many existing IVCTs from certain requirements. 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 would include quality control and post-market reporting requirements. The FDA would have the authority to withdraw from the market IVCTs if there is a reasonable likelihood that such tests will cause death or serious adverse health consequences (among other criteria). Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions. However, 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.

Whether via statute, regulation, or sub-regulatory action, any FDA effort to end enforcement discretion for LDTs is likely to continue to be met with resistance by certain sections of industry. Multiple lawsuits have been filed challenging the April 2024 LDT final rule, in which the plaintiffs argue that the FDA lacks authority to regulate LDTs as medical devices. We cannot predict the likelihood of success of these or any other such actions, nor can we quantify the effect of such efforts on our business.

Healthcare, Fraud, Abuse and Anti-Kickback Laws

The federal 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, to another person or entity if the payment is intended to induce the recipient to refer an individual to a person or to purchase, order, arrange for or recommend the purchase of any item or service that is reimbursable under any federal health care program. A violation of the Anti-Kickback Statute, which is an intent-based statute, may result in imprisonment of up to 10 years and fines of up to \$100,000 for each violation, or both. Convictions under the Anti-Kickback Statute result in mandatory exclusion from federal health care programs, generally for a minimum of five years. In addition, the United States Department of Health and Human Services (HHS) has the authority to impose civil monetary penalties and fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs. Civil monetary penalties may be imposed of up to \$124,732 per violation and damages of up to three times the total amount of remuneration offered, paid, solicited or received (these per-claim penalties are adjusted for inflation from time to time). Violations of the Anti-Kickback Statute may, also incur liability under the federal False Claims Act, discussed in more detail below, which prohibits, among other things, 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 health care programs, a number of states have passed statutes substantially similar to the Anti-Kickback Statute, which prohibit similar conduct toward other payers, including some that apply to all health plans, third-party payers, and cash-pay patients. Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed to improperly 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. Several 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 for or purchases of items or services reimbursable by federal health care programs.

In addition to the Anti-Kickback Statute, the Eliminating Kickbacks in Recovery Act of 2018, (EKRA) was enacted 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, among other things, pay any remuneration to induce referrals to, or in exchange for an individual 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 proposed or final 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, among other things, 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 False Claims Act authorizes actions to be brought on behalf of the federal government by a private party, known as a relator, 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 relator succeeds in obtaining redress without the government’s involvement, then the relator 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 between \$13,946 and \$27,894 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 clinical laboratory services and certain other “designated health 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 False Claims Act litigation that the Stark Law applies to Medicaid claims. Some states have also enacted state Stark Law equivalents that can apply, for example, to that state’s Medicaid plan and/or commercial payors and self-pay patients.

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 \$30,868 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 \$205,799 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. Unlike the Anti-Kickback Statute or EKRA, 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 health care 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, EKRA, Stark Law, and other fraud and abuse liability. Our arrangements with healthcare providers are designed to meet available safe harbors and exceptions provided in the anti-kickback laws and self-referral laws and other relevant laws or otherwise comply with such laws. 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. 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 take 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 health care 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 use such individually identifiable health information perform functions as a "business associate" for or on behalf of a covered entity. Individually identifiable health information maintained by covered entities and business associates is referred to as "protected health information" or "PHI." 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 protected 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 protected health information (45 C.F.R. §§ 164.302, et seq.); and "Notification in the Case of Breach of Unsecured Protected Health Information", which requires business associates to provide certain notifications to covered entities and covered entities to provide certain notifications to affected individuals, HHS and, in some cases, relevant media outlets following a breach of unsecured protected health information (45 C.F.R. §§ 164.400, et seq.). As a covered entity, and also in our capacity as a business associate to certain of our customers, we are subject to these standards. 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 protected 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 have enacted privacy and security statutes or regulations regarding individually identifiable health information that, in some cases, are more stringent than those issued under HIPAA and HITECH. 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 preempt 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 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.

More than a dozen states have adopted comprehensive consumer privacy laws that are in effect or will take effect within the next 12 to 24 months, and regulate how certain for-profit businesses collect, use, and disclose the personal information of consumers who reside in each respective state. While the specific consumer rights vary from state-to-state, generally these laws confer to consumers in the state 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 or the use of their information for targeted advertising. These laws also require companies to adopt reasonable measures to safeguard the personal information that is collected 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, de-identified data as defined under HIPAA or in some instances, HIPAA-regulated entities. 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 consumers' personal information, for example from website visitors. These state consumer privacy laws are generally enforced by the respective state Attorney General. California's law also includes a private right of action for certain data breaches.

Washington State has passed the My Health My Data Act or MHMDA, which comes into effect on March 31, 2024. MHMDA regulates consumer health data that is not otherwise subject to HIPAA. The definition of "consumer health data" is broad and applies to a variety of health-related information including non-health information that is used to infer some aspect of current or future medical conditions. MHMDA requires additional transparency requirements related to how companies handle non-HIPAA covered health data as well as additional technical safeguards for "consumer health data." MHMDA also requires that companies obtain the consent of individuals for certain uses of their "consumer health data." MHMDA also gives Washington residents a variety of rights, similar to those in the state consumer privacy laws discussed above, and related to the resident's "consumer health data." Unlike the consumer state laws, MHMDA includes a private right of action. Should the company become subject to an action brought under MHMDA, it could have an impact on our operations. Nevada and Connecticut has passed substantially similar consumer privacy health laws that have or will come into effect in 2024. However, the Nevada and Connecticut laws do not include a private right of action.

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 most recently upheld the surviving elements of the law in 2021.

Further changes to the PPACA remain possible. The Trump Administration has signaled 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 types. 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 health care 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 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 the Centers for Medicare and Medicaid Services (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. Since 2021, we have been contracted with XIFIN, Inc. ("XIFIN"), a healthcare billing services management company, to help manage our third-party billing.

Some billing arrangements require us to bill multiple payers, and there are several other factors that complicate billing (e.g., disparity in coverage and information requirements among various payers; and incomplete or inaccurate billing information provided by ordering physicians). Several private payers have 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 timely 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 Food and Drug Administration (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. 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.

PAMA, as amended by the Protecting Medicare and American Farmers from Sequester Cuts Act, among other laws, revised payment reductions and the data reporting schedule for approved Clinical Diagnostic Laboratory Tests ("CDLTs") that are not Advanced Diagnostic Laboratory Tests. Under these laws, the next data reporting period is January 1, 2025 through March 31, 2025, 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 2025 through 2027. Payments will not be reduced for 2021 through 2024 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 (as amended) calls for further revisions of the Medicare Clinical Laboratory Fee Schedule for years after 2024, based on 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 53% and 51% of our consolidated net revenues during 2024 and 2023, respectively. 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 Medicare fee-for-service programs to the private health insurance plans, called “Medicare Advantage” plans. There has been growth of health insurance payors offering Medicare Advantage plans and of beneficiary enrollment in these plans.

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 does not 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 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. 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 reflected the expansion of the ThyGeNEXT[®] panel to aid in identifying the appropriate patients for surgery.

In January 2022, the Company announced 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. 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 was previously reimbursing the Company for one of its two thyroid tests, and had agreed to retroactively reimburse for the second test once they had completed their internal administrative adjustments. We were notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 would 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.

On June 5, 2023 we announced that Novitas issued the final LCD of Genetic Testing for Oncology (L39365) which, if implemented, would have established non-coverage for the Company's widely used PancaGEN[®] test effective July 17, 2023. On July 6, 2023, Novitas announced that it would not be implementing the final Genetic Testing for Oncology LCD (L39365) as scheduled on July 17, 2023. Novitas then issued a new, virtually identical proposed LCD affecting the same companies and tests and reaching the same conclusions as noted in the previously rescinded LCD on July 27, 2023. In response, we participated in a public meeting presentation and submitted detailed written comments supporting the use of PancaGEN[®]. The timing and content of any final, implemented LCD was uncertain at that time. As a result, we are able to continue offering PancaGEN[®] and the related Point2[®] fluid chemistry tests for amylase, CEA, and glucose throughout 2024. On January 9, 2025, the Company announced the new LCD established non-coverage for its PancaGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancaGEN[®] testing after February 7th, 2025. On January 27, 2025, the Company announced that CMS had directed its MACs, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump Administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect. In the event Novitas ultimately restricts coverage for the PancaGEN[®] test, our liquidity could be negatively impacted.

Reporting Segments

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

Employees

As of March 21, 2025, we had 111 full time employees and 111 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 Waterview Plaza, Suite 310, 2001 Route 46, Parsippany, New Jersey 07054. Our telephone number is (855) 776-6419.

Business Development

Series C Preferred Stock Investment by 1315 Capital and Ampersand

On October 10, 2024, the Company, Ampersand 2018 Limited Partnership ("Ampersand") and 1315 Capital II, L.P. ("1315 Capital and, together with Ampersand, the "Investors") entered into an Exchange Agreement (the "Exchange Agreement") pursuant to which the Company exchanged (the "Exchange") an aggregate of 47,000 shares of the Company's existing Series B convertible preferred stock of the Company, par value \$0.01 per share (the "Series B Preferred Stock"), comprised of 28,000 shares of Series B Preferred Stock held by Ampersand and 19,000 shares of Series B Preferred Stock held by 1315 Capital, which represented all of the Company's issued and outstanding Series B Preferred Stock, for 47,000 newly created shares of Series C Preferred Stock, par value \$0.01 per share (the "Series C Preferred Stock"), at an issuance price per share of \$1,000 (the "Stated Value"). In the Exchange, Ampersand received 28,000 shares of Series C Preferred Stock and 1315 received 19,000 shares of Series C Preferred Stock.

The Series C Preferred Stock is convertible into the Company's common stock, par value \$0.01 per share (the "Common Stock") at a conversion price of \$2.02 per share of Common Stock (subject to further adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares) (the "Series C Conversion Price") which was the closing price of the Common Stock on the date of the Exchange Agreement. The Series C Preferred Stock does not have a liquidation preference over the Common Stock in the event of a sale or dissolution of the Company, does not have director designation rights and includes limited customary protective provisions. The Series B Preferred Stock had a conversion price of \$6.00 per share of Common Stock and included additional protective provisions not applicable to the Series C Preferred Stock, including (i) limitations on the Board of Directors of the Company (the "Board") to declare dividends, (ii) director designation rights for each of the Investors, (iii) liquidation rights of holders upon "deemed liquidation" events, including a liquidation preference over the Common Stock, (iv) limitations on the ability to authorize, issue or create debt securities, (v) limitations on the ability to enter into mergers or acquisitions and (vi) limitations on the ability to conduct public offerings of the Company's Common Stock.

The closing of the transactions contemplated by the Exchange Agreement occurred on October 11, 2024 following the satisfaction of customary conditions set forth in the Exchange Agreement and did not result in the receipt of any cash proceeds by the Company.

Certificate of Designation of Series C Convertible Preferred Stock

In connection with the Exchange, on October 11, 2024, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation"), with the Secretary of State of the State of Delaware. Each capitalized term used herein and not otherwise defined shall have the meaning ascribed to it in the Certificate of Designation.

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 C Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of Common Stock, into which the shares of Series C 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 C Preferred Stock will vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

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 C 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 the product of the Series C Conversion Ratio (the "**Series C Conversion Ratio**") and the number of shares of Series C Preferred Stock to be converted. The Series C Conversion Ratio is calculated by dividing the Stated Value per share of Series C Preferred Stock by the Series C Conversion Price. The Series C Conversion Ratio is subject to adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization which results in the adjustment of the Series C Conversion Price.

The aggregate number of shares of Common Stock that may be issued through conversion of all of the Exchange Shares is 23,267,326 shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares).

Mandatory Conversion

Immediately prior to the Company's listing of Common Stock on The Nasdaq Stock Market, all outstanding shares of Series C Preferred Stock shall automatically convert into a number of shares of Common Stock equal to the product of the Series C Conversion Ratio and the number of shares of Series C Preferred Stock owned by each holder.

Dividends

The Certificate of Designation does not provide for mandatory dividends on the Series C Preferred Stock. Dividends may be declared and paid on the Series C Preferred Stock from funds lawfully available and as determined by the Board.

Protective Provisions

For so long as any shares of Series C Preferred Stock are outstanding, the written consent of each holder of the then outstanding shares of Series C Preferred Stock is required for the Company or its subsidiaries to (i) amend, waive, alter or repeal the preferences, rights, privileges or powers of the holders of the Series C Preferred Stock, (ii) amend, alter or repeal any provision of the Certificate of Designation in a manner adverse to the holders of the Series C Preferred Stock or (iii) authorize, create or issue any equity securities senior to or pari passu with the Series C Preferred Stock.

Liquidation

Upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C Preferred Stock then outstanding will be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders on a pari passu basis with the holders of the Common Stock of the Company.

Amended and Restated Investor Rights Agreement

In connection with the Exchange, on October 10, 2024, the Company and the Investors entered into an amended and restated investor rights agreement (the "Amended and Restated Investor Rights Agreement"), which amended and restated that certain Amended and Restated Investor Rights Agreement, dated as of January 15, 2020, among the Company and the Investors (the "Prior Investor Rights Agreement"). Pursuant to the Amended and Restated Investor Rights Agreement, the Company and the Investors established certain terms and conditions concerning the rights of and restrictions on the Investors with respect to the ownership of the Series C Preferred Stock of the Company.

The Amended and Restated Investor Rights Agreement provides the Investors with (1) demand registration rights exercisable beginning on the date of the Closing and subject to certain limitations described therein, (2) piggy-back registration rights at any time the Company proposes to file a registration statement under the Securities Act, with respect to an offering of equity securities, or securities or other obligations exercisable or exchangeable for, or convertible into, equity securities, subject to certain exceptions described therein, and (3) shelf registration rights.

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.
- 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, particularly with respect to our PancreGEN test which is being reviewed by CMS, 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 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 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.
- Two private equity firms and their affiliate's control, on an as-converted basis, an aggregate of 84% of our outstanding shares of common stock through their holdings of our Series C Preferred Stock, and this concentration of ownership may have a substantial influence on our decisions.
- 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.
- 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.
- 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.
- 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.
- FDA implementation of the LDT final rule would have a material adverse effect on our clinical services and/or cause us to incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and comply with applicable pre- and post-market requirements.

- We may not be able to successfully implement future restructuring activities or other significant organizational changes.
- The loss of members of our senior management team or our inability to attract and retain key personnel could adversely affect our business.
- If we fail to comply with federal, state and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.
- Legislation reforming the U.S. healthcare system may have a material adverse effect on our financial condition and operations.
- Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.
- 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.
- 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.
- The delisting of our common stock from Nasdaq and potential delisting from OTCQX[®] has adversely affected our common stock and business and financial condition.
- The restatement of prior period financial statements may affect investor confidence and raise reputational issues.
- If we do not effectively remediate the material weakness in our internal control existing as of December 31, 2024, or if we otherwise fail 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.
- Any weakness in our disclosure controls and procedures and our internal controls could have a material adverse effect on us.
- We have anti-takeover defenses that could delay or prevent an acquisition and could adversely affect the price of our common stock.

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 maintain being a profitable operating company is dependent upon our ability to continue to generate revenues and/or obtain financing adequate to support our cost structure.

For the fiscal year ended December 31, 2024, we had operating income from continuing operations of \$8.1 million. As of December 31, 2024, we had cash and cash equivalents of \$1.5 million and current liabilities of \$10.6 million. 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.

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 and Medicare Advantage was approximately 53% of our revenue for the fiscal year ended December 31, 2024. 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 was reimbursing the Company for one of its two thyroid tests, and had agreed to retroactively reimburse for the second test once they had completed their internal administrative adjustments. We were notified by CMS/NCCI that processing of claims for dates of service after January 1, 2022 would 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 PancaGEN[®], 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.

On June 5, 2023 we announced that Novitas issued the final LCD of Genetic Testing for Oncology (L39365) which if implemented, would have established non-coverage for the Company's widely used PancaGEN[®] test effective July 17, 2023. On July 6, 2023, Novitas announced that it would not be implementing the final Genetic Testing for Oncology LCD (L39365) as scheduled on July 17, 2023. Novitas then issued a new, virtually identical proposed LCD affecting the same companies and tests and reaching the same conclusions as noted in the previously rescinded LCD on July 27, 2023. In response, we participated in a public meeting presentation and submitted detailed written comments supporting the use of PancaGEN[®]. The timing and content of any final, implemented LCD was uncertain at that time. As a result, we are able to continue offering PancaGEN[®] and the related Point2[®] fluid chemistry tests for amylase, CEA, and glucose throughout 2024. On January 9, 2025, the Company announced the new LCD established non-coverage for its PancaGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancaGEN[®] testing after February 7, 2025. On January 27, 2025, the Company announced that CMS had directed Novitas to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect. In the event Novitas ultimately restricts coverage for the PancaGEN[®] test, our liquidity could be negatively impacted.

Our ThyraMIR[®]v2 and ThyGeNEXT[®] tests are and, until April 24, 2025 our PancaGEN[®] test is 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.

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.

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;
- 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.

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, the proceeds of which were used to repay in full at their maturity the Notes extended by our two private equity investors (the “Term Loan”). The Term Loan 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 Term Loan also contains customary events of default. The Comerica agreement was repaid in full in 2023 and the agreement was terminated in February 2024. The Comerica loan agreement contained affirmative and negative restrictive covenants that were applicable whether or not any amounts are outstanding under the Comerica loan agreement. These restrictive covenants, which included restrictions on certain mergers, acquisitions, investments, encumbrances, etc., could have adversely affected our ability to conduct our business. The Comerica loan agreement also contained financial covenants requiring specified minimum liquidity and minimum revenue thresholds as well as 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. The term loan has been subsequently amended several times. See Note 13, *Notes Payable* to Notes to Consolidated Financial Statements.

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. In addition, we are currently ineligible to use a Form S-3 shelf registration statement. If we are unable to timely repay the BroadOak borrowing when due, BroadOak will have the right to foreclose on our assets. 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 lender will have the right to foreclose on our assets.

In October 2021, the Company entered into an \$8.0 million term loan with BroadOak, which is secured by all of our assets and has a maturity date of December 31, 2025. 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. The term loan has been subsequently amended several times. See Note 13, *Notes Payable* to Notes to Consolidated Financial Statements. We may 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 lender 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 C Preferred Stock.

Two private equity firms and their affiliate's control, on an as-converted basis, an aggregate of 84% of our outstanding shares of common stock through their holdings of our Series C Preferred Stock, and this concentration of ownership may have a substantial influence on our decisions.

Ampersand holds 28,000 shares of our Series C Preferred Stock and 1315 Capital holds 19,000 shares of our Series C Preferred Stock. Accordingly, on an as converted basis, Ampersand and its affiliates beneficially own 50% of the Company's outstanding common stock of 4,423,093 shares and 1315 Capital and its affiliates beneficially own 34%. 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. The Series C Preferred Stock issuance removed the director designation rights that Ampersand and 1315 Capital had as holders of Series B Preferred Stock, now exchanged for Series C Preferred Stock. This concentration of ownership of Ampersand and 1315 Capital 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.

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, particularly with respect to PancreGEN;
- 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.

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

Physicians may generally not order our clinical services tests unless payers reimburse a substantial portion of the test price. There is uncertainty concerning third-party reimbursement of any test incorporating new molecular diagnostic technology. Reimbursement by a payer may depend on a number of factors, including a payer's determination that tests such as our molecular diagnostic tests are: (a) not experimental or investigational; (b) pre-authorized and appropriate for the patient; (c) cost-effective; (d) supported by peer-reviewed publications; and (e) included in clinical practice guidelines. Since each payer generally makes its own decision as to whether to establish a policy or enter into a contract to reimburse our clinical services tests, seeking these approvals is a time-consuming and costly process. Although we have contracted rates of reimbursement with certain payers, which establishes allowable rates of reimbursement for our PancraGEN[®], ThyGeNEXT[®], ThyraMIR[®]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, may establish non-coverage for our tests, 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. See Part I – Item 1 – “Business – Government Regulations and Industry Guidelines - Third Party Coverage and Reimbursement for our Clinical Services – Novitas LCD for PancraGEN[®]”.

We have contracted rates of reimbursement with select payers for PancraGEN[®], 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 maintain profitability. 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 many 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.

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. For more information, on how reimbursement has been affected for our PancreGEN test, please see Part I – **Item 1 – “Business – Government Regulations and Industry Guidelines - Third Party Coverage and Reimbursement for our Clinical Services – Novitas LCD for PancreGEN.”**

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.

FDA implementation of the LDT final rule would have a material adverse effect on our clinical services and/or cause us to incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and comply with applicable pre- and 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* diagnostics or “IVDs”), specimen collection kits, analyte specific reagents (ASRs), and instruments used in conducting diagnostic testing as medical devices. Most tests offered as LDTs have historically been 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.

On April 29, 2024, however, the FDA published a final rule on LDTs, in which the FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories running LDTs will be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements, as well as requirements for maintenance of complaint files under the FDA’s quality systems regulation (QSR). In Phase 2 (effective May 6, 2026), clinical laboratories will be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for the remaining QSR requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories will be required to comply with all remaining applicable QSR requirements. In Phase 4 (effective November 6, 2027), clinical laboratories will be required to comply with premarket review requirements for high-risk tests (i.e., tests subject to the premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories will be required to comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to the de novo or 510(k) requirement).

Under the final rule, several types of tests will be eligible for some degree of continued enforcement discretion. For example, LDTs approved by the New York State Department of Health will be exempt from premarket review requirements but will remain subject to the requirements of Phases 1 through 3. Similarly, LDTs first marketed prior to May 6, 2024 that are not subsequently modified, or are modified only in certain limited ways, will be exempt from the premarket review and most quality systems requirements, but will remain subject to the requirements of Phases 1 and 2. The FDA notes, however, that it retains discretion to pursue enforcement action for violations of the Federal Food, Drug and Cosmetic Act at any time and intends to do so when appropriate. The FDA further explains that it may update any of the enforcement discretion policies set forth in the final rule as circumstances warrant or if the circumstances that inform those policies change, consistent with the FDA's good guidance practices.

If we are required to submit applications to FDA for our currently-marketed clinical tests and any tests that we may develop in the future, 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, authorization or approval, as well as significant adverse publicity. Any other regulatory or legislative framework 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 diagnostic purposes.

If the FDA seeks to enforce the applicable medical device regulations against our clinical services tests, we could also be subject 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

We may not be able to successfully implement future restructuring activities or other significant organizational changes.

We have, from time to time, restructured or made other adjustments to our workforce and manufacturing footprint. For example, in response to the new LCD which established non-coverage for our PancreaGEN[®] test as discussed elsewhere in this Annual Report, we announced that our board of directors had approved the Restructuring Plan (as defined below) to reduce operating costs and better align its workforce with the loss of PancreaGEN[®]. As a result of CMS' determination to delay implementation of the Genetic Testing for Oncology LCD (L39365) until April 24, 2025, the Company is re-evaluating certain parts of the Restructuring Plan and will determine what parts will or will not be postponed, or cancelled. For more information on the Restructuring Plan, please see Part II – **Item 7 – “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Potential Restructuring.”**

In the event we proceed with some or all parts of the Restructuring Plan, there are significant costs involved with the execution of restructuring programs or other significant organizational changes, including expenses related to severance, asset impairments and other potential charges. There are also significant risks involved with such changes, including the potential for significant business disruption, diversion of management’s time and attention from ongoing operations, loss of human capital talent, temporarily reduced productivity and the risk of failing to achieve some or all of the anticipated benefits of the restructuring or organizational changes. We may need to implement additional restructuring plans or other strategic initiatives in the future in response to market or product changes, performance issues, changes in strategy, acquisitions and/or other internal or external considerations. If we are unable to successfully manage and implement any future restructuring plan, we may not achieve or sustain the expected growth or cost savings benefits of these activities, or do so within the expected timeframe, and in such instance, our financial condition and results of operations could be materially adversely impacted.

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

As a small company with approximately 111 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. 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 PancraGEN[®] in the gastrointestinal market, technology such as a next-generation sequencing mutation panel could in the future lead to increased competition.

It is also possible that we face future competition from laboratory developed tests, or LDTs, developed by commercial laboratories such as Quest and/or other diagnostic companies developing new molecular diagnostic tests or technologies. Furthermore, we may be subject to competition as a result of the new, unforeseen technologies that can be developed by our competitors in the gastrointestinal and endocrine cancer molecular diagnostic testing space. To compete successfully, we must be able to demonstrate, among other things, that our test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our tests. Since our clinical services began in 2014, many of our potential competitors have stronger brand recognition and greater financial capabilities than we do. Others may develop a test with a lower price than ours that could be viewed by physicians and payers as functionally equivalent to our molecular diagnostic tests or offer a test at prices designed to promote market penetration, which could force us to lower the price of our clinical services tests and affect our ability to achieve and maintain profitability. If we are unable to compete successfully against current and future competitors, we may be unable to increase market acceptance of our clinical services tests and overall sales, which could prevent us from increasing our revenue or achieving profitability and cause the market price of our common stock to decline. As we add new clinical services tests and other products and services, we will likely face many of these same competitive risks that we do currently.

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, 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 may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

If 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.

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. Recently, in certain states, there has been an increase in private litigation alleging that the use of cookies and similar tracking technologies without consent violates state laws governing “wiretapping,” “trap and trace,” “pen registers,” and similar laws. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, our processing of personal data may become subject to the European Union’s General Data Protection Regulation or the United Kingdom’s General Data Protection Regulation. Each of these regulations requires stringent standards of data privacy and security concerning personal data and potentially significant sanctions. 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 approximately 111 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 maintain profitability 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 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 surviving portions of 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 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 2024, based on surveys of market rates. Further reductions in reimbursement may result from such revisions.

PAMA, as amended by the Protecting Medicare and American Farmers from Sequester Cuts Act, among other laws, 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, 2025 through March 31, 2025, 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 2025 through 2027. Payments will not be reduced for 2021 through 2024 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, among other things, 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, among other things, 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 health care 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, and an entity receiving the referral from billing for, certain designated health services covered by the Medicare program, including clinical laboratory 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 establishes 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, make certain disclosures about our data privacy and security practices to the public and certain state or federal regulators, minimize our use of personal information of consumers, 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, and similar state laws that require 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 certain payments and other transfers of value, directly or indirectly, to physicians (defined to include doctors of medicine, osteopathy, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives, and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- The 21st Century Cures Act information blocking provision prohibiting certain covered actors (including laboratories) from engaging in certain practices that are likely to interfere with the access, exchange, or use of electronic health information;
- 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, as amended, 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 among other requirements, 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 if the test is performed by a physician who does not “share a practice” with the billing physician or other 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. Many of these bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil or 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, arrangements generally must be commercially reasonable and often 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, unless an exception applies. Entities found in violation may be liable for civil monetary penalties of up to \$24,164 for each wrongful act, adjusted for inflation. 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, among other things, pay any remuneration to induce referrals to, or in exchange for, an individual 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. A failure to comply with EKRA could result in substantial penalties and other adverse consequences that adversely affect our business, financial condition and results of operations.

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. 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 incurred net losses from 2015-2022 and may never achieve sustained profitability. As of the fiscal year ended December 31, 2024, we had U.S. federal and state net operating losses, or NOLs, of approximately \$115.0 million and \$55.1 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 \$66.5 million are subject to annual limitation for ownership changes and the Company is utilizing \$4.0 million during the current year. The remaining \$52.5 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. 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. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws or regulations on an investment in our common stock.

Global economic and political instability and geopolitical events could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. Changes to policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, during the prior Trump administration, increased tariffs were implemented on goods imported into the U.S., particularly from China, Canada, and Mexico. On February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. The global credit and financial markets have also generally experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be No assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur.

A weak or declining economy could also result in supply chain disruptions, volatile demand for our products, abrupt changes in our customers' buying patterns, limitations on our customers' access to financial resources and ability to satisfy obligations to us, or other adverse impacts to our ability to place our Growth Direct systems. Furthermore, although we do not have any customer or direct supplier relationships in Ukraine, Russia or the Middle East at this time, the ongoing military conflicts in those regions and related sanctions, as well as export controls or actions that may be initiated by nations including the United States, the European Union, Russia or other jurisdictions, and other potential uncertainties could adversely affect our business and/or our supply chain, business partners or customers. In the event geopolitical tensions fail to abate or deteriorate further, additional governmental sanctions may be enacted adversely impacting the global economy, its banking and monetary systems, markets or customers for our products.

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. 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. 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 2024, our common stock traded at a low of \$0.82 and a high of \$3.54. During 2023, our common stock traded at a low of \$0.62 and a high of \$3.54. 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;
- 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 CMS/Novitas reimbursement decisions of our PancreaGEN product;
- 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 C 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 potential delisting from 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 December 28, 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. On March 20, 2024 we received notice from the OTCQX indicating that the Company's market capitalization has stayed above the required \$5 million for ten consecutive trading days preceding the date of such notice, and that the Company currently satisfies the standards for continued qualification for the OTCQX U.S. tier under the OTCQX Rules for U.S. Companies.

Delisting from the OTCQX could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our Common Stock. Delisting could also have other negative results, including the potential loss of confidence by employees and customers, the loss of institutional investor interest and fewer business development opportunities. The Company may seek an uplisting of its common stock to Nasdaq, but no assurances can be given that a Nasdaq listing will be achieved.

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, such as the material weakness described in Item 9A of this report, 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. See the material weakness described in Item 9A. 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.

We reached a determination to restate certain of our previously issued consolidated financial statements as a result of the identification of errors in previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues.

As discussed in the Explanatory Note, in Note 2 of our consolidated financial statements, *Restatement of Previously Issued Consolidated Financial Statements*, and in Note 22, *Restatement of Unaudited Quarterly Results*, in this Annual Report on Form 10-K for the year ended December 31, 2024, we reached a determination to restate certain of our historical consolidated financial statements and related disclosures for the periods disclosed in those notes after identifying errors in our accounting treatment of accrued royalty expenses. The restatement also included corrections for previously identified immaterial errors in the impacted periods. As a result, we have incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and have become subject to a number of additional risks and uncertainties, which may affect investor confidence in the accuracy of our financial disclosures and may raise reputational risks for our business, both of which could harm our business and 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, 2024, we had 95,460,337 shares of common stock and 4,953,000 shares of preferred stock available for issuance. As of December 31, 2024, we have reserved 481,494 shares of our common stock for issuance under our 2019 Equity Incentive Plan, 1,000,007 shares of our common stock for issuance under our Employee Stock Purchase Plan and 1,796,268 additional shares available for future grants of awards under our 2019 Equity Incentive Plan. As of December 31, 2024, the aggregate number of shares of common stock that may be issued through conversion of all of the outstanding Series C Preferred Stock is 23,267,326. Provided that we have a sufficient number of unreserved authorized capital stock available, we may seek financing that could result in the issuance of additional shares of our capital stock and/or rights to acquire additional shares of our capital stock. We may also make acquisitions that result in issuances of additional shares of our capital stock. Those additional issuances of capital stock could result in substantial dilution of our existing stockholders. Furthermore, the book value per share of our common stock may be reduced. This reduction would occur if the exercise price of any issued warrants, the conversion price of any convertible notes or the conversion ratio of any issued preferred stock is lower than the book value per share of our common stock at the time of such exercise or conversion. Additionally, new investors in any subsequent issuances of our securities could gain rights, preferences and privileges senior to those of holders of common stock.

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

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

As discussed in “Item 9A-Controls and Procedures,” our senior management has identified material weaknesses in our disclosure controls and procedures and our internal controls over financial reporting. We cannot assure you that additional material weaknesses will not be identified in the future. Any such failure could adversely affect our ability to report financial results on a timely and accurate basis, which could have other material effects on our business, reputation, results of operations, financial condition or liquidity. If we do not effectively remediate the material weakness or if we otherwise fail to maintain effective internal control over financial reporting, our ability to report our financial results on a timely and on an accurate basis could be impaired, which may cause investors to lose confidence in our reported financial information which could adversely affect the market price of our common stock.

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 any class or series of preferred stock that may be issued in the future and by the rights of holders of warrants issued in the future.

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 1C. CYBERSECURITY

Cyber Risk Management and Strategy

We operate in the life sciences sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations. We have developed and maintain processes, aligned with industry standards and best practices designed to assess, identify, and manage cybersecurity risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. The scope of these processes includes risks that may be associated with both our internally managed information technology (“IT”) systems and key business functions and sensitive data operated or managed by or maintained at third-party service providers. These processes are managed and monitored by a dedicated information technology team, which is led by our head of IT, and include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data and maintain a stable information technology environment. We constantly monitor our information technology environment for abnormal behavior, conduct penetration and vulnerability testing, data recovery testing, security audits, and ongoing risk assessments, including due diligence on our key technology vendors and other third party service providers that have access to the personal information we collect, use, store, and transmit. We also conduct periodic employee trainings on cyber and information security, among other topics. We leverage standard industry tools from a software and hardware perspective and maintain a cybersecurity risk insurance policy.

We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, which have materially affected us, but we face certain ongoing cybersecurity risks threats that, if realized, are reasonably likely to materially affect us.

Governance Related to Cybersecurity Risks

The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Compliance Committee, which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Compliance Committee receives periodic updates on cybersecurity and information technology matters and related risk exposures. The Board also receives updates from management and the Compliance Committee on cybersecurity risks on at least an annual basis.

Our Vice President of Information Technology has over 15 years of experience managing information technology and cybersecurity matters. The Vice President of Information Technology, together with our senior leadership team, are responsible for assessing and managing cybersecurity risks and they work collaboratively across our company to implement policies and procedures designed to protect our information and systems from cybersecurity threats and to respond promptly to any material cybersecurity incidents in accordance with our incident response plans. A cross-functional team is responsible for responding to cybersecurity incidents.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Parsippany, New Jersey. Our Parsippany, New Jersey lease is month-to-month. 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 “IDXG.” OTCQX Best Market quotations reflect inter-dealer prices and may not necessarily represent actual transactions.

On December 28, 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. On March 20, 2024 we received notice from the OTCQX indicating that the Company’s market capitalization has stayed above the required \$5 million for ten consecutive trading days preceding the date of such notice, and that the Company currently satisfies the standards for continued qualification for the OTCQX U.S. tier under the OTCQX Rules for U.S. Companies.

The Company may seek an uplisting of its common stock to Nasdaq, but no assurances can be given that a Nasdaq listing will be achieved.

Holders of Record

We had 184 stockholders of record as of March 21, 2025. 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.

Unregistered Sales of Equity Securities

On October 10, 2024, we and the Investors entered into the Exchange Agreement pursuant to which the Company exchanged an aggregate of 47,000 shares of the Company’s existing Series B Preferred Stock, comprised of 28,000 shares of Series B Preferred Stock held by Ampersand and 19,000 shares of Series B Preferred Stock held by 1315 Capital, which represented all of the Company’s issued and outstanding Series B Preferred Stock, for 47,000 newly created shares of Series C Preferred Stock. In the Exchange, Ampersand received 28,000 shares of Series C Preferred Stock and 1315 received 19,000 shares of Series C Preferred Stock.

The shares of Series C Preferred Stock issued in the Exchange were not registered under the Securities Act, and were issued in reliance on the exemptions from registration provided by Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder, for transactions not involving a public offering.

In connection with the Exchange, on October 10, 2024, the Company and the Investors entered the Amended and Restated Investor Rights Agreement. Pursuant to the Amended and Restated Investor Rights Agreement, the Company and the Investors established certain terms and conditions concerning the rights of and restrictions on the Investors with respect to the ownership of the Series C Preferred Stock of the Company.

The Amended and Restated Investor Rights Agreement provides the Investors with (1) demand registration rights exercisable beginning on the date of the Closing and subject to certain limitations described therein, (2) piggy-back registration rights at any time the Company proposes to file a registration statement under the Securities Act, with respect to an offering of equity securities, or securities or other obligations exercisable or exchangeable for, or convertible into, equity securities, subject to certain exceptions described therein, and (3) shelf registration rights

Use of Proceeds

None.

Repurchases

None.

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.*

In this Annual Report on Form 10-K, we have restated our previously issued consolidated financial statements as of and for the year ended December 31, 2023. See the “Explanatory Note” preceding Forward Looking Statements for background on the restatement, the fiscal periods impacted, control considerations, and other information. As a result, we have also restated our previously issued financial information as of and for the year ended December 31, 2023 and the relevant unaudited interim financial information for the quarterly periods in 2023 and 2024 in this Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, including but not limited to information within the Results of Operations to conform the discussion with the appropriate restated amounts. See Note 2 to our Consolidated Financial Statements included within Part II, Item 8 contained in this Annual Report on Form 10-K for additional information related to the 2023 Consolidated Financial Statements restatement including descriptions of the errors and the impact to our consolidated financial statements. See also Note 22 to our Consolidated Financial Statements included within Part II, Item 8 contained in this Annual Report for our restatement of unaudited interim condensed consolidated financial statements for 2023 and 2024. As a result of the restatement, it was determined that the Company’s disclosure controls and procedures were not effective as of December 31, 2024, and that the Company had identified material weaknesses in its internal controls over financial reporting, as referenced in Item 9A.

We have not amended and do not plan to amend our previously filed Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q for the periods affected by the restatement. The information that has been previously filed or otherwise reported for these periods is superseded by the information in this Form 10-K. Accordingly, the consolidated financial statements and related financial information contained in such previously filed or furnished reports should no longer be relied upon.

Company Overview

We are a company that provides esoteric molecular diagnostic testing, and pathology services to aid physicians in their evaluation of cancer risk in patients with indeterminate biopsies and a perceived high risk of cancer from clinical features. We develop and commercialize genomic tests and related first-line assays that can personalize medicine to help improve patient diagnosis and management.

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. 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 Solutions business. Effective January 1, 2023, the gapfill price for ThyGeNEXT[®] was set at \$1,266.07.

On June 5, 2023 the Company announced that Novitas issued the final LCD of Genetic Testing for Oncology (L39365) which, if finalized, would have established non-coverage for the Company's widely used PancaGEN[®] test effective July 17, 2023. On July 6, 2023, Novitas announced that it would not be implementing the final Genetic Testing for Oncology LCD (L39365) as scheduled on July 17, 2023. Novitas then issued a new virtually identical proposed LCD affecting the same companies and tests and reaching the same conclusions as noted in the previously rescinded LCD on July 27, 2023. In response, the Company participated in a public meeting presentation and submitted detailed written comments supporting the use of PancaGEN[®]. On July 29, 2024, the Company announced that CMS granted Novitas an undefined extension to the final decision for the LCD. As a result, the Company was able to continue offering PancaGEN[®] and the related Point2[®] fluid chemistry tests for amylase, CEA, and glucose for all of 2024.

On January 9, 2025, the Company announced the new LCD established non-coverage for its PancaGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancaGEN[®] testing after February 7, 2025. As a result of the established non-coverage for PancaGEN[®], the Company announced that its board of directors had approved a restructuring and cost-savings plan to reduce operating costs and better align its workforce with the loss of PancaGEN[®] (the "Restructuring Plan"). For more information, please see *Potential Restructuring* below.

On January 27, 2025, the Company announced that CMS had directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect.

Potential Restructuring

As discussed above in "Impact of Our Reliance on CMS and Novitas," on January 14, 2025, the Board of Directors approved a Restructuring Plan and cost-savings to reduce and better align its workforce with the anticipated loss of PancaGEN[®] coverage by CMS. However, due to the delay in the implementation of the new LCD from February 23, 2025 until April 24, 2025, the Company is re-evaluating certain parts of the Restructuring Plan and will determine what parts will or will not be postponed or cancelled.

Under the Restructuring Plan, if implemented, the Company would reduce its workforce and impacted employees would be eligible to receive severance benefits. The Company expects to incur severance costs in the range of \$0.8 million to \$1.0 million. The Company expects that the loss of PancraGEN[®] coverage, if it were to occur, and related restructuring activities would reduce its annual cost of revenue and operating expenses by approximately \$12.5 million to \$14.5 million which is expected to substantially offset the expected loss of its revenues from the sale of PancraGEN[®] tests. The cost that the Company expects to incur in connection with the Restructuring Plan is subject to several assumptions, and actual results may differ materially. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Restructuring Plan. In the event that CMS/Novitas does not remove coverage for PancraGEN[®], the Company anticipates that the Restructuring Plan will not be implemented in its current form. In the meantime, the Company is re-evaluating certain parts of the Restructuring Plan and will determine what parts will or will not be postponed, or cancelled.

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 increased surveillance or 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: PancraGEN[®], 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, which provides physicians the “molecular only” information provided within PancraGEN; ThyGeNEXT[®], an expanded oncogenic mutation panel that helps “rule-in” and “rule-out” malignancy in thyroid nodules; ThyraMIR[®]v2, used in combination with ThyGeNEXT[®], which further stratifies thyroid nodules for malignancy risk utilizing a proprietary microRNA gene expression classifier; 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.

The global esoteric molecular diagnostics market, valued at \$29.9 billion (USD) in 2023 and is expected to grow to \$48.3 billion (USD) by 2029 with a Compound Annual Growth rate or CAGR of 8.5% between 2023 and 2029, according to MarketsandMarkets™ (Report Code: MD5930, published June 2024).

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.

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 December 28, 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. On March 20, 2024 we received notice from the OTCQX indicating that the Company’s market capitalization has stayed above the required \$5 million for ten consecutive trading days preceding the date of such notice, and that the Company currently satisfies the standards for continued qualification for the OTCQX U.S. tier under the OTCQX Rules for U.S. Companies.

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 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.

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, 2024 and 2023, 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,			
	2024	2024 % to revenue	2023 (as restated)	2023 % to revenue
Revenue, net	\$ 46,926	100.0%	\$ 40,036	100.0%
Cost of revenue	17,001	36.2%	14,980	37.4%
Gross profit	29,925	63.8%	25,056	62.6%
Operating expenses:				
Sales and marketing	11,655	24.8%	10,233	25.6%
Research and development	676	1.4%	636	1.6%
General and administrative	9,486	20.2%	9,363	23.4%
Acquisition related amortization expense	-	0.0%	861	2.2%
Change in fair value of contingent consideration	-	0.0%	7	0.0%
Total operating expenses	21,817	46.5%	21,100	52.7%
Operating income	8,108	17.3%	3,956	9.9%
Interest accretion expense	(34)	-0.1%	(112)	-0.3%
Note payable interest expense	(625)	-1.3%	(896)	-2.2%
Other expense, net	(499)	-1.1%	(667)	-1.7%
Income from continuing operations before tax	6,950	14.8%	2,281	5.7%
Provision for income taxes	4	0.0%	17	0.0%
Income from continuing operations	6,946	14.8%	2,264	5.7%
Loss from discontinued operations, net of tax	(244)	-0.5%	(310)	-0.8%
Net income	\$ 6,702	14.3%	\$ 1,954	4.9%

Revenue, net

Consolidated revenue for the year ended December 31, 2024 increased by \$6.9 million, or 17%, to \$46.9 million, compared to \$40.0 million for the year ended December 31, 2023. The increase in net revenue was largely driven by increased test volumes as compared to the prior year.

Cost of revenue

Consolidated cost of revenue for the year ended December 31, 2024 increased by \$2.0 million, or 14%, to \$17.0 million, compared to \$15.0 million for the year ended December 31, 2023. This increase was primarily driven by the increased test volumes discussed above.

Gross Profit

Consolidated gross profit for the year ended December 31, 2024 increased \$4.8 million, or 19%, to \$29.9 million, compared to \$25.1 million for the year ended December 31, 2023. The increase can be attributed to the increase in revenue.

Sales and marketing expense

Sales and marketing expense was \$11.7 million for the year ended December 31, 2024 and \$10.2 million for the year ended December 31, 2023. The increase was primarily due to increased employee costs. As a percentage of revenue, sales and marketing expense was approximately 25% in both periods.

Research and development

Research and development expense was \$0.7 million for the year ended December 31, 2024 and \$0.6 million for the year ended December 31, 2023. As a percentage of revenue, research and development expense decreased to 1.4% from 1.6% in the prior year period due to the increase in revenue discussed above.

General and administrative

General and administrative expense was approximately \$9.5 million for the year ended December 31, 2024 and \$9.4 million for the year ended December 31, 2023. As a percentage of net revenue, general and administrative expense was 20% for the year ended December 31, 2024 as compared to 23% for the year ended December 31, 2023.

Acquisition related amortization expense

There was no amortization expense for the year ended December 31, 2024. During the year ended December 31, 2023, we recorded amortization expense of approximately \$0.9 million which was related to intangible assets associated with our acquisitions.

Operating income

Operating income from continuing operations was \$8.1 million for the year ended December 31, 2024 as compared to operating income of \$4.0 million for the year ended December 31, 2023. The increase in operating income was primarily attributable to the increases in revenue and gross profit discussed above.

Note payable interest expense

Note payable interest expense was \$0.6 million for the year ended December 31, 2024 and \$0.9 million for the year ended December 31, 2023. The interest expense was from the BroadOak loan.

Other expense, net

During the years ended December 31, 2024 and December 31, 2023, there were other expenses, net of approximately \$0.5 million and \$0.7 million, respectively. The amounts are primarily related to the fair value adjustments recorded on the note payable.

Provision for income taxes

Income tax expense was approximately \$4,000 for the year ended December 31, 2024 and \$17,000 for the year ended December 31, 2023. Income tax expense for both periods was primarily driven by Texas Gross Receipts Tax.

Loss from discontinued operations, net of tax

We had a loss from discontinued operations of approximately \$0.2 million and \$0.3 million for the years ended December 31, 2024 and December 31, 2023, respectively.

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, change in fair value of contingent consideration, and change in fair value of notes payable. 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,	
	2024	2023 (as restated)
Income from continuing operations (GAAP Basis)	\$ 6,946	\$ 2,264
Depreciation and amortization	300	1,026
Stock-based compensation	291	630
Tax expense	4	17
Interest accretion expense	34	112
Financing interest and related costs	625	896
Interest income	(48)	(53)
Change in fair value of note payable	547	678
Change in fair value of contingent consideration	-	7
Adjusted EBITDA	<u>\$ 8,699</u>	<u>\$ 5,577</u>

LIQUIDITY AND CAPITAL RESOURCES

In October 2021, the Company entered into the Term Loan with BroadOak, providing for a term loan in the aggregate principal amount of \$8,000,000. Funding of the Term Loan took place on November 1, 2021. The Term Loan was scheduled to mature 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 the Company's and its subsidiaries' assets and was subordinate to the Company's former \$7,500,000 revolving credit facility with Comerica Bank. The Term Loan has an origination fee of 3% of the Term Loan amount, and a terminal payment equal to (i) 15% of the original principal amount of the Term Loan if the change of control occurs on or prior to the first anniversary of the funding of the Term Loan, (ii) 20% of the original principal amount of the Term Loan if the change of control occurs after the first anniversary but on or prior to the second anniversary of the funding of the Term Loan and (iii) 30% of the original principal amount of the Term Loan if the change of control occurs after the second anniversary of the funding of the Term Loan, or if the Term Loan is repaid on its maturity date. Upon receipt of the term loan, the proceeds were used to repay in full at their maturity the notes extended by Ampersand and 1315 Capital discussed above. See Note 13, *Notes Payable*, for more details. 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 which was converted into a subordinated term loan and was added to the outstanding balance of the Term Loan. See Note 13, *Notes Payable*, for more details.

On October 24, 2023, the Company entered into a Second Amendment to the Loan and Security Agreement with BroadOak (the "Second Amendment"). The primary changes to the Term Loan were as follows:

- The Company made a one-time payment in an aggregate amount equal to \$2,500,000, on October 30, 2023 and applied the payment in full satisfaction of the \$3,000,000 Terminal Payment (as defined in the Term Loan). See Note 13, *Notes Payable*, regarding the Terminal Payment.
- Effective November 1, 2023, the interest rate under the Term Loan was reduced from 9% to 8% through the maturity date of October 31, 2024 or earlier, upon the occurrence of a change in control ("Loan Maturity Date").
- The Company has the option to request an extension of the Loan Maturity Date in writing no less than sixty days prior to the Loan Maturity Date. If BroadOak agreed to the extension, the Loan Maturity Date would automatically be extended.

On March 29, 2024, the Company entered into a Third Amendment to the Loan and Security Agreement with BroadOak (the "Third Amendment"), extending the loan maturity date to June 30, 2025. The primary changes to the Second Amendment were as follows:

- The maturity date was extended to June 30, 2025.
- Beginning April 1, 2024, the Company will make \$500,000 monthly payments with the remaining loan balance due on the new maturity date.

On January 14, 2025, the Company entered into a Fourth Amendment to the Loan and Security Agreement with BroadOak (the "Fourth Amendment"), extending the loan maturity date to December 31, 2025. The primary changes to the Third Amendment were as follows:

- The maturity date was extended to December 31, 2025.
- Beginning July 1, 2025, and continuing through December 1, 2025, the Company will make monthly interest-only payments with the remaining loan balance due on the new maturity date.

The Term Loan 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 Term Loan also contains customary events of default. The balance of the loan at December 31, 2024 was \$4.4 million.

For the year ended December 31, 2024, we had operating income from continuing operations of \$8.1 million. As of the year ended December 31, 2024, we had cash and cash equivalents of \$1.5 million, total current assets of \$11.8 million and current liabilities of \$10.6 million. As of March 21, 2025, we had approximately \$1.3 million of cash on hand, net of restricted cash.

During the year ended December 31, 2024, net cash provided by operating activities was \$4.6 million. The main component of cash provided by operating activities was net income of \$6.7 million. During the year ended December 31, 2023, net cash provided by operating activities was \$3.8 million. The main component of cash provided by operating activities was net income of \$2.0 million, and non-cash expenses of \$2.5 million.

During the year ended December 31, 2024, there was net cash used in investing activities of \$0.9 million which primarily pertained to capital expenditures associated with the lab. During the year ended December 31, 2023, there was net cash used in investing activities of \$0.1 million.

For the year ended December 31, 2024, cash used in financing activities was \$5.8 million, of which \$5.6 million was for principal repayments of the BroadOak loan. See Note 13, *Notes Payable*, for more details. For the year ended December 31, 2023, cash used in financing activities was \$5.0 million, of which \$2.5 million was from the repayment on the Revolving Line and \$2.5 million was the terminal payment made to BroadOak. See Note 13, *Notes Payable*, for more details.

We generated positive cash flows from operations for the year ending December 31, 2024. We intend to meet our ongoing capital needs by using our available cash 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.

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, our 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. The Company may seek an uplisting of its common stock to Nasdaq, but no assurances can be given that a Nasdaq listing will be achieved.

Further, along with many laboratories, we may be affected by the Proposed LCD DL39365, which 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 Medicare coverage for one of our molecular tests, PancreGEN[®]. On June 5, 2023 we announced that Novitas issued the final LCD of Genetic Testing for Oncology (L39365) which, if finalized, would have established non-coverage for the Company's widely used PancreGEN[®] test effective July 17, 2023. On July 6, 2023, Novitas announced that it would not be implementing the final Genetic Testing for Oncology LCD (L39365) as scheduled on July 17, 2023. Novitas then issued a new virtually identical proposed LCD affecting the same companies and tests and reaching the same conclusions as noted in the previously rescinded LCD on July 27, 2023. In response, the Company participated in a public meeting presentation and submitted detailed written comments supporting the use of PancreGEN[®]. On July 29, 2024, the Company announced that CMS granted Novitas an undefined extension to the final decision for the LCD. As a result, we were able to continue offering PancreGEN[®] and the related Point2[®] fluid chemistry tests for amylase, CEA, and glucose for all of 2024.

On January 9, 2025, we announced that the new LCD established non-coverage for the Company's PancreGEN[®] test, and we would stop offering the test and would not accept specimens for first-line fluid chemistry and PancreGEN[®] testing after February 7, 2025. As a result of the established non-coverage for PancreGEN[®], we announced that our board of directors had approved the Restructuring Plan to reduce operating costs and better align our workforce with the loss of PancreGEN[®].

On January 27, 2025, the Company announced that CMS had directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancreaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect.

As a result of CMS' determination to delay implementation of the Genetic Testing for Oncology LCD (L39365), the Company is re-evaluating certain parts of the Restructuring Plan and will determine what parts will or will not be postponed or cancelled.

In the event Novitas ultimately restricts coverage for the PancreaGEN[®] test, the Company's liquidity could be negatively impacted.

As of December 31, 2024, 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:

	<u>Total</u>	<u>Less than 1 Year</u>	<u>1 to 3 Years</u>	<u>3 to 5 Years</u>	<u>After 5 Years</u>
Operating lease obligations	\$ 1,925	\$ 550	\$ 1,100	\$ 275	\$ -
Total	<u>\$ 1,925</u>	<u>\$ 550</u>	<u>\$ 1,100</u>	<u>\$ 275</u>	<u>\$ -</u>

GOVERNANCE OF THE COMPANY

Corporate Governance; Code of Ethics; Insider Trading Policy

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

Our Insider Trading Policy, adopted in March 2025, expressly prohibits our, and our direct and indirect subsidiaries', employees, directors, officers and designated contractors and consultants, who know or have access to material information regarding the Company that has not been fully disclosed to the public from (i) trading in Company securities or engaging in transactions in securities of another company with which the Company conducts business, such as a customer, partner, distributor or supplier, if they are in possession of or otherwise aware of material information relating to such other company obtained in course of employment with, or services performed on behalf of, the Company, (ii) pledging Company securities as collateral for a loan, (iii) engaging in hedging or monetization transactions with respect to Company securities, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds, and (iv) trading in derivative securities related to our Company securities, which includes publicly traded call and put options. Our Insider Trading Policy also provides that the Company will not effect transactions in respect of its securities, or adopt any securities repurchase plans, when it is in possession of material nonpublic information concerning the Company, other than in compliance with applicable law.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and the financial statement schedule specified by this Item 8, together with the report thereon of EisnerAmper 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, 2024. 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 SEC’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 this evaluation, management identified a material weakness in the Company’s internal control over financial reporting in the fourth quarter of 2024 related to the Company’s royalty accrual. It was determined that the Company should not have been accruing royalty expense with respect to certain royalty agreements and therefore had materially misstated their financial statements in prior periods. Management notes that the root cause of the royalty error was a design control failure as there was a lack of process related to communication between the Company’s science team, such as the Chief Scientific Officer, management of the Company, including the Chief Executive Officer (“CEO”), and the accounting team, including the Chief Financial Officer (“CFO”). At the time the initial accrual was made and as the royalty continued to be accrued since that point, there was a lack of control whereby the accounting team was not aware that the Company’s revenue sources, ThyraMIR and ThyGeNEXT, did not utilize the technology covered under the royalty agreements. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective as of the end of the period covered by this Annual Report on Form 10-K as a result of the identified material control weakness.

Remediation Plan - The Company plans to amend its control activities designed to mitigate the material weakness identified, including updating its procedures regarding the review of significant, complex agreements, to include the retention of outside subject matter experts specifically to review the agreements and any complexities that may arise. In addition, the Company plans to establish a quarterly meeting between members of management, including the CEO and CFO, as well as members from the Company’s science team to ensure that management, including those responsible for financial reporting, understand the agreements which are disclosed within the financial statements to ensure proper accounting for these agreements. The Company believes implementation of these processes and appropriate testing of their effectiveness will remediate this material control weakness.

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, 2024, 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, 2024, our internal control over financial reporting was not effective based on those criteria.

Changes in Internal Control over Financial Reporting

During the fourth quarter ended December 31, 2024 management believes that it has completed its remediation plan to address the material weakness that existed at the end of 2023 and through the first three quarters of 2024 related to the timing of revenue recognition. The Company had adopted a remediation plan and updated its procedures regarding the testing of revenue recognition and review the procedures which ensure that revenue is recorded in the period in which it is earned. Other than the completion of this remediation plan there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter covered by this report 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 2025 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 2025 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 2025 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 2025 annual meeting of stockholders and such information is incorporated by reference herein.

ITEM 14. PRINCIPAL ACCOUNTANT 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 2025 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

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	<u>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.</u>
2.2	<u>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.</u>
3.1+	<u>Conformed version of Certificate of Incorporation of Interpace Biosciences, Inc., as amended most recently by the Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock, effective October 11, 2024, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2024.</u>
3.2	<u>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.</u>
4.1	<u>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.</u>
4.2	<u>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.</u>
10.1*	<u>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.</u>
10.2*	<u>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.</u>

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>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>
10.13*	<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>
10.14*	<u>Employment Agreement, dated July 24, 2023, between Christopher McCarthy 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 August 2, 2023.</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>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>
10.18	<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
10.19	<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>
10.20	<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>
10.21	<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>
10.22	<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>
10.23	<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>
10.24	<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>
10.25	<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>

Exhibit No.	Description
10.26	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.
10.27	Second Amendment to 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 24, 2023, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 27, 2023.
10.28*	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.
10.29*	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.
10.30	Third Amendment to 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 March 29, 2024, incorporated by reference to Exhibit 10.39 of the Company's Annual Report on Form 10-K, filed with the SEC on April 1, 2024.
10.31	Series C Preferred Stock Exchange Agreement, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on October 15, 2024.
10.32	Amended and Restated Investor Rights Agreement, dated as of October 10, 2024, by and among Interpace Biosciences, Inc., 1315 Capital II, L.P. 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 October 15, 2024.
10.33	Termination of Support Agreement, dated October 14, 2024, by and between 1315 Capital II, L.P. and Interpace Biosciences, Inc., incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed with the SEC on October 15, 2024.
10.34	Fourth Amendment to Loan and Security Agreement with BroadOak Fund V, L.P., dated January 17, 2025, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed with the SEC on January 21, 2025.
19.1+	Insider Trading Policy.
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 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.
+	Filed herewith.

ITEM 16. Form 10-K Summary

The Company has opted to not provide a summary.

SIGNATURES

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

INTERPACE BIOSCIENCES, INC.

Date: March 31, 2025

/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 31, 2025
<u>/s/ Christopher McCarthy</u> Christopher McCarthy	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2025
<u>/s/ Stephen J. Sullivan</u> Stephen J. Sullivan	Director	March 31, 2025
<u>/s/ Joseph Keegan</u> Joseph Keegan	Director	March 31, 2025
<u>/s/ Vijay Aggarwal</u> Vijay Aggarwal	Director	March 31, 2025
<u>/s/ Fortunato Ron Rocca</u> Fortunato Ron Rocca	Director	March 31, 2025

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, 2024 and 2023, and the related consolidated statements of operations, stockholders’ deficit, and cash flows for each of the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Restatement

As discussed in Note 2 to the financial statements, the 2023 financial statements have been restated to correct a misstatement.

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 31, 2025

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

	<u>December 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u> <u>(as restated)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,461	\$ 3,498
Accounts receivable	8,544	5,078
Other current assets	1,768	1,841
Total current assets	11,773	10,417
Property and equipment, net	1,361	790
Operating lease right of use assets	1,613	1,864
Other long-term assets	45	45
Total assets	<u>\$ 14,792</u>	<u>\$ 13,116</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,659	\$ 1,544
Accrued salary and bonus	2,207	1,969
Other accrued expenses	1,799	2,163
Note payable at fair value, current	4,290	5,100
Current liabilities of discontinued operations	660	660
Total current liabilities	10,615	11,436
Operating lease liabilities, net of current portion	1,183	1,472
Note payable at fair value	-	4,243
Other long-term liabilities	5,211	4,968
Total liabilities	17,009	22,119
Commitments and contingencies (Note 11)		
Redeemable preferred stock, \$.01 par value; 5,000,000 shares authorized, 0 and 47,000 shares Series B issued and outstanding, respectively	-	46,536
Stockholders' deficit:		
Redeemable preferred stock, \$.01 par value; 5,000,000 shares authorized, 47,000 and 0 shares Series C issued and outstanding, respectively	-	-
Common stock, \$.01 par value; 100,000,000 shares authorized; 4,539,663 and 4,447,489 shares issued, respectively; 4,409,323 and 4,351,445 shares outstanding, respectively	406	405
Additional paid-in capital	234,811	188,146
Accumulated deficit	(235,380)	(242,082)
Treasury stock, at cost (130,340 and 96,044 shares, respectively)	(2,054)	(2,008)
Total stockholders' deficit	(2,217)	(55,539)
Total liabilities and stockholders' deficit	<u>14,792</u>	<u>(33,420)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 14,792</u>	<u>\$ 13,116</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,	
	2024	2023 (as restated)
Revenue, net	\$ 46,926	\$ 40,036
Cost of revenue	17,001	14,980
Gross profit	29,925	25,056
Operating expenses:		
Sales and marketing	11,655	10,233
Research and development	676	636
General and administrative	9,486	9,363
Acquisition related amortization expense	-	861
Change in fair value of contingent consideration	-	7
Total operating expenses	21,817	21,100
Operating income from continuing operations	8,108	3,956
Interest accretion expense	(34)	(112)
Note payable interest expense	(625)	(896)
Other expense, net	(499)	(667)
Income from continuing operations before tax	6,950	2,281
Provision for income taxes	4	17
Income from continuing operations	6,946	2,264
Loss from discontinued operations, net of tax	(244)	(310)
Net income	6,702	1,954
Less adjustment for preferred stock deemed dividend	(464)	-
Net income attributable to common stockholders	\$ 6,238	\$ 1,954
Basic net income (loss) per share of common stock:		
From continuing operations	\$ 1.48	\$ 0.52
From discontinued operations	(0.06)	(0.07)
Net income (loss) per basic share of common stock	\$ 1.42	\$ 0.45
Diluted net income (loss) per share of common stock:		
From continuing operations	\$ 0.41	\$ 0.52
From discontinued operations	(0.02)	(0.07)
Net income (loss) per diluted share of common stock	\$ 0.40	\$ 0.45
Weighted average number of common shares and common share equivalents outstanding:		
Basic	4,387	4,317
Diluted	15,734	4,364

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

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

	Preferred Stock		Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance -December 31, 2022 as restated	-	\$ -	4,367,830	\$ 405	71,120	\$ (1,976)	\$ 187,516	\$ (244,036)	\$ (58,091)
Issuance of common stock	-	-	79,659	-	-	-	-	-	-
Treasury stock purchased	-	-	-	-	24,924	(32)	-	-	(32)
Stock-based compensation expense	-	-	-	-	-	-	630	-	630
Net income	-	-	-	-	-	-	-	1,954	1,954
Balance -December 31, 2023 as restated	-	\$ -	4,447,489	\$ 405	96,044	\$ (2,008)	\$ 188,146	\$ (242,082)	\$ (55,539)
Issuance of common stock	-	-	92,174	1	-	-	(1)	-	-
Issuance of Series C preferred stock, net of issuance costs	47,000	-	-	-	-	-	46,375	-	46,375
Treasury stock purchased	-	-	-	-	34,296	(46)	-	-	(46)
Stock-based compensation expense	-	-	-	-	-	-	291	-	291
Net income	-	-	-	-	-	-	-	6,702	6,702
Balance -December 31, 2024	47,000	-	4,539,663	\$ 406	130,340	\$ (2,054)	\$ 234,811	\$ (235,380)	\$ (2,217)

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,	
	2024	2023 (as restated)
Cash Flows From Operating Activities		
Net income	\$ 6,702	\$ 1,954
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	300	1,026
Interest accretion expense	34	112
Amortization of deferred financing fees	-	42
Stock-based compensation	291	630
Amortization on operating lease right of use asset	448	575
Change in fair value of note payable	547	678
Change in fair value of contingent consideration	-	7
Other changes in operating assets and liabilities:		
Accounts receivable	(3,466)	227
Other current assets	73	(89)
Accounts payable	120	489
Accrued salaries and bonus	238	513
Accrued liabilities	(404)	(2,266)
Operating lease liabilities	(480)	(376)
Long-term liabilities	243	267
Net cash provided by operating activities	<u>4,646</u>	<u>3,789</u>
Cash Flows From Investing Activity		
Proceeds from sale of Interpace Pharma Solutions, net	-	383
Purchase of property and equipment	(876)	(470)
Net cash used in investing activities	<u>(876)</u>	<u>(87)</u>
Cash Flows From Financing Activities		
Payments made on note payable	(5,600)	-
Series C Preferred stock issuance costs	(161)	-
Payment of BroadOak terminal payment	-	(2,500)
Payments on line of credit	-	(2,500)
Cash paid for repurchase of restricted shares	(46)	(32)
Net cash used in financing activities	<u>(5,807)</u>	<u>(5,032)</u>
Net decrease in cash and cash equivalents	(2,037)	(1,330)
Cash and cash equivalents from continuing operations – beginning	3,498	4,828
Cash and cash equivalents from discontinued operations – beginning	-	-
Cash and cash equivalents – beginning	<u>\$ 3,498</u>	<u>\$ 4,828</u>
Cash and cash equivalents from continuing operations – ending	\$ 1,461	\$ 3,498
Cash and cash equivalents from discontinued operations – ending	-	-
Cash and cash equivalents – ending	<u><u>\$ 1,461</u></u>	<u><u>\$ 3,498</u></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 esoteric molecular diagnostic testing, and pathology services to aid physicians in their evaluation of cancer risk in patients with indeterminate biopsies and a perceived high risk of cancer from clinical features. We develop and commercialize genomic tests and related first-line assays that can personalize medicine to help improve patient diagnosis and management.

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, notes payable, stock-based compensation, revenue recognition, and unrecognized tax benefits. 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 restated, as of January 1, 2023 was \$5.1 million.

Other current assets

Other current assets consisted of the following as of December 31, 2024 and 2023:

	<u>December 31, 2024</u>	<u>December 31, 2023</u> (as restated)
Lab supplies	\$ 1,211	\$ 1,227
Prepaid expenses	535	590
Other	22	24
Total other current assets	<u>\$ 1,768</u>	<u>\$ 1,841</u>

Property and Equipment, net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized on a straight-line basis, using the estimated useful lives of: five to twelve years for furniture and fixtures; two to five years for office and computer equipment; two 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 7, *Property and Equipment*, for further information.

Contingencies

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

Revenue 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.

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. 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.

See Note 14, *Stock-Based Compensation*, for further information.

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.

2. Restatement of Previously Issued Consolidated Financial Statements

We have restated herein our audited consolidated financial statements as of December 31, 2023 and for the year ended December 31, 2023 as well as unaudited financial statements for the periods as of and the periods ending March 31, 2023, June 30, 2023, September 30, 2023, March 31, 2024, June 30, 2024 and September 30, 2024. We have also restated impacted amounts within the accompanying footnotes to the consolidated financial statements which have been noted as such.

As a result of a review of the Company's existing royalty agreements it was determined that the Company should not have been accruing royalty expenses on certain agreements. As a result, the Company determined that prior period financial statements should be restated.

On February 28, 2025, the Company's management concluded and subsequently confirmed with the Audit Committee of the Company's Board of Directors that (1) the royalty accrual was materially misstated and should be reversed; (2) the consolidated financial statements contained in the Company's Annual Reports on Form 10-K for the years ended December 31, 2015 through December 31, 2023, as well as the consolidated 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, 2024, June 30, 2024, and September 30, 2024 should no longer be relied upon. As a result, the Company is restating its consolidated financial statements for the year ended December 31, 2023, and the quarterly periods for 2023 and 2024.

The following tables present reconciliation from our prior periods as previously reported to the restated values for the consolidated financial statements. A description of misstatements is listed below:

- a) Royalty expense - We recorded royalty expense with respect to certain royalty agreements through September 30, 2024. The reversal of that expense will be reflected in the financial statements below.
- b) Revenue adjustments – Adjustments related to the timing on which revenue is recognized as per our revenue recognition policy. The Company identified a material control weakness in 2023 related to these adjustments.

The following tables present a reconciliation of the as previously reported consolidated financial statements to the restated amounts as of and for the year ended December 31, 2023.

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

	December 31, 2023			
	<u>As Previously Reported</u>	<u>Restatement Amount</u>	<u>Restatement Reference</u>	<u>As Restated</u>
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 3,498	\$ -		\$ 3,498
Accounts receivable	4,983	95	(b)	5,078
Other current assets	1,841			1,841
Total current assets	10,322	95		10,417
Property and equipment, net	790	-		790
Operating lease right of use assets	1,864	-		1,864
Other long-term assets	45	-		45
Total assets	<u>\$ 13,021</u>	<u>\$ 95</u>		<u>\$ 13,116</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,544	\$ -		\$ 1,544
Accrued salary and bonus	1,969	-		1,969
Other accrued expenses	8,201	(6,038)	(a)	2,163
Note payable at fair value, current	5,100	-		5,100
Current liabilities of discontinued operations	660	-		660
Total current liabilities	17,474	(6,038)		11,436
Operating lease liabilities, net of current portion	1,472	-		1,472
Note payable at fair value	4,243	-		4,243
Other long-term liabilities	4,968	-		4,968
Total liabilities	28,157	(6,038)		22,119
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; 4,447,489 shares issued and 4,351,445 shares outstanding;	405	-		405
Additional paid-in capital	188,146	-		188,146
Accumulated deficit	(248,215)	6,133	(a) (b)	(242,082)
Treasury stock, at cost (96,044 shares)	(2,008)	-		(2,008)
Total stockholders' deficit	(61,672)	6,133		(55,539)
Total liabilities and stockholders' deficit	(33,515)	95		(33,420)
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 13,021</u>	<u>\$ 95</u>		<u>\$ 13,116</u>

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

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

	For the Year Ended December 31, 2023			
	<u>As Previously Reported</u>	<u>Restatement Amount</u>	<u>Restatement Reference</u>	<u>As Restated</u>
Revenue, net	\$ 40,214	\$ (178)	(b)	\$ 40,036
Cost of revenue	16,310	(1,330)	(a)	14,980
Gross profit	23,904	1,152		25,056
Operating expenses:				
Sales and marketing	10,233	-		10,233
Research and development	636	-		636
General and administrative	9,363	-		9,363
Acquisition related amortization expense	861	-		861
Change in fair value of contingent consideration	7	-		7
Total operating expenses	21,100	-		21,100
Operating income from continuing operations	2,804	1,152		3,956
Interest accretion expense	(112)	-		(112)
Note payable interest expense	(896)	-		(896)
Other expense, net	(667)	-		(667)
Income from continuing operations before tax	1,129	1,152		2,281
Provision for income taxes	17	-		17
Income from continuing operations	1,112	1,152		2,264
Loss from discontinued operations, net of tax	(310)	-		(310)
Net income	<u>\$ 802</u>	<u>\$ 1,152</u>		<u>\$ 1,954</u>
Basic net income (loss) per share of common stock:				
From continuing operations	\$ 0.26	\$ 0.27		\$ 0.52
From discontinued operations	(0.07)	-		(0.07)
Net income (loss) per basic share of common stock	<u>\$ 0.19</u>	<u>\$ 0.27</u>		<u>\$ 0.45</u>
Diluted net income (loss) per share of common stock:				
From continuing operations	\$ 0.25	\$ 0.26		\$ 0.52
From discontinued operations	(0.07)	-		(0.07)
Net income (loss) per diluted share of common stock	<u>\$ 0.18</u>	<u>\$ 0.26</u>		<u>\$ 0.45</u>
Weighted average number of common shares and common share equivalents outstanding:				
Basic	4,317	4,317		4,317
Diluted	4,364	4,364		4,364

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

Consolidated Statement of Stockholders' Deficit

	<u>Common Stock</u>		<u>Treasury Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance -December 31, 2023 as reported	4,447,489	\$ 405	96,044	\$ (2,008)	\$ 188,146	\$ (248,215)	\$ (61,672)
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	4,981	4,981
Cumulative adjustments to net income	-	-	-	-	-	1,152	1,152
Balance -December 31, 2023 as restated	<u>4,447,489</u>	<u>\$ 405</u>	<u>96,044</u>	<u>\$ (2,008)</u>	<u>\$ 188,146</u>	<u>\$ (242,082)</u>	<u>\$ (55,539)</u>

INTERPACE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited, in thousands)

	For The Year Ended December 31,			
	2023 As Previously Reported	Restatement Amount	Restatement Reference	2023 As Restated
Cash Flows From Operating Activities				
Net income	\$ 802	\$ 1,152	(a) (b)	\$ 1,954
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	1,026	-		1,026
Interest accretion expense	112	-		112
Amortization of deferred financing fees	42	-		42
Amortization on operating lease right of use asset	575	-		575
Stock-based compensation	630	-		630
Credit loss expense	-	-		-
Change in fair value of note payable	678	-		678
Change in fair value of contingent consideration	7	-		7
Other changes in operating assets and liabilities:				
Accounts receivable	49	178	(b)	227
Other current assets	(89)	-		(89)
Accounts payable	489	-		489
Accrued salaries and bonus	513	-		513
Other accrued expenses	(936)	(1,330)	(a)	(2,266)
Operating lease liabilities	(376)	-		(376)
Long-term liabilities	267	-		267
Net cash provided by operating activities	3,789	-		3,789
Cash Flows From Investing Activity				
Proceeds from sale of Interpace Pharma Solutions, net	383	-		383
Purchase of property and equipment	(470)	-		(470)
Net cash used in investing activities	(87)	-		(87)
Cash Flows From Financing Activities				
Payment of BroadOak terminal payment	(2,500)	-		(2,500)
Payments on line of credit	(2,500)	-		(2,500)
Cash paid for repurchase of restricted shares	(32)	-		(32)
Net cash used in financing activities	(5,032)	-		(5,032)
Net decrease in cash and cash equivalents	(1,330)	-		(1,330)
Cash and cash equivalents from continuing operations— beginning	4,828	-		4,828
Cash and cash equivalents from discontinued operations— beginning	-	-		-
Cash and cash equivalents – beginning	\$ 4,828	\$ -		\$ 4,828
Cash and cash equivalents from continuing operations— ending	\$ 3,498	-		\$ 3,498
Cash and cash equivalents from discontinued operations— ending	-	-		-
Cash and cash equivalents – ending	\$ 3,498	\$ -		\$ 3,498

3. Recent Accounting Standards

Accounting Pronouncements Adopted

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. This was adopted on January 1, 2024 and there was no impact upon adoption.

In November 2023, the FASB modified authoritative guidance within the codification’s Segment Reporting topic (ASC 280), which enhanced the disclosure requirements for significant segment expenses and other segment items. The authoritative guidance will become effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. The adoption of this standard for the year ended December 31, 2024 did not have a material impact on the Company’s consolidated financial results, but resulted in enhanced disclosures as included in Note 15, *Segments*.

Accounting Pronouncements Pending

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact the adoption of this standard on its financial statements but does not expect it to be material.

4. Liquidity

In October 2021, the Company entered into a \$7.5 million revolving credit facility with Comerica Bank (“Comerica”) (the “Comerica Loan Agreement”). In February 2024, the Company terminated the Comerica Loan Agreement. The Company did not owe anything outstanding on the line of credit at the time of termination and does not owe anything further to Comerica. See Note 19, *Revolving Line of Credit*. Also in October 2021, the Company entered into an \$8.0 million term loan with BroadOak Fund V, L.P. (“BroadOak”) (the “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”) and 1315 Capital II, L.P. (“1315 Capital”). 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 Term Loan balance. The Term Loan has been subsequently amended. See Note 13, *Notes Payable*, for more details.

At December 31, 2024, the Company has a \$4.4 million principal balance of notes payable that required the principal to be paid on or before the maturity date of June 30, 2025. In January 2025, the Company had the terms of the Loan Agreement updated. See Note 21, *Subsequent Events*, for more details.

Further, along with many laboratories, the Company may be affected by the Proposed Local Coverage Determination (“LCD”) DL39365, which 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 Medicare coverage for one of our molecular tests, PancaGEN[®]. On June 5, 2023, the Company announced that Novitas issued the final LCD of Genetic Testing for Oncology (L39365) which, if finalized, would have established non-coverage for the Company’s widely used PancaGEN[®] test effective July 17, 2023. On July 6, 2023, Novitas announced that it would not be implementing the final Genetic Testing for Oncology LCD (L39365) as scheduled on July 17, 2023. Novitas then issued a new virtually identical proposed LCD affecting the same companies and tests and reaching the same conclusions as noted in the previously rescinded LCD on July 27, 2023. In response, the Company participated in a public meeting presentation and submitted detailed written comments supporting the use of PancaGEN[®]. On July 29, 2024, the Company announced that the Center for Medicare and Medicaid Services (“CMS”) granted Novitas an undefined extension to the final decision for the LCD. As a result, the Company was able to continue offering PancaGEN[®] and the related Point2[®] fluid chemistry tests for amylase, CEA, and glucose for all of 2024.

On January 9, 2025, the Company announced the new LCD established non-coverage for its PancaGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancaGEN[®] testing after February 7, 2025. As a result of the established non-coverage for PancaGEN[®], the Company announced, in January 2025, that its board of directors had approved a restructuring and cost-savings plan to reduce operating costs and better align its workforce with the loss of PancaGEN[®] (the “Restructuring Plan”).

On January 27, 2025, the Company announced that CMS had directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect.

As a result of CMS’ determination to delay implementation of the Genetic Testing for Oncology LCD (L39365), the Company is re-evaluating certain parts of the Restructuring Plan and will determine what parts will or will not be postponed or cancelled.

For the year ended December 31, 2024, the Company had operating income from continuing operations of \$8.1 million. As of December 31, 2024, the Company had cash and cash equivalents of \$1.5 million, total current assets of \$11.8 million and current liabilities of \$10.6 million. As of March 21, 2025, the Company had approximately \$1.3 million of cash on hand.

The Company intends to meet its ongoing capital needs by using its available cash, 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.

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 may seek an uplisting of its common stock to Nasdaq, but no assurances can be given that a Nasdaq listing will be achieved.

With the improvement in operating cash flows associated with the disposition of the Pharma Solutions business, and the Company’s improved operating performance, 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 from the date of issuance of the consolidated financial statements.

5. Discontinued Operations

Liabilities classified as discontinued operations as of both December 31, 2024 and December 31, 2023 consists of accrued expenses which are liabilities related to the former Commercial Services business unit.

The table below presents the significant components of its former Pharma Solutions and Commercial Services business units' results included within loss from discontinued operations, net of tax in the consolidated statements of operations for the years ended December 31, 2024 and 2023.

	For The Years Ended December 31,	
	2024	2023 (as restated)
Revenue, net	\$ -	\$ -
Loss from discontinued operations	-	(43)
Income tax expense	244	267
Loss from discontinued operations, net of tax	<u>\$ (244)</u>	<u>\$ (310)</u>

The income tax expense for the years ended December 31, 2024 and December 31, 2023 primarily pertained to the interest accrued on uncertain tax position liabilities.

There were no cash flows associated with discontinued operations in 2024. Cash used from discontinued operations, operating activities, for the year ended December 31, 2023 was approximately \$0.1 million. There was cash provided by discontinued operations, investing activities, for the year ended December 31, 2023 of \$0.4 million which pertained to the net proceeds released from escrow for the Pharma Solutions sale net of final working capital adjustments. There was no depreciation and amortization expense within discontinued operations for the years ended December 31, 2024 and December 31, 2023.

6. Fair Value Measurements

Cash and cash equivalents, accounts receivable, and accounts payable approximate fair value due to their relative short-term nature. The Company's financial liabilities reflected at fair value in the consolidated financial statements include contingent consideration and notes payable. 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, 2024		Fair Value Measurements As of December 31, 2024		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Note payable:					
BroadOak loan	\$ 4,400	\$ 4,290	\$ -	\$ -	\$ 4,290
	<u>\$ 4,400</u>	<u>\$ 4,290</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 4,290</u>

	As of December 31, 2023		Fair Value Measurements As of December 31, 2023		
	Carrying Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen ⁽¹⁾	\$ 453	\$ 453	\$ -	\$ -	\$ 453
Note payable:					
BroadOak loan	10,000	9,343	-	-	9,343
	<u>\$ 10,453</u>	<u>\$ 9,796</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 9,796</u>

(1)(2) See Note 10, *Accrued Expenses and Other 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. This liability was settled in 2024.

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.

	December 31, 2023	Payments	Accretion/Interest Accrued	Adjustment to Fair Value/	
				Mark to Market	December 31, 2024
Asuragen	\$ 453	\$ (487)	\$ 34	\$ -	\$ -
BroadOak loans	9,343	(5,600)	-	547	4,290
	<u>\$ 9,796</u>	<u>\$ (6,087)</u>	<u>\$ 34</u>	<u>\$ 547</u>	<u>\$ 4,290</u>

7. Property and Equipment

Property and equipment consisted of the following as of December 31, 2024 and 2023:

	<u>December 31,</u>	
	<u>2024</u>	<u>2023</u>
Furniture and fixtures	\$ 83	\$ 69
Lab and office equipment	3,126	2,510
Computer equipment	261	233
Internal-use software	253	253
Leasehold improvements	483	269
Property and equipment	4,206	3,334
Less accumulated depreciation and amortization	(2,845)	(2,544)
Net property and equipment	<u>\$ 1,361</u>	<u>\$ 790</u>

Depreciation and amortization expense from continuing operations was approximately \$0.3 million and \$0.2 million for the years ended December 31, 2024 and 2023, respectively. There was \$20,000 and zero internal-use software amortization expense included in depreciation and amortization expense in 2024 and 2023, respectively, and \$0.1 million of internal use unamortized software costs at December 31, 2024 and December 31, 2023, respectively.

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 operating lease expense from continuing operations under these agreements for the years ended December 31, 2024 and 2023 was approximately \$0.7 million and \$0.8 million, respectively. Total cash paid under these agreements for the years ended December 31, 2024 and 2023 was approximately \$0.7 million and \$0.8 million, respectively.

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

	<u>Classification on the Balance Sheet</u>	<u>December 31, 2024</u>	<u>December 31, 2023</u>
Assets			
Operating lease assets	Operating lease right of use assets	1,613	1,864
Total lease assets		<u>\$ 1,613</u>	<u>\$ 1,864</u>
Liabilities			
Current			
Operating lease liabilities	Other accrued expenses	383	377
Total current lease liabilities		<u>\$ 383</u>	<u>\$ 377</u>
Noncurrent			
Operating lease liabilities	Operating lease liabilities, net of current portion	1,183	1,472
Total long-term lease liabilities		<u>1,183</u>	<u>1,472</u>
Total lease liabilities		<u>\$ 1,566</u>	<u>\$ 1,849</u>

The weighted average remaining lease term for the Company's operating leases was 3.5 years as of December 31, 2024 and 4.3 years as of December 31, 2023 and the weighted average discount rate for those leases was 12.0% and 11.8% as of December 31, 2024 and December 31, 2023, 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, 2024:

	Operating Leases
2025	\$ 550
2026	550
2027	550
2028	275
Total minimum lease payments	<u>1,925</u>
Less: amount of lease payments representing effects of discounting	<u>359</u>
Present value of future minimum lease payments	1,566
Less: current obligations under leases	<u>383</u>
Long-term lease obligations	<u>\$ 1,183</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, 2024 and December 31, 2023 was approximately \$0.3 million in both periods.

10. Accrued Expenses and Other Long-Term Liabilities

Other accrued expenses consisted of the following as of December 31, 2024 and 2023:

	<u>December 31, 2024</u>	<u>December 31, 2023</u> (as restated)
Accrued royalties	\$ -	\$ 230
Contingent consideration	-	453
Operating lease liability	383	377
Accrued sales and marketing	22	43
Accrued lab costs	173	68
Accrued professional fees	458	241
Taxes payable	262	261
Unclaimed property	35	35
All others	466	455
Total other accrued expenses	<u>\$ 1,799</u>	<u>\$ 2,163</u>

Other long-term liabilities consisted of uncertain tax positions as of December 31, 2024 and 2023.

11. Commitments and Contingencies

Litigation

From time to time, the Company may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. When the Company is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, the Company will record a liability for the loss. In addition to the estimated loss, the recorded liability includes probable and estimable legal costs associated with the claim or potential claim. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm the Company's business. There is no pending litigation involving the Company at this time.

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 or services that 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. There is also the risk of employment related litigation and other litigation in the ordinary course of business.

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. Preferred Stock

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 ("New Investment Shares"). 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 had a conversion price of \$6.00.

On October 10, 2024, the Company and the Investors entered into an Exchange Agreement (the "Exchange Agreement") pursuant to which the Investors exchanged (the "Exchange") an aggregate of 47,000 shares of the Company's Series B Preferred Stock, comprised of 28,000 shares of Series B Preferred Stock held by Ampersand and 19,000 shares of Series B Preferred Stock held by 1315 Capital, which represented all of the Company's issued and outstanding Series B Preferred Stock, for 47,000 newly created shares of Series C Preferred Stock, at an issuance price per share of \$1,000. In the Exchange, Ampersand received 28,000 shares of Series C Preferred Stock and 1315 received 19,000 shares of Series C Preferred Stock. The Company recorded approximately \$0.2 million in issuance costs related to this transaction.

The Series C Preferred Stock is convertible into the Company's common stock at a conversion price of \$2.02 per share of common stock (subject to further adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares) which was the closing price of the common stock on the date of the Exchange Agreement. The Series C Preferred Stock does not have a liquidation preference over the common stock in the event of a sale or dissolution of the Company, does not have director designation rights and includes limited customary protective provisions. The Series B Preferred Stock had a conversion price of \$6.00 per share of common stock and included additional protective provisions not applicable to the Series C Preferred Stock, including (i) limitations on the Board to declare dividends, (ii) director designation rights for each of the Investors, (iii) liquidation rights of holders upon "deemed liquidation" events, including a liquidation preference over the common stock, (iv) limitations on the ability to authorize, issue or create debt securities, (v) limitations on the ability to enter into mergers or acquisitions and (vi) limitations on the ability to conduct public offerings of the Company's common stock.

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 C Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of Common Stock, into which the shares of Series C 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 C 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 Series C Preferred Stock does not have director designation rights.

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 C 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 the product of the Series C Conversion Ratio (the "Series C Conversion Ratio") and the number of shares of Series C Preferred Stock to be converted. The Series C Conversion Ratio is calculated by dividing the Stated Value per share of Series C Preferred Stock by the Series C Conversion Price. The Series C Conversion Ratio is subject to adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization which results in the adjustment of the Series C Conversion Price.

The aggregate number of shares of Common Stock that may be issued through conversion of all of the Exchange Shares is 23,267,326 shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares).

Mandatory Conversion

Immediately prior to the Company's listing of Common Stock on The Nasdaq Stock Market, all outstanding shares of Series C Preferred Stock shall automatically convert into a number of shares of Common Stock equal to the product of the Series C Conversion Ratio and the number of shares of Series C Preferred Stock owned by each holder.

Liquidation

Upon any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C Preferred Stock then outstanding will be entitled to be paid out of the assets of the Corporation available for distribution to its stockholders on a pari passu basis with the holders of the Common Stock of the Company.

As of December 31, 2024, there were 47,000 Series C Preferred Stock issued and outstanding and as of December 31, 2023, there were 47,000 Series B Preferred Stock issued and outstanding.

13. Notes Payable

BroadOak Loan

On October 29, 2021, the Company and its subsidiaries entered into the Term Loan with BroadOak, providing for a term loan in the aggregate principal amount of \$8,000,000. Funding of the Term Loan took place on November 1, 2021. The Term Loan was scheduled to mature 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 was subordinate to the Company's \$7,500,000 revolving credit facility with Comerica Bank. See Note 19, *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 Term Loan 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 Term Loan also contains customary events of default.

The Company concluded that the Term Loan 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 stockholders' deficit. Accordingly, the Company elected the fair value option for the Note.

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, which was converted into a subordinated term loan and was added to the outstanding balance of the Term Loan.

On October 24, 2023, the Company entered into a Second Amendment to Loan and Security Agreement (the "Second Amendment") with BroadOak. The primary changes to the original Term Loan were as follows:

- The Company made a one-time payment in an aggregate amount equal to \$2,500,000, on October 30, 2023 and applied the payment in full satisfaction of the \$3,000,000 Terminal Payment (as defined in the Term Loan). See above regarding the Terminal Payment.
- Effective November 1, 2023, the interest rate under the Term Loan was reduced from 9% to 8% through the maturity date of October 31, 2024 or earlier, upon the occurrence of a change in control ("Loan Maturity Date").
- The Company had the option to request an extension of the Loan Maturity Date in writing no less than sixty days prior to the Loan Maturity Date. If BroadOak agreed to the extension, the Loan Maturity Date would automatically be extended.

The Second Amendment was treated as a debt modification which is accounted for prospectively. Since the Term Loan is carried at fair value under the fair value option, the Second Amendment did not result in any extinguishment gain or loss upon amendment, and the impact of the revised terms was incorporated into the Company's fourth quarter 2023 fair value calculation.

On March 29, 2024, the Company entered into a Third Amendment to Loan and Security Agreement with BroadOak (the "Third Amendment"). The primary changes to the Second Amendment were as follows:

- The maturity date was extended to June 30, 2025.
- Beginning April 1, 2024, the Company made \$500,000 monthly payments with the remaining loan balance due on the new maturity date.

The Third Amendment was treated as a debt modification which is accounted for prospectively. Since the Term Loan is carried at fair value under the fair value option, the Third Amendment did not result in any extinguishment gain or loss upon amendment, and the impact of the revised terms was incorporated into the Company's first quarter 2024 fair value calculation.

The balance of the loan outstanding at December 31, 2024 was \$4.4 million.

In January 2025, the Company entered into a Fourth Amendment of the Term Loan. See Note 21, *Subsequent Events*, for more details.

14. 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. 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, 2024, the Company has reserved 481,494 shares of its common stock for issuance under our 2019 Equity Incentive Plan, 1,000,007 shares of its common stock for issuance under our Employee Stock Purchase Plan and 1,796,268 additional shares available for future grants of awards under its 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.

There were no stock options granted in 2024 or 2023. There were no options exercised in 2024 or 2023.

Stock-based compensation from continuing operations for the years ended December 31, 2024 and 2023 is as follows:

	2024	2023
RSUs and restricted stock	\$ 199	\$ 313
Performance-based awards	-	58
Options	92	259
Total stock-based compensation expense	<u>\$ 291</u>	<u>\$ 630</u>

A summary of stock option activity for the year ended December 31, 2024, 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, 2024	455,844	\$ 6.52	6.47	\$ -
Granted	-	-	-	-
Forfeited or expired	(179,020)	5.50	-	-
Outstanding at December 31, 2024	<u>276,824</u>	7.18	5.49	-
Exercisable at December 31, 2024	264,484	7.28	5.42	-
Vested and expected to vest	276,523	7.19	5.49	-

A summary of the change in of the Company's non-vested options for the year ended December 31, 2024 is presented below:

	Shares	Weighted- Average Grant Date Fair Value
Nonvested at January 1, 2024	119,018	\$ 4.55
Granted	-	-
Vested	(29,344)	4.77
Forfeited	(77,334)	4.47
Nonvested at December 31, 2024	<u>12,340</u>	<u>\$ 4.50</u>

The aggregate fair value of options vested during the years ended December 31, 2024 and 2023 was \$0.1 million and \$0.6 million, respectively. The weighted-average grant date fair value of options vested during the year ended December 31, 2023 was \$4.70.

A summary of the Company's non-vested shares of restricted stock and restricted stock units for the year ended December 31, 2023, 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, 2024	236,844	\$ 2.14	0.84	\$ 255,792
Granted	60,000	1.04	-	-
Vested	(92,174)	2.47	-	-
Forfeited	-	-	-	-
Nonvested at December 31, 2024	<u>204,670</u>	<u>\$ 1.66</u>	<u>0.79</u>	<u>\$ 552,609</u>

The aggregate fair value of restricted stock units vested during each of the years ended December 31, 2024 and 2023 was \$0.2 million and \$0.3 million, respectively.

As of December 31, 2024, there was approximately \$0.1 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.

15. Segments

The Company operates and manages its business as a single reporting segment. The business provides esoteric molecular diagnostic testing, and pathology services to aid physicians in their evaluation of cancer risk in patients with indeterminate biopsies and a perceived high risk of cancer from clinical features. We develop and commercialize genomic tests and related first-line assays that can personalize medicine to help improve patient diagnosis and management. The Company's chief operating decision maker ("CODM") is the chief executive officer.

The CODM assesses performance for the segment and decides how to allocate resources based on consolidated net income that is also reported on the consolidated statements of operations. The monitoring of budgeted versus actual results is used in assessing performance of the segment and in establishing resource allocation across the organization.

The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. All the Company's long-lived assets are located in the United States. The accounting policies of the segment are the same as those described in Note 1, *Nature of Business and Significant Accounting Policies* included in this Annual Report on Form 10-K.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to the Company's reportable segment for the periods presented:

	For The Years	
	Ended December 31,	
	2024	2023
		(as restated)
Revenue, net:	\$ 46,926	\$ 40,036
Less:		
Cost of revenue:		
Fixed	6,790	5,763
Variable	10,211	9,217
Sales and marketing	11,655	10,233
Research and development	676	636
General and administrative	9,486	9,363
Other operating expenses	-	868
Interest & other expense, net	1,158	1,675
Provision for income taxes	4	17
Segment net income	6,946	2,264
Reconciliation of profit or loss:		
Loss on discontinued operations	(244)	(310)
Consolidated net income	<u>\$ 6,702</u>	<u>\$ 1,954</u>

Adjusted EBITDA, a non-GAAP financial measure, is a metric used by the CODM to measure cash flow of the ongoing business. Adjusted EBITDA is defined as income or loss from continuing operations, plus depreciation and amortization, non-cash stock-based compensation, interest and taxes, and other non-cash expenses including asset impairment costs, change in fair value of contingent consideration, and change in fair value of notes payable. 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,	
	2024	2023 (as restated)
Income from continuing operations (GAAP Basis)	\$ 6,946	\$ 2,264
Depreciation and amortization	300	1,026
Stock-based compensation	291	630
Tax expense	4	17
Interest accretion expense	34	112
Financing interest and related costs	625	896
Interest income	(48)	(53)
Change in fair value of note payable	547	678
Change in fair value of contingent consideration	-	7
Adjusted EBITDA	\$ 8,699	\$ 5,577

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, 2024 and 2023, respectively. For the years ended December 31, 2024 and December 31, 2023, revenue from Medicare was approximately 36% and 41% of total revenue, respectively.

Customer	Years Ended December 31,	
	2024	2023 (as restated)
Medicare	\$ 17,008	\$ 16,415
Commercial Payors	\$ 10,782	\$ 9,529
Client Billings	\$ 10,951	\$ 8,167
Medicare Advantage	\$ 7,556	\$ 5,605

17. Income Taxes

The provision for income taxes on continuing operations for the years ended December 31, 2024 and 2023 is comprised of the following:

	2024	2023
Current:		
Federal	\$ -	\$ -
State	4	17
Total current	<u>4</u>	<u>17</u>
Deferred:		
Federal	-	-
State	-	-
Total deferred	<u>-</u>	<u>-</u>
Provision for income taxes	<u>\$ 4</u>	<u>\$ 17</u>

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, 2024 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, 2024 and 2023 are as follows:

	2024	2023 (as restated)
Deferred tax assets:		
Federal net operating loss carryforwards	\$ 24,148	\$ 25,006
State net operating loss carryforwards	3,288	3,541
Compensation	2,034	2,021
Allowances and reserves	474	421
Intangible assets	2,624	3,201
State taxes	1,094	1,049
Credit carryforward	1	1
163(j) interest	1,130	1,326
Deferred revenue	92	94
Capitalized 174	350	268
Valuation allowance	(35,067)	(36,907)
	<u>168</u>	<u>21</u>
Deferred tax liability:		
Property and equipment	(156)	(17)
Leases	(12)	(4)
Deferred tax liability-net valuation allowance	<u>\$ -</u>	<u>\$ -</u>

The Company's deferred tax asset and deferred tax liabilities as of both December 31, 2024 and 2023 periods was \$0 as they are fully offset by a valuation allowance. The NOL carry forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. During 2021, the Company completed a Section 382 analysis of the available NOLs under Section 382 of the Internal Revenue Code and determined that the Company underwent an ownership change on March 30, 2017 and July 15, 2019. As a result, NOLs attributable to the pre-ownership change are subject to a substantial annual limitation under Section 382. The Company has approximately \$115.0 million of federal net operating losses after adjusting for the impact of the Section 382 ownership change. Federal Net Operating Losses of \$66.5 million are subject to annual limitation for ownership changes and the Company is utilizing \$4.0 million of the available amount during the current year. The remaining \$52.5 million of NOLs incurred post July 15, 2019 may be subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period. These NOLs can be carried forward indefinitely, but the deductibility of such federal NOLs are limited to 80% of Federal Taxable Income. The Company has approximately \$55.1 million of state net operating losses carryforwards after adjusting for the impact of the Section 382 ownership change. Current state net operating losses not utilized begin to expire this year.

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>2024</u>	<u>2023</u> <u>(as restated)</u>
Federal statutory rate	21.0%	21.0%
State income tax rate, net of Federal tax benefit	3.0%	2.8%
Meals and entertainment	0.5%	1.0%
Valuation allowance	(24.5)%	(24.1)%
Effective tax rate	<u>0.0%</u>	<u>0.7%</u>

The following table summarizes the change in uncertain tax benefit reserves for the two years ended December 31, 2024:

	<u>Unrecognized Tax Benefits</u>
Balance of unrecognized benefits as of January 1, 2023	\$ 877
Additions for tax positions of prior years	-
Balance as of December 31, 2023	<u>\$ 877</u>
Additions for tax positions of prior years	-
Balance as of December 31, 2024	<u>\$ 877</u>

As of both December 31, 2024 and 2023, the total amount of gross unrecognized tax benefits was \$0.9 million. The total amount of unrecognized tax benefits that, if recognized, would affect the effective tax rate as of both December 31, 2024 and 2023 was \$0.9 million.

The Company recognized interest and penalties of \$0.4 million, and a release of \$0.2 million related to uncertain tax positions in income tax expense during the year ended December 31, 2024. The Company recognized interest and penalties of \$0.2 million, and there was no release related to uncertain tax positions in income tax expense during the year ended December 31, 2023. At December 31, 2024 and 2023, accrued interest and penalties, net were \$4.2 million and \$4.0 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, 2024:

Jurisdiction	Tax Years
Federal	2020 – 2024
State and Local	2019 – 2024

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, 2024.

18. Basic and Diluted Net Income (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, 2024 and 2023 are as follows (rounded to thousands):

	Years Ended December 31,	
	2024	2023
Basic weighted average number of common shares	4,387	4,317
Potential dilutive effect of stock-based awards	35	47
Dilutive effect of preferred stock	11,312	-
Diluted weighted average number of common shares	15,734	4,364

The following outstanding stock-based awards were excluded from the computation of the effect of dilutive securities on income per share for the following periods as they would have been anti-dilutive (rounded to thousands):

	Years Ended December 31,	
	2024	2023
Options	277	456
Restricted stock units (RSUs)	169	237
	446	693

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 could use the proceeds of the Credit Facility for working capital and other general corporate purposes.

On October 6, 2023, effective September 30, 2023, the Company entered into a Fifth Amendment to its Loan and Security Agreement (the “Fifth Amendment to the Comerica Loan Agreement”) with Comerica providing for a revolving credit facility of up to \$5,000,000.

In February 2024, the Company terminated the Comerica Loan Agreement. The Company did not owe anything outstanding on the line of credit at the time of termination and does not owe anything further to Comerica.

20. Supplemental Cash Flow Information

Supplemental Disclosure of Other Cash Flow Information (in thousands)

	Years Ended December 31,	
	2024	2023
Cash paid for taxes	\$ 274	\$ 270
Cash paid for interest	\$ 625	\$ 1,092

Supplemental Disclosures of Non Cash Activities (in thousands)

	Years Ended December 31,	
	2024	2023
Purchase of property and equipment included in accounts payable	\$ -	\$ 5
Lease remeasurement	177	-
Conversion of preferred shares from Series B to Series C	46,375	-

21. Subsequent Events

LCD Update

On January 9, 2025, the Company announced the new LCD established non-coverage for its PancaGEN[®] test, and it would stop offering the test and would not accept specimens for first-line fluid chemistry and PancaGEN[®] testing after February 7, 2025. As a result of the established non-coverage for PancaGEN[®], the Company announced that its board of directors had approved a restructuring and cost-savings plan to reduce operating costs and better align the Company workforce with the loss of PancaGEN[®].

On January 27, 2025, the Company announced that CMS had directed its Medicare Administrative Contractors, Novitas and First Coast Service Options, Inc., to delay implementation of the Genetic Testing for Oncology LCD (L39365), from February 23, 2025 until April 24, 2025. The Company stated that this change of effective date will allow the Trump administration time to fully review the proposed policy changes, re-evaluate for themselves the supporting clinical evidence for the PancaGEN[®] assay, and fully assess the negative impact on patient care if the currently proposed LCD comes into effect.

BroadOak Amendment

On January 14, 2025, the Company entered into a Fourth Amendment to the Loan and Security Agreement with BroadOak, extending the loan maturity date to December 31, 2025. The primary changes to the Third Amendment were as follows:

- The maturity date was extended to December 31, 2025.
- Beginning July 1, 2025, and continuing through December 1, 2025, the Company will make monthly interest-only payments with the remaining loan balance due on the new maturity date.

22. Restatement of Unaudited Quarterly Results

The financial results data, presented on a quarterly basis for the years ended December 31, 2024 and 2023 are unaudited. This data has been prepared in accordance with U.S. GAAP for interim financial information and, in the opinion of management, reflect all adjustments necessary for a fair statement of the results of operations for the periods presented.

We have restated herein our previously issued unaudited quarterly financial results for the quarters ended March 31, 2024 and 2023, June 30, 2024 and 2023 and September 30, 2024 and 2023. The information has been prepared on the same basis as the consolidated financial statements. The related adjustments to the unaudited quarterly financial information resulting from similar adjustments discussed in Note 2 are also presented below. See Note 2 for descriptions of the misstatements in each category of restatements referenced by (a) and (b).

Presented below are the restated condensed consolidated balance sheets, condensed consolidated statements of operations, consolidated statements of stockholders' deficit and condensed consolidated statements of cash flows for each of the interim periods within the years ended December 31, 2024 and 2023.

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

	March 31, 2023			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 5,596	\$ -		\$ 5,596
Accounts receivable	4,715	102	(b)	4,817
Other current assets	2,173	-		2,173
Total current assets	12,484	102		12,586
Property and equipment, net	506	-		506
Other intangible assets, net	544	-		544
Operating lease right of use assets	2,298	-		2,298
Other long-term assets	45	-		45
Total assets	<u>\$ 15,877</u>	<u>\$ 102</u>		<u>\$ 15,979</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,582	\$ -		\$ 1,582
Accrued salary and bonus	888	-		888
Other accrued expenses	8,323	(5,042)	(a)	3,281
Line of credit - current	2,200	-		2,200
Current liabilities of discontinued operations	858	-		858
Total current liabilities	13,851	(5,042)		8,809
Contingent consideration	368	-		368
Operating lease liabilities, net of current portion	1,748	-		1,748
Note payable at fair value	11,132	-		11,132
Other long-term liabilities	4,780	-		4,780
Total liabilities	31,879	(5,042)		26,837
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; 4,390,826 shares issued and 4,311,414 shares outstanding;	405	-		405
Additional paid-in capital	187,708	-		187,708
Accumulated deficit	(248,666)	5,144	(a) (b)	(243,522)
Treasury stock, at cost (79,412 shares)	(1,985)	-		(1,985)
Total stockholders' deficit	(62,538)	5,144		(57,394)
Total liabilities and stockholders' deficit	<u>(30,659)</u>	<u>102</u>		<u>(30,557)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 15,877</u>	<u>\$ 102</u>		<u>\$ 15,979</u>

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

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

	For the Three Months Ended March 31, 2023			
	<u>As Previously Reported</u>	<u>Restatement Amount</u>	<u>Restatement Reference</u>	<u>As Restated</u>
Revenue, net	\$ 9,826	\$ (171)	(b)	\$ 9,655
Cost of revenue	3,848	(334)	(a)	3,514
Gross profit	<u>5,978</u>	<u>163</u>		<u>6,141</u>
Operating expenses:				
Sales and marketing	2,342	-		2,342
Research and development	149	-		149
General and administrative	2,494	-		2,494
Acquisition related amortization expense	318	-		318
Total operating expenses	<u>5,303</u>	<u>-</u>		<u>5,303</u>
Operating income from continuing operations	675	163		838
Interest accretion expense	(35)	-		(35)
Note payable interest expense	(225)	-		(225)
Other expense, net	19	-		19
Income from continuing operations before tax	<u>434</u>	<u>163</u>		<u>597</u>
Provision for income taxes	4	-		4
Income from continuing operations	<u>430</u>	<u>163</u>		<u>593</u>
Loss from discontinued operations, net of tax	<u>(79)</u>	<u>-</u>		<u>(79)</u>
Net income	<u>\$ 351</u>	<u>\$ 163</u>		<u>\$ 514</u>
Basic net income (loss) per share of common stock:				
From continuing operations	\$ 0.10	\$ 0.04		\$ 0.14
From discontinued operations	(0.02)	-		(0.02)
Net income (loss) per basic share of common stock	<u>\$ 0.08</u>	<u>\$ 0.04</u>		<u>\$ 0.12</u>
Diluted net income (loss) per share of common stock:				
From continuing operations	\$ 0.10	\$ 0.04		\$ 0.14
From discontinued operations	(0.02)	-		(0.02)
Net income (loss) per diluted share of common stock	<u>\$ 0.08</u>	<u>\$ 0.04</u>		<u>\$ 0.12</u>
Weighted average number of common shares and common share equivalents outstanding:				
Basic	4,307	4,307		4,307
Diluted	4,308	4,308		4,308

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

Consolidated Statements of Stockholders' Deficit (unaudited)

	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
Balance -March 31, 2023 as reported	4,390,826	\$ 405	79,412	\$ (1,985)	\$ 187,708	\$ (248,666)	\$ (62,538)
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	4,981	4,981
Cumulative adjustments to net income	-	-	-	-	-	163	163
Balance -March 31, 2023 as restated	<u>4,390,826</u>	<u>\$ 405</u>	<u>79,412</u>	<u>\$ (1,985)</u>	<u>\$ 187,708</u>	<u>\$ (243,522)</u>	<u>\$ (57,394)</u>

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

	For The Three Months Ended March 31,			
	2023 As Previously Reported	Restatement Amount	Restatement Reference	2023 As Restated
Cash Flows From Operating Activities				
Net income	\$ 351	\$ 163	(a) (b)	\$ 514
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	356	-		356
Interest accretion expense	35	-		35
Amortization of deferred financing fees	14	-		14
Stock-based compensation	192	-		192
Change in fair value of note payable	(33)	-		(33)
Other changes in operating assets and liabilities:				
Accounts receivable	317	171	(b)	488
Other current assets	107	-		107
Accounts payable	532	-		532
Accrued salaries and bonus	(568)	-		(568)
Other accrued expenses	(249)	(334)	(a)	(583)
Long-term liabilities	79	-		79
Net cash provided by operating activities	<u>1,133</u>	<u>-</u>		<u>1,133</u>
Cash Flows From Investing Activity				
Purchase of property and equipment	(65)	-		(65)
Net cash used in investing activities	<u>(65)</u>	<u>-</u>		<u>(65)</u>
Cash Flows From Financing Activities				
Payments on line of credit	(300)	-		(300)
Net cash (used in) provided by financing activities	<u>(300)</u>	<u>-</u>		<u>(300)</u>
Net increase in cash and cash equivalents	768	-		768
Cash and cash equivalents from continuing operations– beginning	4,828	-		4,828
Cash and cash equivalents from discontinued operations– beginning	-	-		-
Cash and cash equivalents – beginning	<u>\$ 4,828</u>	<u>\$ -</u>		<u>\$ 4,828</u>
Cash and cash equivalents from continuing operations– ending	<u>\$ 5,596</u>	<u>\$ -</u>		<u>\$ 5,596</u>
Cash and cash equivalents from discontinued operations– ending	<u>-</u>	<u>-</u>		<u>-</u>
Cash and cash equivalents – ending	<u><u>\$ 5,596</u></u>	<u><u>\$ -</u></u>		<u><u>\$ 5,596</u></u>

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

	June 30, 2023			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 5,079	\$ -		\$ 5,079
Accounts receivable	5,529	121	(b)	5,650
Other current assets	2,367	-		2,367
Total current assets	12,975	121		13,096
Property and equipment, net	606	-		606
Other intangible assets, net	226	-		226
Operating lease right of use assets	2,090	-		2,090
Other long-term assets	45	-		45
Total assets	<u>\$ 15,942</u>	<u>\$ 121</u>		<u>\$ 16,063</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,689	\$ -		\$ 1,689
Accrued salary and bonus	1,127	-		1,127
Other accrued expenses	8,391	(5,407)	(a)	2,984
Line of credit - current	1,500	-		1,500
Current liabilities of discontinued operations	858	-		858
Total current liabilities	13,565	(5,407)		8,158
Contingent consideration	231	-		231
Operating lease liabilities, net of current portion	1,646	-		1,646
Note payable at fair value	11,307	-		11,307
Other long-term liabilities	4,863	-		4,863
Total liabilities	31,612	(5,407)		26,205
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; 4,390,826 shares issued and 4,311,414 shares outstanding;	405	-		405
Additional paid-in capital	187,865	-		187,865
Accumulated deficit	(248,491)	5,528	(a) (b)	(242,963)
Treasury stock, at cost (79,412 shares)	(1,985)	-		(1,985)
Total stockholders' deficit	(62,206)	5,528		(56,678)
Total liabilities and stockholders' deficit	<u>(30,594)</u>	<u>121</u>		<u>(30,473)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 15,942</u>	<u>\$ 121</u>		<u>\$ 16,063</u>

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

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATION

(unaudited, in thousands, except for per share data)

	For the Three Months Ended June 30, 2023				For the Six Months Ended June 30, 2023			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
Revenue, net	\$ 11,026	\$ 19	(b)	\$ 11,045	\$ 20,853	\$ (152)	(b)	\$ 20,701
Cost of revenue	4,191	(365)	(a)	3,826	8,039	(699)	(a)	7,340
Gross profit	6,835	384		7,219	12,814	547		13,361
Operating expenses:								
Sales and marketing	2,605	-		2,605	4,947	-		4,947
Research and development	186	-		186	335	-		335
General and administrative	2,894	-		2,894	5,389	-		5,389
Acquisition related amortization expense	318	-		318	635	-		635
Total operating expenses	6,003	-		6,003	11,306	-		11,306
Operating income from continuing operations	832	384		1,216	1,508	547		2,055
Interest accretion expense	(31)	-		(31)	(66)	-		(66)
Note payable interest expense	(228)	-		(228)	(453)	-		(453)
Other expense, net	(174)	-		(174)	(156)	-		(156)
Income from continuing operations before tax	399	384		783	833	547		1,380
Provision for income taxes	4	-		4	8	-		8
Income from continuing operations	395	384		779	825	547		1,372
Loss from discontinued operations, net of tax	(220)	-		(220)	(299)	-		(299)
Net income	\$ 175	\$ 384		\$ 559	\$ 526	\$ 547		\$ 1,073
Basic net income (loss) per share of common stock:								
From continuing operations	\$ 0.09	\$ 0.09		\$ 0.18	\$ 0.19	\$ 0.13		\$ 0.32
From discontinued operations	(0.05)	-		(0.05)	(0.07)	-		(0.07)
Net income (loss) per basic share of common stock	\$ 0.04	\$ 0.09		\$ 0.13	\$ 0.12	\$ 0.13		\$ 0.25
Diluted net income (loss) per share of common stock:								
From continuing operations	\$ 0.09	\$ 0.09		\$ 0.18	\$ 0.19	\$ 0.13		\$ 0.32
From discontinued operations	(0.05)	-		(0.05)	(0.07)	-		(0.07)
Net income (loss) per diluted share of common stock	\$ 0.04	\$ 0.09		\$ 0.13	\$ 0.12	\$ 0.13		\$ 0.25
Weighted average number of common shares and common share equivalents outstanding:								
Basic	4,311	4,311		4,311	4,309	4,309		4,309
Diluted	4,316	4,316		4,316	4,313	4,313		4,313

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

Consolidated Statements of Stockholders' Deficit (unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -March 31, 2023 as reported	4,390,826	\$ 405	79,412	\$ (1,985)	\$ 187,708	\$ (248,666)	\$ (62,538)
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	4,981	4,981
Cumulative adjustments to net income	-	-	-	-	-	163	163
Balance -March 31, 2023 as restated	4,390,826	\$ 405	79,412	\$ (1,985)	\$ 187,708	\$ (243,522)	\$ (57,394)
Balance -June 30, 2023 as reported	4,390,826	\$ 405	79,412	\$ (1,985)	\$ 187,865	\$ (248,491)	\$ (62,206)
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	5,144	5,144
Cumulative adjustments to net income	-	-	-	-	-	384	384
Balance -June 30, 2023 as restated	4,390,826	\$ 405	79,412	\$ (1,985)	\$ 187,865	\$ (242,963)	\$ (56,678)

INTERPACE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited, in thousands)

	For The Six Months Ended June 30,			
	<u>2023</u>			<u>2023</u>
	<u>As Previously</u>	<u>Restatement</u>	<u>Restatement</u>	<u>As Restated</u>
	<u>Reported</u>	<u>Amount</u>	<u>Reference</u>	
Cash Flows From Operating Activities				
Net income	\$ 526	\$ 547	(a) (b)	\$ 1,073
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	714	-		714
Interest accretion expense	66	-		66
Amortization of deferred financing fees	28	-		28
Stock-based compensation	349	-		349
Change in fair value of note payable	142	-		142
Other changes in operating assets and liabilities:				
Accounts receivable	(497)	152	(b)	(345)
Other current assets	(101)	-		(101)
Operating lease right of use assets	349	-		349
Accounts payable	610	-		610
Accrued salaries and bonus	(329)	-		(329)
Other accrued expenses	(138)	(699)	(a)	(837)
Operating lease liabilities	(337)	-		(337)
Long-term liabilities	162	-		162
Net cash provided by operating activities	<u>1,544</u>	<u>-</u>		<u>1,544</u>
Cash Flows From Investing Activity				
Working capital adjustment on sale of Interpace Pharma Solutions	(117)	-		(117)
Purchase of property and equipment	(176)	-		(176)
Net cash used in investing activities	<u>(293)</u>	<u>-</u>		<u>(293)</u>
Cash Flows From Financing Activities				
Payments on line of credit	(1,000)	-		(1,000)
Net cash used in financing activities	<u>(1,000)</u>	<u>-</u>		<u>(1,000)</u>
Net increase in cash and cash equivalents	251	-		251
Cash and cash equivalents from continuing operations– beginning	4,828	-		4,828
Cash and cash equivalents from discontinued operations– beginning	-	-		-
Cash and cash equivalents – beginning	<u>\$ 4,828</u>	<u>\$ -</u>		<u>\$ 4,828</u>
Cash and cash equivalents from continuing operations– ending	\$ 5,079	\$ -		\$ 5,079
Cash and cash equivalents from discontinued operations– ending	-	-		-
Cash and cash equivalents – ending	<u>\$ 5,079</u>	<u>\$ -</u>		<u>\$ 5,079</u>

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

	As Previously Reported	September 30, 2023		
		Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 5,032	\$ -		\$ 5,032
Accounts receivable	4,830	246	(b)	5,076
Other current assets	1,576	-		1,576
Total current assets	<u>11,438</u>	<u>246</u>		<u>11,684</u>
Property and equipment, net	762	-		762
Other intangible assets, net	27	-		27
Operating lease right of use assets	1,978	-		1,978
Other long-term assets	45	-		45
Total assets	<u>\$ 14,250</u>	<u>\$ 246</u>		<u>\$ 14,496</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,352	\$ -		\$ 1,352
Accrued salary and bonus	1,299	-		1,299
Other accrued expenses	8,815	(5,710)	(a)	3,105
Current liabilities of discontinued operations	858	-		858
Total current liabilities	<u>12,324</u>	<u>(5,710)</u>		<u>6,614</u>
Operating lease liabilities, net of current portion	1,556	-		1,556
Note payable at fair value	11,565	-		11,565
Other long-term liabilities	4,949	-		4,949
Total liabilities	<u>30,394</u>	<u>(5,710)</u>		<u>24,684</u>
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; 4,407,492 shares issued and 4,321,772 shares outstanding;	405	-		405
Additional paid-in capital	188,017	-		188,017
Accumulated deficit	(249,105)	5,956	(a) (b)	(243,149)
Treasury stock, at cost (85,720 shares)	(1,997)	-		(1,997)
Total stockholders' deficit	<u>(62,680)</u>	<u>5,956</u>		<u>(56,724)</u>
Total liabilities and stockholders' deficit	<u>(32,286)</u>	<u>246</u>		<u>(32,040)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 14,250</u>	<u>\$ 246</u>		<u>\$ 14,496</u>

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

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATION

(unaudited, in thousands, except for per share data)

	For the Three Months Ended September 30, 2023				For the Nine Months Ended September 30, 2023			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
Revenue, net	\$ 9,078	\$ 125	(b)	\$ 9,203	\$ 29,931	\$ (27)	(b)	\$ 29,904
Cost of revenue	4,124	(303)	(a)	3,821	12,163	(1,002)	(a)	11,161
Gross profit	4,954	428		5,382	17,768	975		18,743
Operating expenses:								
Sales and marketing	2,498	-		2,498	7,444	-		7,444
Research and development	149	-		149	484	-		484
General and administrative	2,124	-		2,124	7,515	-		7,515
Acquisition related amortization expense	199	-		199	834	-		834
Total operating expenses	4,970	-		4,970	16,277	-		16,277
Operating (loss) income from continuing operations	(16)	428		412	1,491	975		2,466
Interest accretion expense	(26)	-		(26)	(92)	-		(92)
Note payable interest expense	(230)	-		(230)	(682)	-		(682)
Other expense, net	(252)	-		(252)	(408)	-		(408)
Loss (income) from continuing operations before tax	(524)	428		(96)	309	975		1,284
Provision for income taxes	4	-		4	12	-		12
(Loss) income from continuing operations	(528)	428		(100)	297	975		1,272
Loss from discontinued operations, net of tax	(86)	-		(86)	(385)	-		(385)
Net (loss) income	\$ (614)	\$ 428		\$ (186)	\$ (88)	\$ 975		\$ 887
Basic net income (loss) per share of common stock:								
From continuing operations	\$ (0.12)	\$ 0.10		\$ (0.02)	\$ 0.07	\$ 0.23		\$ 0.29
From discontinued operations	(0.02)	-		(0.02)	(0.09)	-		(0.09)
Net income (loss) per basic share of common stock	\$ (0.14)	\$ 0.10		\$ (0.04)	\$ (0.02)	\$ 0.23		\$ 0.21
Diluted net income (loss) per share of common stock:								
From continuing operations	\$ (0.12)	\$ 0.10		\$ (0.02)	\$ 0.07	\$ 0.22		\$ 0.29
From discontinued operations	(0.02)	-		(0.02)	(0.09)	-		(0.09)
Net income (loss) per diluted share of common stock	\$ (0.14)	\$ 0.10		\$ (0.04)	\$ (0.02)	\$ 0.22		\$ 0.20
Weighted average number of common shares and common share equivalents outstanding:								
Basic	4,319	4,319		4,319	4,313	4,313		4,313
Diluted	4,319	4,319		4,319	4,355	4,355		4,355

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

Consolidated Statement of Stockholders' Deficit (unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -March 31, 2023 as reported	<u>4,390,826</u>	<u>\$ 405</u>	<u>79,412</u>	<u>\$ (1,985)</u>	<u>\$ 187,708</u>	<u>\$ (248,666)</u>	<u>\$ (62,538)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	4,981	4,981
Cumulative adjustments to net income	-	-	-	-	-	163	163
Balance -March 31, 2023 as restated	<u>4,390,826</u>	<u>\$ 405</u>	<u>79,412</u>	<u>\$ (1,985)</u>	<u>\$ 187,708</u>	<u>\$ (243,522)</u>	<u>\$ (57,394)</u>
Balance -June 30, 2023 as reported	<u>4,390,826</u>	<u>\$ 405</u>	<u>79,412</u>	<u>\$ (1,985)</u>	<u>\$ 187,865</u>	<u>\$ (248,491)</u>	<u>\$ (62,206)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	5,144	5,144
Cumulative adjustments to net income	-	-	-	-	-	384	384
Balance -June 30, 2023 as restated	<u>4,390,826</u>	<u>\$ 405</u>	<u>79,412</u>	<u>\$ (1,985)</u>	<u>\$ 187,865</u>	<u>\$ (242,963)</u>	<u>\$ (56,678)</u>
Balance -September 30, 2023 as reported	<u>4,407,492</u>	<u>\$ 405</u>	<u>85,720</u>	<u>\$ (1,997)</u>	<u>\$ 188,017</u>	<u>\$ (249,105)</u>	<u>\$ (62,680)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	5,528	5,528
Cumulative adjustments to net income	-	-	-	-	-	428	428
Balance -September 30, 2023 as restated	<u><u>4,407,492</u></u>	<u><u>\$ 405</u></u>	<u><u>85,720</u></u>	<u><u>\$ (1,997)</u></u>	<u><u>\$ 188,017</u></u>	<u><u>\$ (243,149)</u></u>	<u><u>\$ (56,724)</u></u>

INTERPACE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited, in thousands)

	For The Nine Months Ended September 30,			
	2023 As Previously Reported	Restatement Amount	Restatement Reference	2023 As Restated
Cash Flows From Operating Activities				
Net (loss) income	\$ (88)	\$ 975	(a) (b)	\$ 887
Adjustments to reconcile net (loss) income to net cash used in operating activities:				
Depreciation and amortization	954	-		954
Interest accretion expense	92	-		92
Amortization of deferred financing fees	42	-		42
Stock-based compensation	501	-		501
Change in fair value of note payable	400	-		400
Other changes in operating assets and liabilities:				
Accounts receivable	202	27	(b)	229
Other current assets	176	-		176
Operating lease right of use assets	461	-		461
Accounts payable	228	-		228
Accrued salaries and bonus	(157)	-		(157)
Other accrued expenses	(118)	(1,002)	(a)	(1,120)
Operating lease liabilities	(292)	-		(292)
Long-term liabilities	248	-		248
Net cash provided by operating activities	<u>2,649</u>	<u>-</u>		<u>2,649</u>
Cash Flows From Investing Activity				
Proceeds from sale of Interpace Pharma Solutions, net	500	-		500
Working capital adjustment on sale of Interpace Pharma Solutions	(117)	-		(117)
Purchase of property and equipment	(328)	-		(328)
Net cash provided by investing activities	<u>55</u>	<u>-</u>		<u>55</u>
Cash Flows From Financing Activities				
Payments on line of credit	(2,500)	-		(2,500)
Net cash used in financing activities	<u>(2,500)</u>	<u>-</u>		<u>(2,500)</u>
Net increase in cash and cash equivalents	204	-		204
Cash and cash equivalents from continuing operations– beginning	4,828	-		4,828
Cash and cash equivalents from discontinued operations– beginning	-	-		-
Cash and cash equivalents – beginning	<u>\$ 4,828</u>	<u>\$ -</u>		<u>\$ 4,828</u>
Cash and cash equivalents from continuing operations– ending	<u>\$ 5,032</u>	<u>\$ -</u>		<u>\$ 5,032</u>
Cash and cash equivalents from discontinued operations– ending	-	-		-
Cash and cash equivalents – ending	<u><u>\$ 5,032</u></u>	<u><u>\$ -</u></u>		<u><u>\$ 5,032</u></u>

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEET

(unaudited, in thousands, except share and per share data)

	March 31, 2024			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 2,812	\$ -		\$ 2,812
Accounts receivable	5,006	-		5,006
Other current assets	1,598	-		1,598
Total current assets	9,416	-		9,416
Property and equipment, net	925	-		925
Operating lease right of use assets	1,756	-		1,756
Other long-term assets	45	-		45
Total assets	<u>\$ 12,142</u>	<u>\$ -</u>		<u>\$ 12,142</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,363	\$ -		\$ 1,363
Accrued salary and bonus	878	-		878
Other accrued expenses	8,574	(6,373)	(a)	2,201
Note payable at fair value, current	7,498	-		7,498
Current liabilities of discontinued operations	660	-		660
Total current liabilities	18,973	(6,373)		12,600
Operating lease liabilities, net of current portion	1,359	-		1,359
Note payable at fair value	1,343	-		1,343
Other long-term liabilities	5,072	-		5,072
Total liabilities	26,747	(6,373)		20,374
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; 4,487,157 shares issued and 4,376,398 shares outstanding;	406	-		406
Additional paid-in capital	188,224	-		188,224
Accumulated deficit	(247,747)	6,373	(a)	(241,374)
Treasury stock, at cost (110,759 shares)	(2,024)	-		(2,024)
Total stockholders' deficit	(61,141)	6,373		(54,768)
Total liabilities and stockholders' deficit	<u>(34,394)</u>	<u>-</u>		<u>(34,394)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 12,142</u>	<u>\$ -</u>		<u>\$ 12,142</u>

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

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

	For the Three Months Ended March 31, 2024			
	<u>As Previously Reported</u>	<u>Restatement Amount</u>	<u>Restatement Reference</u>	<u>As Restated</u>
Revenue, net	\$ 10,273	\$ (95)	(b)	\$ 10,178
Cost of revenue	4,202	(335)	(a)	3,867
Gross profit	<u>6,071</u>	<u>240</u>		<u>6,311</u>
Operating expenses:				
Sales and marketing	2,821	-		2,821
Research and development	137	-		137
General and administrative	2,239	-		2,239
Total operating expenses	<u>5,197</u>	<u>-</u>		<u>5,197</u>
Operating income from continuing operations	874	240		1,114
Interest accretion expense	(19)	-		(19)
Note payable interest expense	(197)	-		(197)
Other expense, net	(82)	-		(82)
Income from continuing operations before tax	576	240		816
Provision for income taxes	4	-		4
Income from continuing operations	572	240		812
Loss from discontinued operations, net of tax	(104)	-		(104)
Net income	<u>\$ 468</u>	<u>\$ 240</u>		<u>\$ 708</u>
Basic net income (loss) per share of common stock:				
From continuing operations	\$ 0.13	\$ 0.05		\$ 0.19
From discontinued operations	(0.02)	-		(0.02)
Net income (loss) per basic share of common stock	<u>\$ 0.11</u>	<u>\$ 0.05</u>		<u>\$ 0.16</u>
Diluted net income (loss) per share of common stock:				
From continuing operations	\$ 0.13	\$ 0.05		\$ 0.19
From discontinued operations	(0.02)	-		(0.02)
Net income (loss) per diluted share of common stock	<u>\$ 0.11</u>	<u>\$ 0.05</u>		<u>\$ 0.16</u>
Weighted average number of common shares and common share equivalents outstanding:				
Basic	4,370	4,370		4,370
Diluted	4,384	4,384		4,384

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

Consolidated Statement of Stockholders' Deficit (unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -March 31, 2024 as reported	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,224</u>	<u>\$ (247,747)</u>	<u>\$ (61,141)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,133	6,133
Cumulative adjustments to net income	-	-	-	-	-	240	240
Balance -March 31, 2024 as restated	<u><u>4,487,157</u></u>	<u><u>\$ 406</u></u>	<u><u>110,759</u></u>	<u><u>\$ (2,024)</u></u>	<u><u>\$ 188,224</u></u>	<u><u>\$ (247,507)</u></u>	<u><u>\$ (54,768)</u></u>

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

	For The Three Months Ended March 31,			
	2024 As Previously Reported	Restatement Amount	Restatement Reference	2024 As Restated
Cash Flows From Operating Activities				
Net income	\$ 468	\$ 240		\$ 708
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	52	-		52
Interest accretion expense	19	-		19
Bad debt expense reversal	(100)	-		(100)
Stock-based compensation	79	-		79
Credit loss expense	26	-		26
Change in fair value of note payable	98	-		98
Amortization on operating lease right of use asset	108	-		108
Other changes in operating assets and liabilities:				
Accounts receivable	(49)	95	(b)	46
Other current assets	343	-		343
Accounts payable	(176)	-		(176)
Accrued salaries and bonus	(1,091)	-		(1,091)
Other accrued expenses	176	(335)	(a)	(159)
Operating lease liabilities	(115)	-		(115)
Long-term liabilities	104	-		104
Net cash used in operating activities	(58)	-		(58)
Cash Flows From Investing Activity				
Purchase of property and equipment	(28)	-		(28)
Net cash used in investing activities	(28)	-		(28)
Cash Flows From Financing Activities				
Payments made on note payable	(600)	-		(600)
Net cash used in financing activities	(600)	-		(600)
Net decrease in cash and cash equivalents	(686)	-		(686)
Cash and cash equivalents from continuing operations– beginning	3,498	-		3,498
Cash and cash equivalents from discontinued operations– beginning	-	-		-
Cash and cash equivalents – beginning	\$ 3,498	\$ -		\$ 3,498
Cash and cash equivalents from continuing operations– ending	\$ 2,812	\$ -		\$ 2,812
Cash and cash equivalents from discontinued operations– ending	-	-		-
Cash and cash equivalents – ending	\$ 2,812	\$ -		\$ 2,812

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

	June 30, 2024			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 2,019	\$ -		\$ 2,019
Accounts receivable	6,206	-		6,206
Other current assets	1,941	-		1,941
Total current assets	10,166	-		10,166
Property and equipment, net	1,126	-		1,126
Operating lease right of use assets	1,635	-		1,635
Other long-term assets	45	-		45
Total assets	<u>\$ 12,972</u>	<u>\$ -</u>		<u>\$ 12,972</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,761	\$ -		\$ 1,761
Accrued salary and bonus	1,243	-		1,243
Other accrued expenses	8,582	(6,748)	(a)	1,834
Note payable at fair value, current	6,784	-		6,784
Current liabilities of discontinued operations	660	-		660
Total current liabilities	19,030	(6,748)		12,282
Operating lease liabilities, net of current portion	1,286	-		1,286
Other long-term liabilities	5,146	-		5,146
Total liabilities	25,462	(6,748)		18,714
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; 4,487,157 shares issued and 4,376,398 shares outstanding;	406	-		406
Additional paid-in capital	188,277	-		188,277
Accumulated deficit	(245,685)	6,748	(a)	(238,937)
Treasury stock, at cost (110,759 shares)	(2,024)	-		(2,024)
Total stockholders' deficit	(59,026)	6,748		(52,278)
Total liabilities and stockholders' deficit	<u>(33,564)</u>	<u>-</u>		<u>(33,564)</u>
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 12,972</u>	<u>\$ -</u>		<u>\$ 12,972</u>

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

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

	For the Three Months Ended June 30, 2024				For the Six Months Ended June 30, 2024			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
Revenue, net	\$ 12,042	\$ -		\$ 12,042	\$ 22,314	\$ (95)	(b)	\$ 22,219
Cost of revenue	4,611	(375)	(a)	4,236	8,812	(710)	(a)	8,102
Gross profit	7,431	375		7,806	13,502	615		14,117
Operating expenses:								
Sales and marketing	2,887	-		2,887	5,707	-		5,707
Research and development	146	-		146	283	-		283
General and administrative	2,141	-		2,141	4,381	-		4,381
Total operating expenses	5,174	-		5,174	10,371	-		10,371
Operating income from continuing operations	2,257	375		2,632	3,131	615		3,746
Interest accretion expense	(12)	-		(12)	(30)	-		(30)
Note payable interest expense	(176)	-		(176)	(373)	-		(373)
Other expense, net	71	-		71	(12)	-		(12)
Income from continuing operations before tax	2,140	375		2,515	2,716	615		3,331
Provision for income taxes	4	-		4	8	-		8
Income from continuing operations	2,136	375		2,511	2,708	615		3,323
Loss from discontinued operations, net of tax	(74)	-		(74)	(178)	-		(178)
Net income	\$ 2,062	\$ 375		\$ 2,437	\$ 2,530	\$ 615		\$ 3,145
Basic net income (loss) per share of common stock:								
From continuing operations	\$ 0.49	\$ 0.09		\$ 0.57	\$ 0.62	\$ 0.14		\$ 0.76
From discontinued operations	(0.02)	-		(0.02)	(0.04)	-		(0.04)
Net income (loss) per basic share of common stock	\$ 0.47	\$ 0.09		\$ 0.56	\$ 0.58	\$ 0.14		\$ 0.72
Diluted net income (loss) per share of common stock:								
From continuing operations	\$ 0.49	\$ 0.09		\$ 0.57	\$ 0.62	\$ 0.14		\$ 0.76
From discontinued operations	(0.02)	-		(0.02)	(0.04)	-		(0.04)
Net income (loss) per diluted share of common stock	\$ 0.47	\$ 0.09		\$ 0.55	\$ 0.58	\$ 0.14		\$ 0.72
Weighted average number of common shares and common share equivalents outstanding:								
Basic	4,376	4,376		4,376	4,373	4,373		4,373
Diluted	4,401	4,401		4,401	4,393	4,393		4,393

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

Consolidated Statement of Stockholders' Deficit (unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -March 31, 2024 as reported	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,224</u>	<u>\$ (247,747)</u>	<u>\$ (61,141)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,133	6,133
Cumulative adjustments to net income	-	-	-	-	-	240	240
Balance -March 31, 2024 as restated	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,224</u>	<u>\$ (247,507)</u>	<u>\$ (54,768)</u>
Balance -June 30, 2024 as reported	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,277</u>	<u>\$ (245,685)</u>	<u>\$ (59,026)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,373	6,373
Cumulative adjustments to net income	-	-	-	-	-	375	375
Balance -June 30, 2024 as restated	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,277</u>	<u>\$ (245,310)</u>	<u>\$ (52,278)</u>

INTERPACE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited, in thousands)

	For The Six Months Ended June 30,			
	2024 As Previously Reported	Restatement Amount	Restatement Reference	2024 As Restated
Cash Flows From Operating Activities				
Net income	\$ 2,530	\$ 615	(a)	\$ 3,145
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	119	-		119
Interest accretion expense	30	-		30
Bad debt expense reversal	(100)	-		(100)
Stock-based compensation	132	-		132
Credit loss expense	26	-		26
Change in fair value of note payable	41	-		41
Amortization on operating lease right of use asset	229	-		229
Other changes in operating assets and liabilities:				
Accounts receivable	(1,249)	95	(b)	(1,154)
Other current assets	-	-		-
Accounts payable	(13)	-		(13)
Accrued salaries and bonus	(726)	-		(726)
Other accrued expenses	337	(710)	(a)	(373)
Operating lease liabilities	(188)	-		(188)
Long-term liabilities	178	-		178
Net cash provided by operating activities	1,346	-		1,346
Cash Flows From Investing Activity				
Purchase of property and equipment	(225)	-		(225)
Net cash used in investing activities	(225)	-		(225)
Cash Flows From Financing Activities				
Payments made on note payable	(2,600)	-		(2,600)
Net cash used in financing activities	(2,600)	-		(2,600)
Net decrease in cash and cash equivalents	(1,479)	-		(1,479)
Cash and cash equivalents from continuing operations— beginning	3,498	-		3,498
Cash and cash equivalents from discontinued operations— beginning	-	-		-
Cash and cash equivalents – beginning	\$ 3,498	\$ -		\$ 3,498
Cash and cash equivalents from continuing operations— ending	\$ 2,019	\$ -		\$ 2,019
Cash and cash equivalents from discontinued operations— ending	-	-		-
Cash and cash equivalents – ending	\$ 2,019	\$ -		\$ 2,019

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

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

	September 30, 2024			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 2,113	\$ -		\$ 2,113
Accounts receivable	7,293	-		7,293
Other current assets	1,704	-		1,704
Total current assets	11,110	-		11,110
Property and equipment, net	1,352	-		1,352
Operating lease right of use assets	1,532	-		1,532
Other long-term assets	45	-		45
Total assets	<u>\$ 14,039</u>	<u>\$ -</u>		<u>\$ 14,039</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 1,701	\$ -		\$ 1,701
Accrued salary and bonus	1,687	-		1,687
Other accrued expenses	9,033	(7,144)	(a)	1,889
Note payable at fair value, current	5,688	-		5,688
Current liabilities of discontinued operations	660	-		660
Total current liabilities	18,769	(7,144)		11,625
Operating lease liabilities, net of current portion	1,189	-		1,189
Other long-term liabilities	5,227	-		5,227
Total liabilities	25,185	(7,144)		18,041
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; 4,532,991 shares issued and 4,404,795 shares outstanding;	406	-		406
Additional paid-in capital	188,363	-		188,363
Accumulated deficit	(244,405)	7,144	(a)	(237,261)
Treasury stock, at cost (128,196 shares)	(2,046)	-		(2,046)
Total stockholders' deficit	(57,682)	7,144		(50,538)
Total liabilities and stockholders' deficit	(32,497)	-		(32,497)
Total liabilities, preferred stock and stockholders' deficit	<u>\$ 14,039</u>	<u>\$ -</u>		<u>\$ 14,039</u>

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

INTERPACE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATION

(unaudited, in thousands, except for per share data)

	For the Three Months Ended September 30, 2024				For the Nine Months Ended September 30, 2024			
	As Previously Reported	Restatement Amount	Restatement Reference	As Restated	As Previously Reported	Restatement Amount	Restatement Reference	As Restated
Revenue, net	\$ 12,295	\$ -		\$ 12,295	\$ 34,610	\$ (95)	(b)	\$ 34,515
Cost of revenue	4,789	(396)	(a)	4,393	13,602	(1,106)	(a)	12,496
Gross profit	7,506	396		7,902	21,008	1,011		22,019
Operating expenses:								
Sales and marketing	2,864	-		2,864	8,571	-		8,571
Research and development	199	-		199	483	-		483
General and administrative	2,538	-		2,538	6,918	-		6,918
Total operating expenses	5,601	-		5,601	15,972	-		15,972
Operating income from continuing operations	1,905	396		2,301	5,036	1,011		6,047
Interest accretion expense	(4)	-		(4)	(34)	-		(34)
Note payable interest expense	(141)	-		(141)	(514)	-		(514)
Other expense, net	(394)	-		(394)	(406)	-		(406)
Income from continuing operations before tax	1,366	396		1,762	4,082	1,011		5,093
Provision for income taxes	4	-		4	12	-		12
Income from continuing operations	1,362	396		1,758	4,070	1,011		5,081
Loss from discontinued operations, net of tax	(82)	-		(82)	(260)	-		(260)
Net income	\$ 1,280	\$ 396		\$ 1,676	\$ 3,810	\$ 1,011		\$ 4,821
Basic net income (loss) per share of common stock:								
From continuing operations	\$ 0.31	\$ 0.09		\$ 0.40	\$ 0.93	\$ 0.23		\$ 1.16
From discontinued operations	(0.02)	-		(0.02)	(0.06)	-		(0.06)
Net income (loss) per basic share of common stock	\$ 0.29	\$ 0.09		\$ 0.38	\$ 0.87	\$ 0.23		\$ 1.10
Diluted net income (loss) per share of common stock:								
From continuing operations	\$ 0.31	\$ 0.09		\$ 0.40	\$ 0.92	\$ 0.23		\$ 1.15
From discontinued operations	(0.02)	-		(0.02)	(0.06)	-		(0.06)
Net income (loss) per diluted share of common stock	\$ 0.29	\$ 0.09		\$ 0.38	\$ 0.87	\$ 0.23		\$ 1.09
Weighted average number of common shares and common share equivalents outstanding:								
Basic	4,393	4,393		4,393	4,380	4,380		4,380
Diluted	4,423	4,423		4,423	4,404	4,404		4,404

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

Consolidated Statement of Stockholders' Deficit (unaudited)

	Common Stock		Treasury Stock		Additional Paid in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance -March 31, 2024 as reported	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,224</u>	<u>\$ (247,747)</u>	<u>\$ (61,141)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,133	6,133
Cumulative adjustments to net income	-	-	-	-	-	240	240
Balance -March 31, 2024 as restated	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,224</u>	<u>\$ (247,507)</u>	<u>\$ (54,768)</u>
Balance -June 30, 2024 as reported	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,277</u>	<u>\$ (245,685)</u>	<u>\$ (59,026)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,373	6,373
Cumulative adjustments to net income	-	-	-	-	-	375	375
Balance -June 30, 2024 as restated	<u>4,487,157</u>	<u>\$ 406</u>	<u>110,759</u>	<u>\$ (2,024)</u>	<u>\$ 188,277</u>	<u>\$ (245,310)</u>	<u>\$ (52,278)</u>
Balance -September 30, 2024 as reported	<u>4,532,991</u>	<u>\$ 406</u>	<u>128,196</u>	<u>\$ (2,046)</u>	<u>\$ 188,363</u>	<u>\$ (244,405)</u>	<u>\$ (57,682)</u>
Cumulative adjustments to accumulated deficit in prior years	-	-	-	-	-	6,748	6,748
Cumulative adjustments to net income	-	-	-	-	-	396	396
Balance -September 30, 2024 as restated	<u>4,532,991</u>	<u>\$ 406</u>	<u>128,196</u>	<u>\$ (2,046)</u>	<u>\$ 188,363</u>	<u>\$ (244,009)</u>	<u>\$ (50,538)</u>

INTERPACE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(unaudited, in thousands)

	For The Nine Months Ended September 30,			
	2024	Restatement Amount	Restatement Reference	2023
	As Previously Reported			As Restated
Cash Flows From Operating Activities				
Net income	\$ 3,810	\$ 1,011	(a)	\$ 4,821
Adjustments to reconcile net income to net cash used in operating activities:				
Depreciation and amortization	205	-		205
Interest accretion expense	34	-		34
Bad debt expense reversal	(100)	-		(100)
Credit loss expense	26	-		26
Stock-based compensation	218	-		218
Change in fair value of note payable	445	-		445
Amortization on operating lease right of use asset	332	-		332
Other changes in operating assets and liabilities:				-
Accounts receivable	(2,336)	95	(b)	(2,241)
Other current assets	237	-		237
Accounts payable	137	-		137
Accrued salaries and bonus	(320)	-		(320)
Other accrued expenses	870	(1,106)	(a)	(236)
Operating lease liabilities	(355)	-		(355)
Long-term liabilities	259	-		259
Net cash provided by (used in) operating activities	<u>3,462</u>	<u>-</u>		<u>3,462</u>
Cash Flows From Investing Activity				
Purchase of property and equipment	(747)	-		(747)
Net cash provided by investing activities	<u>(747)</u>	<u>-</u>		<u>(747)</u>
Cash Flows From Financing Activities				
Payments made on note payable	(4,100)	-		(4,100)
Net cash used in financing activities	<u>(4,100)</u>	<u>-</u>		<u>(4,100)</u>
Net decrease in cash and cash equivalents	(1,385)	-		(1,385)
Cash and cash equivalents from continuing operations– beginning	3,498	-		3,498
Cash and cash equivalents from discontinued operations– beginning	-	-		-
Cash and cash equivalents – beginning	<u>\$ 3,498</u>	<u>\$ -</u>		<u>\$ 3,498</u>
Cash and cash equivalents from continuing operations– ending	\$ 2,113	\$ -		\$ 2,113
Cash and cash equivalents from discontinued operations– ending	-	-		-
Cash and cash equivalents – ending	<u>\$ 2,113</u>	<u>\$ -</u>		<u>\$ 2,113</u>

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

INTERPACE BIOSCIENCES, INC.
INSIDER TRADING POLICY

POLICY PRINCIPLES

1. Employees, directors, officers and designated contractors and consultants (each a “Covered Person,” and collectively, “Covered Persons”) of Interpace Biosciences, Inc. and its direct and indirect subsidiaries (together, the “Company”) (or any other person or entity subject to this Insider Trading Policy (this “Policy”)) are responsible for understanding the obligations that come with having access to material nonpublic information and wanting to transact in securities issued by the Company and/or other entities.
2. Covered Persons may not trade in the Company’s securities if they are in possession of or otherwise aware of material nonpublic information regarding the Company. In addition, Covered Persons may not engage in transactions in securities of another company with which the Company conducts business, such as a customer, partner, distributor or supplier, if they are in possession of or otherwise aware of material nonpublic information relating to such other company obtained in course of employment with, or services performed on behalf of, the Company.
3. Covered Persons may not directly or indirectly disclose material nonpublic information outside of the Company, unless the disclosure is made in accordance with a specific Company policy that authorizes such disclosure.
4. Covered Persons may not directly or indirectly disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information.
5. Covered Persons may not directly or indirectly recommend the purchase or sale of any Company securities.
6. Covered Persons may not directly or indirectly assist anyone engaged in the above activities.
7. The Company itself must comply with U.S. securities laws applicable to its own securities trading activities and will not effect transactions in respect of its securities, or adopt any securities repurchase plans, when it is in possession of material nonpublic information concerning the Company, other than in compliance with applicable law, subject to the policies and procedures adopted by the Company.
8. Changes to this Policy require approval by the Company’s Board of Directors or a duly appointed committee of the Board of Directors.

POLICY Q&A**Policy Scope and Purpose****Q: Why do we have an insider trading policy?**

- A: During the course of your relationship with the Company, you may receive material information that is not yet publicly available (“material nonpublic information”) about the Company or other companies. Material nonpublic information may give you, or someone to whom you pass that information, an advantage over others when deciding whether to buy, sell or otherwise transact in Company securities or the securities of another company. This Policy sets forth guidelines with respect to transactions in Company securities, or the securities issued by other companies, by persons subject to this Policy.

Q: Who is subject to this Policy?

A: This Policy applies to you and all other Covered Persons. This Policy also applies to members of your family who reside with you, any other persons with whom you share a household, any family members who do not live in your household but whose transactions in the Company's securities are directed by you or subject to your influence or control, persons who are your economic dependents, and, unless otherwise determined by the Company, any other individuals or entities whose transactions in securities you influence, direct, or control (including, e.g., a venture or other investment fund, if you influence, direct, or control transactions by the fund) (collectively, "Related Persons"). You are responsible for making sure that your Related Persons comply with this Policy.

In addition, if you are an officer or director of the Company, or a designated employee, contractor or consultant of the Company (collectively, "Specified Personnel"), you and your Related Persons are subject to the quarterly trading blackout periods and pre-clearance procedures described below.

This Policy applies also to the Company with respect to transactions in its own securities (particularly repurchases), including persons with oversight responsibility over those Company transactions.

Q: Whose responsibility is it to comply with this Policy?

A: Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities while in possession of or otherwise aware of material nonpublic information relating to the Company. Each individual is responsible for making sure that he or she and his or her Related Persons comply with this Policy. In all cases, the responsibility for determining whether an individual is in possession of or otherwise aware of material nonpublic information rests with that individual, and any action on the part of the Company or any Covered Persons pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this Policy or applicable securities laws.

Q: What transactions are subject to this Policy?

A: This Policy applies to all transactions in "securities" whether issued by the Company or another entity, as well as derivative securities such as exchange-traded put or call options or swaps. Accordingly, for purposes of this policy, the terms "trade," "trading," and "transactions" include not only purchases and sales of the Company's common stock but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants, and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

Insider Trading and Material Nonpublic Information

Q: What is insider trading?

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. **Bottom line: If, during the course of your relationship with the Company, you become aware of material nonpublic information about the Company or another company and you trade in the Company's or such other company's securities, you may have broken the law and violated this Policy.**

Q: When is information considered material?

A: As a general matter, information is considered "material" if it would be considered important to a reasonable investor in deciding whether to buy, hold or sell a security, or if the information otherwise significantly alters the total mix of information publicly known about a company or its securities. It is not always easy to figure out whether information would be considered "material." Information that could be expected to affect the market price of a security is often considered "material." If the information makes you want to buy or sell a security, it would likely have the same effect on others and likely would be considered "material." Keep in mind that both positive and negative information can be material. Furthermore, information could be material because of its expected effect on the price of the Company's outstanding securities, the securities of another company not related to the Company or the securities of several such companies.

Q: What are examples of material information?

A: There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material information. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- projections of future earnings or losses, or other earnings guidance;
- reimbursement, including loss of coverage from government programs;
- financial results or forecasts;
- acquisitions, dispositions or other strategic transactions;
- events regarding the Company's securities (e.g., repurchase plans, stock splits, public or private equity or debt offerings, or changes in the Company's dividend policies or amounts);
- significant related party transactions;
- gain or loss of a license agreement or other contract with customers or suppliers;
- changes or new corporate partner relationships or collaborations;
- status of development of clinical service products and other product solutions or regulatory approvals;
- clinical data relating to clinical service products and other product solutions of the Company;
- timelines for pre-clinical studies or clinical trials;
- regulatory developments;
- changes in patents, trademarks or other intellectual property rights;
- major contracts or contract cancellations;

- pricing changes or discount policies;
- significant product problems or security incidents;
- top management or control changes;
- financial restatements or significant write-offs;
- employee layoffs;
- a significant cybersecurity incident, such as a data breach, or any other significant disruption in the Company’s operations or breach or unauthorized access of its property or assets, including its facilities or information technology infrastructure;
- tender offers or proxy fights;
- actual or threatened major litigation, U.S. Securities and Exchange Commission (“SEC”) or other investigations, or a major development in or the resolution of any such litigation or investigation;
- impending bankruptcy;
- communications with government agencies; and
- the imposition of an event-specific restriction on trading in the Company’s securities or the securities of another company or the extension or termination of such restriction.

Q: When is information considered public?

A: The prohibition on trading when you have material nonpublic information lifts once that information becomes “public.” For information to be considered “public,” it must be widely disseminated through a press release, a filing with the SEC or other widely disseminated announcement and digested by the market so the investing public has sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy ***only after two (2) full trading days have elapsed since the information was publicly disclosed.*** For example, if we announce material nonpublic information before trading begins on Wednesday, then the information would be considered publicly disseminated by the time trading begins on Friday. If we announce material nonpublic information after trading ends on Wednesday, then information would be considered publicly disseminated by the time trading ends on Friday.

In addition, as discussed further below, **Specified Personnel and their Related Persons may not trade securities of the Company during any trading “blackout” period even if they are not aware of any material nonpublic information.** This Policy describes the quarterly trading blackout period, and additional event-driven trading blackout periods (which may apply to you even if the quarterly trading blackout periods do not) may be announced by email.

Q: Who can be guilty of insider trading?

A: Anyone who buys or sells a security while in possession of or otherwise aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors, and others who don’t even work at the Company. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

Q: What if I am aware of material nonpublic information when I trade, but the reason I trade is because of something else, like to pay medical bills?

A: The prohibition against insider trading is absolute. It applies even if the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of any material nonpublic information relating to the Company, or any other entity whose equity securities you are trading, at the time of the transaction.

Q: Do the U.S. securities laws take into account mitigating circumstance, like avoiding a loss or planning a transaction before I had material nonpublic information?

A: No. The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

Q: What if I don't buy or sell anything, but I tell someone else material nonpublic information and he or she buys or sells?

A: That is called "tipping." You are the "tipper," and the other person is called the "tippee." If the tippee buys or sells while in possession of that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the Company or another company with anyone outside the Company, *including spouses, family members, friends, or business associates* (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company). This includes anonymous discussions on the internet about the Company or companies with which the Company does business. Advising others to trade while in possession of material nonpublic information is illegal and squarely prohibited by this Policy.

You can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. *For these and other reasons, no Covered Person (or any other person subject to this Policy) may either (a) recommend to another person that they buy, hold or sell the Company's securities at any time or (b) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that material nonpublic information, or outside of the Company to other persons (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company).*

Q: What if I don't tell someone inside information itself; I just tell him or her whether to buy or sell?

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell the Company's common stock or any derivative security related to the Company's common stock, since that could be a form of tipping.

Q: Do the provisions of this Policy or the insider trading laws apply to me if I work outside the U.S. or trade in securities on a foreign exchange?

A: Yes. The same rules apply to U.S. and foreign employees and consultants. The SEC (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, the US insider trading laws may in certain circumstances apply to trading securities issued by a foreign company and traded on a foreign exchange. In any event, our policies apply to you, as a Covered Person, no matter where you work.

Q: So if I do not trade Company securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, directors, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Company stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our directors, employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire Policy carefully.

Q: Are there any exceptions to this policy?

A: Bona fide gifts for estate planning purposes, including gifts to a trust, family limited partnership, charitable foundation or similar entity, as long as you or members of your immediate family remain the sole beneficiaries of the transferred shares and the terms of the transfer ensure that the shares remain subject to the same restrictions that apply to you under this Policy, are not subject to this Policy's restrictions.

A Covered Person who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the Chief Executive Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Chief Executive Officer concludes that the person is not in fact aware of any material nonpublic information relating to the Company or its securities, and there appears to be no significant risk that the trade may subsequently be questioned. An exception will not be granted during an event-specific trading blackout.

Blackout Periods

Q: What is a quarterly trading blackout period?

A: To minimize the appearance of insider trading by the Specified Personnel and their Related Persons, we have established quarterly trading blackout periods (as defined below) during which they — regardless of whether they are in possession of material nonpublic information or not — may not conduct any trades in Company securities. That means that, except as described in this Policy, all Specified Personnel and their Related Persons will be able to trade in Company securities *only* during limited open trading window periods that generally will begin after two (2) full trading days have elapsed since the public dissemination of Company's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Company securities if you are in fact in possession of or otherwise aware of material nonpublic information.

Q: What are the Company's quarterly trading blackout periods?

A: Each quarterly trading blackout period will generally begin at the start of the fifteenth (15th) day of the third month of each fiscal quarter (or, if that day is not a trading day, then the end of the preceding trading day) and end after two (2) full trading days have elapsed since the public dissemination of the Company's financial results for that quarter.

Q: Can the Company's quarterly trading blackout periods change?

A: The quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer there exists undisclosed information that would make trades by Specified Personnel or their Related Persons inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

Q: Does the Company have blackout periods other than quarterly trading blackout periods?

A: Yes. From time to time, an event may occur that is material to the Company and is known by only a few officers, directors, employees, contractors and/or consultants. So long as the event remains material and nonpublic, the persons designated by the Chief Executive Officer may not trade in the Company's securities. In that situation, the Company will notify the designated individuals that neither they nor their Related Persons may trade in the Company's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information.

Q: If I am subject to a blackout period and I have an open order to buy or sell the Company securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?

A: No, unless it is in connection with a Rule 10b5-1 Plan (as defined below). If you have any open orders when a blackout period commences other than in connection with a Rule 10b5-1 Plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a Rule 10b5-1 Plan, you will have violated this Policy and may also have violated insider trading laws.

Q: Can I exercise options granted to me by the Company, or participate in a Company employee stock purchase plan, during a trading blackout period or when I possess or am otherwise aware of material nonpublic information?

A: As a general matter, you may purchase shares by exercising your options or participating in a Company employee stock purchase plan, but you may not tender or sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period applicable to you or at any time that you are aware of material nonpublic information. To be clear, you may not tender shares for net-settlement of options or effect a broker-assisted cashless exercise (because these cashless exercise transactions include a market sale) during a trading blackout period applicable to you or at any time that you are aware of material nonpublic information.

Q: What are the rules that apply to Rule 10b5-1 Plans?

A: Rule 10b5-1 of the Securities Act of 1934, as amended (the “Exchange Act”) provides a defense from insider trading liability. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a written trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act that meets certain conditions specified in the rule (a “Rule 10b5-1 Plan”). If the plan meets the requirements of Rule 10b5-1, Company securities may be purchased or sold without regard to certain insider trading restrictions. To comply with this Policy, a Rule 10b5-1 Plan must be pre-approved by the Chief Executive Officer and meet the requirements of Rule 10b5-1. A Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party and, once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade.

Persons subject to this Policy may only have one outstanding Rule 10b5-1 Plan at any one time (subject to certain exceptions). All Rule 10b5-1 Plans must have a “cooling off period,” the length of which will depend on the status of the person subject to this Policy. For directors and executive officers, the applicable “cooling off period” is the later of (x) ninety (90) days after the adoption and (y) three (3) business days following the disclosure of the Company’s financial results in a Form 10-Q or Form 10-K for the fiscal quarter in which the plan was adopted, subject to a maximum of 120 days. For all other Covered Persons, the applicable “cooling off period” is at least thirty (30) days from the time the trading plan is executed to the time of the first trade pursuant to the plan. The Company does not permit a Rule 10b5-1 Plan to be entered into during a blackout period. Any plan participant must act in good faith with respect to their Rule 10b5-1 Plan.

Rule 10b5-1 Plans will be considered by the Chief Executive Officer on a case-by-case basis. Any Rule 10b5-1 Plan must be submitted to the Chief Executive Officer for approval at least five (5) days prior to the entry into the Rule 10b5-1 Plan. The adoption, modification, or cancellation of any Rule 10b5-1 Plan must be approved by the Chief Executive Officer. The Company also reserves the right from time to time to suspend, discontinue under a Rule 10b5-1 Plan if the Company’s Board of Directors, in its discretion, determines that such suspension, discontinuation or other prohibition is in the best interests of the Company.

Pledging Shares, Hedging and Other Speculation in Company Common Stock

Q: Can I pledge my Company shares as collateral for a loan?

A: No. Pledging your shares as collateral for a loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

Q: Can I hedge my ownership position in the Company?

A: No. Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds are prohibited by this Policy.

Q: Why are hedging transactions prohibited?

A: Such transactions may permit a person subject to this Policy to continue to own the Company’s securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the person may no longer have the same objectives as the Company’s other stockholders. Therefore, all persons subject to this Policy are prohibited from engaging in any such transactions.

Q: Am I allowed to trade derivative securities of the Company's common stock?

A: No. You may not trade in derivative securities related to the Company's common stock, which include publicly traded call and put options. In addition, you may not engage in short selling of Company common stock or in any other inherently speculative transactions with respect to the Company's securities at any time.

Q: What are derivative securities?

A: "Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under the Company's equity compensation plans, which are not derivative securities for purposes of this Policy.

Q: What is short selling?

A: "Short selling" is profiting when you expect the price of the stock to decline and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

Q: Why does the Company prohibit trading in derivative securities and short selling?

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. The Company is dedicated to building stockholder value; short selling the Company's common stock conflicts with the Company's values and would not be well-received by its stockholders.

Q: What if I purchased publicly traded options or other derivative securities before I became subject to this Policy?

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period applicable to you or at any time that you are aware of material nonpublic information.

Q: What are the concerns about standing and limit orders?

A: Standing and limit orders are instructions to purchase or sell securities once the value of those securities reaches a certain price. Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts, since there is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Covered Person is in possession of or otherwise aware of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a person subject to this Policy determines that they must use a standing order or limit order (other than under an approved Rule 10b5-1 Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "quarterly trading blackout periods" and "event-specific trading blackouts" outlined above.

Pre-Clearance of Transactions in Company Stock

Q: Who is required to pre-clear and provide advance notice of transactions?

A: In addition to the requirements above, all Specified Personnel and Related Persons face a further restriction: Even during an open trading window, they may not engage in any transaction in the Company's securities without first obtaining pre-clearance of the transaction from the Chief Executive Officer at least three (3) business days in advance of the proposed transaction. The Chief Executive Officer will then determine whether the transaction may proceed and, if so, will help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five (5) trading days after approval will require new pre-clearance. The Company may choose to shorten this period. A previously submitted and approved Rule 10b5-1 Plan shall constitute advance notice and pre-clearance for purposes of this Policy.

Q: Are individuals subject to pre-clearance required to provide advanced notice of stock option exercises?

A: Yes. Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Chief Executive Officer. Once any transaction takes place, the officer, director or applicable member of management must immediately notify the Chief Executive Officer so that the Company may assist in any Section 16 reporting obligations.

Q: What additional requirements apply to individuals subject to Section 16?

A: Officers and directors, who are subject to the reporting obligations under Section 16 of the Exchange Act, should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4, and 5) and any notices of sale required by Rule 144.

Sanctions and Other Information

Q: What happens if I violate this Policy?

A: Violating the Company's policies may result in disciplinary action, which may include termination of your employment or other relationship with the Company.

Q: What are the sanctions if I trade on material nonpublic information or tip off someone else?

A: In addition to disciplinary action by the Company — which may include termination of employment — you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three (3) times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three (3) times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other “controlling persons” if they fail to take reasonable steps to prevent insider trading by company personnel. Regulators have also prosecuted insider trading violations where an employee or insider has traded in the stock of another related company based on material nonpublic information learned in connection with their employment or role as an insider.

Q: What is “loss avoided”?

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

Q: How long does this Policy apply to me?

A: This Policy continues to apply to your transactions in the Company’s securities and the securities of other applicable companies as more specifically set forth in this Policy, even after your relationship with the Company has ended. If you are aware of material nonpublic information when your relationship with the Company ends, you may not trade the Company’s securities or the securities of other applicable companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave the Company during a trading blackout period applicable to you, then you may not trade the Company’s securities or the securities of other applicable companies until the trading blackout period has ended.

Q: Who should I contact if I have questions about this Policy or specific trades?

A: You should email the Company’s Chief Executive Officer, Tom Burnell, at tburnell@interpace.com.¹

Q: Do changes to this policy require approval by the Company’s Board of Directors?

A: Yes. Changes to this policy require approval by the Company’s Board of Directors or a duly appointed committee of the Board of Directors.

Acknowledgement and Certification

All Covered Persons are required to sign the attached acknowledgement and certification.

¹NTD: Consider a designated email for all trading window and preclearance matters, such as preclearance@interpace.com.

INTERPACE BIOSCIENCES, INC.
Insider Trading Policy
Acknowledgment and Certification

To: **Interpace Biosciences, Inc.**

I, _____, have received and read a copy of the Interpace Biosciences, Inc. Insider Trading Policy. I hereby agree to comply with the specific requirements of the policy in all respects during my employment or other service relationship with Interpace Biosciences, Inc. I understand that the policy constitutes a material term of my employment or other service relationship with Interpace Biosciences, Inc. (or a subsidiary thereof) and that my failure to comply in all respects with the policy is a basis for termination for cause.

(Signature)

(Name)

(Date)

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, 333-234284 and 333-224554) of our report dated March 31, 2025, on our audits of the financial statements as of December 31, 2024 and 2023 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 31, 2025.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 31, 2025

**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, 2024 of Interpace Biosciences, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2025

/s/ Thomas W. Burnell

Chief Executive Officer
(Principal Executive Officer)

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

I, Christopher McCarthy, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2024 of Interpace Biosciences, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2025

/s/ Christopher McCarthy

Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Annual Report of Interpace Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas W. Burnell, as Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

Date: March 31, 2025

/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, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher McCarthy, as Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

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

Date: March 31, 2025

/s/ Christopher McCarthy

Chief Financial Officer
(Principal Financial Officer)
