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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): January 9, 2025

INTERPACE BIOSCIENCES, INC.
(Exact name of Registrant as specified in its charter)

DELAWARE	**0-24249**	**22-2919486**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

Waterview Plaza, Suite 310
2001 Route 46,
Parsippany, NJ 07054
(Address, including zip code, of Principal Executive Offices)

(855) 776-6419
Registrant's telephone number, including area code

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ 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. ☐

Item 8.01. Other Events.

On January 9, 2025, Interpace Biosciences, Inc. (the "Company") issued a press release announcing that Interpace Diagnostics, LLC, a subsidiary of the Company, responded to the final Local Coverage Determination ("LCD") of Genetic Testing for Oncology (L39365) issued by the Centers for Medicare & Medicaid Services. The new LCD establishes non-coverage for the Company's PancraGEN® test, a molecular diagnostic test that assesses pancreatic cyst cancer risk ("PancraGEN").

Because PancraGEN is primarily ordered for Medicare patients, the Company will no longer be offering its PancraGEN test. Specimens for first-line fluid chemistry and PancraGEN testing will not be accepted after February 7, 2025 as a result of the new LCD.

A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are being filed herewith:

Exhibit No.	Description
99.1	Press Release dated January 9, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Interpace Biosciences, Inc.

By: */s/ Thomas W. Burnell*
Name: Thomas W. Burnell
Title: President and Chief Executive Officer

Date: January 10, 2025

Exhibit 99.1

Effective 02/07/2025, Interpace Diagnostics® to No Longer Offer PancraGEN®, a Molecular Diagnostic Test That Assesses Pancreatic Cyst Cancer Risk

PARSIPPANY, NJ, January 9, 2025 (GLOBE NEWSWIRE) – Interpace Diagnostics®, a subsidiary of Interpace Biosciences®, ("Interpace" or the "Company") (OTCQX: IDXG) today responded to the final Local Coverage Determination (LCD) of Genetic Testing for Oncology (L39365) issued by the Centers for Medicare & Medicaid Services (CMS). The new LCD establishes non-coverage for the Company's widely used PancraGEN® test.

PancraGEN is a DNA-based diagnostic molecular test. It uniquely assesses the risk of pancreatic cyst progression to cancer by integrating the results of first-line tests and procedures with molecular test results. It has been offered since 2013 and provides insight to physicians to aid their diagnosis of pancreatic cancer and help inform the optimal management of patients, including through the reduction of unnecessary surgeries.

According to Tom Burnell, President and CEO of Interpace, "It is extremely unfortunate that CMS, through its Medicare Administrative Contractor (MAC), Novitas, is ending coverage for PancraGEN—an important and widely utilized test." He continued, "For over a decade, CMS has provided reimbursement for PancraGEN, allowing Interpace to offer testing which has helped over 80,000 patients and their physicians determine a course of treatment best suited to each patient's individual needs. The ability of PancraGEN to differentiate high from low malignancy potential in pancreatic cysts has been proven by up to ~8 years of follow-up. It is unfortunate that this decision will result in unnecessary surgeries and added healthcare costs."

Dr. Nicole Massoll, Chief Medical Officer for Interpace Diagnostics, further stated that "The ever-increasing adoption of molecular diagnostic tests is fully aligned to the medical and scientific communities' growing understanding of molecular genetics and the improvements in patient care made possible by important and highly informative diagnostic tests, such as PancraGEN."

Because PancraGEN is primarily ordered for Medicare patients, Interpace will not be able to continue offering this test. Specimens for first-line fluid chemistry and PancraGEN testing will not be accepted after February 7, 2025.

Finally, Mr. Burnell added, "This decision is inconsistent with advancing medicine and goals to improve the quality of patient care. While Interpace will consider any and all remedies or actions against Novitas/CMS, the impending loss of Medicare reimbursement will necessitate the restructuring of Interpace. A plan has been developed and is ready for implementation. The Company is sustainable without PancraGEN and we expect that our testing franchise for indeterminant thyroid nodules, ThyGeNEXT® + ThyraMIR®v2, will allow us to remain profitable in 2025 and beyond."

About Interpace Biosciences

Interpace Biosciences is an emerging leader in enabling personalized medicine, offering specialized services along the therapeutic value chain from early diagnosis and prognostic planning to targeted therapeutic applications.

Clinical services, through Interpace Diagnostics, provide clinically useful molecular diagnostic tests and bioinformatics and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. Interpace has three commercialized molecular tests and one test in a clinical evaluation program (CEP): ThyGeNEXT® for the diagnosis of thyroid cancer from thyroid nodules utilizing a next-generation sequencing assay; ThyraMIR®v2, used in combination with ThyGeNEXT®, for the diagnosis of thyroid cancer utilizing a proprietary microRNA pairwise expression profiler along with algorithmic classification; and RespriDX®, that differentiates lung cancer of primary versus metastatic origin. In addition, BarreGEN®, a molecular-based assay that helps resolve the risk of progression of Barrett's Esophagus to esophageal cancer, is currently in a CEP, whereby we gather information from physicians using BarreGEN to assist us in gathering clinical evidence relative to the safety and performance of the test and also providing data that will potentially support payer reimbursement.

For more information, please visit Interpace Biosciences' website atwww.interpace.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, relating to the Company's future financial and operating performance. The Company has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on current expectations, assumptions and uncertainties 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 the Company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from those expressed or implied by any forward-looking statements, including, but not limited to, the possibility that the Company's estimates of future revenue, cash flows and adjusted EBITDA may prove to be materially inaccurate, the Company's prior history of operating losses, the Company's ability to adequately finance its business and seek alternative sources of financing, the Company's ability to repay borrowings from BroadOak, the Company's dependence on sales and reimbursements from its clinical services, the Company's ability to retain or secure reimbursement including its reliance on third parties to process and transmit claims to payers and the adverse impact of any delay, data loss, or other disruption in processing or transmitting such claims, the Company's revenue recognition being based in part on estimates for future collections which estimates may prove to be incorrect, and the Company's ability to restructure itself in light of the loss of reimbursement for its PancraGEN product.

Additionally, all forward-looking statements are subject to the "Risk Factors" detailed from time to time in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as amended, Current Reports on Form 8-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the Company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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