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): April 25, 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 2.05 Costs Associated with Exit or Disposal Activities.

On April 24, 2025, Interpace Biosciences, Inc. (the "Company") announced that the Genetic Testing for Oncology (L39365) Local Coverage Determination ("LCD") issued by the Medicare Administrative Contractor Novitas Solutions will go into effect, ending reimbursement for the Company's PancraGEN® test. The Centers for Medicare & Medicaid Services delayed implementation by 60 days earlier in the year and confirmed finalization of the LCD as of April 24, 2025. Specimens for first-line fluid chemistry and PancraGEN® testing will not be accepted by the Company after May 2, 2025.

As a result of the established non-coverage for the Company's PancraGEN® test, on April 25, 2025, the Company announced implementation of its previously approved restructuring and cost-savings plan to reduce operating costs and better align its workforce with the loss of PancraGEN® (the "Restructuring Plan"). The Company expects the implementation of the Restructuring Plan to be substantially completed by the end of the second quarter of 2025.

Under the Restructuring Plan, the Company is reducing its workforce and impacted employees will be eligible to receive severance benefits. The Company expects to incur severance costs in the range of $0.5 million to $0.6 million to be recorded primarily in the second quarter of 2025 which is in addition to the $0.2 million previously recorded in the first quarter of 2025.

The Company expects that the loss of PancraGEN® and related restructuring activities will reduce its annualized 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 approximately one-third of its revenues. 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.

Item 8.01 Other Events.

On April 24, 2025, the Company issued a press release announcing that the Genetic Testing for Oncology (L39365) LCD issued by the Medicare Administrative Contractor Novitas Solutions will go into effect, ending reimbursement for the Company's PancraGEN® test and that the Company's Restructuring Plan would be implemented. 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.

Exhibit No.	Description
99.1	Press Release, dated April 24, 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: April 30, 2025

April 24, 2025

Effective May 2, 2025, Interpace Diagnostics® Will No Longer Accept Specimens for PancraGEN®, a Molecular Diagnostic Test That Assesses Pancreatic Cyst Cancer Risk

Interpace Expects to Remain Profitable as a Thyroid-focused Business

PARSIPPANY, NJ, April 24, 2025 (GLOBE NEWSWIRE) -- Interpace Diagnostics®, a subsidiary of Interpace Biosciences®, ("Interpace" or the "Company") (OTCQX: IDXG) today announced that the Genetic Testing for Oncology (L39365) Local Coverage Determination (LCD) issued by the Medicare Administrative Contractor Novitas Solutions will go into effect, ending reimbursement for their PancraGEN® test. The Centers for Medicare & Medicaid Services (CMS) delayed implementation by 60 days earlier in the year and confirmed finalization of the LCD as of today, April 24, 2025.

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. Because PancraGEN is primarily ordered for Medicare patients, the decision to end reimbursement coverage means that Interpace will not be able to continue offering this test. Specimens for first-line fluid chemistry and PancraGEN testing will not be accepted by Interpace after May 2, 2025.

Rob Renjilian, Chief Commercial Officer for Interpace, stated, "PancraGEN has been offered for over a decade and is well-used by clinicians to aid their diagnosis of pancreatic cancer, helping to inform their optimal management of patients, including the reduction of unnecessary surgeries." He continued, "We know that clinicians rely on our testing and understand the challenges this decision imposes on the physicians we serve—and on their patients. We will be working with them to help during this transition as best as possible."

Tom Burnell, President and CEO of Interpace, stated, "It is extremely unfortunate that, despite compelling evidence of the utility of this test, this decision by CMS and Novitas ends reimbursement coverage for PancraGEN. This decision necessitates that we no longer accept pancreatic cyst fluid specimens for testing." He went on to say, "We highly value the physicians we serve. However, as a publicly traded company, we are obligated to help ensure profitability for our shareholders. Without reimbursement, we cannot continue to offer the PancraGEN test indefinitely, though we will be running the test without reimbursement, for a limited period of time, between April 24, 2025 and May 2, 2025, to allow the Company time to communicate with our customers regarding this situation and to process specimens already in transit to Interpace." Mr. Burnell then continued, "The loss of Medicare

reimbursement also necessitates the restructuring of Interpace. Our plan is in place, and its implementation will continue forward. As stated previously, we believe the Company is sustainable without PancraGEN and we expect that our testing franchise for indeterminate thyroid nodules, ThyGeNEXT® + ThyraMIR®v2, will allow us to continue 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, 2024, 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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Source: Interpace Biosciences, Inc.