

**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): August 15, 2022

INTERPACE BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

**DELAWARE
(State or other jurisdiction
of incorporation)**

**0-24249
(Commission
File Number)**

**22-2919486
(IRS Employer
Identification No.)**

**Morris Corporate Center 1, Building C
300 Interpace Parkway,
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 2.02 Results of Operations and Financial Condition.

On August 15, 2022, Interpace Biosciences, Inc. issued a press release announcing its results of operations and financial condition for the quarter ended June 30, 2022. The full text of the press release is set forth as Exhibit 99.1 attached hereto and is incorporated herein by reference.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
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99.1	Press Release, dated August 15, 2022
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: August 15, 2022

**Interpace Biosciences Announces Second Quarter 2022 Financial and Business Results
and New Clinical Validation Data; Diagnostic Accuracy Significantly Improved**

- **Q2 Revenue of \$9.4 million down 16% versus Prior Year driven by an unexpected retroactive price decrease on ThyGeNEXT®**
- **2022 Year to Date Net Loss Improves by \$1.5 million**
- **Days Sales Outstanding (DSO) decreased by 15%**

PARSIPPANY, NJ, August 15, 2022 (GLOBE NEWSWIRE) — Interpace Biosciences, Inc. (“Interpace” or the “Company”) (OTCQX: IDYG) today announced financial results for the second quarter ended June 30, 2022 and provided a business and financial update.

Second quarter Net Revenue was \$9.4 million, a 16% decrease as compared to the same period of 2021. During the second quarter the Company was notified by Novitas, its CME intermediary, that pricing for one of its flagship thyroid cancer screening tests was reduced by 70% retroactive to the beginning of 2022. Our Net Loss in the second quarter of 2022 was \$3.9 million, \$0.5 million worse than the prior year quarter, driven primarily by a \$1.8 million decrease in Net Revenue. Partially offsetting this impact is a \$1.0 million decrease in Operating Expense. Improvements in our cash collection processes resulted in a 15% decrease in our Days Sales Outstanding in the second quarter of 2022 as compared to the comparable prior year quarter.

Volume in both our Thyroid and Pancreas franchises for the second quarter of 2022 were the highest in Company history, however, our second quarter revenue was significantly negatively impacted by a \$0.7 million adjustment related to the ThyGeNEXT® pricing change for revenues recorded in the first quarter of 2022.

Interpace also announced today new clinical validation data for our thyroid cancer test platform (ThyGeNEXT® + ThyraMIR®) was published online within THYROID®, the leading peer-reviewed journal for original research on thyroid cancer. These new data demonstrated that the addition of microRNA pairwise expression profiling (ThyraMIR®v2) provided clinically and statistically superior risk stratification of indeterminate thyroid nodules beyond that of the algorithmic classification analysis provided by the original ThyraMIR® assay.

Additionally, the Company will be launching Point2Glucose™—a new pancreatic cyst fluid tumor marker diagnostic test offering that requires a very low volume of cyst fluid (0.2ml). Intracystic glucose is considered to be more accurate than the current diagnostic standard, carcinoembryonic antigen (CEA). Point2Glucose™ has been validated specifically for use in pancreatic cyst fluid and has been shown to be able to provide an accurate result even with viscous or bloody samples.

Dr. Syd Finkelstein, Chief Scientific Officer of Interpace Diagnostics, commented that “miRNA analysis may also reduce the risk of RNA sampling error because miRNAs can migrate throughout the thyroid nodule. As a result, they may be less affected by spatial variability than the distribution of cells with DNA mutations.”

Further commenting was Dr. Carl Malchoff, Professor Emeritus, Medicine/Endocrinology, Founder of the Endocrine Neoplasia Program at UConn Health, and a co-author of the manuscript, “The addition of pairwise microRNA expression profiling represents a clinically important development in precision molecular diagnosis of indeterminate thyroid nodules. For 87% of samples the positive and negative predictive values are ≥ 90% across a broad range of cancer prevalence (16% to 84%). Furthermore, as with earlier versions, this assay is performed using fresh FNA samples or diagnostic cytology slides, eliminating the need for an additional biopsy, refrigerated storage, or special shipping.”

Tom Burnell, Ph.D., President and CEO of Interpace Biosciences, added “Mutational analysis alone is often insufficient to accurately “rule-in” or “rule-out” malignancy in indeterminate thyroid nodules. We have previously demonstrated the utility of pairwise miRNA analysis in the diagnosis of medullary thyroid cancer and are excited to be able to bring this more precise risk estimation to clinicians, who must integrate various risk and benefits when deciding for or against surgery.” He further stated, “The diagnosis and prognosis of thyroid and other cancers aligns fully to the Interpace corporate goal of improving health care by enabling personalized medicine.”

Second Quarter and Year to Date 2022 Financial Performance

For the Second Quarter of 2022 as Compared to the Second Quarter of 2021

- Net Revenue was \$9.4 million, a decrease of 16% versus the prior year quarter. The Net Revenue decrease is driven by lower ThyGeNEXT® reimbursement rates and Pharma services volume.
- Gross Profit percentage was 37% compared to 48% for the prior year quarter, a 1,100 basis-point decline year over year. The Gross Profit decline is attributed to the lower reimbursement rate on the ThyGeNEXT® product.
- Loss from Continuing Operations was \$(3.9) million vs \$(3.4) million in the prior year quarter, driven by lower revenue, and partially offset by lower operating expenses.
- Adjusted EBITDA was \$(2.9) million vs \$(0.3) million in the prior year quarter.
- Q2 2022 cash collections totalled \$10.1 million. Days Sales Outstanding (DSO) decreased by 15% year over year to 59 days.
- Our June 30, 2021 cash balance was \$3.8 million, net of restricted cash. June 30, 2022 cash balance was \$ 1.9 million, net of restricted cash.

For the Six Months Ended June 30, 2022 as Compared to the Six Months Ended June 30, 2021

- Net Revenue was \$19.7 million for the first six months of 2022, a 6% decrease over the prior year period. The lower revenue is attributable to the ThyGeNEXT® reimbursement rate decline, along with lower Pharma services volume.
- Gross Profit percentage was 43% compared to 47% for the first months of 2021, a 400 basis-point decline. The decline in gross profit is directly tied to lower ThyGeNEXT® reimbursement.
- Loss from Continuing Operations was \$(6.1) million vs. \$(7.5) million prior year to date, an improvement of \$1.5 million. This improvement is driven by a \$2.3 million decline in operating expenses versus prior year.
- Adjusted EBITDA was \$(3.7) million vs. \$(1.3) million in the prior quarter.

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, provides clinically useful molecular diagnostic tests, bioinformatics and pathology services for evaluating risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. Interpace has five commercialized molecular tests and one test in a clinical evaluation program (CEP): PancreGEN® for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; PanDNA, a “molecular only” version of PancreGEN® that provides physicians a snapshot of a limited number of factors; ThyGeNEXT® for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay; ThyraMIR® for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay; 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 clinical evaluation program (CEP) whereby we gather information from physicians using BarreGEN® to assist us in gathering clinical evidence relative to the safety and performance of the test and also providing data that will potentially support payer reimbursement.

Pharma services, through Interpace Pharma Solutions, provides pharmacogenomics testing, genotyping, biorepository and other customized services to the pharmaceutical and biotech industries. Pharma services also advances personalized medicine by partnering with pharmaceutical, academic, and technology leaders to effectively integrate pharmacogenomics into their drug development and clinical trial programs with the goals of delivering safer, more effective drugs to market more quickly, while also improving patient care.

For more information, please visit Interpace Biosciences’ website at www.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 forwardlooking 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 reimbursement of the Company’s tests being subject to review by CMS, the adverse impact of the COVID19 pandemic on the Company’s operations and revenues, the substantial doubt about the Company’s ability to continue as a going concern, the possibility that the Company’s estimates of future revenue, cash flows and adjusted EBITDA may prove to be materially inaccurate, the Company’s 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 with Comerica Bank and 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, and the Company’s revenue recognition being based in part on estimates for future collections which estimates may prove to be incorrect. 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, 2021, 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.

Contacts:

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

	Three Months Ended		Six Months Ended	
	June 30,	2021	June 30,	2021
	2022	2021	2022	2021
Revenue, net	\$ 9,351	\$ 11,155	\$ 19,728	\$ 20,989
Cost of revenue	5,850	5,800	11,234	11,116
Gross Profit	3,501	5,355	8,494	9,873
Sales and marketing	2,774	2,776	5,190	5,128
Research and development	267	424	566	1,060
General and administrative	3,907	3,326	7,597	6,362
Transition expenses	61	858	146	2,111
Gain on DiamiR transaction	-	(235)	-	(235)
Acquisition amortization expense	535	1,112	1,071	2,224
Change in fair value of contingent consideration	(311)	-	(311)	(57)
Total operating expenses	7,233	8,261	14,259	16,593
Operating loss	(3,732)	(2,906)	(5,765)	(6,720)
Interest accretion expense	36	(135)	(85)	(270)
Related party interest	-	(163)	-	(308)
Note payable interest	(210)	-	(390)	-
Other income (expense), net	35	(168)	194	(212)
Loss from continuing operations before tax	(3,871)	(3,372)	(6,046)	(7,510)
Provision for income taxes	16	16	34	31
Loss from continuing operations	(3,887)	(3,388)	(6,080)	(7,541)
Loss from discontinued operations, net of tax	(52)	(58)	(106)	(112)

Net loss	(3,939)	(3,446)	(6,186)	(7,653)
Basic and diluted loss per share of common stock:				
From continuing operations	\$ (0.92)	\$ (0.83)	\$ (1.44)	\$ (1.84)
From discontinued operations	(0.01)	(0.01)	(0.03)	(0.03)
Net loss per basic share of common stock	<u>\$ (0.93)</u>	<u>\$ (0.84)</u>	<u>\$ (1.47)</u>	<u>\$ (1.87)</u>

Weighted average number of common shares and common share equivalents outstanding:

Basic	4,229	4,102	4,219	4,095
Diluted	4,229	4,102	4,219	4,095

Selected Balance Sheet Data (Unaudited)
(\$ in thousands)

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash, cash equivalents and restricted cash	\$ 2,115	\$ 3,314
Total current assets	11,258	12,166
Total current liabilities	18,449	15,682
Total assets	35,488	38,427
Total liabilities	36,904	34,309
Total stockholders' deficit	(47,952)	(42,418)

Selected Cash Flow Data (Unaudited)
(\$ in thousands)

	For the Six Months Ended June 30,	
	<u>2022</u>	<u>2021</u>
Net loss	\$ (6,186)	\$ (7,653)
Net cash used in operating activities	\$ (4,172)	\$ (6,825)
Net cash used in investing activities	(86)	(9)
Net cash provided by financing activities	3,059	7,503
Change in cash, cash equivalents and restricted cash	(1,199)	669
Cash, cash equivalents and restricted cash – beginning	3,314	3,372
Cash, cash equivalents and restricted cash – ending	<u>\$ 2,115</u>	<u>\$ 4,041</u>

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

	Quarters Ended June 30,		Six Months Ended June 30,	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Loss from continuing operations (GAAP Basis)	\$ (3,887)	\$ (3,388)	\$ (6,080)	\$ (7,541)
Bad debt (recovery) expense	-	-	-	(140)
Transition expenses	61	858	146	2,111
Depreciation and amortization	790	1,411	1,571	2,943
Stock-based compensation	334	551	659	837
Taxes	16	16	34	31
Financing interest and related costs	210	163	390	308
Interest accretion expense	(36)	135	85	270
Gain on DiamiR transaction	-	(235)	-	(235)
Mark to market on warrant liability	(5)	168	(68)	209
Change in fair value of note payable	(53)	-	(160)	-
Change in fair value of contingent consideration	(311)	-	(311)	(57)
Adjusted EBITDA	<u>\$ (2,881)</u>	<u>\$ (321)</u>	<u>\$ (3,734)</u>	<u>\$ (1,264)</u>

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 document, we discuss Adjusted EBITDA, a non-GAAP financial measure. Adjusted EBITDA is a metric used by management to measure cash flow of the ongoing

business. Adjusted EBITDA is defined as income or loss from continuing operations, plus depreciation and amortization, acquisition related expenses, transition expenses, non-cash stock based compensation and ESPP plans, interest and taxes, and other non-cash expenses including asset impairment costs, bad debt expense, receipt of stimulus grants, loss on extinguishment of debt, goodwill impairment and change in fair value of contingent consideration, and warrant liability. The table above includes a reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure.
