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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 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	**22-2919486**
(State or other jurisdiction of Incorporation or organization)	(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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	**Shares Outstanding August 2, 2024**
Common Stock, par value $0.01 per share	4,394,312

INTERPACE BIOSICENCES, INC.
FORM 10-Q FOR PERIOD ENDED JUNE 30, 2024
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PART I. FINANCIAL INFORMATION

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

	June 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,019	$ 3,498
Accounts receivable, net of allowance for credit loss of $26 and $0, respectively	6,206	4,983
Other current assets	1,941	1,841
Total current assets	10,166	10,322
Property and equipment, net	1,126	790
Operating lease right of use assets	1,635	1,864
Other long-term assets	45	45
Total assets	$ 12,972	$ 13,021
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 1,761	$ 1,544
Accrued salary and bonus	1,243	1,969
Other accrued expenses	8,582	8,201
Note payable at fair value, current	6,784	5,100
Current liabilities of discontinued operations	660	660
Total current liabilities	19,030	17,474
Operating lease liabilities, net of current portion	1,286	1,472
Note payable at fair value	-	4,243
Other long-term liabilities	5,146	4,968
Total liabilities	25,462	28,157
Commitments and contingencies (Note 8)		
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 and 4,447,489 shares issued, respectively; 4,376,398 and 4,351,445 shares outstanding, respectively	406	405
Additional paid-in capital	188,277	188,146
Accumulated deficit	(245,685)	(248,215)
Treasury stock, at cost (110,759 and 96,044 shares, respectively)	(2,024)	(2,008)
Total stockholders' deficit	(59,026)	(61,672)
Total liabilities and stockholders' deficit	(33,564)	(33,515)
Total liabilities, preferred stock and stockholders' deficit	$ 12,972	$ 13,021

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

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

	For The Three Months Ended June 30,		For The Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue, net	$ 12,042	$ 11,026	$ 22,314	$ 20,853
Cost of revenue	4,611	4,191	8,812	8,039
Gross profit	7,431	6,835	13,502	12,814
Operating expenses:				
Sales and marketing	2,887	2,605	5,707	4,947
Research and development	146	186	283	335
General and administrative	2,141	2,894	4,381	5,389
Acquisition related amortization expense	-	318	-	635
Total operating expenses	5,174	6,003	10,371	11,306
Operating income from continuing operations	2,257	832	3,131	1,508
Interest accretion expense	(12)	(31)	(30)	(66)
Note payable interest	(176)	(228)	(373)	(453)
Other income (expense), net	71	(174)	(12)	(156)
Income from continuing operations before tax	2,140	399	2,716	833
Provision for income taxes	4	4	8	8
Income from continuing operations	2,136	395	2,708	825
Loss from discontinued operations, net of tax	(74)	(220)	(178)	(299)
Net income	$ 2,062	$ 175	$ 2,530	$ 526
Basic income (loss) per share of common stock:				
From continuing operations	$ 0.49	$ 0.09	$ 0.62	$ 0.19
From discontinued operations	(0.02)	(0.05)	(0.04)	(0.07)
Net income per basic share of common stock	$ 0.47	$ 0.04	$ 0.58	$ 0.12
Diluted income (loss) per share of common stock:				
From continuing operations	$ 0.49	$ 0.09	$ 0.62	$ 0.19
From discontinued operations	(0.02)	(0.05)	(0.04)	(0.07)
Net income per diluted share of common stock	$ 0.47	$ 0.04	$ 0.58	$ 0.12
Weighted average number of common shares and common share equivalents outstanding:				
Basic	4,376	4,311	4,373	4,309
Diluted	4,401	4,316	4,393	4,313

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

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

	Common Stock		Treasury Stock		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance -December 31, 2022	4,367,830	$ 405	71,120	$ (1,976)	$ 187,516	$ (249,017)	$ (63,072)
Issuance of common stock	22,996	-	-	-	-	-	-
Treasury stock purchased		-	8,292	(9)	-	-	(9)
Stock-based compensation expense	-	-	-	-	192	-	192
Net income	-	-	-	-	-	351	351
Balance -March 31, 2023	4,390,826	$ 405	79,412	$ (1,985)	$ 187,708	$ (248,666)	$ (62,538)
Stock-based compensation expense	-	-	-	-	157	-	157
Net income	-	-	-	-	-	175	175
Balance -June 30, 2023	4,390,826	$ 405	79,412	$ (1,985)	$ 187,865	$ (248,491)	$ (62,206)
Balance -December 31, 2023	4,447,489	$ 405	96,044	$ (2,008)	$ 188,146	$ (248,215)	$ (61,672)
Issuance of common stock	39,668	1	-	-	(1)	-	-
Treasury stock purchased	-	-	14,715	(16)	-	-	(16)
Stock-based compensation expense	-	-	-	-	79	-	79
Net income	-	-	-	-	-	468	468
Balance -March 31, 2024	4,487,157	$ 406	110,759	$ (2,024)	$ 188,224	$ (247,747)	$ (61,141)
Stock-based compensation expense	-	-	-	-	53	-	53
Net income	-	-	-	-	-	2,062	2,062
Balance -June 30, 2024	4,487,157	$ 406	110,759	$ (2,024)	$ 188,277	$ (245,685)	$ (59,026)

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

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

	For The Six Months Ended June 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net income	$ 2,530	$ 526
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	119	714
Interest accretion expense	30	66
Amortization of deferred financing fees	-	28
Stock-based compensation	132	349
Bad debt expense reversal	(100)	-
Credit loss expense	26	-
Change in fair value of note payable	41	142
Amortization on operating lease right of use asset	229	349
Other changes in operating assets and liabilities:		
Accounts receivable	(1,249)	(497)
Other current assets	-	(101)
Accounts payable	(13)	610
Accrued salaries and bonus	(726)	(329)
Other accrued expenses	337	(138)
Operating lease liabilities	(188)	(337)
Other long-term liabilities	178	162
Net cash provided by operating activities	1,346	1,544
Cash Flows From Investing Activity		
Working capital adjustment on sale of Interpace Pharma Solutions	-	(117)
Purchase of property and equipment	(225)	(176)
Net cash used in investing activities	(225)	(293)
Cash Flows From Financing Activities		
Payments made on note payable	(2,600)	-
Payments on line of credit	-	(1,000)
Net cash used in financing activities	(2,600)	(1,000)
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,479)	251
Cash, cash equivalents and restricted cash from continuing operations– beginning	3,498	4,828
Cash, cash equivalents and restricted cash from discontinued operations– beginning	-	-
Cash, cash equivalents and restricted cash – beginning	$ 3,498	$ 4,828
Cash, cash equivalents and restricted cash from continuing operations– ending	$ 2,019	$ 5,079
Cash, cash equivalents and restricted cash from discontinued operations– ending	-	-
Cash, cash equivalents and restricted cash – ending	$ 2,019	$ 5,079

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

1. OVERVIEW

Nature of Business

Interpace Biosciences, Inc. ("Interpace" or the "Company") is a company that provides molecular diagnostics, bioinformatics and pathology services for evaluation of risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. The Company develops and commercializes genomic tests and related first line assays principally focused on early detection of patients with indeterminate biopsies and at high risk of cancer using the latest technology.

2. BASIS OF PRESENTATION

The accompanying unaudited interim condensed consolidated financial statements and related notes (the "Interim Financial Statements") should be read in conjunction with the consolidated financial statements of the Company and its wholly-owned subsidiaries (Interpace Diagnostics Lab Inc., Interpace Diagnostics Corporation, and Interpace Diagnostics, LLC), and related notes as included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities & Exchange Commission ("SEC") on April 1, 2024 and as amended on April 26, 2024.

The Interim Financial Statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") for interim financial reporting and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The Interim Financial Statements include all normal recurring adjustments that, in the judgment of management, are necessary for a fair presentation of such interim financial statements. Discontinued operations include the Company's wholly owned subsidiaries: Group DCA, LLC, InServe Support Solutions; and TVG, Inc., its Commercial Services business unit, which was sold on December 22, 2015 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. Operating results for the three-month period ended June 30, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024.

3. 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 16, *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") (the "Ampersand Note") and 1315 Capital II, L.P ("1315 Capital") (the "1315 Capital Note"). In May 2022, the Company entered into a Subordinated Convertible Promissory Note agreement with BroadOak for an additional $2.0 million (the "Convertible Note"), which was converted into a subordinated term loan and was added to the outstanding Term Loan balance. The Term Loan has been subsequently amended. See Note 13, *Notes Payable*, for more details.

Along with many laboratories, the Company may be affected by the Proposed Local Coverage Determination ("LCD") DL39365, which is currently under consideration by Novitas, the Company's medical administrator contractor. If finalized, this Proposed LCD, which governs "Genetic Testing for Oncology," could impact the existing Medicare coverage for one of our molecular tests, PancraGEN®. 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 PancraGEN® 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 PancraGEN®. The timing and content of any final implemented LCD is uncertain at this time; the process could potentially take a year or longer from issuance of the updated proposed LCD to reach a conclusion. 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 is able to continue offering PancraGEN® and the related Point2® fluid chemistry tests for amylase, CEA, and glucose. In the event Novitas ultimately restricts coverage for the PancraGEN® test, the Company's liquidity could be negatively impacted.

For the six months ended June 30, 2024, the Company had operating income from continuing operations of $3.1 million. As of June 30, 2024, the Company had cash and cash equivalents of $2.0 million, total current assets of $10.2 million and current liabilities of $19.0 million. As of August 2, 2024, the Company had approximately $1.8 million of cash and cash equivalents.

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.

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 the filing of this report.

4. DISCONTINUED OPERATIONS

Liabilities classified as discontinued operations as of both June 30, 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 business unit's results included within loss from discontinued operations, net of tax in the condensed consolidated statements of operations for the three- and six months ended June 30, 2024 and 2023.

	For The Three Months Ended June 30,		For The Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue, net	$ -	$ -	$ -	$ -
Loss from discontinued operations	-	(137)	-	(137)
Income tax expense	74	83	178	162
Loss from discontinued operations, net of tax	$ (74)	$ (220)	$ (178)	$ (299)

Cash used from discontinued operations, operating activities, was $20,000, and investing activities was $0.1 million for the six months ended June 30, 2023. There was no cash used from discontinued operations for the six months ended June 30, 2024.There was no depreciation and amortization expense for the three or six months ended June 30, 2024 and June 30, 2023, respectively, in discontinued operations.

5. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Accounting Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts of assets and liabilities reported and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management's estimates are based on historical experience, facts and circumstances available at the time, and various other assumptions that are believed to be reasonable under the circumstances. Significant estimates include accounting for valuation allowances related to deferred income taxes, contingent consideration, allowances for credit losses, revenue recognition, unrecognized tax benefits, and asset impairments involving intangible assets. The Company periodically reviews these matters and reflects changes in estimates in earnings as appropriate. Actual results could materially differ from those estimates.

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

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed in the period in which they have been earned. These costs are recorded in sales and marketing expense in the condensed consolidated statements of operations.

Accounts Receivable

The Company's accounts receivable represent unconditional rights to consideration and are generated using its clinical services. 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 allowance for credit losses balance was $26,000 and $0 at June 30, 2024 and December 31, 2023, respectively.

Leases

The Company determines if an arrangement contains a lease in whole or in part at the inception of the contract. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term while lease liabilities represent our obligation to make lease payments arising from the lease. All leases with terms greater than twelve months result in the recognition of a ROU asset and a liability at the lease commencement date based on the present value of the lease payments over the lease term. Unless a lease provides all of the information required to determine the implicit interest rate, we use our incremental borrowing rate based on the information available at the commencement date in determining the present value of the lease payments. We use the implicit interest rate in the lease when readily determinable.

Our lease terms include all non-cancelable periods and may include options to extend (or to not terminate) the lease when it is reasonably certain that we will exercise that option. Leases with terms of twelve months or less at the commencement date are expensed on a straight-line basis over the lease term and do not result in the recognition of an asset or liability. See Note 7, *Leases*.

Other Current Assets

Other current assets consisted of the following as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Lab supplies	$ 1,231	$ 1,227
Prepaid expenses	667	590
Other	43	24
Total other current assets	$ 1,941	$ 1,841

Long-Lived Assets, including Finite-Lived Intangible Assets

Finite-lived intangible assets are stated at cost less accumulated amortization. Amortization of finite-lived acquired intangible assets is recognized on a straight-line basis, using the estimated useful lives of the assets of approximately two years to ten years in acquisition-related amortization expense in the condensed consolidated statements of operations.

The Company reviews the recoverability of long-lived assets and finite-lived intangible assets whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized by reducing the recorded value of the asset to its fair value measured by future discounted cash flows. This analysis requires estimates of the amount and timing of projected cash flows and, where applicable, judgments associated with, among other factors, the appropriate discount rate. Such estimates are critical in determining whether any impairment charge should be recorded and the amount of such charge if an impairment loss is deemed to be necessary.

Basic and Diluted Net Income (Loss) per Share

A reconciliation of the number of shares of common stock, par value $0.01 per share, used in the calculation of basic and diluted income (loss) per share for the three- and six-month periods ended June 30, 2024 and 2023 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Basic weighted average number of common shares	4,376	4,311	4,373	4,309
Potential dilutive effect of stock-based awards	25	5	20	4
Diluted weighted average number of common shares	4,401	4,316	4,393	4,313

The Company's Series B Redeemable Preferred Stock, on an as converted basis into common stock of 7,833,334 shares for the three- and six-months ended June 30, 2024, and the following outstanding stock-based awards, were excluded from the computation of the effect of dilutive securities on income (loss) per share for the following periods as they would have been anti-dilutive (rounded to thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Options	288	475	288	475
Restricted stock units (RSUs)	182	215	187	217
	470	690	475	692

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 condensed consolidated financial statements include contingent consideration, warrant liability and note 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 incorporate certain assumptions and projections 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 June 30, 2024		Fair Value Measurements As of June 30, 2024		
	Amount	Fair Value	Level 1	Level 2	Level 3
Liabilities:					
Contingent consideration:					
Asuragen [1]	$ 30	$ 30	$ -	$ -	$ 30
Note payable:					
BroadOak loan	7,400	6,784	-	-	6,784
	$ 7,430	$ 6,814	$ -	$ -	$ 6,814

(1) See Note 9, *Other Accrued Expenses*

	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
	$ 10,453	$ 9,796	$ -	$ -	$ 9,796

(1) See Note 9, *Other Accrued Expenses*

In connection with the acquisition of certain assets from Asuragen, Inc., 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.

In connection with the Term Loan, the Company records the 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.

A roll forward of the carrying value of the Contingent Consideration Liability and BroadOak Loan to June 30, 2024 is as follows:

	December 31, 2023	Payments	Transferred to Accrued Expenses	Accretion/ Interest Accrued	Adjustment to Fair Value/ Mark to Market	June 30, 2024
Asuragen	$ 453	$ -	$ (453)	$ 30	$ -	$ 30
BroadOak loans	9,343	(2,600)	-	-	41	6,784
	$ 9,796	$ (2,600)	$ (453)	$ 30	$ 41	$ 6,814

Certain of the Company's non-financial assets, such as intangible assets are measured at fair value on a nonrecurring basis when there is an indicator of impairment and recorded at fair value only when an impairment charge is recognized.

7. LEASES

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

	Classification on the Balance Sheet	June 30, 2024	December 31, 2023
Assets			
Operating lease assets	Operating lease right of use assets	1,635	1,864
Total lease assets		$ 1,635	$ 1,864
Liabilities			
Current			
Operating lease liabilities	Other accrued expenses	319	377
Total current lease liabilities		$ 319	$ 377
Noncurrent			
Operating lease liabilities	Operating lease liabilities, net of current portion	1,286	1,472
Total long-term lease liabilities		1,286	1,472
Total lease liabilities		$ 1,605	$ 1,849

The weighted average remaining lease term for the Company's operating leases was 3.9 years as of June 30, 2024 and the weighted average discount rate for those leases was 11.9%. Total operating lease expense from continuing operations under these agreements for both the three months ended June 30, 2024 and 2023 was approximately $0.2 million and for the six months ended June 30, 2024 and 2023 was approximately $0.3 million and $0.4 million, respectively. Total cash paid under these agreements for both the six months ended June 30, 2024 and 2023 was approximately $0.4 million, respectively. The Company's operating lease expenses are recorded within "Cost of revenue" and "General and administrative expenses."

The table below reconciles the cash flows to the lease liabilities recorded on the Company's Condensed Consolidated Balance Sheet as of June 30, 2024:

	Operating Leases
2024 - remaining six months	$ 268
2025	450
2026	500
2027	550
2028	275
Total minimum lease payments	2,043
Less: amount of lease payments representing effects of discounting	438
Present value of future minimum lease payments	1,605
Less: current obligations under leases	319
Long-term lease obligations	$ 1,286

8. 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.

9. OTHER ACCRUED EXPENSES

Other accrued expenses consisted of the following as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Accrued royalties	$ 7,010	$ 6,268
Contingent consideration	30	453
Operating lease liability	319	377
Accrued sales and marketing - diagnostics	28	43
Accrued lab costs - diagnostics	103	68
Accrued professional fees	162	241
Taxes payable	308	261
All others	622	490
Total other accrued expenses	$ 8,582	$ 8,201

10. STOCK-BASED COMPENSATION

Historically, stock options have been granted with an exercise price equal to the market value of the common stock on the date of grant, with expiration 10 years from the date they are granted, and generally vest 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 Board members and employees generally have a three-year graded vesting period and are subject to accelerated vesting and forfeiture under certain circumstances.

There were no stock option awards issued during the six months ended June 30, 2024 and June 30, 2023.

The Company recognized approximately $0.1 million and $0.2 million of stock-based compensation expense within continuing operations during the three-month periods ended June 30, 2024 and 2023, respectively and approximately $0.1 million and $0.3 million for the six-month periods ended June 30, 2024 and 2023, respectively. The following table has a breakout of stock-based compensation expense from continuing operations by line item.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of revenue	$ -	$ 12	$ 4	$ 26
Sales and marketing	23	30	53	60
General and administrative	30	115	75	263
Total stock compensation expense	$ 53	$ 157	$ 132	$ 349

11. INCOME TAXES

Generally, accounting standards require companies to provide for income taxes each quarter based on their estimate of the effective tax rate for the full year. The authoritative guidance for accounting for income taxes allows use of the discrete method when it provides a better estimate of income tax expense. Due to the Company's valuation allowance position, it is the Company's position that the discrete method provides a more accurate estimate of income tax expense and therefore income tax expense for the current quarter has been presented using the discrete method. As the year progresses, the Company refines its estimate based on the facts and circumstances by each tax jurisdiction. The following table summarizes income tax expense on income from continuing operations and the effective tax rate for the three- and six-month periods ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Provision for income tax	$ 4	$ 4	$ 8	$ 8
Effective income tax rate	0.2%	1.0%	0.3%	1.0%

Income tax expense for both periods was primarily due to state franchise taxes.

Other long-term liabilities consisted of uncertain tax positions as of June 30, 2024 and December 31, 2023.

12. SEGMENT INFORMATION

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

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 16, 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 Note met the definition of a "recognized financial liability" which is an acceptable financial instrument eligible for the fair value option under ASC 825-10-15-4, and did not meet the definition of any of the financial instruments listed within ASC 825-10-15-5 that are not eligible for the fair value option. The Note is not convertible and does not have any component recorded to 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.

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 will make $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 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 first quarter 2024 fair value calculation.

The balance of the loan outstanding at June 30, 2024 was $7.4 million.

14. SUPPLEMENTAL CASH FLOW INFORMATION

Supplemental Disclosures of Non-Cash Activities
(in thousands)

	Six Months Ended June 30,	
	2024	**2023**
Taxes accrued for repurchase of restricted shares	$ 16	$ 9
Purchase of property and equipment included in accounts payable	230	29

15. MEZZANINE EQUITY

Redeemable Preferred Stock

On January 10, 2020, the Company entered into a Securities Purchase and Exchange Agreement (the "Securities Purchase and Exchange Agreement") with 1315 Capital and Ampersand (collectively, the "Investors") pursuant to which the Company agreed to sell to the Investors an aggregate of $20.0 million in Series B Preferred Stock of the Company, at an issuance price per share of $1,000 ("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 has a conversion price of $6.00.

Voting

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Series B Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of the Company's common stock into which the shares of Series B Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Certificate of Designation"), holders of Series B Preferred Stock will vote together with the holders of common stock as a single class and on an as-converted to common stock basis.

Director Designation Rights

The Certificate of Designation also provides each Investor with the following director designation rights: for so long such Investor holds at least sixty percent (60%) of the Series B Preferred Stock issued to it on the Issuance Date (as defined therein), such Investor will be entitled to elect two directors to the Company's Board of Directors (the "Board"), provided that one of the directors qualifies as an "independent director" under Rule 5605(a)(2) of the listing rules of the Nasdaq Stock Market (or any successor rule or similar rule promulgated by another exchange on which the Company's securities are then listed or designated) ("Independent Director"). However, if at any time such Investor holds less than sixty percent (60%), but at least forty percent (40%), of the Series B Preferred Stock issued to them on the Issuance Date, such Investor would only be entitled to elect one director to the Board. Any director elected pursuant to the terms of the Certificate of Designation may be removed without cause by, and only by, the affirmative vote of the holders of Series B Preferred Stock. A vacancy in any directorship filled by the holders of Series B Preferred Stock may be filled only by vote or written consent in lieu of a meeting of such holders of Series B Preferred Stock or by any remaining director or directors elected by such holders of Series B Preferred Stock.

On November 15, 2023, Edward Chan, a director designated by 1315 Capital to the Board, provided notice to the Company of his resignation from the Board, effective immediately. Further, on December 7, 2023, Robert Gorman, a director designated by Ampersand to the Board, provided notice to the Company of his resignation as a director and as Chairman of the Board, effective immediately.

As of the date of this report, each of 1315 Capital and Ampersand has appointed one director to the Board, and each has not appointed a second director to the Board.

Conversion

The Certificate of Designation provides that from and after the Issuance Date and subject to the terms of the Certificate of Designation, each share of Series B Preferred Stock is convertible, at any time and from time to time, at the option of the holder into a number of shares of common stock equal to dividing the amount equal to the greater of the Stated Value of such Series B Preferred Stock, plus any dividends declared but unpaid thereon, or such amount per share as would have been payable had each such share been converted into common stock immediately prior to a liquidation, by six dollars ($6.00) (subject to adjustment in the event of any stock dividend, stock split, combination, or other similar recapitalization affecting such shares). The aggregate number of shares of common stock that may be issued through conversion of all of the New Investment Shares and Exchange Shares is 7,833,334 shares (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting such shares).

Mandatory Conversion

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

Liquidation

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

As of June 30, 2024 and December 31, 2023, there were 47,000 issued and outstanding shares of Series B Preferred Stock, respectively.

16. 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 Bank 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.

17. 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.

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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements that are not historical facts, including statements about our plans, objectives, beliefs and expectations, are forward-looking statements. Forward-looking statements include statements preceded by, followed by or that include the words "believes," "expects," "anticipates," "plans," "estimates," "intends," "projects," "should," "could," "may," "will" or similar words and expressions. These forward-looking statements are contained throughout this Form 10-Q.

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 history of operating losses prior to fiscal 2023;
- 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 PancraGEN® molecular test long-term under the existing local coverage determination ("LCD"), given that such LCD is currently under review by Novitas, the Company's Medicare administrative contractor;
- 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 obligations to make royalty and milestone payments to our licensors;

- our dependence on third parties for the supply of some of the materials used in our clinical services tests;
- the potential adverse impact of current and future laws, licensing requirements and governmental regulations upon our business operations, including but not limited to the evolving U.S. regulatory environment related to laboratory developed tests ("LDTs"), pricing of our tests and services and patient access limitations;
- our reliance on our sales and marketing activities for future business growth and our ability to continue to expand our sales and marketing activities;
- our being subject to the controlling interests of our two private equity investors who control, on an as-converted basis, an aggregate of 64.2% of our outstanding shares of common stock through their holdings of our Series B Preferred Stock, and this concentration of ownership along with their authority for designation rights for a majority of our directors and their right to approve certain of our actions has a substantial influence on our decisions;
- 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;
- geopolitical and other economic and political conditions or events (such as the wars in Ukraine and Israel/Gaza);
- 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" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024, and as amended on April 26, 2024, 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 as expressed in the forward-looking statements discussed in this Form 10-Q. 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 the report in which they are set forth and, except as may be required by law, we undertake no obligation to revise or update publicly any forward-looking statements for any reason.

OVERVIEW

We are a fully integrated commercial company that provides molecular diagnostics, bioinformatics and pathology services for evaluation of risk of cancer by leveraging the latest technology in personalized medicine for improved patient diagnosis and management. We develop and commercialize genomic tests and related first line assays principally focused on early detection of patients with indeterminate biopsies and at high risk of cancer using the latest technology.

Impact of Our Reliance on CMS and Novitas

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, PancraGEN®. 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 PancraGEN® 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 PancraGEN®. The timing and content of any final implemented LCD is uncertain at this time; the process could potentially take a year or longer from issuance of the updated proposed LCD to reach a conclusion. 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 are able to continue offering PancraGEN® and the related Point2® fluid chemistry tests for amylase, CEA, and glucose. In the event Novitas ultimately restricts coverage for the PancraGEN® test, the Company's liquidity could be negatively impacted.

U.S. Food and Drug Administration Regulation of 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 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. On May 29, 2024, the American Clinical Laboratory Association filed a lawsuit challenging the April 2024 LDT final rule, in which the plaintiffs argue that FDA lacks authority to regulate LDTs as medical devices. We cannot predict the likelihood of success of this or any other such actions, nor can we quantify the effect of such efforts on our business.

Revenue Recognition

Clinical services derive revenues from the performance of proprietary assays or tests. Our performance obligation is fulfilled upon completion, review and release of test results to the customer, at which time we bill third-party payers or direct-bill payers for the tests performed. Under Accounting Standards Codification 606, revenue is recognized based upon 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. To the extent that the transaction price includes variable consideration, for all third party and direct-bill payers and proprietary tests, we estimate the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience.

The ultimate amounts received from the third-party and direct-bill payers and related estimated reimbursement rates are regularly reviewed and we 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 affects net revenue in the period such variances become known.

Cost of Revenue

Cost of revenue consists primarily of the costs associated with operating our laboratory 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.

CONDENSED CONSOLIDATED RESULTS OF OPERATIONS

The following table sets forth, for the periods indicated, certain statements of operations data. The trends illustrated in this table may not be indicative of future results.

Condensed Consolidated Results of Continuing Operations for the Quarter Ended June 30, 2024 Compared to the Quarter Ended June 30, 2023 (unaudited, in thousands)

	Three Months Ended June 30,			
	2024	2024 % to revenue	2023	2023 % to revenue
Revenue, net	$ 12,042	100.0%	$ 11,026	100.0%
Cost of revenue	4,611	38.3%	4,191	38.0%
Gross profit	7,431	61.7%	6,835	62.0%
Operating expenses:				
Sales and marketing	2,887	24.0%	2,605	23.6%
Research and development	146	1.2%	186	1.7%
General and administrative	2,141	17.8%	2,894	26.2%
Acquisition related amortization expense	-	0.0%	318	2.9%
Total operating expenses	5,174	43.0%	6,003	54.4%
Operating income	2,257	18.7%	832	7.5%
Interest accretion expense	(12)	-0.1%	(31)	-0.3%
Note payable interest	(176)	-1.5%	(228)	-2.1%
Other income (expense), net	71	0.6%	(174)	-1.6%
Income from continuing operations before tax	2,140	17.8%	399	3.6%
Provision for income taxes	4	0.0%	4	0.0%
Income from continuing operations	2,136	17.7%	395	3.6%
Loss from discontinued operations, net of tax	(74)	-0.6%	(220)	-2.0%
Net income	$ 2,062	17.1%	$ 175	1.6%

Revenue, net

Revenue, net for the three months ended June 30, 2024 increased by $1.0 million, or 9%, to $12.0 million, compared to $11.0 million for the three months ended June 30, 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 three months ended June 30, 2024 was $4.6 million, as compared to $4.2 million for the three months ended June 30, 2023. As a percentage of revenue, cost of revenue was approximately 38% for both the three months ended June 30, 2024 and the three months ended June 30, 2023.

Gross profit

Consolidated gross profit was approximately $7.4 million for the three months ended June 30, 2024 and $6.8 million for the three months ended June 30, 2023. The gross profit percentage was approximately 62% for both the three months ended June 30, 3024 and June 30, 2023, respectively.

Sales and marketing expense

Sales and marketing expense was approximately $2.9 million for the three months ended June 30, 2024 and $2.6 million for the three months ended June 30, 2023. The increase was primarily attributable to increased headcount and related employee costs. As a percentage of revenue, sales and marketing expense was approximately 24% in both periods.

Research and development

Research and development expense was approximately $0.1 million for the three months ended June 30, 2024 and $0.2 million for the three months ended June 30, 2023. As a percentage of revenue, research and development expense decreased to 1% from 2% in the comparable prior year period.

General and administrative

General and administrative expense was approximately $2.1 million for the three months ended June 30, 2024 and $2.9 million for the three months ended June 30, 2023. The decrease can be primarily attributed to a decrease in legal and related professional fees.

Acquisition amortization expense

During the three months ended June 30, 2023, we recorded amortization expense of approximately $0.3 million, which was related to intangible assets associated with prior acquisitions. There was no amortization expense during the three months ended June 30, 2024.

Operating income

Operating income from continuing operations was $2.3 million for the three months ended June 30, 2024 as compared to operating income from continuing operations of $0.8 million for the three months ended June 30, 2023. The increase in operating income from continuing operations was primarily attributable to the increase in revenue and lower general and administrative expenses discussed above.

Provision for income taxes

Income tax expense was approximately $4,000 for both the three months ended June 30, 2024 and the three months ended June 30, 2023.

Loss from discontinued operations, net of tax

We had a loss from discontinued operations of approximately $0.1 million for the three months ended June 30, 2024 and a loss from discontinued operations of approximately $0.2 million for the three months ended June 30, 2023.

Condensed Consolidated Results of Continuing Operations for the Six Months Ended June 30, 2024 Compared to the Six Months Ended June 30, 2023 (unaudited, in thousands)

	Six Months Ended June 30,			
	2024	2024 % to revenue	2023	2023 % to revenue
Revenue, net	$ 22,314	100.0%	$ 20,853	100.0%
Cost of revenue	8,812	39.5%	8,039	38.6%
Gross profit	13,502	60.5%	12,814	61.4%
Operating expenses:				
Sales and marketing	5,707	25.6%	4,947	23.7%
Research and development	283	1.3%	335	1.6%
General and administrative	4,381	19.6%	5,389	25.8%
Acquisition related amortization expense	-	0.0%	635	3.0%
Total operating expenses	10,371	46.5%	11,306	54.2%
Operating income	3,131	14.0%	1,508	7.2%
Interest accretion expense	(30)	-0.1%	(66)	-0.3%
Note payable interest	(373)	-1.7%	(453)	-2.2%
Other expense, net	(12)	-0.1%	(156)	-0.7%
Income from continuing operations before tax	2,716	12.2%	833	4.0%
Provision for income taxes	8	0.0%	8	0.0%
Income from continuing operations	2,708	12.1%	825	4.0%
Loss from discontinued operations, net of tax	(178)	-0.8%	(299)	-1.4%
Net income	$ 2,530	11.3%	$ 526	2.5%

Revenue, net

Revenue, net for the six months ended June 30, 2024 increased by $1.5 million, or 7%, to $22.3 million, compared to $20.9 million for the six months ended June 30, 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 six months ended June 30, 2024 was $8.8 million, as compared to $8.0 million for the six months ended June 30, 2023. As a percentage of revenue, cost of revenue was approximately 40% for the six months ended June 30, 2024 as compared to 39% for the six months ended June 30, 2023.

Gross profit

Consolidated gross profit was approximately $13.5 million for the six months ended June 30, 2024 and $12.8 million for the six months ended June 30, 2023. The gross profit percentage was approximately 60% for the six months ended June 30, 3024 and 61% for the six months ended June 30, 2023. The increase was primarily due to the increase in revenue discussed above.

Sales and marketing expense

Sales and marketing expense was approximately $5.7 million for the six months ended June 30, 2024 and $4.9 million for the six months ended June 30, 2023. The increase was primarily due to increased employee costs. As a percentage of revenue, sales and marketing expense increased to 26% from 24% in the comparable prior year period due to the increase in sales and marketing expense.

Research and development

Research and development expense was approximately $0.3 million for both the six months ended June 30, 2024 and June 30, 2023, respectively. As a percentage of revenue, research and development expense decreased to 1% from 2% in the comparable prior year period.

General and administrative

General and administrative expense was approximately $4.4 million for the six months ended June 30, 2024 and $5.4 million for the three months ended June 30, 2023. The decrease can be primarily attributed to a decrease in legal and related professional fees.

Acquisition amortization expense

During the six months ended June 30, 2023, we recorded amortization expense of approximately $0.6 million, which was related to intangible assets associated with prior acquisitions. There was no amortization expense during the six months ended June 30, 2024.

Operating income

Operating income from continuing operations was $3.1 million for the six months ended June 30, 2024 as compared to operating income from continuing operations of $1.5 million for the six months ended June 30, 2023. The increase in operating income from continuing operations was primarily attributable to the increase in revenue and lower general and administrative expenses discussed above.

Provision for income taxes

Income tax expense was approximately $8,000 for both the six months ended June 30, 2024 and June 30, 2023.

Loss from discontinued operations, net of tax

We had a loss from discontinued operations of approximately $0.2 million for the six months ended June 30, 2024 and a loss from discontinued operations of approximately $0.3 million for the six months ended June 30, 2023.

Non-GAAP Financial Measures

In addition to the United States generally accepted accounting principles ("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 Quarterly Report on Form 10-Q, 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, non-cash stock based compensation, interest and taxes, and other non-cash expenses including change in fair value of notes payable and warrant liability. The table below includes a reconciliation of this non-GAAP financial measure to the most directly comparable GAAP financial measure.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Income from continuing operations (GAAP Basis)	$ 2,136	$ 395	$ 2,708	$ 825
Depreciation and amortization	67	357	119	714
Stock-based compensation	53	157	132	349
Taxes expense	4	4	8	8
Interest accretion expense	12	31	30	66
Note payable interest	176	228	373	453
Interest income	(14)	(13)	(29)	(13)
Change in fair value of note payable	(57)	165	41	142
Adjusted EBITDA	$ 2,377	$ 1,324	$ 3,382	$ 2,544

LIQUIDITY AND CAPITAL RESOURCES

In October 2021, the Company entered into a Loan and Security Agreement with BroadOak, providing for a term loan in the aggregate principal amount of $8,000,000 (the "Term Loan"). Funding of the Term Loan took place on November 1, 2021. The Term Loan 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 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.

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 June 30, 2024 was $7.4 million.

For the six months ended June 30, 2024, we had operating income from continuing operations of $3.1 million. As of the six months ended June 30, 2024, we had cash and cash equivalents of $2.0 million, total current assets of $10.2 million and current liabilities of $19.0 million. As of August 2, 2024, we had approximately $1.8 million of cash and cash equivalents.

During the six months ended June 30, 2024, net cash provided by operating activities was $1.3 million. The main component of cash provided by operating activities was our net income of $2.5 million, partially offset by an increase in accounts receivable of $1.2 million. During the six months ended June 30, 2023, net cash provided by operating activities was $1.5 million. The main component of cash provided by operating activities was our net income of $0.5 million, which included non-cash expenses of $1.3 million.

For both periods net cash used in investing activities was primarily related to the purchase of lab equipment.

For the six months ended June 30, 2024, cash used in financing activities was $2.6 million, which were payments made on the BroadOak Term Loan. For the six months ended June 30, 2023, cash used in financing activities was $1.0 million, which were payments made on the Comerica Revolving Line of Credit.

We intend to meet our ongoing capital needs by using our available cash generated from operations 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.

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, PancraGEN®. 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 PancraGEN® 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 PancraGEN®. The timing and content of any final implemented LCD is uncertain at this time; the process could potentially take a year or longer from issuance of the updated proposed LCD to reach a conclusion. 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 are able to continue offering PancraGEN® and the related Point2® fluid chemistry tests for amylase, CEA, and glucose. In the event Novitas ultimately restricts coverage for the PancraGEN® test, the Company's liquidity could be negatively impacted.

Inflation

We do not believe that inflation had a significant impact on our results of operations for the periods presented. However, inflation and supply chain disruptions, whether caused by restrictions or slowdowns in shipping or logistics, increases in demand for certain goods used in our operations, or otherwise, could impact our operations in the near term.

Critical Accounting Estimates

See Note 5, *Summary of Significant Accounting Policies* and Note 17, *Recent Accounting Standards* to the Interim Financial Statements included elsewhere in this Quarterly Report on Form 10-Q for information regarding newly adopted and recent accounting pronouncements. See also Note 1, *Nature of Business and Significant Accounting Policies* to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023, as amended, for a discussion of our critical accounting policies. There have been no material changes to such critical accounting policies. We believe our most critical accounting policies include accounting for contingent consideration, revenue recognition, long-lived assets, research and development expenses and stock-based compensation expense.

Off-Balance Sheet Arrangements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As a smaller reporting company, we are electing scaled disclosure reporting obligations and therefore are not required to provide the information requested by this Item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under 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 management's evaluation of the Company's disclosure controls and procedures, the principal executive officer and principal financial officer of the Company identified a material weakness in the Company's internal control over financial reporting in the quarterly period ended March 31, 2024 related to the timing of revenue recognition based on the Company's revenue recognition policy and have concluded that the Company's disclosure controls and procedures were not effective as of June 30, 2024 as a result of such material weakness in the Company's internal control over financial reporting.

The Company has adopted a remediation plan, pursuant to which the Company plans to amend its internal controls to mitigate the material weakness, which was identified by management, including by updating its procedures regarding the testing of revenue recognition, and reviewing the procedures which ensure that revenue is recorded in the period in which it is earned. The Company believes implementation of these processes and appropriate testing of their effectiveness will remediate the material weakness in the Company's internal control over financial reporting.

Changes in Internal Controls over Financial Reporting

Other than the material weakness and the adoption of the remediation plan discussed above, 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.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K of the Company filed with the SEC on April 1, 2024, as amended, and as updated and supplemented below and in subsequent filings. These risk factors could materially harm our business, operating results and financial condition. Additional factors and uncertainties not currently known to us or that we currently consider immaterial also may materially adversely affect our business, financial condition or future results.

If the FDA implements its plans to regulate LDTs, such activities could 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 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 NYSDOH 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. FDA notes, however, that it retains discretion to pursue enforcement action for violations of the FDCA at any time and intends to do so when appropriate. 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 FDA's good guidance practices. We are actively reviewing the final rule to evaluate its applicability to our operations, and the extent to which we may be required to modify our operations to comply with its requirements.

On May 29, 2024, the American Clinical Laboratory Association filed a lawsuit challenging the FDA's authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. The outcome of this lawsuit is uncertain at this time.

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 proposals that would increase general FDA oversight of clinical laboratories or LDTs could negatively impact our business if additional requirements are imposed. We are monitoring developments and anticipate that our clinical services products will be able to comply with requirements that are ultimately imposed by the FDA. In the meantime, we maintain our CLIA accreditation and state licenses, which permit the use of LDTs for diagnostic purposes.

If the FDA seeks to enforce the applicable medical device regulations against our clinical services tests, we could be subject to a wide range of penalties and would likely be prohibited from continuing to offer the applicable tests in interstate commerce until we have obtained FDA approval, authorization or clearance through the Premarket Approval (PMA), de novo or 510(k) process, respectively, as applicable. Additionally, we could be subject to enforcement for noncompliance with the FDA's regulations on marketing and promotional communications, manufacturing, quality and safety standards, labeling, storage, registration and listing, recordkeeping, adverse event reporting, and any other regulations applicable to IVDs. Any adverse enforcement action against us may have a material adverse effect on our clinical services and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description
3.1	Conformed version of Certificate of Incorporation of Interpace Biosciences, Inc., as amended by the Certificate of Amendment, effective January 15, 2020, and the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, filed January 17, 2020, incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on April 22, 2020, as amended from time to time.
3.2	Amended and Restated Bylaws of Interpace Biosciences, Inc., incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K, filed with the SEC on November 14, 2019.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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).

* Filed Herewith.

+ Exhibits 32.1 and 32.2 are being furnished herewith and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference to any registration statement or other document filed under the Securities Act or the Exchange Act, except as otherwise stated in any such filing.

SIGNATURES

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, thereunto duly authorized.

Date: August 8, 2024

Interpace Biosciences, Inc.
(Registrant)

/s/ Thomas W. Burnell
Thomas W. Burnell
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2024

/s/ Christopher McCarthy
Christopher McCarthy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Thomas W. Burnell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 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: August 8, 2024

/s/ Thomas W. Burnell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Christopher McCarthy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 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: August 8, 2024

/s/ Christopher McCarthy
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 Quarterly Report of Interpace Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 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: August 8, 2024

/s/ Thomas W. Burnell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Quarterly Report of Interpace Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 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: August 8, 2024

/s/ Christopher McCarthy
Chief Financial Officer
(Principal Financial Officer)