Spectral AI Announces 2024 Third Quarter Financial Results

Nov 06, 2024

Revenue Rose to $8.2 Million
Company Reaffirms Timeline for Regulatory Submission to U.S. FDA

Q3 2024 Overview

- Research & Development Revenue Rose 138% to $8.2 Million
- Last Patient Out at Burn Centers for U.S. Burn Pivotal Study; Top Line Study Results Expected in Q4 2024
- U.S. FDA Submission on Track for Q2 2025
- Completed Proof-of-Concept Module for Wound Measurement Technology

DALLAS, Nov. 06, 2024 (GLOBE NEWSWIRE) -- **Spectral AI, Inc. (Nasdaq: MDAI) ("Spectral AI" or the "Company")**, an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, today announced financial results for the third quarter ended September 30, 2024 ("Q3 2024") and provided an update on ongoing activities to commercialize its proprietary, AI-driven DeepView® System for burn indication ("DeepView AI®-Burn").

Dr. J. Michael DiMaio, the Company's Founder and recently appointed Chairman of the Board of Directors, said, "My confidence in the potential of DeepView AI®-Burn to change the standard of care in burn wound assessment and improve patient outcomes has never been greater. We achieved a critical clinical milestone with the announcement of last patient out at our U.S. Burn Pivotal Study and remain on schedule for our De Novo submission to the U.S. Food and Drug Administration ("FDA") in the second quarter of 2025 for the use of DeepView AI ®-Burn in burn centers. We are prioritizing our regulatory pathways for burn, fortifying our long-standing relationships with U.S. Government agencies, developing strategic partnerships that can expand our global reach, and capitalizing on the platform nature of our proprietary technology to pursue additional pipeline applications. We are fortunate to have the support of a team of dedicated professionals, an engaged and committed management team and Board, and $150 million of non-dilutive U.S. Government funding to advance our technology towards commercialization. We look forward to our future with great confidence."

DeepView AI®-Burn Highlights

- Final group of burn center patients in U.S. Burn Pivotal Study completed clinical visits, with top line study results expected in December 2024.
- Received a new award of over $850,000 from the Medical Technology Enterprise Consortium ("MTEC") to support the ongoing development of DeepView SnapShot ® M, the Company's handheld predictive burn wound healing device targeted for use in battlefield assessment. Total non-dilutive U.S. Government funding for DeepView SnapShot® M now exceeds $7.0 million.
- Completion of a proof-of-concept module for the Company's wound measurement technology that calculates the total body surface area ("TBSA") of a burn. This technology provides an accurate, and standardized measurement that the Company believes is a significant improvement over current wound size measurement technology and can improve patient treatment decisions.

Upcoming Milestones

- Top line results from U.S. Burn Pivotal Study Expected Q4 2024
- U.S. FDA submission for the use of DeepView AI®-Burn in burn centers in Q2 2025

Plan to Spin-Off Spectral IP Subsidiary

On November 6, 2024, the Company announced its intent to spin-off its Spectral IP, Inc. subsidiary ("Spectral IP") to continue to seek ways to maximize shareholder value. The Company anticipates that the transaction will be in the form of a stock distribution to its shareholders of Spectral IP, which will become a new, independent publicly-traded company.

Q3 2024 FINANCIAL RESULTS OVERVIEW

All comparisons are to the third quarter ended September 30, 2023 ("Q3 2023") unless otherwise stated.

Research and Development Revenue[1]
Research & Development Revenue for Q3 2024 rose 138% to $8.2 million from $3.4 million, primarily reflecting an increased level of work on the Company's Project BioShield (PBS) contract with BARDA, and awards and work performed on other U.S. Government contracts.

Gross Margin
Gross margin for Q3 2024 improved to 44.9% from 42.8%, reflecting increased development activity and higher Research and Development revenue.

General & Administrative Expense
General & administrative expenses in Q3 2024 declined to $4.6 million, or 55.7% of revenue, from $5.6 million, or 163.9% of revenue. This was driven primarily by an approximately $1.0 million reduction in non-revenue generating research and development activities associated with the Company's strategic shift to a larger focus on advancing the BARDA PBS contract.

Operating Loss
Operating loss narrowed to $(0.9) million from $(4.2) million, reflecting higher Research and Development revenue, improved gross margin, and reduced operating costs.

Net Loss
Net loss for Q3 2024 was $(1.5) million, or $(0.08) per share, compared to a net loss of $(10.6) million, or $(0.77) per share. Net loss in Q3 2024 included $1.1 million in borrowing related costs as compared to no such costs in the prior year period. Net loss in Q3 2023 included, among other items, $7.6 million in non-recurring transaction costs associated with the September 2023 consummation of the Company's business combination and Nasdaq listing.

Adjusted EBITDA
Adjusted EBITDA loss for Q3 2024 was $(0.7) million compared to a loss of $(3.9) million.

Financial Condition
As of September 30, 2024, the Company had $3.7 million in cash, short-term notes payable of $5.0 million, and $1.0 million of long-term debt relating to Spectral IP. Cash at September 30, 2024 included $0.9 million in Spectral IP.

2024 Guidance
The Company reiterates its revenue guidance of approximately $28.0 million for FY 2024.

CONFERENCE CALL

The Company will host a conference call today at 5:00 pm Eastern Time to discuss these results.

Investors interested in participating in the live call can dial:

- 833-630-1956 – U.S.
- 412-317-1837 – International

A simultaneous webcast of the call may be accessed online from the Events & Presentations section of the Investor Relations page of the Company's website at https://investors.spectral-ai.com/news-events/events.

About Spectral AI
Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown®" with its DeepView® System. DeepView is a predictive device that offers clinicians an objective and immediate assessment of a wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of exceeding the current standard of care in the future, DeepView is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. For more information about DeepView, visit www.spectral-ai.com.

Forward-Looking Statements
Certain statements made in this release are "forward looking statements" within the meaning of the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company's strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words "estimates," "projected," "expects," "anticipates," "forecasts," "plans," "intends," "believes," "seeks," "may," "will," "should," "future," "propose" and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements.

These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company's control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" sections of the Company's filings with the SEC, including the Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Investors:

The Equity Group
Devin Sullivan
Managing Director
dsullivan@equityny.com

Conor Rodriguez
Analyst

crodriguez@equityny.com

Spectral AI, Inc.
Unaudited Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 3,702	$ 4,790
Accounts receivable, net	2,834	2,346
Inventory	443	230
Deferred offering costs	-	283
Prepaid expenses	1,506	1,452
Other current assets	1,011	801
Total current assets	9,496	9,902
Non-current assets:		
Property and equipment, net	5	12
Right-of-use assets	2,101	778
Total Assets	$ 11,602	$ 10,692
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,797	$ 2,683
Accrued expenses	3,253	4,300
Deferred revenue	731	2,311
Lease liabilities, short-term	212	853
Notes payable	597	436
Notes payable - at fair value	4,377	-
Warrant liabilities	1,101	1,818
Total current liabilities	13,068	12,401
Notes payable - related party	1,000	-
Lease liabilities, long-term	1,870	-
Total Liabilities	15,938	12,401
Stockholders' Deficit		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of September 30, 2024 and December 31, 2023	-	-
Common stock ($0.0001 par value); 80,000,000 shares authorized; 18,513,073 and 16,294,935 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	35,998	31,065
Accumulated other comprehensive income	25	12
Accumulated deficit	(40,361)	(32,788)
Total Stockholders' Deficit	(4,336)	(1,709)
Total Liabilities and Stockholders' Deficit	$ 11,602	$ 10,692

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

Spectral AI, Inc.
Unaudited Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Research and development revenue	$ 8,173	$ 3,440	$ 21,977	$ 12,769
Cost of revenue	(4,506)	(1,968)	(12,051)	(7,325)
Gross profit	3,667	1,472	9,926	5,444
Operating costs and expenses:				
General and administrative	4,553	5,638	15,397	15,499

Total operating costs and expenses	4,553	5,638	15,397	15,499
Operating loss	(886)	(4,166)	(5,471)	(10,055)
Other income (expense):				
Net interest (expense) income	(8)	42	-	128
Borrowing related costs	(1,059)	-	(2,034)	-
Change in fair value of warrant liability	350	1,069	718	1,004
Change in fair value of notes payable	94	-	(7)	--
Foreign exchange transaction loss, net	(9)	(24)	(34)	(11)
Other income (expenses), including transactions costs	51	(7,604)	(617)	(8,342)
Total other expense, net	(581)	(6,517)	(1,974)	(7,221)
Loss before income taxes	(1,467)	(10,683)	(7,445)	(17,276)
Income tax benefit (provision)	(37)	54	(128)	(32)
Net loss	$ (1,504)	$ (10,629)	$ (7,573)	$ (17,308)
Net loss per share of common stock				
Basic and Diluted	$ (0.08)	$ (0.77)	$ (0.44)	$ (1.29)
Weighted average common shares outstanding				
Basic and Diluted	17,862,240	13,822,990	17,342,203	13,410,287
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ 15	$ (3)	$ 13	$ -
Total comprehensive loss	$ (1,489)	$ (10,632)	$ (7,560)	$ (17,308)

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Spectral AI, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands, except share and per share data)

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (7,573)	$ (17,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	7	7
Stock-based compensation	858	975
Amortization of right-of-use assets	448	530
Issuance of shares for transaction costs	-	1,800
Commitment to issue shares for transaction costs	-	2,550
Change in fair value of warrant liabilities	(718)	(1,004)
Change in fair value of notes payable	7	-
Costs from issuance of common stock	372	-
Issuance of shares for borrowing related costs	280	-
Changes in operating assets and liabilities:		
Accounts receivable	(488)	982
Inventory	(213)	(220)
Unbilled revenue	-	491
Prepaid expenses	542	(469)
Other assets	(208)	(197)
Accounts payable	188	(554)
Accrued expenses	(1,047)	1,225
Deferred revenue	(1,580)	795
Lease liabilities	(542)	(468)
Net cash used in operating activities	(9,668)	(10,865)
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,667	3,351
Cash received in Business Combination	-	660
Proceeds from notes payable	11,500	-
Proceeds from notes payable - related party	1,000	-
Payments for notes payable	(6,600)	(288)
Stock option exercises	-	316
Net cash provided by financing activities	8,567	4,039

Effect of exchange rate changes on cash	13	-
Net decrease in cash	(1,088)	(6,826)
Cash, beginning of period	4,790	14,174
Cash, end of period	$ 3,702	$ 7,348
Supplemental cash flow information:		
Cash paid for interest	$ -	$ 6
Cash paid for taxes	$ 20	$ 114
Noncash operating and financing activities disclosure:		
Recognition of Right-of-use assets and related lease liabilities upon lease amendment	$ 1,771	$ 483
Issuance of common stock for net liabilities upon Business Combination	$ -	$ 3,034
Prepaid asset acquired, net of cancellation, for debt and accounts payable	$ 596	$ 955
Issuance of common stock to settle accounts and notes payable	$ 1,245	$ 150

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Spectral AI, Inc.
Reconciliation of GAAP Net Loss to EBITDA and ADJUSTED EBITDA

Adjusted EBITDA

We define Adjusted EBITDA as net loss excluding income taxes, depreciation of property and equipment, net interest income, stock compensation, transaction costs and any non-operating financial income and expense.

The following table presents our Adjusted EBITDA for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
	(In thousands)			
Net loss	$ (1,504)	$ (10,629)	$ (7,573)	$ (17,308)
Adjust:				
Depreciation expense	2	2	7	7
Provision for income taxes	37	(54)	128	32
Net interest (income) expense	8	(42)	-	(128)
EBITDA	**(1,457)**	**(10,723)**	**(7,438)**	**(17,397)**
Additional adjustments:				
Stock-based compensation	173	279	858	975
Borrowing related costs	1,059	-	2,034	-
Change in fair value of warrant liability	(350)	(1,069)	(718)	(1,004)
Change in fair value of notes payable	(94)	-	7	-
Foreign exchange transaction (gain) loss	9	24	34	11
Other (income) expenses, including transaction costs	(51)	7,604	617	8,342
Adjusted EBITDA	**$ (711)**	**$ (3,885)**	**$ (4,606)**	**$ (9,073)**

We use Adjusted EBITDA as a non-GAAP metric when measuring performance, including when measuring current period results against prior periods' Adjusted EBITDA. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP and should not be considered as a substitute for, or superior to, GAAP results. In addition, Adjusted EBITDA should not be construed as an indicator of our operating performance, liquidity or cash flows generated by operating, investing and financing activities, as there may be significant factors or trends that it fails to address.

Because of their non-standardized definitions, non-GAAP measures (unlike GAAP measures) may not be comparable to the calculation of similar measures of other companies. We caution investors that non-GAAP financial information, by its nature, departs from traditional accounting conventions. Supplemental non-GAAP measures are presented solely to permit investors to more fully understand how Spectral AI's management assesses underlying performance.

[1]Research and Development Revenue consisted primarily of funding from the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services.