Spectral AI Announces 2024 Second Quarter Financial Results

Aug 12, 2024

Second Quarter Revenue Totals $7.5 Million

Total Enrollment Exceeds 85% for Burn Center Pivotal U.S. Clinical Trial

Q2 2024 Overview

- Research & Development Revenue of $7.5 Million
- Cash Position of $6.9 Million
- On Track to Generate First Commercial Revenues in the U.K. Later this Year
- Burn Pivotal Study Nearing Completion Paving the Way for U.S. FDA Submission in Early 2025
- Announced Collaboration with PolyNovo Ltd. Providing Introduction to Australian Market
- Continued Progress in Handheld Burn Wound Diagnostic Technology
- Added to Russell Microcap® Index effective July 1, 2024

DALLAS, Aug. 12, 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 second quarter ended June 30, 2024 ("Q2 2024") and provided an update on its ongoing business activities.

"This is one of the most exciting and consequential periods in our history, and I am proud to see the teams advancing our proprietary, AI-driven DeepView™ System for burn indication ("DeepView AI- Burn") along multiple fronts, including clinical, developmental and commercial," said Peter M. Carlson, CEO of Spectral AI. "The upcoming completion of enrollment at burn centers for our U.S. Burn Pivotal Study, continued development of both our cart-based device and the handheld diagnostic tool, and anticipation of our first commercial revenues in the U.K. later this year validate our vison and reinforce our strategic imperatives."

CLINCIAL TRIAL UPDATES

- Patient enrollment for the 2024 U.S. Burn Pivotal Study continues to progress well at burn centers, where total enrollment now exceeds 85%. This pivotal study, which is designed to validate the AI-driven algorithm of DeepView AI-Burn, will be the final clinical trial before the Company seeks regulatory approval in 2025 and is one of the largest burn studies ever conducted in the United States.
- Building on this momentum, the Company will pursue a De Novo classification from the U.S. Food and Drug Administration ("FDA") for DeepView AI-Burn for use in burn centers and expects to submit the request in the second quarter of 2025. A subsequent 510k application will be made for the use of DeepView AI-Burn in emergency departments after receiving approval for use in burn centers.
- The Company paused patient enrollment for the U.S. DFU Clinical Validation Study at 475 subjects, having achieved sufficient enrollment for development of a robust DFU data set. Management is assessing the insights of this study while focusing on the burn indication, where the opportunity for near-term market penetration is the greatest.

SELECT BUSINESS HIGHLIGHTS

Product Deployment and Market Development

- Deployed a total of five DeepView Burn devices at facilities across the U.K. in connection with the February 2024 receipt of UKCA Authorization. These deployments will increase familiarity of the device in advance of commercialization later this year and provide real-word data that enhances the AI-algorithm.
- Continued to make progress in the development of DeepView SnapShot® M, a handheld diagnostic tool targeted for use in battlefield burn assessment that is based on the DeepView™ System platform. DeepView SnapShot® M is designed to be an integral part of the triage process by providing a quick and accurate wound assessment so that those with more severe burn injuries can be prioritized for treatment and evacuation. A poster presentation highlighting DeepView SnapShot® M is scheduled for the 2024 Military Health System Research Symposium (MHSRS) being held August 26-29, 2024.
- Signed a Memorandum of Understanding with PolyNovo Limited to support the Company's application to the Australian Special Access Scheme to allow for the deployment of two DeepView Burn systems at the Royal Adelaide Hospital and The Alfred Hospital in Melbourne.

Corporate

- Received the final $2.5 million principal advance under its existing standby equity purchase agreement.
- Added to the Russell Microcap® Index effective July 1, 2024.
- Continued to strengthen and protect its proprietary DeepView™ System wound assessment platform via a 30% increase in the Company's patent portfolio to 26 granted patents from 20. The Company also announced an additional 38 pending patent applications worldwide.

Q2 2024 FINANCIAL RESULTS OVERVIEW
All comparisons are to the second quarter ended June 30, 2023 ("Q2 2023") unless otherwise stated.

Research & Development Revenue [1]
Research & Development Revenue for Q2 2024 rose 76% to $7.5 million from $4.3 million, primarily reflecting an increased level of activity under the Company's Project BioShield (PBS) contract with BARDA for the advanced development of the DeepView™ System.

Gross Margin
Gross margin for Q2 2024 improved to 44.3% from 42.1%, due to a higher reimbursement rate under the BARDA PBS Contract as compared to the rate associated with the now completed BARDA Burn II contract.

General & Administrative Expense
General & administrative expenses in Q2 2024 rose to $5.8 million, or 77% of revenues, from $4.8 million, or 112% of revenues.

Operating Loss
Operating loss narrowed to $(2.4) million from $(3.0) million.

Net Loss
Net loss for Q2 2024 narrowed to $(2.9) million, or $(0.16) per share, as compared to a net loss of $(3.1) million, or $(0.23) per share.

Financial Condition
As of June 30, 2024, cash was $6.9 million as compared to $4.8 million at December 31, 2023. Cash at June 30, 2024 included $0.9 million in cash in the Company's newly formed wholly-owned subsidiary Spectral IP, Inc.

2024 Guidance
The Company reiterates its revenue guidance of approximately $28.0 million for FY 2024. Financial guidance for FY 2024 does not reflect contributions from the sale of the DeepView™ System for burn in the U.K. that is expected to begin in Q4 2024 or any additional material financial contributions that may result from the commercialization of our DeepView™ System.

[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.

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. The DeepView™ System 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 to change the current standard of care, the DeepView™ System 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 the DeepView™ System, 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.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 6,877	$ 4,790
Accounts receivable, net	2,295	2,346
Inventory	267	230
Deferred offering costs	-	283
Prepaid expenses	1,249	1,452
Other current assets	973	801
Total current assets	11,661	9,902
Non-current assets:		
Property and equipment, net	7	12
Right-of-use assets	2,229	778
Total Assets	$ 13,897	$ 10,692
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,403	$ 2,683
Accrued expenses	2,733	4,300
Deferred revenue	1,315	2,311
Lease liabilities, short-term	224	853
Notes payable	-	436
Notes payable - at fair value	7,001	-

Notes payable - related party	1,000	-
Warrant liabilities	1,450	1,818
Total current liabilities	16,126	12,401
Lease liabilities, long-term	2,036	-
Total Liabilities	18,162	12,401
Stockholders' Deficit		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	-	-
Common stock ($0.0001 par value); 80,000,000 shares authorized; 17,606,367 and 16,294,935 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	34,580	31,065
Accumulated other comprehensive income	10	12
Accumulated deficit	(38,857)	(32,788)
Total Stockholders' Deficit	(4,265)	(1,709)
Total Liabilities and Stockholders' Deficit	$ 13,897	$ 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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Research and development revenue	$ 7,478	$ 4,251	$ 13,804	$ 9,329
Cost of revenue	(4,164)	(2,460)	(7,545)	(5,357)
Gross profit	3,314	1,791	6,259	3,972
Operating costs and expenses:				
General and administrative	5,756	4,782	10,844	9,861
Total operating costs and expenses	5,756	4,782	10,844	9,861
Operating loss	(2,442)	(2,991)	(4,585)	(5,889)
Other income (expense):				
Net interest (expense) income	(6)	42	8	86
Borrowing related costs	(699)	-	(975)	-
Change in fair value of warrant liability	348	(81)	368	(65)
Change in fair value of notes payable	(167)	-	(101)	-
Foreign exchange transaction (loss) gain, net	(9)	-	(25)	13
Other income (expenses), including transactions costs	180	-	(668)	(738)
Total other expense, net	(353)	(39)	(1,393)	(704)
Loss before income taxes	(2,795)	(3,030)	(5,978)	(6,593)
Income tax provision	(69)	(40)	(91)	(86)
Net loss	$ (2,864)	$ (3,070)	$ (6,069)	$ (6,679)
Net loss per share of common stock				
Basic and Diluted	$ (0.16)	$ (0.23)	$ (0.36)	$ (0.51)
Weighted average common shares outstanding				
Basic and Diluted	17,598,357	13,210,320	17,079,328	13,200,515
Other comprehensive income (loss):				
Foreign currency translation adjustments	$ -	$ 2	$ (2)	$ 3
Total comprehensive loss	$ (2,864)	$ (3,068)	$ (6,071)	$ (6,676)

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

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (6,069)	$ (6,679)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5	5
Stock-based compensation	685	696
Amortization of right-of-use assets	320	350
Change in fair value of warrant liabilities	(368)	65
Change in fair value of notes payable	101	-
Costs from issuance of common stock	372	-
Changes in operating assets and liabilities:		
Accounts receivable	51	774
Inventory	(37)	-
Unbilled revenue	-	527
Prepaid expenses	203	(11)
Other assets	(172)	(322)
Accounts payable	(206)	(752)
Accrued expenses	(1,567)	(405)
Deferred revenue	(996)	509
Lease liabilities	(364)	(284)
Net cash used in operating activities	(8,042)	(5,527)
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,667	-
Proceeds from notes payable	9,200	-
Proceeds from notes payable - related party	1,000	-
Payments of deferred offering costs	-	(306)
Payments for notes payable	(2,736)	(175)
Stock option exercises	-	-
Net cash provided by (used in) financing activities	10,131	(481)
Effect of exchange rate changes on cash	(2)	-
Net increase (decrease) in cash	2,087	(6,008)
Cash, beginning of period	4,790	14,174
Cash, end of period	$ 6,877	$ 8,166
Supplemental cash flow information:		
Cash paid for interest	$ -	$ (3)
Cash paid for taxes	$ -	$ -
Noncash operating and financing activities disclosure:		
Recognition of Right-of-use assets and related lease liabilities upon lease amendment	$ 1,771	$ 483
Unpaid deferred offering costs	$ -	$ 818
Broker receivable for stock option exercises	$ -	$ 6