Spectral AI Announces 2023 Third Quarter Financial Results

Highlights Continuing Progress in Developing and Commercializing AI-Driven DeepView® System Wound Healing Assessment Technology

Affirms Full Year Revenue Guidance for 2023 and 2024

DALLAS, November 13, 2023 - 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, 2023 ("Q3 2023").

"This has been an extraordinary period for Spectral AI, highlighted by our September listing on Nasdaq, continued progress towards developing and commercializing our AI-Driven DeepView® System wound healing assessment platform for burn and diabetic foot ulcers ("DFU"), and the recent receipt of the largest contract in our history a $149 million award from the United States government to advance our DeepView® System for burn wound assessment," said Wensheng Fan, CEO of Spectral AI.

"We believe that our DeepView® System is the only digital predictive medical diagnostic product that provides clinicians with an objective and immediate assessment of a wound's healing potential through the application of AI. Multiple clinical studies have validated the efficacy of our DeepView® System in assessing - within seconds - whether a wound will heal on its own or will require medical intervention to do so. In the case of burn, where our DeepView® System's current accuracy is 92% for adults and 88% for pediatrics, a non-healing assessment may suggest a surgical referral as well as determining which specific areas require excision and grafting. For DFU, where our DeepView® System's accuracy is 86%, a non-healing assessment may justify the immediate use of advanced wound care therapy as opposed to the current 'wait-and-see' approach. In each case, our DeepView® System is designed to support clinicians in placing their patients on an informed, defined, and immediate path to healing, while improving outcomes, reducing hospital stays, and eliminating unnecessary expenses."

Mr. Fan concluded, "We are preparing across all fronts for the commercial launch of our DeepView® System as early as 2024 following the receipt of necessary regulatory approvals. To that end, we remain on track to submit applications for FDA, UKCA, and CE mark approval for the DeepView® System DFU indication and 3D wound measurement in 2024 and for FDA and CE mark approval for the burn indication in 2025. As previously announced, we also expect 2024 revenue growth of approximately 60% from anticipated 2023 levels."

Q3 2023 FINANCIAL RESULTS OVERVIEW

All comparisons are to the third quarter ended September 30, 2022 ("Q3 2022") unless otherwise stated.

- Research & Development Revenue[1] was $3.4 million compared to $7.0 million, primarily due to decreased research and development work performed pursuant to the BARDA Burn II contract as clinical trials under this contract were nearing completion. New patient enrollments in our BARDA clinical study declined as the Company is completing enrollment and transitioning to the closeout phase of the study.
- Cost of revenue declined by $1.8 million, or 48.4%, primarily due to decreased activity to fulfill the BARDA Burn II contract consistent with decreased Research & Development revenue.
- Gross margin declined to 42.8% from 45.9%, primarily due to the commencement of Phase II of the Medical Technology Enterprise Consortium ("MTEC") contract, which has a lower gross margin than the BARDA Burn II contract.
- General & administrative expenses were $5.6 million compared to $3.5 million, the result of increased headcount required to support our organizational growth, and R&D initiatives associated largely with ongoing studies in support of planned regulatory applications for our DFU indication.
- Non-recurring transaction costs associated with the September 2023 consummation of the Company's business combination that resulted in our Nasdaq listing were $7.6 million as compared to no such costs.
- Net loss was $(10.6) million, or $(0.77) per share, compared to a net loss of $(0.4) million, or $(0.03) per share. Net loss for Q3 2023 included the above-referenced $7.6 million in non-recurring transaction costs.
- Adjusted EBITDA loss was $(3.9) million compared to Adjusted EBITDA of $0.0 million.
- As of September 30, 2023, cash and cash equivalents totaled $7.3 million and the Company had no long-term debt.

2023 and 2024 Guidance

The Company is reiterating its revenue guidance of approximately $17.4 million for full year 2023 and approximately $28.0 million for full year 2024. Financial guidance for FY2024 does not reflect the material financial contributions the Company expects would result from the commercialization of our DeepView® System for DFU and 3D wound measurement following the receipt of necessary regulatory clearances.

Q3 2023 OPERATIONS OVERVIEW

Burn Indication

- Awarded a new contract from the U.S. Government valued at up to $149 million to support the clinical validation and FDA clearance of our DeepView® System for burn wound assessment. Together with the previous contracts, this brings total U.S. Government awards to the Company since 2019 to more than $246.0 million.

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[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.

- Announced that the imaging component of the DeepView SnapShot® Wound Imaging System ("SnapShot®") achieved UK Conformity Assessed (UKCA)-mark for use in the United Kingdom and Class 1 medical device classification with the United States Food and Drug Administration (FDA). The Company is now pursuing the approval of its integrated AI application to obtain both UKCA and FDA approval for the commercialization of the complete DeepView® System in the U.S. and around the world.

- Continued to pursue horizon indication uses of the DeepView® System by commencing Phase II design and development activities for DeepView SnapShot® M, a handheld, portable and wireless device capable of performing digital burn assessment in military and combat environments. The Company is advancing this product under a $4 million contract award in April 2023 from MTEC, a biomedical technology consortium working in partnership with the U.S. Department of Defense.

- Commenced enrolling an additional 150 adult and pediatric subjects across at least 15 clinical sites in the U.S. and EU to expand one of the largest, multi-center burn studies ever conducted, which the Company completed in Q2 2023. The results of this expanded study will allow the Company to complete the development of the AI algorithm for burn and support its applications for FDA and CE Mark approval for the DeepView® System burn indication, which are planned for 2025.

DFU Indication

- Added seven additional clinical sites to its third multi-center DFU validation study in the U.S. Data collected from this third study will be used to further test the wound healing prediction capability of our DeepView® System's DFU healing prediction algorithm and support the Company's applications for FDA, UCKA and CE Mark approval for our DeepView® System's DFU indication, which is planned for 2024.

Corporate

- Completed the business combination with Rosecliff Acquisition Corp I, subsequent to which the Company commenced trading on Nasdaq on September 12, 2023 following its delisting from the AIM Market of the London Stock Exchange.
- Received ISO 13485 certification for the manufacture and distribution of the DeepView® System.
- Appointed healthcare services leader and population health expert Deepak Sadagopan, MHCDS, to its board of directors.
- Appointed Professor Paul Chadwick, former CEO of the Royal College of Podiatry UK, as Executive Vice President of the Company's UK subsidiary where he will be responsible for the market expansion of our DeepView® System in the EMEA.

CONFERENCE CALL

The Company will host a conference call on Tuesday, November 14, 2023 at 9:00 am Eastern Time to discuss the 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 diagnostic 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 substantially 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.

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 7,348	$ 14,174
Accounts receivable, net	1,312	2,294
Inventory	220	-
Unbilled revenue	127	618
Prepaid expenses	1,755	331
Other current assets	594	270
Total current assets	11,356	17,687
Non-current assets:		
Property and equipment, net	14	21
Right-of-use assets	961	1,008
Total Assets	$ 12,331	$ 18,716
Commitments and contingencies (Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,275	$ 2,759
Accrued expenses	3,983	2,631
Deferred revenue	795	-
Lease liabilities, short-term	813	680
Notes payable	632	175
Warrant liabilities	1,149	129
Total current liabilities	10,647	6,374
Lease liabilities, long-term	228	346
Total Liabilities	10,875	6,720
Stockholders' Equity		
Preferred stock ($0.0001 par value); 1,000,000 shares authorized; no shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock ($0.0001 par value); 80,000,000 shares authorized; 15,688,268 and 13,127,472 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	2	1
Additional paid-in capital	30,696	23,929
Accumulated deficit	(29,242)	(11,934)
Total stockholders' equity	1,456	11,996
Total Liabilities and Stockholders' Equity	$ 12,331	$ 18,716

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development revenue	$ 3,440	$ 7,038	$ 12,769	$ 19,272
Cost of revenue	(1,968)	(3,811)	(7,325)	(10,943)
Gross profit	1,472	3,227	5,444	8,329
Operating costs and expenses:				
General and administrative	5,638	3,478	15,499	9,207
Total operating costs and expenses	5,638	3,478	15,499	9,207
Operating loss	(4,166)	(251)	(10,055)	(878)
Other income (expense):				
Net interest income	42	2	128	1
Change in fair value of warrant liability	1,069	22	1,004	50
Foreign exchange transaction loss, net	(24)	(51)	(11)	(255)
Transaction costs	(7,604)	-	(8,342)	-
Other expense	-	(17)	-	-
Total other expense, net	(6,517)	(44)	(7,221)	(204)
Loss before income taxes	(10,683)	(295)	(17,276)	(1,082)
Income tax benefit (provision)	54	(85)	(32)	(91)
Net loss	$ (10,629)	$ (380)	$ (17,308)	$ (1,173)
Net loss per share of common stock				
Basic and Diluted	$ (0.77)	$ (0.03)	$ (1.29)	$ (0.09)
Weighted average common shares outstanding				
Basic and Diluted	13,822,990	13,145,834	13,410,287	13,127,825

Non-GAAP Financial Measures

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.

Adjusted EBITDA

We define Adjusted EBITDA as net loss excluding income taxes, depreciation of property and equipment, 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, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
	(In thousands)			
Net loss	$ (10,629)	$ (380)	$ (17,308)	$ (1,173)
Adjust:				
Depreciation expense	2	-	7	6
Provision for income taxes	(54)	85	32	91
Net interest income	(42)	(2)	(128)	(1)
EBITDA	**(10,723)**	**(297)**	**(17,397)**	**(1,077)**
Additional adjustments:				
Stock-based compensation	279	247	975	874
Change in fair value of warrant liability	(1,069)	(22)	(1,004)	(50)
Foreign exchange transaction gain	24	51	11	255
Transaction costs	7,604	-	8,342	-
Other income	-	17	-	-
Adjusted EBITDA	**$ (3,885)**	**$ (4)**	**$ (9,073)**	**$ 2**