

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENDRA Life Sciences Inc.

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

August 17, 2020

ENDRA Life Sciences Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-37969

26-0579295

(State or other jurisdiction of incorporation)

(Commission File Number)

(IRS Employer Identification No.)

3600 Green Court, Suite 350 Ann Arbor, MI

48105

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code

(734) 335-0468

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	NDRA	The Nasdaq Stock Market LLC
Warrants, each to purchase one share of Common Stock	NDRAW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On August 17, 2020, ENDRA Life Sciences Inc. issued a press release announcing its financial results for the quarter and year ended June 30, 2020. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	Press Release dated August 17, 2020, furnished herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

August 17, 2020

ENDRA Life Sciences Inc.

By: /s/ Francois Michelin

Name: Francois Michelin

Title: President and Chief Executive Officer

ENDRA Life Sciences Provides Business Update and Reports Second Quarter 2020 Financial Results

ANN ARBOR, MI / ACCESSWIRE / August 17, 2020 / ENDRA Life Sciences Inc. ("ENDRA") (NASDAQ:NDRA), the pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS[®]), today provided a business update and reported second quarter 2020 financial results.

"During the second quarter, we achieved another major milestone on the path to commercializing TAEUS with our 510(k) Premarket Notification submission to the U.S. Food and Drug Administration ("FDA)," said Francois Michelin, Chairman and Chief Executive Officer. "The submission represents the culmination of years of scientific research, quality system implementation, clinical data collection, and biocompatibility and safety testing. I'm very proud of the ENDRA team, especially for working tirelessly through an unprecedented global pandemic to ensure the submission was made on the aggressive schedule we set before COVID-19 was a consideration."

As Renaud Maloberti, Chief Commercial Officer, explained, "The FDA submission builds on the receipt of the CE Mark in Europe for our TAEUS liver system in the first quarter and positions the company to begin commercialization in two major markets in the second half of 2020 to start positively impacting the lives of more than 1 billion people globally affected by Non-Alcoholic Fatty Liver Disease (NAFLD) and Non-Alcoholic Steatohepatitis (NASH)."

Q2 2020 and Recent Business Highlights

- Completed 510(k) Premarket Notification submission to the U.S. Food and Drug Administration ("FDA") for TAEUS Fatty Liver Imaging Probe ("FLIP") on schedule, setting stage for potential clearance and commercialization in the U.S. in 2020.
- Secured new partnership with the Medical College of Wisconsin ("MCW"), a world-renowned healthcare institution, for a clinical study of ENDRA's Thermo-Acoustic Enhanced Ultrasound (TAEUS[™]) device for assessing Non-Alcoholic Fatty Liver Disease ("NAFLD"). This represents the third research partnership for ENDRA, which will help bolster the clinical evidence and further establish the clinical utility of the TAEUS device in patients with NAFLD, as commercialization gets underway.
- Advanced European commercialization strategy, following CE Mark approval, including advancing to final stages of establishing initial evaluation sites in key markets, as well as hiring an initial salesperson in the U.K. and identifying leading candidates in other key markets.
- Increased intellectual property (IP) portfolio to 72 assets defined, filed and issued, including key platform patents in the United States, Europe and China to defend our technology and current and future clinical applications for which there are currently no practical clinical tools.
- Remain on track with key milestones of establishing clinical evaluation reference sites in Q3 and initial sales in Europe in Q4 2020.

Financial Results for Quarter Ended March 31, 2020

- Operating expenses increased to \$2.9 million in the second quarter of 2020, up from \$2.3 million in the same period in 2019. The increase in operating expenses was primarily due to expenses related to the development of our TAEUS product line, and costs associated with the pre-commercialization of TAEUS.
- Net loss in Q2 2020 totaled \$2.9 million, or (\$0.20) per basic and diluted share, as compared to a net loss of \$2.3 million, or (\$0.31) per basic and diluted share in Q2 2019.
- Cash balance at June 30, 2020 was \$749,000 and totaled approximately \$2.4 million as of August 14, 2020 due primarily to voluntary early warrant conversions, compared to \$6.2 million at December 31, 2019, with no long-term debt outstanding.

Conference Call and Webcast Access

Management will host a conference call and webcast today at 4:30 p.m. ET to discuss the results and provide an update on recent corporate developments.

Dial-in Number

U.S./Canada Dial-in Number: 844-369-8774

International Dial-in Number: 862-298-0844

Replay Dial-in Number: 877-481-4010

Replay International Dial-in Number: 919-882-2331

Replay Passcode: 36535

A telephone replay will be available August 17, 2020 through 4:30 p.m. ET on August 24, 2020.

A live audio webcast will be available through the Events and Presentations page of the Investors section of the company's website at www.endrainc.com. A replay of the webcast will be available on the website for 90 days.

About ENDRA Life Sciences Inc.

ENDRA Life Sciences Inc. is the pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS[®]), a ground-breaking technology that mirrors some applications similar to MRI, but at 50X lower cost, at the point of patient care. TAEUS is designed to work in concert with one million ultrasound systems in global use today. TAEUS is initially focused on the measurement of fat in the liver, as a means to assess and monitor NAFLD and NASH, chronic liver conditions that affect over 1 billion people globally, and for which there are no practical diagnostic tools. Beyond the liver, ENDRA is exploring several other clinical applications of TAEUS, including visualization of tissue temperature during energy-based surgical procedures.www.endrainc.com

Forward-Looking Statements

All statements in this release that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "could," "seek," "intend," "plan," "goal," "estimate," "anticipate" or other comparable terms. Examples of forward-looking statements include, among others, estimates of the timing of future events and achievements, such as the expectations listed above under the heading "2020 Guidance"; making our 510(k) submission with the FDA and commercializing the TAEUS device; and expectations concerning ENDRA's business strategy. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements, as a result of various factors including, among others, our ability to develop a commercially feasible technology; receipt of necessary regulatory approvals; the impact of COVID-19 on our business plans; our ability to find and maintain development partners, market acceptance of our technology, the amount and nature of competition in our industry; our ability to protect our intellectual property; and the other risks and uncertainties described in ENDRA's filings with the Securities and Exchange Commission. The forward-looking statements made in this release speak only as of the date of this release, and ENDRA assumes no obligation to update any such forward-looking statements to reflect actual results or changes in expectations, except as otherwise required by law.

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ENDRA Life Sciences Inc.

Condensed Consolidated Balance Sheets

Assets	June 30, 2020	December 31, 2019
Assets	(unaudited)	
Cash	\$ 748,561	\$ 6,174,207
Prepaid expenses	1,064,146	116,749
Inventory	340,687	113,442
Other current assets	121,951	130,701
Total Current Assets	2,275,345	6,535,099
Other Assets		
Fixed assets, net	214,587	236,251
Right of use assets	372,720	404,919
Total Assets	\$ 2,862,652	\$ 7,176,269
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,169,237	\$ 1,708,525
Convertible notes payable, net of discount	-	298,069
Lease liabilities, current portion	71,085	66,193
Total Current Liabilities	1,240,322	2,072,787
Long Term Debt		
Loans	337,084	-
Lease liabilities	308,366	342,812
Total Long Term Debt	645,450	342,812
Total Liabilities	1,885,772	2,415,599
Stockholders' Equity		
Series A Preferred Stock, \$0.0001 par value; 10,000 shares authorized; 896.225 and 6,338.490 shares issued and outstanding	1	1
Series B Preferred Stock, \$0.0001 par value; 1,000 shares authorized; 0 and 351.711 shares issued and outstanding	-	-
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 16,437,491 and 8,421,401 shares issued and outstanding	1,644	842
Additional paid in capital	52,227,904	49,933,736
Stock payable	181,437	43,528
Accumulated deficit	(51,434,106)	(45,217,437)
Total Stockholders' Equity	976,880	4,760,670
Total Liabilities and Stockholders' Equity	\$ 2,862,652	\$ 7,176,269

ENDRA Life Sciences Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Operating Expenses				
Research and development	\$ 1,487,049	\$ 1,304,808	\$ 3,005,195	\$ 3,078,306
Sales and marketing	134,763	88,343	249,718	145,161
General and administrative	1,269,467	932,021	2,737,212	1,848,924
Total operating expenses	<u>2,891,279</u>	<u>2,325,172</u>	<u>5,992,125</u>	<u>5,072,391</u>
Operating loss	<u>(2,891,279)</u>	<u>(2,325,172)</u>	<u>(5,992,125)</u>	<u>(5,072,391)</u>
Other Expenses				
Amortization of debt discount	(3,858)	-	(232,426)	-
Other income (expense)	1,265	(9,199)	7,882	(10,716)
Total other expenses	<u>(2,593)</u>	<u>(9,199)</u>	<u>(224,544)</u>	<u>(10,716)</u>
Loss from operations before income taxes	<u>(2,893,872)</u>	<u>(2,334,371)</u>	<u>(6,216,669)</u>	<u>(5,083,107)</u>
Provision for income taxes	-	-	-	-
Net Loss	<u>\$ (2,893,872)</u>	<u>\$ (2,334,371)</u>	<u>\$ (6,216,669)</u>	<u>\$ (5,083,107)</u>
Net loss per share - basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.31)</u>	<u>\$ (0.45)</u>	<u>\$ (0.68)</u>
Weighted average common shares - basic and diluted	<u>14,735,662</u>	<u>7,422,642</u>	<u>13,803,215</u>	<u>7,422,642</u>

ENDRA Life Sciences Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cash Flows from Operating Activities		
Net loss	\$ (6,216,669)	\$ (5,083,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44,014	39,744
Common stock, options and warrants issued for services	1,057,120	659,217
Amortization of debt discount	232,426	
Amortization of right of use assets	32,199	
Changes in operating assets and liabilities:		
Prepaid expenses	(947,397)	(98,358)
Lease liability	(29,554)	
Inventory	(227,245)	(14,837)
Other assets	8,750	(93,075)
Accounts payable and accrued liabilities	(493,676)	391,809
Net cash used in operating activities	<u>(6,540,032)</u>	<u>(4,198,607)</u>
Cash Flows from Investing Activities		
Purchases of fixed assets	(22,350)	(5,238)
Net cash used in investing activities	<u>(22,350)</u>	<u>(5,238)</u>
Cash Flows from Financing Activities		
Proceeds from warrant exercise	50,438	-
Proceeds from loans	337,084	-
Proceeds from issuance of common stock	791,474	-
Payment for settlement of notes with stock	(42,260)	-
Net cash provided by financing activities	<u>1,136,736</u>	<u>-</u>
Net decrease in cash	(5,425,646)	(4,203,845)
Cash, beginning of period	6,174,207	6,471,375
Cash, end of period	<u>\$ 748,561</u>	<u>\$ 2,267,530</u>
Supplemental disclosures of cash items		
Interest paid	\$ 1,920	\$ -
Supplemental disclosures of non-cash items		
Conversion of convertible notes and accrued interest	\$ 493,814	\$ -
Conversion of Series A Convertible Preferred Stock	\$ 636	\$ -
Conversion of Series B Convertible Preferred Stock	\$ 36	\$ -
Stock dividend payable	\$ (137,909)	\$ -
Stock paid and payable for services	\$ 40,000	\$ -
Lease liability for right of use asset at inception	\$ -	\$ 439,355

SOURCE: ENDRA Life Sciences Inc.