

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENDRA Life Sciences Inc.

Form: 8-K

Date Filed: 2020-11-16

Corporate Issuer CIK: 1681682

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) November 16, 2020

ENDRA Life Sciences Inc.
(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-37969</u> (Commission File Number)	<u>26-0579295</u> (IRS Employer Identification No.)
<u>3600 Green Court, Suite 350 Ann Arbor, MI</u> (Address of principal executive offices)		<u>48105</u> (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 November 16, 2020, ENDRA Life Sciences Inc. issued a press release announcing its financial results for the quarter ended September 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 16, 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.

November 16, 2020

ENDRA Life Sciences Inc.

By: /s/ Francois Michelin

Name: Francois Michelin

Title: President and Chief Executive Officer

ENDRA Life Sciences Reports Third Quarter 2020 Financial Results and Provides Business Update**Conference call begins at 4:30 p.m. Eastern time today**

ANN ARBOR, MI / ACCESSWIRE / November 16, 2020 / [ENDRA Life Sciences Inc.](#) ("ENDRA") (NASDAQ:NDRA), the pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS®), today reported financial results for the three months ended September 30, 2020 and provided a business update. Highlights of the third quarter of 2020 and recent weeks include:

- Installed the first TAEUS system at Rocky Vista University College of Osteopathic Medicine (RVUCOM), one of three research partnerships for ENDRA. The data from the RVUCOM study, along with other announced and future studies, will bolster the clinical evidence base and support the clinical utility of the TAEUS system in patients with non-alcoholic fatty liver disease (NAFLD) and inflammation (NASH) to support current and future commercialization efforts.
 - Secured the first clinical evaluation reference site in Germany and advanced two more European sites to final legal review, which the Company expects to execute before the end of the year. The Company also continued efforts to build out its strategic salesforce with key hires in the U.K. and Germany, while also identifying leading candidates in other major European markets.
 - Showcased TAEUS technology at important clinical conferences and trade shows, including The Digital International Liver Congress (ILC), hosted by the European Association for the Study of the Liver (EASL), and The Liver Meeting, sponsored by the American Association for the Study of Liver Diseases (AASLD). ENDRA's participation in these conferences helped to expand its qualified sales pipeline to more than 4,000 global clinicians, highlighting its unique position where there are no other practical clinical tools currently available.
 - Increased its intellectual property portfolio to 76 assets, up from 64 at the end of 2019, including adding key platform patents in the United States, Europe and China to protect current and future clinical applications of the Company's technology.
 - Received approximately \$5 million from the early exercise of common stock warrants. These proceeds extend ENDRA's cash runway through key business inflection points, including establishing evaluation reference sites and initial sales in Europe, as well as the potential receipt of FDA clearance to begin commercialization in the U.S.
 - Remained on track to execute key milestones of establishing additional clinical evaluation reference sites in Europe in the fourth quarter of 2020.
-

Commenting on the quarter and recent weeks, Francois Michelin, chairman and chief executive officer of ENDRA, said, "I'm pleased with our continued progress to keep the company on track during these challenging times, including advancing our key European commercialization initiatives, as well as installing the first TAEUS system at Rocky Vista. In addition, we continue to work with the U.S. Food and Drug Administration to respond to questions related to our 510(k) Premarket Notification submission, with expectations that TAEUS will receive clearance."

Renaud Maloberti, chief commercial officer, added, "The global pandemic is not tempering the enthusiasm of clinicians for our TAEUS solution to the growing NAFLD/NASH challenge, which impacts more than 1 billion people globally. We continue to make meaningful progress toward our first TAEUS system sale."

Financial Results for Quarter Ended September 30, 2020

- Operating expenses increased to \$3.3 million in the third quarter of 2020, up from \$2.6 million in the same period in 2019. The increase was primarily due to expenses related to the development of the TAEUS product line, regulatory submissions, and costs associated with TAEUS pre-commercialization activities.
- Net loss in the third quarter of 2020 was \$3.3 million, or (\$0.15) per share, compared with a net loss of \$3.4 million, or (\$0.46) per share, in the third quarter of 2019.
- The Company had cash and cash equivalents of \$3.8 million as of September 30, 2020, compared with \$6.2 million as of December 31, 2019, with no long-term debt.

Conference Call and Webcast Access

Management will host a conference call and webcast today at 4:30 p.m. ET to discuss these 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: 38486

A telephone replay will be available from November 16, 2020 through 4:30 p.m. ET on November 23, 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 is the pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS), a ground-breaking technology being developed to visualize tissue like MRI, but at 1/50th the cost and at the point of patient care. TAEUS is designed to work in concert with the over one million ultrasound systems in use globally today. TAEUS is initially focused on the measurement of fat in the liver as a means to assess and monitor Non-Alcoholic Fatty Liver Disease (NAFLD) and inflammation (NASH), chronic liver conditions that affect over one 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. For more information, please visit www.endrainc.com. *See more. Do more. Live better*®.

Forward-Looking Statements

All statements in this news 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 regarding commercializing the TAEUS device, establishing evaluation reference sites and initial sales in Europe, receipt of U.S. Food and Drug Administration regulatory approval, 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 and 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 news release speak only as of the date of issuance, 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.

Company Contact:

David Wells
Chief Financial Officer
(734) 997-0464
investors@endrainc.com
www.endrainc.com

Investor Relations Contact:

Kim Sutton Golodetz
LHA Investor Relations
(212) 838-3777
kgolodetz@lhai.com

ENDRA Life Sciences Inc.
Condensed Consolidated Balance Sheets

	September 30, 2020	December 31, 2019
Assets		
	(unaudited)	
Assets		
Cash	\$ 3,793,292	\$ 6,174,207
Prepaid expenses	561,554	116,749
Inventory	323,208	113,442
Other current assets	101,451	130,701
Total Current Assets	4,779,505	6,535,099
Other Assets		
Fixed assets, net	225,620	236,251
Right of use assets	356,060	404,919
Total Assets	\$ 5,361,185	\$ 7,176,269
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 1,325,005	\$ 1,708,525
Convertible notes payable, net of discount	-	298,069
Lease liabilities, current portion	73,624	66,193
Total Current Liabilities	1,398,629	2,072,787
Long Term Debt		
Loans	337,084	-
Lease liabilities	290,489	342,812
Total Long Term Debt	627,573	342,812
Total Liabilities	2,026,202	2,415,599
Stockholders' Equity		
Series A Convertible Preferred Stock, \$0.0001 par value; 10,000 shares authorized; 190 and 6,338 shares issued and outstanding, respectively	1	1
Series B Convertible Preferred Stock, \$0.0001 par value; 1,000 shares authorized; no shares and 352 shares issued and outstanding, respectively	-	-
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 25,015,710 and 8,421,401 shares issued and outstanding, respectively	2,500	842
Additional paid in capital	58,281,673	49,933,736
Stock payable	224,163	43,528
Stock receivable	(85,626)	-
Accumulated deficit	(55,087,728)	(45,217,437)
Total Stockholders' Equity	3,334,983	4,760,670
Total Liabilities and Stockholders' Equity	\$ 5,361,185	\$ 7,176,269

ENDRA Life Sciences Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Operating Expenses				
Research and development	\$ 1,769,339	\$ 1,468,441	\$ 4,774,534	\$ 4,546,746
Sales and marketing	139,751	100,203	389,469	245,364
General and administrative	1,346,360	1,071,889	4,083,572	2,920,815
Total operating expenses	<u>3,255,450</u>	<u>2,640,533</u>	<u>9,247,575</u>	<u>7,712,925</u>
Operating loss	<u>(3,255,450)</u>	<u>(2,640,533)</u>	<u>(9,247,575)</u>	<u>(7,712,925)</u>
Other Expenses				
Amortization of debt discount	-	(728,417)	(232,426)	(728,417)
Other income (expense)	(2,621)	(44,612)	5,261	(55,328)
Total other expenses	<u>(2,621)</u>	<u>(773,029)</u>	<u>(227,165)</u>	<u>(783,745)</u>
Loss from operations before income taxes	<u>(3,258,071)</u>	<u>(3,413,562)</u>	<u>(9,474,740)</u>	<u>(8,496,670)</u>
Provision for income taxes	-	-	-	-
Net Loss	<u>\$ (3,258,071)</u>	<u>\$ (3,413,562)</u>	<u>\$ (9,474,740)</u>	<u>\$ (8,496,670)</u>
Deemed dividend	(395,551)	-	(395,551)	-
Net Loss attributable to common stockholders	<u>\$ (3,653,622)</u>	<u>\$ (3,413,562)</u>	<u>\$ (9,870,291)</u>	<u>\$ (8,496,670)</u>
Net loss per share – basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.46)</u>	<u>\$ (0.41)</u>	<u>\$ (1.14)</u>
Weighted average common shares – basic and diluted	<u>23,889,591</u>	<u>7,428,788</u>	<u>23,808,012</u>	<u>7,424,713</u>

ENDRA Life Sciences Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Cash Flows from Operating Activities		
Net loss	\$ (9,474,740)	\$ (8,496,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	45,114	59,673
Common stock, options and warrants issued for services	1,559,232	1,020,300
Amortization of debt discount	232,426	728,417
Amortization of right of use assets	48,859	-
Stock payable for investor relations	30,000	-
Changes in operating assets and liabilities:		
Increase in prepaid expenses	(444,805)	(61,234)
Decrease in lease liability	(44,892)	-
Increase in inventory	(209,766)	(68,387)
Decrease (increase) in other asset	29,250	(93,075)
(Decrease) increase in accounts payable and accrued liabilities	(444,167)	229,640
Net cash used in operating activities	<u>(8,673,489)</u>	<u>(6,681,336)</u>
Cash Flows from Investing Activities		
Purchases of fixed assets	(10,483)	(5,238)
Net cash used in investing activities	<u>(10,483)</u>	<u>(5,238)</u>
Cash Flows from Financing Activities		
Proceeds from senior secured convertible promissory notes, net of fees	-	2,490,501
Proceeds from warrant exercise	4,644,084	-
Proceeds from loans	337,084	-
Proceeds from issuance of common stock	1,321,890	-
Net cash provided by financing activities	<u>6,303,058</u>	<u>2,490,501</u>
Net decrease in cash	(2,380,914)	(4,196,073)
Cash, beginning of period	6,174,207	6,471,375
Cash, end of period	<u>\$ 3,793,293</u>	<u>\$ 2,275,302</u>
Supplemental disclosures of cash items		
Interest paid	\$ 1,920	\$ -
Income tax paid	\$ -	\$ -
Supplemental disclosures of non-cash items		
Discount on convertible notes	\$ -	\$ 2,490,501
Conversion of convertible notes and accrued interest	\$ 493,814	\$ 140,405
Deemed dividend related to warrant repriced	\$ 395,551	-
Conversion of Series A Convertible Preferred Stock	\$ (717)	-
Conversion of Series B Convertible Preferred Stock	\$ (36)	-
Stock dividend payable	\$ (47,641)	-
Right of use asset	\$ 356,060	\$ (420,488)
Lease liability	\$ 364,113	\$ 424,210