

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

ENDRA Life Sciences Inc.

Form: 8-K

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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) May 17, 2021

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 May 17, 2021, ENDRA Life Sciences Inc. issued a press release announcing its financial results for the quarter ended March 31, 2021. 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

99.1 Press Release dated May 17, 2021, 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.

May 17, 2021

ENDRA Life Sciences Inc.

By: /s/ Francois Michelin

Name: Francois Michelin

Title: President and Chief Executive Officer

ENDRA Life Sciences Reports First Quarter 2021 Financial Results and Provides Business Update

Conference call begins at 4:30 p.m. Eastern time today

ANN ARBOR, Mich. (May 17, 2021) - [ENDRA Life Sciences Inc.](#) ("ENDRA") (NASDAQ: NDRA), a pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS®), today reported financial results for the three months ended March 31, 2021 and provided a business update. Highlights of the first quarter of 2021 and recent weeks include the following:

- **Began screening patients for real-world clinical validation of TAEUS at Rocky Vista University College of Osteopathic Medicine.** All clinical evaluation sites will compare the liver fat measurements of the TAEUS system to the gold standard MRI-PDFF.
- **Partnered with Hepion Pharmaceuticals, a clinical-stage company focused on AI-driven therapeutic drug development for the treatment of nonalcoholic steatohepatitis ("NASH") and liver disease.** ENDRA signed a collaboration agreement with Hepion to incorporate TAEUS as an add-on technology to support Hepion's patient screening and biomarker measurement during its upcoming Phase 2b study of CRV431.
- **Secured a new clinical study partnership with Inselspital University Hospital in Bern, Switzerland.** This is the third clinical research partnership for ENDRA in Europe and the sixth globally. Data from the Inselspital Bern study, along with other ongoing or to-be-initiated studies, will be used to bolster clinical evidence and further establish the clinical utility of the TAEUS device for assessing non-alcoholic fatty liver disease ("NAFLD").
- **Added two sales representatives to the commercial team in Europe** in anticipation of COVID-19-related restrictions being lifted, bringing the ENDRA EU team to four.
- **Strengthened balance sheet** via exercise of warrants and proceeds from existing ATM facility. Cash and cash equivalents as of March 31, 2021 were \$16.8 million.
- **Strengthened TAEUS intellectual property protection with issuance of additional U.S. patents.** Since the beginning of the year, four U.S. patents have been issued to further protect the Company's proprietary TAEUS technology. ENDRA's intellectual property portfolio continues to grow and currently stands at 85 global assets, defined as patents issued, filed, licensed or in preparation.

"We continue to advance commercialization initiatives by driving awareness of our TAEUS system and expanding our European sales team. In April, ENDRA presented at the American Institute of Ultrasound in Medicine's Annual Integrative Ultrasound Meeting, highlighting the features and benefits of the TAEUS system. We have several more industry conferences planned through the balance of the year to exhibit TAEUS and expand our database of potential customers." stated Francois Michelin, Chairman and Chief Executive Officer of ENDRA. "As we await a decision from the U.S. FDA regarding our 510(k) application, we remain confident in our submission and look forward to a favorable outcome. In the interim, and unrelated to our application, we continue to support our domestic clinical evaluation partners to assess and monitor chronic liver conditions."

Renaud Maloberti, Chief Commercial Officer, commented, "Although the environment continues to be challenging in many European countries as COVID-19 vaccines have not been administered as quickly as in the U.S., our growing commercial team is cultivating existing clinician contacts and positioned to develop new ones to establish a strong foundation of leads when in-person meetings and product demonstrations resume. In addition, this commercialization effort includes working closely with our partner, GE Healthcare, to leverage their extensive base of ultrasound customers. The teams' initial focus is to increase local interest for ENDRA's technology among radiologists while also targeting clinicians in hepatology, endocrinology and primary care which represent a significant market opportunity for TAEUS."

First Quarter 2021 Financial Results

- Operating expenses decreased to \$2.6 million in the first quarter of 2021 from \$3.1 million in the same period in 2020. The decrease was primarily due to reduced spending for outsourced product development and investor relations and legal fees.
 - Net loss in the first quarter of 2021 was \$2.3 million, or \$0.06 per share, compared with a net loss of \$3.3 million, or \$0.29 per share, in the first quarter of 2020.
 - Cash and cash equivalents were \$16.8 million as of March 31, 2021.
 - In the first quarter of 2021, ENDRA received exercise notices for 3.6 million warrants resulting in additional cash proceeds of \$2.8 million, and sold approximately 3.9 million shares through its ATM facility for gross proceeds of \$9.8 million.
 - The Paycheck Protection Program loan in the amount of \$308,600 received during 2020 has been forgiven in full by the Small Business Administration and was treated as 'Other Income' per GAAP regulations.
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Conference Call and Webcast

Management will host a conference call and webcast today at 4:30 p.m. Eastern time to discuss these results, provide an update on recent corporate developments and answer questions.

Dial-in Numbers

U.S./Canada: 888-506-0062
International: 973-528-0011

Replay Dial-in Numbers

U.S./Canada: 877-481-4010
International: 919-882-2331
Replay Passcode: 40908
The telephone replay will be available through 4:30 p.m. Eastern time on May 24, 2021

Webcast

A live audio webcast will be available through the [Events & 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 60 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 and 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 regarding milestones and future sales, 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	March 31, 2021 (Unaudited)	December 31, 2020
Current Assets		
Cash	\$ 16,842,753	\$ 7,227,316
Prepaid expenses	776,092	390,800
Inventory	726,608	589,620
Other current assets	5,986	5,986
Total Current Assets	18,351,439	8,213,722
Non-Current Assets		
Fixed assets, net	225,817	212,242
Right of use assets	321,563	339,012
Total Assets	\$ 18,898,819	\$ 8,764,976
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued liabilities	\$ 686,650	\$ 910,183
Lease liabilities, current portion	79,175	76,480
Total Current Liabilities	765,825	986,663
Long Term Debt		
Loans	28,484	337,084
Lease liabilities	252,345	271,908
Total Long Term Debt	280,829	608,992
Total Liabilities	1,046,654	1,595,655
Stockholders' Equity		
Series A Convertible Preferred Stock, \$0.0001 par value; 10,000 shares authorized; 141.397 and 196.794 shares issued and outstanding, respectively	1	1
Series B Convertible Preferred Stock, \$0.0001 par value; 1,000 shares authorized; no shares issued and outstanding	-	-
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 41,614,653 and 34,049,704 shares issued and outstanding, respectively	4,161	3,404
Additional paid in capital	77,460,997	64,493,611
Stock payable	115,842	10,794
Accumulated deficit	(59,728,836)	(57,338,489)
Total Stockholders' Equity	17,852,165	7,169,321
Total Liabilities and Stockholders' Equity	\$ 18,898,819	\$ 8,764,976

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Operating Expenses		
Research and development	\$ 1,141,486	\$ 1,518,146
Sales and marketing	160,935	114,955
General and administrative	1,273,418	1,467,745
Total operating expenses	<u>2,575,839</u>	<u>3,100,846</u>
Operating loss	<u>(2,575,839)</u>	<u>(3,100,846)</u>
Other Expenses		
Amortization of debt discount	-	(228,568)
Gain on extinguishment of debt	308,600	-
Other income (expense)	(2,037)	6,617
Total other expenses	<u>306,563</u>	<u>(221,951)</u>
Loss from operations before income taxes	<u>(2,269,276)</u>	<u>(3,322,797)</u>
Provision for income taxes	-	-
Net Loss	<u>\$ (2,269,276)</u>	<u>\$ (3,322,797)</u>
Deemed dividend	(121,071)	-
Net loss attributable to common stockholders	<u>\$ (2,390,347)</u>	<u>\$ (3,322,797)</u>
Net loss per share - basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.29)</u>
Weighted average common shares - basic and diluted	<u>37,772,515</u>	<u>11,508,843</u>

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Cash Flows from Operating Activities		
Net loss	\$ (2,269,276)	\$ (3,322,797)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	31,425	21,586
Common stock, options and warrants issued for services	321,949	511,080
Amortization of debt discount	-	228,568
Amortization of right of use assets	17,449	15,915
Stock payable for investor relations	46,250	40,000
Gain on extinguishment of debt	(308,600)	-
Changes in operating assets and liabilities:		
Increase in prepaid expenses	(385,292)	(256,505)
Increase in inventory	(136,988)	(61,493)
Decrease in other current asset	-	8,750
Decrease in accounts payable and accrued liabilities	(223,532)	(258,878)
Decrease in lease liability	(16,868)	(14,593)
Net cash used in operating activities	<u>(2,923,483)</u>	<u>(3,088,367)</u>
Cash Flows from Investing Activities		
Purchases of fixed assets	(45,000)	(22,350)
Net cash used in investing activities	<u>(45,000)</u>	<u>(22,350)</u>
Cash Flows from Financing Activities		
Proceeds from warrant exercises	2,785,627	39,238
Proceeds from issuance of common stock	9,798,293	-
Net cash provided by financing activities	<u>12,583,920</u>	<u>39,238</u>
Net increase (decrease) in cash	9,615,437	(3,071,479)
Cash, beginning of period	7,227,316	6,174,207
Cash, end of period	<u>\$ 16,842,753</u>	<u>\$ 3,102,728</u>
Supplemental disclosures of cash items		
Interest paid	\$ -	\$ 1,920
Income tax paid	\$ -	\$ -
Supplemental disclosures of non-cash items		
Conversion of convertible notes and accrued interest	\$ -	\$ 493,814
Deemed dividend	\$ 121,071	\$ -
Conversion of Series A Convertible Preferred Stock	\$ (7)	\$ (452)
Conversion of Series B Convertible Preferred Stock	\$ -	\$ (23)
Stock dividend payable	\$ (22,337)	\$ 34,066
Right of use asset	\$ 321,563	\$ 389,004
Lease liability	\$ 331,520	\$ 394,412

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