

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## ENDRA Life Sciences Inc.

**Form: 8-K**

**Date Filed: 2021-03-25**

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) March 25, 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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 March 25, 2021, ENDRA Life Sciences Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release dated March 25, 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.

March 25, 2021

**ENDRA Life Sciences Inc.**

By: /s/ Francois Michelon

Name: Francois Michelon

Title: President and Chief Executive Officer

---

**ENDRA Life Sciences Reports 2020 Fourth Quarter and Full Year Financial Results, Provides Business Update**

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

**ANN ARBOR, Mich. (March 25, 2021)** – [ENDRA Life Sciences Inc.](#) (“ENDRA”) (NASDAQ: NDRA), a pioneer of Thermo Acoustic Enhanced UltraSound (TAEUS®), today reported financial results for the three and twelve months ended December 31, 2020 and provided a business update. Highlights of the fourth quarter of 2020 and recent weeks include the following:

- **Partnered with Hepion Pharmaceuticals, Inc. (NASDAQ: HEPA), a clinical-stage biopharmaceutical company focused on AI-driven therapeutic drug development for the treatment of 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. The 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).
  - **Began screening patients for real-world clinical validation.** The first patient in a clinical study by an ENDRA clinical research partner took place at Rocky Vista University College of Osteopathic Medicine (“RVUCOM”). The TAEUS system was installed at RVUCOM’s Ivins, Utah location in November 2020 with the first patient of a targeted 200, scanned in February 2021.
  - **Strengthened TAEUS intellectual property protection with issuance of two additional U.S. and one Chinese patents.** ENDRA’s intellectual property portfolio continues to grow and currently stands at 82 global assets, defined as patents issued, filed, licensed or in preparation.
  - **Extended collaboration agreement with GE Healthcare for two additional years.** GE Healthcare will continue to support ENDRA’s commercialization activities for its TAEUS technology for use in a fatty liver application by, among other things, facilitating introductions to GE Healthcare clinical ultrasound customers worldwide.
  - **Strengthened balance sheet with receipt of \$18.5 million from the sale of common stock.** As previously announced on December 18, 2020, the Company sold 7.9 million shares of common stock for gross proceeds of \$5.5 million. Subsequent to the year end, the Company has raised an additional \$10.1 million from its at-the-market (“ATM”) offering via the sale of 3.9 million shares at a weighted average cost of \$2.58 per share, and \$2.9 million from the cash exercise of approximately 3.6 million warrants.
  - **Executed first distribution agreement for TAEUS.** Quang Phat Technology Science Equipment Co. Ltd, signed an exclusive distribution agreement for the initial sale of up to 40 TAEUS liver systems in Vietnam. Sales are expected to begin as soon as TAEUS receives U.S. Food and Drug Administration (FDA) clearance and local regulatory approvals.
-

"Despite the challenges related to COVID-19 we faced throughout most of 2020, I am delighted with the progress the ENDRA team made to advance our commercialization strategy for the TAEUS system. We finished the year strong and are doing everything within our control to prepare for success when the healthcare system resumes services at pre-pandemic levels. This includes actively communicating with the FDA regarding our 510(k) submission in preparation for the potential clearance to begin commercialization in the U.S.," stated Francois Michelin, Chairman and Chief Executive Officer of ENDRA. "At the same time, we remain focused on gathering additional data to bolster TAEUS' clinical utility to assess and monitor chronic liver conditions. While unrelated to our FDA application, we believe these independent evaluations will assist our future commercialization efforts by documenting TAEUS' clinical and economic value versus MRI."

Renaud Maloberti, Chief Commercial Officer, added, "As we experience an improving environment with the easing of restrictions as COVID-19 cases decrease globally, our clinical study partners are enthusiastic to move forward with their TAEUS evaluations, a key part of our launch strategy. In parallel, we are building our European sales team, members of which are collaborating with GE Healthcare and engaging with clinicians via Zoom. We believe ENDRA is poised to begin reporting commercial sales in 2021 as we address this significant market opportunity with a differentiated product and compelling benefits to physicians, patients and healthcare systems."

#### **Fourth Quarter 2020 Financial Results**

- Operating expenses decreased to \$2.3 million in the fourth quarter of 2020, down from \$3.1 million in the same period in 2019. The decrease was primarily due to expenses related to the development of TAEUS as the product was substantially completed and ready for sale .
- Net loss in the fourth quarter of 2020 was \$ 2.3 million, or (\$0.10) per share, compared with a net loss of \$ 4.8 million in the fourth quarter of 2019.

#### **Full Year 2020 Financial Results**

- Operating expenses increased to \$ 11.5 million in 2020, up from \$ 10.8 million in 2019. The increase in general and administration expenses and sales and marketing, was partially offset by decreased spending in research and development.
- Net loss in 2020 was \$ 11.7 million, or (\$0.63) per share, compared with a net loss of \$ 13.3 million, or (\$2.34) per share, in 2019.
- Cash was provided through the sale of common stock for proceeds totaling \$6.8 million and the exercise of warrants for proceeds totaling \$4.7 million during 2020.
- The Company had cash and cash equivalents of \$ 7.2 million as of December 31, 2020, compared with \$ 6.2 million as of December 31, 2019, with no long-term debt.
- Subsequent to December 31, 2020, the Company has received exercise notices for 3.6 million warrants resulting in additional cash proceeds of \$2.9 million, as well sold approximately 3.9 million shares through its ATM facility with Ascendant Capital for gross proceeds of \$10.1 million.

#### **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: 40227

The telephone replay will be available through 4:30 p.m. Eastern time on April 1, 2021

---

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](http://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 CT or 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](http://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.

#### **Company Contact:**

David Wells  
Chief Financial Officer  
(734) 997-0464  
investors@endrainc.com  
[www.endrainc.com](http://www.endrainc.com)

#### **Investor Relations Contact:**

Yvonne Briggs  
LHA Investor Relations  
(310) 691-7100  
[ybriggs@lhai.com](mailto:ybriggs@lhai.com)

---

**ENDRA Life Sciences Inc.**  
Balance Sheets

<u>Assets</u>	December 31, 2020	December 31, 2019
<b>Current Assets</b>		
Cash	\$ 7,227,316	\$ 6,174,207
Prepaid expenses	390,800	116,749
Inventory	589,620	113,442
Other current assets	5,986	130,701
Total Current Assets	<u>8,213,722</u>	<u>6,535,099</u>
<b>Non-Current Assets</b>		
Fixed assets, net	212,242	236,251
Right of use assets	339,012	404,919
<b>Total Assets</b>	<u>\$ 8,764,976</u>	<u>\$ 7,176,269</u>
<b><u>Liabilities and Stockholders' Equity</u></b>		
<b>Current Liabilities</b>		
Accounts payable and accrued liabilities	\$ 910,183	\$ 1,708,525
Convertible notes payable, net of discount	-	298,069
Lease liabilities, current portion	76,480	66,193
Total Current Liabilities	<u>986,663</u>	<u>2,072,787</u>
<b>Long Term Debt</b>		
Loans	337,084	-
Lease liabilities	271,908	342,812
Total Long Term Debt	<u>608,992</u>	<u>342,812</u>
<b>Total Liabilities</b>	<u>1,595,655</u>	<u>2,415,599</u>
<b>Stockholders' Equity</b>		
Preferred stock series A, \$0.0001 par value; 10,000 shares authorized; 190.288 and 6,338.490 shares issued and outstanding, respectively	1	1
Preferred stock series B, \$0.0001 par value; 1,000 shares authorized; no shares and 351.711 shares issued and outstanding, respectively	-	-
Common stock, \$0.0001 par value; 80,000,000 shares authorized; 34,049,704 and 8,421,401 shares issued and outstanding, respectively	3,404	842
Additional paid in capital	64,488,558	49,933,736
Stock payable	15,847	43,528
Accumulated deficit	(57,338,489)	(45,217,437)
Total Stockholders' Equity	<u>7,169,321</u>	<u>4,760,670</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 8,764,976</u>	<u>\$ 7,176,269</u>



**ENDRA Life Sciences Inc.**  
Statements of Operations

	Year Ended December 31, 2020	Year Ended December 31, 2019
<b>Operating Expenses</b>		
Research and development	\$ 5,917,944	\$ 6,574,999
Sales and marketing	581,893	412,434
General and administrative	5,002,080	3,856,159
Total operating expenses	<u>11,501,917</u>	<u>10,843,592</u>
Operating loss	<u>(11,501,917)</u>	<u>(10,843,592)</u>
<b>Other Expenses</b>		
Amortization of debt discount	(232,426)	(2,355,469)
Other income (expense)	8,842	(106,903)
Total other expenses	<u>(223,584)</u>	<u>(2,462,372)</u>
Loss from operations before income taxes	(11,725,501)	(13,305,964)
Provision for income taxes	-	-
<b>Net Loss</b>	<u>\$ (11,725,501)</u>	<u>\$ (13,305,964)</u>
Fair value adjustment related to warrants repricing	(395,551)	-
Deemed dividend related to preferred stock	-	(4,219,777)
Net Loss attributable to common stockholders	<u>\$ (12,121,052)</u>	<u>\$ (17,525,741)</u>
<b>Net loss per share – basic and diluted</b>	<u>\$ (0.63)</u>	<u>\$ (2.34)</u>
<b>Weighted average common shares – basic and diluted</b>	<u>19,192,226</u>	<u>7,499,984</u>

**ENDRA Life Sciences Inc.**  
Statement of Cash Flows

	Year Ended December 31, 2020	Year Ended December 31, 2019
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (11,725,501)	\$ (13,305,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	99,342	80,577
Common stock, options and warrants issued for services	2,102,353	1,399,547
Amortization of debt discount	232,426	2,355,469
Impairment of other assets	-	249,256
Amortization of right of use assets	65,907	34,434
Changes in operating assets and liabilities:		
Increase in prepaid expenses	(274,051)	28,675
Decrease in lease liability	(60,617)	(30,348)
Increase in inventory	(476,178)	(53,998)
Decrease in Other Current Assets	124,715	(106,642)
Decrease in accounts payable and accrued liabilities	(858,991)	760,143
Net cash used in operating activities	<u>(10,770,595)</u>	<u>(8,588,851)</u>
<b>Cash Flows from Investing Activities</b>		
Purchases of fixed assets	(51,333)	(43,595)
Net cash used in investing activities	<u>(51,333)</u>	<u>(43,595)</u>
<b>Cash Flows from Financing Activities</b>		
Proceeds from senior secured convertible promissory notes, net of fees	-	2,490,501
Proceeds from issuance of Series A Convertible Preferred Stock	-	5,344,257
Proceeds from issuance of Series B Convertible Preferred Stock	-	375,520
Proceeds from warrant exercise	4,757,011	-
Proceeds from loans	337,084	-
Proceeds from issuance of common stock	6,780,942	125,000
Net cash provided by financing activities	<u>11,875,037</u>	<u>8,335,278</u>
Net decrease in cash	1,053,109	(297,168)
Cash, beginning of period	6,174,207	6,471,375
<b>Cash, end of period</b>	<u>\$ 7,227,316</u>	<u>\$ 6,174,207</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	\$ 140,406
Exchange of balance in convertible notes and accrued interest for Series A preferred stock	\$ -	\$ 1,943,195
Deemed dividend	\$ 395,551	\$ 4,219,777
Conversion of Series A Convertible Preferred Stock	\$ (717)	\$ -
Conversion of Series B Convertible Preferred Stock	\$ (36)	\$ -
Stock dividend payable	\$ (49,649)	\$ -
Right of use asset	\$ 339,012	\$ 404,919
Lease liability	\$ 348,388	\$ 409,005

###