

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## ENDRA Life Sciences Inc.

**Form: 8-K**

**Date Filed: 2020-09-02**

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) September 1, 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 shares 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 7.01 Regulation FD Disclosure.**

On September 1, 2020, ENDRA Life Sciences Inc. posted an updated investor presentation (the "Investor Presentation") on its website at <http://investors.endrainc.com>. The Investor Presentation discloses that, as of August 28, 2020, the Company's cash balance was \$4.2 million. The Investor Presentation is also furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, 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 into 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
<a href="#">99.1</a>	ENDRA Life Sciences Inc. September 2020 Investor Presentation, 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.

September 2, 2020

**ENDRA Life Sciences Inc.**

By: /s/ Francois Michelin

Name: Francois Michelin

Title: President and Chief Executive Officer



## Addressing the Need in Liver Disease (NAFLD-NASH) Assessment

INVESTOR PRESENTATION  
SEPTEMBER 2020



NASDAQ: NDRA



## Safe Harbor

Certain statements made in this presentation are forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding the timing of our clinical trials, our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Actual results may differ materially from those discussed as a result of various factors, including, but not limited to: our limited operating history and our ability to achieve profitability; our potential inability to develop commercially feasible applications; our need to secure required regulatory approvals from governmental authorities in the European Union, United States and other jurisdictions; our dependence on third parties to design, manufacture, obtain required regulatory approvals, market and distribute our TAEUS™ applications; our ability to commercialize any of our TAEUS™ applications and the pricing of any such applications; our ability to protect our intellectual property and the risk we may infringe on the intellectual property of others; and our ability to obtain adequate financing in the future. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date hereof and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise. We anticipate that subsequent events and developments will cause our views to change.

In this presentation, we refer to information regarding potential markets for products and other industry data. We believe that all such information has been obtained from reliable sources that are customarily relied upon by companies in our industry. However, we have not independently verified any such information.

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## ENDRA Life Sciences Snapshot

GOAL: VISUALIZE HUMAN TISSUE LIKE MRI ... AT 50X LOWER COST<sup>1</sup> & POINT OF PATIENT CARE



Plug-and-play imaging platform with \$18 billion opportunity to expand utility of 365,000<sup>2</sup> ultrasound systems

Multiple potential clinical applications and revenue streams



1<sup>st</sup> clinical application: Liver disease (NAFLD-NASH) affecting 1 billion<sup>3</sup> people

Regulatory approval secured in Europe. 510(k) submitted in U.S.

Commercialization starting in 2020



~20 employees

Based in Ann Arbor, Michigan, USA

Capital efficient operating model

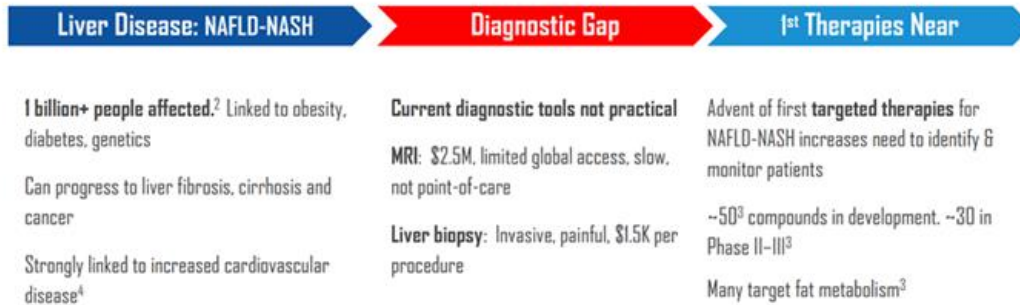


Leadership, advisors, & partners from GE Healthcare, UPMC, Tufts

72 IP assets<sup>4</sup>

## Focused on a Large and Rapidly Growing Market: NAFLD-NASH

TOTAL ANNUAL DIRECT MEDICAL COSTS IN U.S. FOR NAFLD: ~\$103B<sup>1</sup>

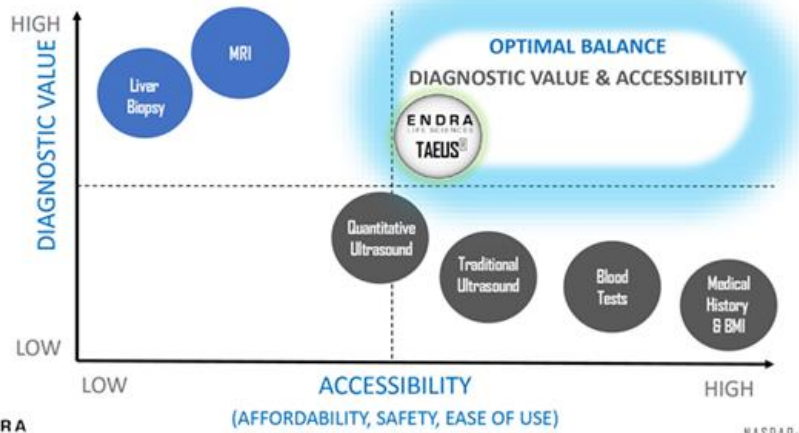


Non-Alcoholic Fatty Liver Disease (NAFLD): Still up of fat in the liver  
Non-Alcoholic Steatohepatitis (NASH): NAFLD + inflammation  
1, 2, 3, 4 Sources & Exemptions page 16



## Measuring Liver Fat in NAFLD-NASH Patients

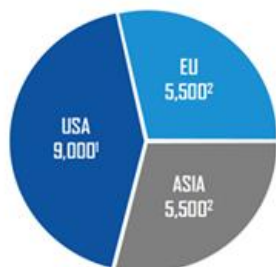
CURRENTLY NO PRACTICAL & RIGOROUS TOOL FOR STAGING STEATOSIS



## Total Addressable Market for NAFLD-NASH Fat Measurement Tool

\$1 BILLION OPPORTUNITY ... WITH UPSIDE

Estimated 2019 Number of Facilities<sup>1</sup>  
Performing Abdominal-Liver Ultrasound Scans



Facilities (hospitals, clinics, private practices) currently doing abdo-liver ultrasound scans, who could potentially buy 1 unit of ENDRA's liver tech.

20,000

Target avg. selling price per unit of ENDRA's liver technology

x \$50K

Base Addressable Market

=

\$1 billion

### Additional Opportunities

- New, non-radiology facilities focused on metabolism & liver: gastro-hepatology, endocrinology, primary care
- Other global markets: Latin America, Middle East
- >1 ENDRA liver unit sale per facility (E.g. hospital)
- ENDRA licensing, disposables, service



1, 2 Source: E. Acemoglu page 6

NASDAQ: NDRA 6

## Solution: Thermo Acoustic Enhanced UltraSound (TAEUS®)

### RF SIGNALS QUANTITATE LIVER FAT FRACTION



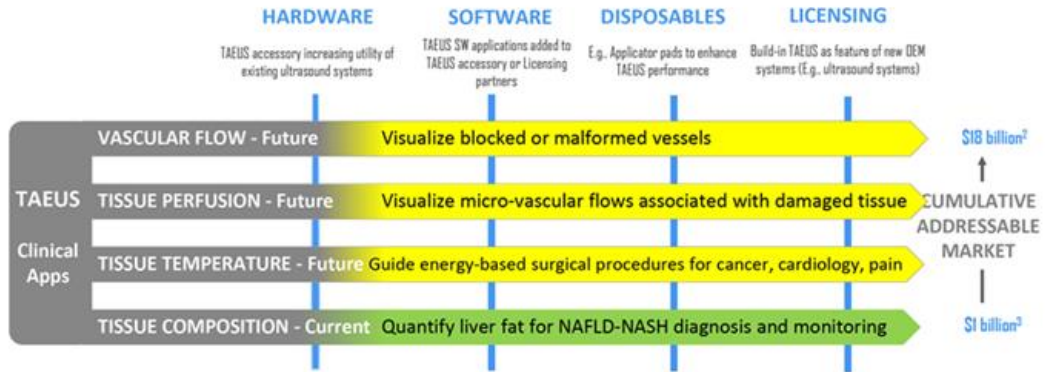
- ✓ Secured ISO 13485 Certification
- ✓ Completed first human feasibility study (N=19)
  - **Sensitivity 0.88 Specificity 0.82 AUROC 0.91 @ MRI-PDFF 6% steatosis**
- ✓ Obtained CE Mark: European regulatory approval
- ✓ Protected by 72+ IP assets

#### Liver Fat Assessment Procedure

- Locate liver with any traditional B-mode ultrasound
- Apply TAEUS: RF pulses create sonic waves that differentiate fat vs. lean
- Each TAEUS scan takes 1.5 seconds. Repeat multiple scans across liver

# TAEUS® Platform Evolution<sup>1</sup>

MULTIPLE POTENTIAL CLINICAL APPLICATIONS & REVENUE STREAMS TO SCALE BUSINESS



## ENDRA 2020 Milestones: Liver Application

SECURE REGULATORY APPROVALS AND INSTALL FIRST COMMERCIAL SYSTEMS

1H '20

- ✓ Obtain CE Mark certification
- ✓ Add hepatology influencer to ENDRA clinical advisory board: Dr. Malik @ Tufts
- ✓ Surpass 70 IP assets<sup>1</sup> in portfolio
- ✓ Submit 510(k) application

2H '20

- Announce additional EU & US evaluation sites
- Execute controlled launch in EU with early adopters & small ENDRA commercial team
- Receive 510(k) clearance
- Execute controlled launch in U.S. with early adopters & small ENDRA commercial team

## ENDRA Partners

SUPPORTING TECHNICAL, CLINICAL & COMMERCIAL DEVELOPMENT OF TAEUS



### Strategic partnership

- Supports product development & introductions to GE ultrasound customers
- GE option for 1 year sales exclusivity on TAEUS liver application, and other rights



### Clinical evaluation agreements

- Help grow ENDRA's base of clinical evidence
- Opportunity to leverage as reference sites to support commercialization after regulatory approval



Ladak Laboratory

### Artificial Intelligence collaboration

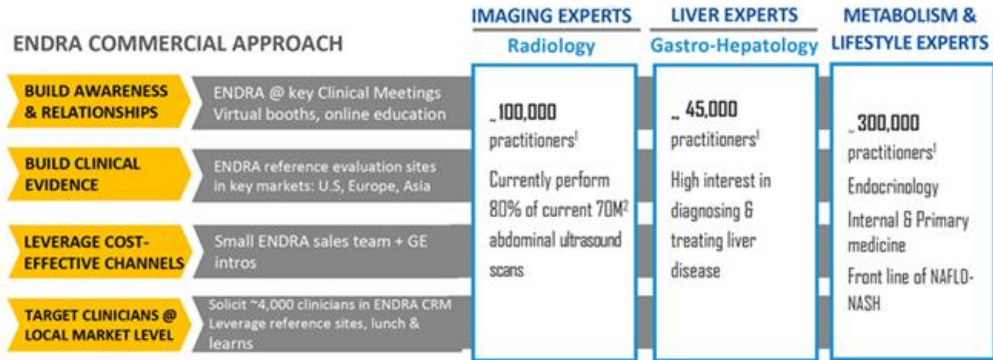
- Support advanced TAEUS computational models
- Automate operator-dependent tasks



NASDAQ: NORA 10

## Commercialization: Targeting High Value Clinical Segments

BUILD AWARENESS AND CLINICAL EVIDENCE & DEPLOY LOCAL TACTICS



# Leadership

## MANAGEMENT



**Francois Michelin**  
Chairman & CEO  
20+ years in med-tech  
GE Healthcare, Smith & Nephew,  
Biomet



**Michael Thornton**  
CTO  
15+ years med-tech  
Founder, Enhanced  
Vision Systems (sold to GE)



**Renaud Maloberti**  
CCO  
20+ years in med-tech, 12 years in  
ultrasound  
Fujifilm, BK Medical, GE  
Healthcare



**Amy Sitzler**  
VP Engineering  
20 years in engineering &  
quality at GE Healthcare



**David Wells**  
CFO  
30 years in finance and operations  
IBM, Bank of America

## INDEPENDENT DIRECTORS

**Sam Gambhir, MD, PhD**  
In Memoriam: 1952-2020  
Chair of Radiology,  
Stanford University

**Michael Harsh**  
Chief Technology Officer (Ret.), GE  
Healthcare

**Anthony  
DiGiandomenico**  
Co-founder, MDB Capital

**Alex Tokman**  
10 years GE Healthcare  
Allen Institute for Artificial  
Intelligence

**Lou Basenese**  
Equity research and advisory

## SCIENTIFIC ADVISORS



**Jing Gao, MD**  
Weill Cornell Medicine  
Rocky Vista University

**Jon Rubin MD, PhD**  
Univ. of Michigan (Ret)

**Raza Malik MD, PhD**  
Tufts Medical Center



## ENDRA Investment Highlights

- Addressing clear unmet need in liver disease (NAFLD-NASH), affecting 1B+ people
- Aligned with advent of first targeted NAFLD-NASH therapies increasing need to identify patients
- 72+ IP assets
- Blue-chip commercial and clinical partnerships
- CE Mark granted, 510(k) submitted
- Commercialization starting in 2020

### KEY STATISTICS (as of August 28, 2020)

Cash Balance	\$4.2M
Common Stock Price (NASDAQ: NDRA)	\$0.82
Common Shares Outstanding	24.2M
Fully Diluted Shares Outstanding	34.6M
Market Capitalization	\$20.0M
Management / Director Ownership*	12.0%

\* Based on fully diluted shares, assumes full vesting of all options



## CONTACT US

### ENDRA LIFE SCIENCES

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## Liver Fat Measurement Tools: Relative Performance & Accessibility

Liver Fat (Steatosis) Test	AUROC <sup>1</sup>	Sensitivity <sup>2</sup>	Specificity <sup>3</sup>	Diagnostic Value	Accessibility (Affordability, Safety, Ease of Use)	Other Considerations
<b>Liver Biopsy</b>	Historical Gold Standard for NASH Diagnosis			++	-	<ul style="list-style-type: none"> <li>Measurement variability due to pathology interpretation</li> <li>Invasive. Requires surgical training</li> </ul>
<b>Blood Tests (E.g., ALT)</b> <small>Livesey 2005 (J Hepatol 52: 201-212)</small>	0.88	0.91	0.77	-	+	<ul style="list-style-type: none"> <li>Low relative AUROC &amp; specificity vs other tests</li> <li>Susceptible to non-NASH related diseases</li> </ul>
<b>Magnetic Resonance Imaging (MRI)</b> <small>Wang 2005 (Electromedical 5:502)</small>	0.98	0.90	0.93	+++	-	<ul style="list-style-type: none"> <li>Becoming Gold Standard for research studies</li> <li>Not practical for daily clinical practice. Costs \$2M - \$3M</li> <li>Slow &amp; Complex, not point of care. Limited access.</li> <li>Patient restrictions: hip replacements, obesity, tattoos...</li> </ul>
<b>Thermo Acoustic Enhanced Ultrasound (TAEUS)</b> <small>Wang 2005 (JAMA's Feasibility Study website.com)</small>	0.91	0.88	0.82	++	+++	<ul style="list-style-type: none"> <li>Ease of use -15 mins training, 15 secs/scan.</li> <li>Point-of-care. Works with any B-mode ultrasound.</li> <li>Low cost - \$50K</li> <li>Strict quantitative measurement. Accurate, repeatable</li> </ul>
<b>Qualitative Ultrasound: B-Mode</b> <small>Pap 2013 (J 200)</small>	0.81	0.81 - 0.83	0.70	-	++	<ul style="list-style-type: none"> <li>Broadly available, easy to use, point of care and safe</li> <li>Not recommended for low to medium fat level (&lt;25%)</li> <li>High level of training. Variable results, operator dependent</li> </ul>
<b>Quantitative Ultrasound: Backscatter, Attenuation, Elastography</b> <small>Lu 2005 (Clinical Electromedical &amp; Hepatology 11) Page 2013 (J 200) Cohen 2008 (Hepatology 47:6) Edwards, Deeks, Newcombe 2003 (Electromedical)</small>	0.70 - 0.95	0.75 - 0.87	0.70 - 0.91	+	+	<ul style="list-style-type: none"> <li>Varied AUROC, sensitivity &amp; specificity</li> <li>Cumbersome techniques, some require use of phantom</li> <li>Expensive, high level of training</li> <li>Variable results. Operator dependent</li> </ul>

<sup>1</sup> AUROC (Area Under Receiver Operator Curve). Measures the relationship between sensitivity and specificity as the Reference threshold changes (E.g. MF liver fat threshold of 0%, 0.5%, 1%, etc.)

<sup>2</sup> Sensitivity: The percentage of people correctly identified as having liver fat above the reference threshold (E.g. 8%).

<sup>3</sup> Specificity: The percentage of people correctly identified as NOT having liver fat above the reference threshold (E.g. 9%).

# Sources & Assumptions

## PAGE 3

1. \$50K ENDRA device estimated price compared to \$1.5M MRI price
2. 2020 addressable systems comprised of cart based, non pre-natal ultrasounds, a subset of estimated 3M installed global systems, based on GlobalData MedPoint, 2014 report indicating 800,000 units growing at 4.5% CAGR. Estimated market size assumes a \$50,000 unit price
3. Hepatology, The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Younossi, Sissatt, Henry, Stepanova, Razula, Hunt, Beckerman, 2016
4. IP Asset: filed, issued and licensed patents and pending patent applications

## PAGE 4

1. Hepatology, The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Younossi, Sissatt, Henry, Stepanova, Razula, Hunt, Beckerman, 2016
2. The LANCET, Vincent Wai Sun Wong, November 2015
3. ENDRA estimate based on information from [clinicaltrials.gov](https://www.clinicaltrials.gov)  
Note: Company logos listed for purpose of illustrating broad but non-exhaustive interest in liver disease. Does not reflect a relationship with ENDRA
4. *Cardiovascular Risk in Non-Alcoholic Fatty Liver Disease: Mechanisms and Therapeutic Implications* Claudio Tena, International Journal of Environmental Research and Public Health, Aug 2018

## PAGE 6

1. Based on 2017 U.S. Medicare Provider Utilization and Payment Data: Physician and Other Supplier public use files from CMS (sites performing CPT 76705 procedures). 2017 facilities grossed up 3% CAGR to estimate 2018 facilities. Facilities range from large hospitals to individual practices.
2. ENDRA estimate of non-US facilities performing abdominal liver ultrasound scans, derived from US facilities and installed

base of ultrasound systems in global use.

## PAGE 8

1. Prospective applications of TAEUS imaging include differentiating lean and fatty tissue, mapping changes in tissue temperature during thermal therapies, reading vascular flow and imaging tissue perfusion. Output types may vary among applications. The output from the TAEUS device for use in diagnosing NAFLD currently in development consists of quantitated liver fat fraction data.
2. 2020 addressable systems comprised of cart based, non pre-natal ultrasounds, a subset of estimated 3M installed global systems, based on GlobalData MedPoint, 2014 report indicating 800,000 units growing at 4.5% CAGR. Estimated market size assumes a \$50,000 unit price
3. See page 6 of this presentation for calculation of estimated addressable market for NAFLD NAFLD diagnostic tool

## PAGE 9

1. IP Asset: filed, issued and licensed patents and pending patent applications

## PAGE 11

1. ENDRA global estimate derived from Association of American Medical Colleges, AMA, Euro Stats, 2015 and other sources
2. ENDRA global estimate derived from Diagnostic Ultrasound Imaging Global Analysis & Market Forecasts, GlobalData, 2014

