

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## ENDRA Life Sciences Inc.

**Form: 8-K**

**Date Filed: 2021-03-05**

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 5, 2021

**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 March 5, 2021, ENDRA Life Sciences Inc. (the "Company") posted on its website at <http://investors.endrainc.com> an updated investor presentation that includes an interim cash balance of the Company of \$9.5 million as of February 28, 2021. A copy of the updated 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	ENDRA Life Sciences Inc. March 2021 Investor Presentation, furnished herewith.

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**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 5, 2021

**ENDRA Life Sciences Inc.**

By: /s/ Francois Michelon

Name: Francois Michelon

Title: President and Chief Executive Officer

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**Practical Assessment  
of Hepatic Steatosis for  
NAFLD - NASH**

**INVESTOR PRESENTATION**  
MARCH 2021



NASDAQ: NDRA



## Forward-Looking Statements

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' Goal

*SEE MORE. DO MORE. LIVE BETTER.®*

Commercialize **Thermo Acoustic Enhanced UltraSound (TAEUS®)**,  
a technology that enhances existing ultrasound systems to visualize tissue  
similar to an MRI, but at 50X<sup>1</sup> lower cost and at the point of patient care.

## ENDRA Life Sciences



### PLATFORM TECHNOLOGY

Opportunities in a variety of clinical applications

Multiple potential revenue streams: hardware, software, services, disposables, licensing

80 IP assets<sup>1</sup>



### 1<sup>st</sup> APPLICATION: LIVER DISEASE

1.4B people<sup>2</sup> affected by excess liver fat and inflammation

~50 pharma therapies in development

No practical diagnostic tools exist

\$21B market opportunity<sup>3</sup>

CE mark received, 510(k) submitted



### OPERATIONS & PARTNERS

Lean operations: ~20 employees, Ann Arbor, Michigan

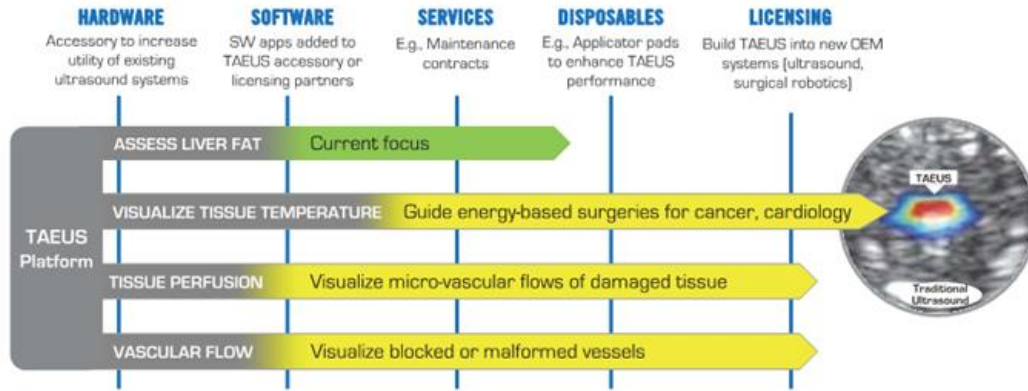
Partners & advisors: UPMC, Tufts, GE Healthcare, University of Michigan, others

AI collaboration with Western University



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

MULTIPLE POTENTIAL CLINICAL APPLICATIONS & REVENUE STREAMS TO SCALE BUSINESS



## Large Unmet Clinical Need: NAFLD-NASH Diagnostics

RAMPANT DISEASE, APPROACHING THERAPIES ... BUT NO PRACTICAL DIAGNOSTIC TOOLS

### Liver Disease: NAFLD-NASH

**1.4 billion people affected.**<sup>1</sup>

Linked to obesity, diabetes, genetics

Can progress to fibrosis, cirrhosis  
cancer and cardiovascular disease<sup>2</sup>

Annual U.S direct medical costs  
>\$100 billion<sup>3</sup>

### Diagnostic Gap

**No practical diagnostic tools:**

- **MRI:** \$2M-\$3M, 5+ tons, purpose-built room, relatively few systems vs ultrasound, concentrated in urban areas
- **Liver biopsy:** Invasive, painful, impractical to do frequently

### 1<sup>st</sup> Therapies Near

Advent of first **targeted therapies** for NAFLD-NASH increases need to identify & monitor patients

~50 compounds in development<sup>4</sup>  
including ~30 in Phase II-III<sup>4</sup>

Many target fat metabolism<sup>4</sup>

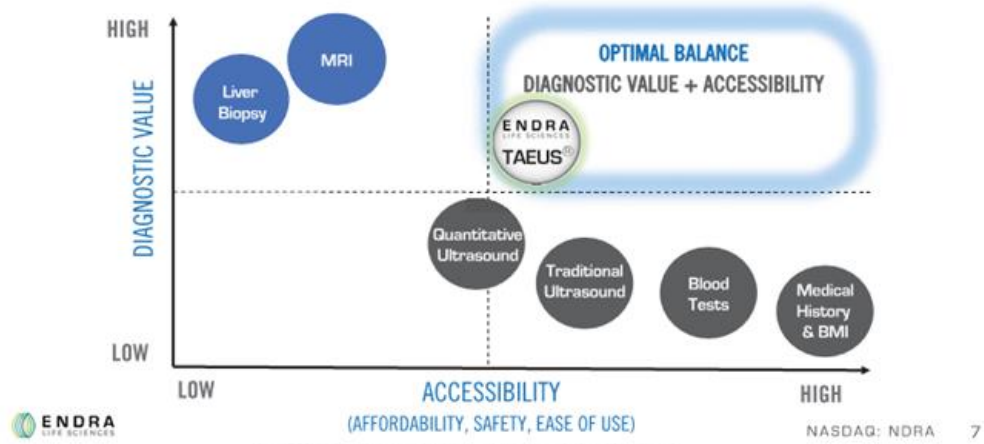


Non-Alcoholic Fatty Liver Disease (NAFLD): Buildup of fat in the liver  
Non-Alcoholic Steatohepatitis (NASH): NAFLD + inflammation  
1, 2, 3, 4: Sources & Assumptions in Appendix

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## Assessing & Monitoring Liver Fat of 1 Billion+ NAFLD-NASH Patients

NO TOOL HAS BALANCED DIAGNOSTIC VALUE + ACCESSIBILITY

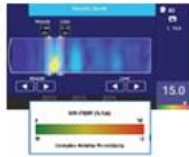


## ENDRA's TAEUS®: Enhancing Traditional Ultrasound

RADIO FREQUENCY PULSES CREATE SONIC WAVES THAT QUANTITATE LIVER FAT FRACTION



Illustration of TAEUS probe



Screen shot of TAEUS measurement



- ✓ TAEUS directly measures a material property of liver tissue that is only affected by the amount of fat (triglyceride), and has not been found to be confounded by fibrosis like other methods (attenuation, back-scatter)
- ✓ Completed first human feasibility study (n=19), validated against MRI-PDFF  
**Sensitivity 0.88 Specificity 0.82 AUROC 0.91 @ MRI-PDFF 6% steatosis**
- ✓ CE mark in Europe; 510(k) submitted to U.S. FDA

### TAEUS Procedure

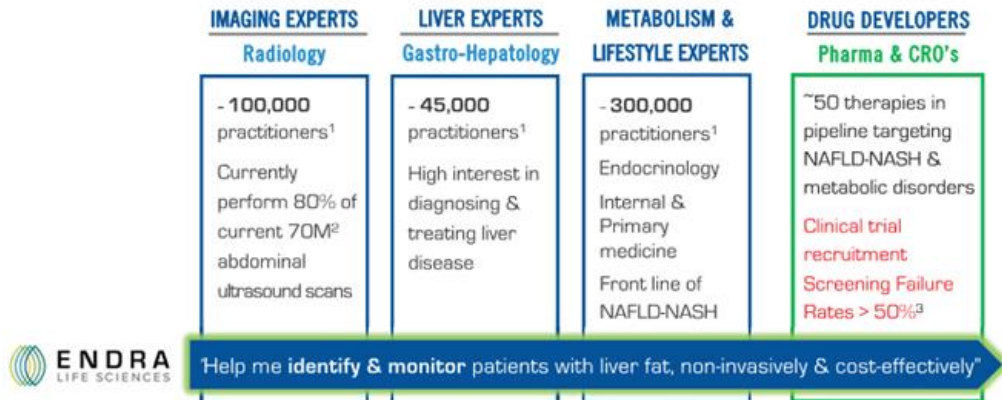
- As little as 15 minutes of user training. Easy-to-interpret results
- Locate liver with any traditional B-mode ultrasound
- Apply & activate TAEUS probe; each scan takes 1.5 seconds

TAEUS is not yet approved for sale in the U.S.

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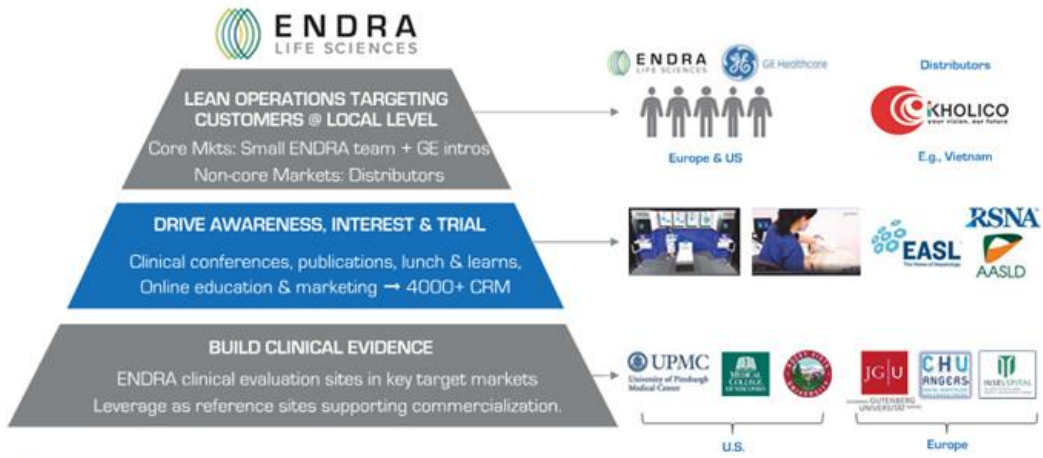
# TAEUS® Liver: Targeting High-Value Segments

CLINICIANS & DRUG DEVELOPERS STRUGGLE WITH MRI-BIOPSY LIMITATIONS



<sup>1,2,3</sup> Sources & Assumptions in Appendix

## TAEUS Liver Commercialization: 3 Core Strategies



## Global Environment

### DESPITE 2020 HEADWINDS... ENDRA IS POSITIONED FOR SUCCESS IN 2021

#### Encouraging signs of progress at healthcare provider level

Global MRI imaging (used for comparison in ENDRA's clinical studies) has been experiencing 3 to 8 week backlogs, driven by:

- Reduced hospital staff available to perform scans
- Increased COVID-related precautions (cleaning MRI rooms)
- However, volume of delayed procedures is now returning ...good sign

#### In spite of Covid-19 conditions, ENDRA still moving forward on key objectives

- Advancing key clinical and commercial relationships. Insepsital (Switzerland), GE renewal, Vietnam distributor
- Building lean ENDRA commercial team: Prospecting locally. Ready as markets open
- Leveraging e-marketing tools (E.g., clinical conferences) to maintain awareness & interest with clinicians

## Anticipated Milestones: ENDRA Liver Application

BUILD CLINICAL EVIDENCE, SECURE US REGULATORY APPROVAL, RAMP COMMERCIALIZATION

2021

- Receive FDA 510(k) clearance
- Ramp commercialization in EU & US; first revenue from sale of TAEUS
- Collect & publish TAEUS clinical evidence from global reference partners
- Forge new/ deeper alliances with drug developers and medical device OEM's
- Establish clinical evaluations in Asia
- Surpass 80 intellectual property assets in portfolio



## Financial Information

KEY STATISTICS	Feb 28, 2021 Pro-Forma <sup>1</sup>
Cash Balance <sup>2</sup>	\$9.5M
Common Shares Outstanding	38.5M
Fully Diluted Shares Outstanding	44.6M
Market Capitalization <sup>3</sup>	\$96.3M
Management / Director Ownership <sup>4</sup>	10.9%

<sup>1</sup> Pro forma results for February 28, 2021 have not been audited and are subject to change.  
<sup>2</sup> Includes proceeds from conversion of warrants, and sale of shares on ATM facility.  
<sup>3</sup> Based on closing price of \$2.50 for common stock on February 26, 2021.  
<sup>4</sup> Based on fully diluted shares, assumes full vesting of all options.

## CONTACT US

### ENDRA LIFE SCIENCES

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

*See more. Do more. Live better.®*



## APPENDIX

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## Leadership & Advisors

### MANAGEMENT



**Francois Michelon**  
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**  
COO  
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: 1962-2020  
Chair of Radiology,  
Stanford University

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

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

**Alex Tokman**  
President, iJUNU, Inc.  
GE Healthcare  
Allen Institute for AI (AI2)

**Lou Basenese**  
Equity research & advisory

### SCIENTIFIC ADVISORS



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

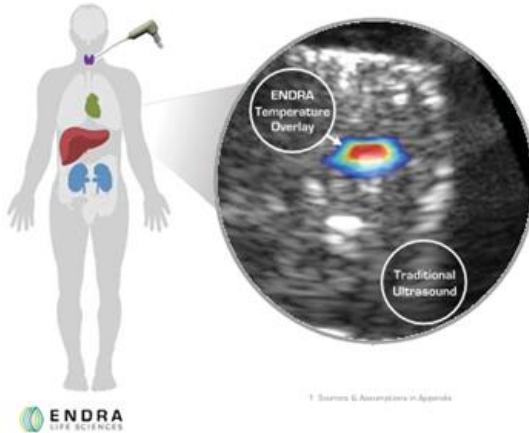
**Jon Rubin MD, PhD**  
Univ. of Michigan (Ret.)

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

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## Future TAEUS Application: Guidance of Energy-Based Surgery

SHOW HEAT OR COLD SIGNATURE OF THERMO-ABLATIVE PROCEDURES FOR CANCER, CARDIOLOGY, PAIN



### THERMO-ABLATIVE PROCEDURES

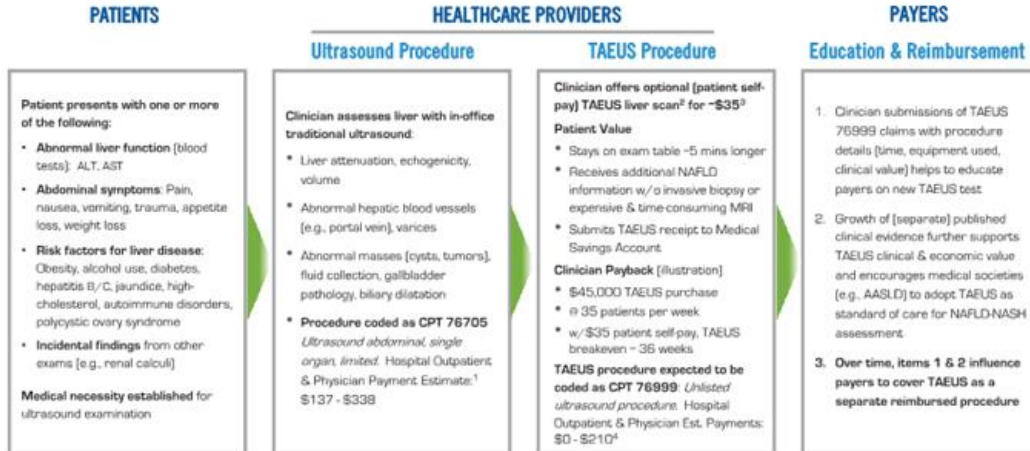
- 5+ million procedures annually<sup>1</sup> growing at 15%<sup>1</sup> CAGR, driven by aging-related diseases: cancer, pain, cardiology
- Current surgical guidance tools are inaccurate or impractical: Printed guidelines or expensive MRI

*"Doctors aren't always sure where the [thermo-ablative] energy is going. They could hit a vessel or another heat-sink in the body and the academic models fall apart and treatment is ineffective."*

Jonathan Rubin, M.D.  
Head for Ultrasound & Abdominal Interventional Radiology (Retired),  
The University of Michigan

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## Expected TAEUS Economic & Clinical Value To Stakeholders



## 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 (Liver fat)	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>Lammi, 2019 [J Acquir Immune Defic Syndr 80(4)]</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>Wong, 2016 [Gastroenterology 150(2)]</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>ENDRA, 2019 [Abstracts: Feasibility Study, endra.com]</small>	0.91	0.88	0.82	++	+++	<ul style="list-style-type: none"> <li>Ease of use: ~15 mins training, 1.5 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>Page, 2017 [AJR 208]</small>	0.81	0.61 - 0.89	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 (~25%)</li> <li>High level of training. Variable results, operator dependent</li> </ul>
<b>Quantitative Ultrasound: Backscatter, Attenuation, Elastography</b> <small>Li, 2015 [Clinical Gastroenterology &amp; Hepatology 13] Page: 2017 [AJR 208] Cohen, 2018 [Hepatology 67(5)] Eklova, Oskik, Noursara 2019 [Gastroenterology]</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. MR liver fat threshold of 6%, 10%, 15%, Etc)

<sup>2</sup> **Sensitivity** The percentage of people correctly identified as having liver fat above the reference threshold (E.g. 6%)

<sup>3</sup> **Specificity** The percentage of people correctly identified as NOT having liver fat above the reference threshold (E.g. 6%)

## Sources & Assumptions

### PAGE 3

- 1 \$50K ENDRA device estimated price compared to \$2.5M MRI price

### PAGE 4

- 1 IP Asset, filed, issued and licensed patents and pending patent applications
- 2 Hepatology. The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Younossi, Bassett, Henry, Stepanova, Raouf, Hunt, Beckerman, 2016
- 3 GrandView Research, 2020. [Liver Disease Diagnostics, Market Estimates & Trend Analysis from 2020 to 2027](#)

### PAGE 6

- 1 The LANCET. Vincent Wai-Sun Wong, November 2015
- 2 [Candicicidin: Role in Non-Alcoholic Fatty Liver Disease: Mechanisms and Therapeutic Implications](#) Claudio Tania, IJCI Journal of Environmental Research and Public Health, Aug 2019
- 3 Hepatology. The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. Younossi, Bassett, Henry, Stepanova, Raouf, Hunt, Beckerman, 2016
- 4 ENDRA estimate based on information from [clinicaltrials.gov](#)

### PAGE 9

- 1 ENDRA global estimate derived from Association of American Medical Colleges, AMA, Euro Statix, 2015 and other sources
- 2 ENDRA global estimate derived from [Diagnostic Ultrasound Imaging Global Analysis & Market Forecasts](#) GlobalData, 2014
- 3 [Unique Insights Gained From Multiple NASH Studies, Overcoming Key Challenges to Design and Execute More Efficient Clinical Trials](#), OVMANDE-LABORIP CSCVMER002-0019, 2019

### PAGE 16

- 1 ENDRA estimate derived from Grand View Research, [Global Radiofrequency Ablation Devices Market Segment Forecast to 2020](#) Oct, 2014. Note: Procedure volumes are for RF ablation procedures only. Procedure volumes are larger when including other energy-based ablation technologies such as microwave, cryotherapy and HIFU.

### PAGE 17

- 1 Estimated payment range for CPT 76725 includes Medicare vs. Private Insurance, and hospital and physician fees. Source: Medicare Fee Schedules (HCPO and Physician) and Kaiser Family Foundation [ <https://www.kff.org> ]
- 2 Once TAEUS is FDA approved
- 3 Suggested patient self-pay of \$25 to \$50. Pricing determined by healthcare provider
- 4 Estimated payment range for assorted applicable procedures coded under CPT 76999, including Medicare and Private insurance payments, including hospital and physician fees. ENDRA's TAEUS is not expected to immediately secure reimbursement. Source: Medicare Fee Schedules (HCPO and Physician) and Kaiser Family Foundation [ <https://www.kff.org> ]