Overview

Last year, for the first time, the US government invested more than one hundred million dollars in focused ultrasound research in a single year. These funds were spread over 21 different federal agencies.

For the third year in a row, more than 300 million dollars was invested in focused ultrasound industry companies, bringing the three-year total of investments to more than one billion dollars. The cumulative amount of money invested in focused ultrasound research and the industry is over three billion.

In 2022 we saw the first investment in focused ultrasound from a pharmaceutical company, Eli Lilly. Large publicly traded medical device companies with venture arms continue to invest in focused ultrasound as well. We saw the first investment from Boston Scientific in 2022 and a second investment from Johnson and Johnson Innovation. Additionally, 2022 included second investments from venture investors OrbiMed Advisors and the Yongjin Group.
Cumulative FUS Funding

- Industry investment
- US government grants

Cumulative funding: $3.14B
## 2022 FUS Industry Investments*

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Funding type</th>
<th>Investors</th>
<th>Funding date</th>
<th>Money raised, millions $US</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insightec LTD</strong></td>
<td>Debt</td>
<td>Perceptive Advisors, The Community Fund</td>
<td>9.1.2022</td>
<td>$100.0M</td>
</tr>
<tr>
<td><strong>HistoSonics INC</strong></td>
<td>Series D</td>
<td>Johnson &amp; Johnson Innovation, Lumira Ventures, State of Wisconsin Investment Board, Venture Investors LLC, Yonjin Venture</td>
<td>12.13.2022</td>
<td>$85.0M</td>
</tr>
<tr>
<td><strong>SonoThera INC</strong></td>
<td>Series A</td>
<td>Alexandria Venture Investments, ARCH Venture Partners, Eli Lilly &amp; CO, Foothill Ventures, Formic Ventures, Illumina Ventures, Johnson &amp; Johnson Innovation, Lifespan Investments, Medical Excellence Capital LLC, Wilson Sonsini Goodrich &amp; Rosati</td>
<td>12.5.2022</td>
<td>$60.8M</td>
</tr>
<tr>
<td><strong>Carthera SA</strong></td>
<td>Series D</td>
<td>Boston Scientific Ventures, European Innovation Council</td>
<td>11.21.2022</td>
<td>$34.2M</td>
</tr>
<tr>
<td><strong>Sonire Therapeutics INC</strong></td>
<td>Series B</td>
<td>Carbon Ventures CO LTD/QR Investment CO LTD, Daiwa Corporate Investment CO LTD, Fast Track Initiative INC, FFG Venture Business Partners INC, Higin Capital CO LTD, JA Mitsui Leasing LTD, Japan Growth Capital Investment CORP, Mitsubishi UFJ Capital CO LTD, Nissay Capital CO LTD, Resona Capital CO LTD, SBI Investment CO LTD</td>
<td>11.30.2022</td>
<td>$17.1M</td>
</tr>
</tbody>
</table>

*Source: www.crunchbase.com and industry press releases
2022 FUS Industry Investments* continued

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Funding type</th>
<th>Investors</th>
<th>Funding date</th>
<th>Money raised, millions $US</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpheus Medical INC</td>
<td>Series A</td>
<td>Action Potential Venture Capital LTD, BrightEdge, OrbiMed Advisors LLC, SV Health Investors</td>
<td>11.10.2022</td>
<td>$ 14.0M</td>
</tr>
<tr>
<td>OrthoSon LTD</td>
<td>Series B</td>
<td>Big Pi Capital, Yongjin Group</td>
<td>6.1.2022</td>
<td>$ 9.0M</td>
</tr>
<tr>
<td>Theraclion SA</td>
<td>Post-IPO Equity</td>
<td>—</td>
<td>2.25.2022</td>
<td>$ 7.3M</td>
</tr>
<tr>
<td>Applaud Medical INC</td>
<td>Unknown Round</td>
<td>—</td>
<td>7.27.2022</td>
<td>$ 5.7M</td>
</tr>
<tr>
<td>Zeta Surgical INC</td>
<td>Seed</td>
<td>Trevor Fetter, Innospark Ventures LLC, Vishal Rao, TSVC, Y Combinator Management LLC</td>
<td>3.10.2022</td>
<td>$ 5.2M</td>
</tr>
<tr>
<td>Vensica Therapeutics</td>
<td>Unknown Round</td>
<td>Merz Pharmaceuticals LLC</td>
<td>2.7.2022</td>
<td>$ 3.0M</td>
</tr>
<tr>
<td>Exact Therapeutics AS</td>
<td>Grant</td>
<td>Research Council of Norway</td>
<td>6.23.2022</td>
<td>$ 1.8M</td>
</tr>
<tr>
<td></td>
<td>Grant</td>
<td>Research Council of Norway</td>
<td>12.22.2022</td>
<td>$ 1.6M</td>
</tr>
<tr>
<td>SonoVascular INC</td>
<td>Debt</td>
<td>—</td>
<td>1.13.2022</td>
<td>$ 0.75M</td>
</tr>
<tr>
<td>Acoustiic INC</td>
<td>Grant</td>
<td>National Institutes of Health (SBIR)</td>
<td>9.15.2022</td>
<td>$ 0.40M</td>
</tr>
<tr>
<td></td>
<td>Grant</td>
<td>National Institutes of Health (SBIR)</td>
<td>9.16.2022</td>
<td>$ 0.40M</td>
</tr>
<tr>
<td>Microvascular Therapeutics LLC</td>
<td>Grant</td>
<td>National Institutes of Health (SBIR)</td>
<td>9.19.2022</td>
<td>$ 0.40M</td>
</tr>
<tr>
<td></td>
<td>Grant</td>
<td>National Institutes of Health (SBIR)</td>
<td>6.6.2022</td>
<td>$ 0.35M</td>
</tr>
<tr>
<td></td>
<td>Grant</td>
<td>National Institutes of Health (SBIR)</td>
<td>4.1.2022</td>
<td>$ 0.29M</td>
</tr>
</tbody>
</table>

$362.3 M USD Total

*Source: www.crunchbase.com and industry press releases
FUS Industry Investments by Stage

Source: www.crunchbase.com and industry press releases
FUS Market Projection

Revenue in millions of dollars

$1,500M

17% compound annual growth rate

$370M

FUS Industry Investments Over Time

Source: www.crunchbase.com and industry press releases

Annual investments trends

Focused ultrasound investments were down slightly in 2022 as compared to the previous few years. This follows a trend of decreased healthcare investments in general as related to the state of the overall economy.

Market value and growth rate estimates were compiled from the following websites:


https://360researchreports.com/global-high-intensity-focused-ultrasound-system-market-19851546


https://www.industrydataanalytics.com/reports/high-intensity-focused-ultrasound-hifu-market


https://www.marketresearchfuture.com/reports/high-intensity-focused-ultrasound-therapy-market-885

**FUS Industry Investments**

Annual

Dollars in millions

<table>
<thead>
<tr>
<th>Year</th>
<th>Investment in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>$362m</td>
</tr>
<tr>
<td>2021</td>
<td>$393m</td>
</tr>
<tr>
<td>2020</td>
<td>$327m</td>
</tr>
<tr>
<td>2019</td>
<td>$112m</td>
</tr>
<tr>
<td>2018</td>
<td>$218m</td>
</tr>
</tbody>
</table>

**18+ invested in the last 3 years**

In looking at the graph above, it is easy to see the step change in the investments in focused ultrasound in the past three years. With a cumulative investment total of more than three billion, it is notable that over one-third of that money has been invested in the last three years alone. This is indicative of both the fact that the ecosystem is growing—there are more companies to invest in—and that the investment rounds are getting larger as the companies in the field mature.
Flow of Investments

<table>
<thead>
<tr>
<th>Region</th>
<th>Cumulative Investments</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>$1,247m</td>
</tr>
<tr>
<td>Europe</td>
<td>$257m</td>
</tr>
<tr>
<td>Asia</td>
<td>$208m</td>
</tr>
</tbody>
</table>

**Disbursement to FUS Companies**

<table>
<thead>
<tr>
<th>Region</th>
<th>Cumulative Disbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>$920m</td>
</tr>
<tr>
<td>Europe</td>
<td>$211m</td>
</tr>
<tr>
<td>Asia</td>
<td>$581m</td>
</tr>
</tbody>
</table>

**Source**

- North America: $866.4m
- Europe: $24.2m
- Asia: $29.5m
- Total: $920.1m

- North America: $17.0m
- Europe: $162.2m
- Asia: $31.6m
- Total: $211.2m

- North America: $363.4m
- Europe: $70.7m
- Asia: $147.3m
- Total: $581.4m

* Source: www.crunchbase.com and industry press releases

1 Due to variable levels of data completeness, the value of total investments will not be the same as that on page XII.3.
Focused Ultrasound Industry Patents

Patents issued through the World Intellectual Property Organization, WIPO, were mostly nationalized to all countries that recognize WIPO. Notably absent from WIPO countries is China, which is home to 10 of 69 focused ultrasound device manufacturers.

Specifically reviewing the data, not depicted graphically, for the last several years, we see most patents issued by the US Patent and Trademark Office, USPTO, were from US-based inventors or assignees, while 58 percent of WIPO patents had applicants based in the US. This is likely due to academic patent foundations in the US that are far more prolific than those of other countries.

Sources
https://ppubs.uspto.gov/pubwebapp/
https://patentscope.wipo.int/search/en/structuredSearch.jsf
Terms searched: “focused ultrasound”, HiFU, MRgFUS, LIFU, "ultrasound ablation", LIPU
Focused Ultrasound Industry Patents continued

**Patents Cumulative**

- **784** United States
- **947** Outside United States

**Snapshot of Growth in Patents**

- **5** 1995
- **38** 2006*
- **114** 2022

**Source**

- **US**
  - 1995: 4
  - 2006*: 5
  - 2022: 55
- **Outside US**
  - 1995: 1
  - 2006*: 33
  - 2022: 59

**Total**

- 1995: 5
- 2006*: 38
- 2022: 114

*Focused Ultrasound Foundation founded

Research—United States Top Federal Government Funders

- NCI
- NIBIB
- NINDS
- NHLBI

Dollars in millions

- $36M
- 30
- 24
- 18
- 12
- 6

*The first record of funded focused ultrasound research by the United States Federal Government was in 2004.

**Sources**

https://projectreporter.nih.gov/reporter.cfm

https://www.usaspending.gov/search

Terms searched: “focused ultrasound”, HIFU, LIFU, LIPU, MRgFUS, “ultrasound ablation”

United States federal government
focused ultrasound grants

Encouragingly, there continues to be an increase in federal funding for focused ultrasound–related projects in the United States. Even though the National Institutes of Health, NIH, budget has been stagnant over the last 15 years, the portion of funding allocated to focused ultrasound research is growing. Funding increases of this nature are typical for medical innovations that have shown the most potential for improving patient health. 2022 funding totals are $37M higher than 2021 funding totals $13M increase in focused ultrasound spending by National Institute of Neurological Disorders and Stroke, NINDS over 2021 levels.
## Total FUS Funding by United States Government Agencies

<table>
<thead>
<tr>
<th>2022 FUS funding$</th>
<th>Total FUS funding$</th>
<th>Granting agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>$22,758,433</td>
<td>$263,805,286</td>
<td>NCI</td>
</tr>
<tr>
<td>$22,595,070</td>
<td>$152,764,408</td>
<td>NIBIB</td>
</tr>
<tr>
<td>$34,786,085</td>
<td>$107,726,646</td>
<td>NINDS</td>
</tr>
<tr>
<td>$12,343,551</td>
<td>$46,992,424</td>
<td>NHLBI</td>
</tr>
<tr>
<td>—</td>
<td>$32,924,533</td>
<td>NCRR</td>
</tr>
<tr>
<td>$4,667,333</td>
<td>$25,418,689</td>
<td>NIMH</td>
</tr>
<tr>
<td>$2,013,843</td>
<td>$15,734,754</td>
<td>OD</td>
</tr>
<tr>
<td>$4,640,121</td>
<td>$14,261,179</td>
<td>NSF</td>
</tr>
<tr>
<td>$5,047,165</td>
<td>$13,407,872</td>
<td>NEI</td>
</tr>
<tr>
<td>—</td>
<td>$11,593,232</td>
<td>NIDDK</td>
</tr>
<tr>
<td>$4,410,972</td>
<td>$11,583,061</td>
<td>NICHD</td>
</tr>
<tr>
<td>$905,525</td>
<td>$11,261,396</td>
<td>NIA</td>
</tr>
<tr>
<td>$2,084,213</td>
<td>$9,520,073</td>
<td>CDMRP</td>
</tr>
<tr>
<td>$635,781</td>
<td>$7,703,166</td>
<td>NIDA</td>
</tr>
<tr>
<td>—</td>
<td>$6,106,583</td>
<td>NIGMS</td>
</tr>
<tr>
<td>$968,750</td>
<td>$2,974,108</td>
<td>FIC</td>
</tr>
<tr>
<td>$913,858</td>
<td>$2,772,219</td>
<td>CNRM</td>
</tr>
<tr>
<td>$403,750</td>
<td>$2,193,730</td>
<td>NIDCR</td>
</tr>
<tr>
<td>$1,349,403</td>
<td>$1,926,163</td>
<td>NIAMS</td>
</tr>
<tr>
<td>$1,516,636</td>
<td>$1,516,636</td>
<td>NINR</td>
</tr>
<tr>
<td>—</td>
<td>$909,727</td>
<td>NIDCD</td>
</tr>
</tbody>
</table>

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1. 2021 funding for focused ultrasound was $85,244,178.
2. The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

Sources
- https://projectreporter.nih.gov/reporter.cfm
- https://www.usaspending.gov/search
- Terms searched: “focused ultrasound”, HIFU, LIFU, LIPU, MRgFUS, “ultrasound ablation”
## Total FUS Funding by United States Government Agencies

<table>
<thead>
<tr>
<th>2022 FUS funding</th>
<th>Total FUS funding 2004–2022</th>
<th>Granting agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>$30,000</td>
<td>$779,990</td>
<td>NCMHD</td>
</tr>
<tr>
<td>$314,663</td>
<td>$662,410</td>
<td>NIAAA</td>
</tr>
<tr>
<td>$77,152</td>
<td>$236,003</td>
<td>CLC</td>
</tr>
<tr>
<td>—</td>
<td>$233,196</td>
<td>NHGRI</td>
</tr>
<tr>
<td>$74,250</td>
<td>$74,250</td>
<td>NCATS</td>
</tr>
<tr>
<td>$122,536,554</td>
<td>$745,071,734</td>
<td>TOTAL</td>
</tr>
</tbody>
</table>

1 2021 funding for focused ultrasound was $85,244,178.
2 The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

Sources
- https://projectreporter.nih.gov/reporter.cfm
- https://www.usaspending.gov/search
- Terms searched: “focused ultrasound”, HIFU, LIFU, LIPU, MRgFUS, “ultrasound ablation”
Annual US FUS Research Funding

*The first record of funding for focused ultrasound research by the US Federal Government was in 2004.

Sources
https://projectreporter.nih.gov/reporter.cfm
https://www.usaspending.gov/search
Terms searched: “focused ultrasound”, HIFU, LIFU, LIPU, MRgFUS, “ultrasound ablation”

**Clinical trails and MOA research fuel funding**

As demonstrated by the graph above, NIH funding has steadily increased since 2016, with near exponential growth over the past three years. We believe this is due to plethora of research that has reached clinical trial stage along with the diversity of mechanisms of action being explored by the research community beyond thermal ablation.