

UP AND ONWARD

Volume 03

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A Note From the CEO

Today, we take good internet connection for granted, but without it, so much of the internet's potential would be unrealized. Similarly, connecting to the brain and nervous system offers potential for numerous medical breakthroughs. However, these connections are hampered with problems.

That's where Actuated comes in. Our technology is helping world-class brain researchers improve connections to the brain. In the long term, we see our technology enabling neural researchers to dramatically improve therapy for chronic diseases arising from neural disfunction. Our first entrant in this space is our NeuralGlider® Inserter, which has been well received by the market and is currently being utilized by neural research centers such as University of North Carolina at Chapel Hill, Lawrence Livermore National Laboratory, Carnegie Mellon University and University of Pittsburgh.

Our GripTract-GI™ Endoscopic Tissue Manipulator, a patented minimally invasive alternative to stomach surgery, completed a safety study yielding positive results. We are receiving interest from a growing number of clinicians. A 510(k) submission is planned by end of 2022. Our BabyGentleStick™ Heel Stick Helper, a less painful way to draw blood from neonates, has two IRB-approved clinical studies at Nationwide Children's Hospital and Penn State Children's Hospital that are progressing. A 510(k) submission is planned by end of 2022.

Excited by our future, we doubled our facility's size and added more commercial and clinical expertise. With this expansion, we are growing a new business unit in which Actuated selectively takes on medical device projects which apply our unique expertise in tissue mechanics and device solutions. We are moving Up and Onward.

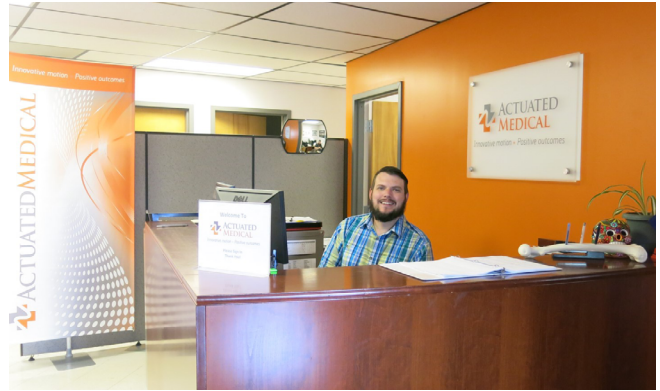
Up and Onward,
Maureen L. Mulvihill, Ph.D.
President & CEO





Actuated Medical Expansion

We have expanded! Take a look inside our new 20,000 sq. ft. state-of-the-art, FDA compliant facility space.





Our Team

21
employees



Our Skilled Team Includes...

- + Neuroscience & Physiology
- + Polymer & Materials Science
- + Engineering & Manufacturing
- + Quality Control / Quality Assurance
- + MedTech Commercialization

Expanding our Expertise...

Frederick A. Browne, M.D. was appointed as Actuated Medical's Chief Medical Officer in 2021.

As Actuated Medical's CMO, Dr. Browne brings a unique perspective of clinical needs and healthcare administration to the team. He has served since 2014 as VP and CMO of Griffin Hospital in Derby, CT, and is an Adjunct Professor in the newly accredited Masters of Physician Assistant Studies program at Sacred Heart University in Stamford, CT.



6
board members



Our Board of Directors bring...

- + MedTech commercialization expertise
- + Business, sales, and marketing know-how
- + Supply chain and manufacturing mastery
- + Expanded, forward-thinking thought

Expanding our Expertise...

Niall Sweeney, MBA, was hired as Actuated Medical's Chief Operations Officer in 2021.

Niall focuses on accelerating the commercialization of Actuated's medical device technologies and monetizing their value. Niall has delivered results for corporations such as Stryker, BD, and Quest Diagnostics. In the hospital supplies business, he spearheaded the development of BD's safety needles, creating a \$200 million business.





Our Team

7
**medical advisory
board members**



Our MAB advises on...

- + Civilian and military medical needs
- + Clinical best practices
- + Clinical and device usability
- + Health economics and hospital purchasing

Expanding our Expertise...

K. Marya Chaisson, M.D. was appointed to Actuated Medical's Advisory Board in 2021.

Dr. Chaisson advises the Actuated Medical team on critical care, sleep medicine, and pulmonary standard practice. She is the Medical Director of critical care, medical student affairs, and the Sleep Wellness Center at Griffin Hospital in Derby, CT. She is certified in critical care, internal, pulmonary, hyperbaric, and sleep medicines.



Highly Engaged Team

Our team continues to feel passionate, committed and dedicated.

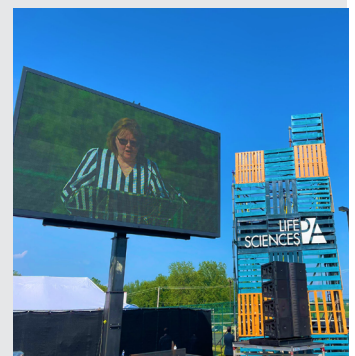
Actuated Engagement

79%*

*The National Average is 36%.

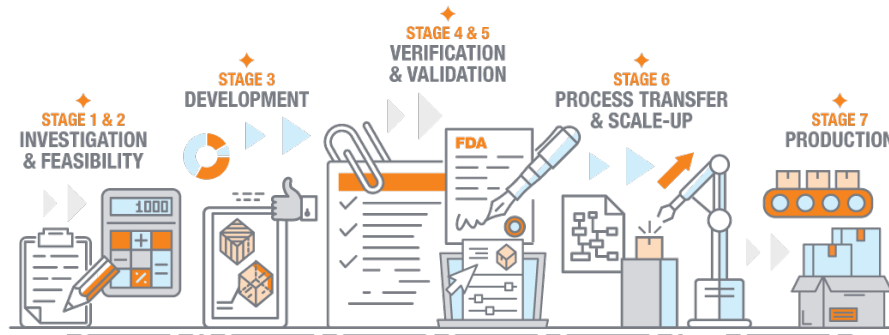
Maureen was awarded the Life Sciences Pennsylvania 2020 CEO of the Year award at the annual awards ceremony in May 2021.

The quick response by the Actuated team to the Covid PPE shortage was recognized by Life Sciences Pennsylvania with the 2020 CEO of the Year Award. Over 85k reusable face shields were shipped to first responders, nursing homes, schools, and individuals across the US.





Contract Services Expansion



Contract Services at Actuated Medical specialize in taking medical device ideas to market - from start to finish. Our process makes it possible for Actuated to accommodate small or varying quantities giving our clients the flexibility to scale up or down as needed. Our team of leading experts is there to help from initial investigation and feasibility through production.

We focus on medical devices. Therefore we can:

- + Engage effectively with clinicians and understand their language
- + Conduct in vitro and in vivo testing
- + Apply design control effectively
- + Secure FDA clearances

We have advanced expertise in these areas:

- + Tissue Dynamics & Insertion
 - Brain
 - Peripheral nerves
 - Blood vessels
- + Acoustic Design & Devices
- + Electronics & Software Development
- + Novel 3D Printing Techniques & Materials
 - Patient specific fabrication
 - Flexible materials

What our clients are saying...



I took my patent to Actuated Medical, and they completed all the V&V testing, wrote and submitted the 510(k) application. Because of Actuated my patent is a medical device.

Brian Shippert, MD
Emergency Medicine,
Shippert Tech, LLC



We have had the pleasure of working with Actuated Medical on a rapid development and prototyping project. We have been extremely impressed with their engineering quality, knowledge of the prototyping and manufacturing space, and ability to move quickly from innovation through small-scale manufacturing.

Doug Clift, COO, Canopy





Product Updates

Commercial Products



+ Over the years, Actuated has developed the know-how and expertise to insert needles into tissue with less trauma and reduced force. This expertise led to the development of the NeuralGlider Inserter. NeuralGlider is helping researchers implant neural devices into the brain with greater precision and less trauma. In the future, the technology will assist clinicians in controlling brain computer interfaces. NeuralGlider is being sold by NeuroNexus, Inc. and Plexon, Inc. The Actuated neural devices research team is working with world-class researchers at Carnegie Mellon, University of Pittsburgh, University of North Carolina at Chapel Hill (UNC), Lawrence Livermore National Lab, Tulane University, to name a few. UT Dallas and UNC researchers have already published their research using the NeuralGlider Inserter (see www.neuralglider.com).



+ The TubeClear System has continued to have repeat sales at facilities such as Harborview (Seattle, WA), UC Davis (Sacramento, CA), Omaha VA Medical Center (Omaha, NE). A new customer, NeuroRestorative (Riverton, UT) completed a four week clinical evaluation. By using the TubeClear System, NeuroRestorative not only provided their residents a greater sense of relief, but they also saved over \$8,000 in one month. The NeuroRestorative nurses wrote a white paper about better resident care and cost saving (see www.tubeclear.com). Texas Children's and Baylor University Medical Center are working on IRB submission for a Pediatric Study with the TubeClear System.



Pipeline Products



+ The GripTract GI Endoscopic Tissue Manipulator is a patented innovative device that gives clinicians 'fingers' at the end of the endoscope to move tissue improving visualization. It is gaining significant clinical interest due to its ability to provide tissue lifting during procedures. Clinicians at Penn State College of Medicine have worked with the Actuated team to perform safety and efficacy studies. This data will be presented by Dr. E. M. Pauli, Director of Endoscopic Surgery and Chief, Division of Minimally Invasive and Bariatric Surgery, Penn State, during the Next Big Thing Session at the 2022 SAGES Conference in Denver, CO, March 18, 2022. An FDA 510(k) submission is planned for the end of 2022.



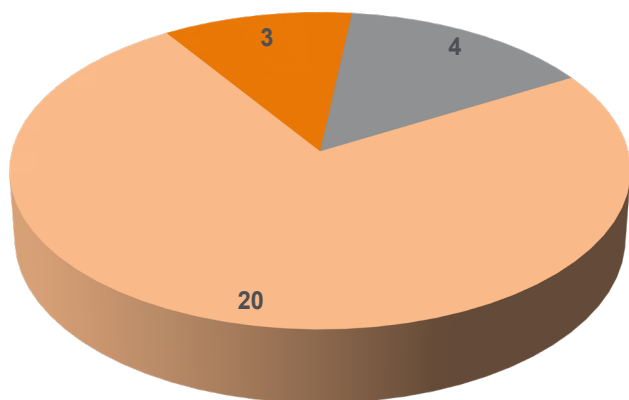
+ The BabyGentleStick Heel Stick Helper is currently being clinically evaluated at the Penn State Children's Hospital (Hershey, PA) and Nationwide Children's Hospital (Columbus, OH) under two IRB approved studies. An FDA 510(k) submission is planned for the end of 2022.





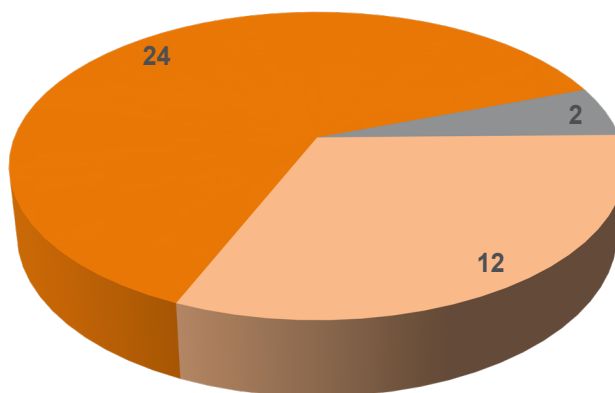
Intellectual Property Updates

27 Active / Pending Patents:



■ Tissue Penetrating ■ Occlusion clearing ■ Motion Gripping

38 Issued Patents: 25 US & 13 Int'l.



■ Tissue Penetrating ■ Occlusion Clearing ■ Motion Gripping

Equity Holdings

Obvius Robotics Inc. Closed Seed Round.

Registered Trademarks

ACTUATED
MEDICAL®

 ACTUATED
MEDICAL®
Innovative motion + Positive outcomes

Innovative
Motion®

 TubeClear® TubeClear®  GentleSharp® GentleSharp®
 NeuralGlider® NeuralGlider®

Sales and Revenue

2021 Grant Revenue:

\$3.9M

2021 Product Sales:

\$0.4M



Key Performance Indicators (KPIs) What We Measure

Quality Policy

We the employees of Actuated Medical are striving to **IMPROVE PATIENT OUTCOMES** by designing the next generation of **INNOVATIVE AND ADVANCED MEDICAL DEVICES**. **SAFETY, EFFECTIVENESS, CONTINUOUS IMPROVEMENT, AND REGULATORY COMPLIANCE** of our products is our focus. **EXCEEDING CUSTOMER EXPECTATIONS** is our driving force. We are maintaining the effectiveness of our QMS through our quality objectives.

Improve Patient Outcomes

- + Minimum of 12 Customer Discovery Interviews per project.
- + Commercial revenue growth from previous year.
- + 100% Compliance to AdvaMed Code of Ethics.
- + Minimum 80% of program quarterly goals are met.

Innovative Medical Devices

- + Notebooks will be co-signed weekly for at least 26 of 52 weeks.
- + \$3M in non-dilutive grant/contract revenue.
- + Four quarterly patent strategy meetings per year.
- + Minimum 1 new product launch.

Safety and Effectiveness

- + Zero (0) FDA-reportable adverse events.
- + Zero (0) OSHA reportable events.
- + 95% conforming lots.
- + Zero (0) complaints for defective products.

Continuous Improvement

- + Minimum 6 Continuous Improvement Initiatives or Preventive Actions implemented.
- + Annual Employee Engagement survey with employee engagement $\geq 70\%$.
- + 100% Employees at 40 Hours of Professional Advancement Hours.
- + Feedback response rate $\geq 5\%$ on post market surveillance customer surveys.

Regulatory Compliance

- + Minimum 1 FDA presubmission meeting for each medical device.
- + Pass annual ISO 13485:2016/MDSAP external audit.
- + Pass quarterly IEC external audits.
- + All internal audits completed on-time.

Exceeding Customer Expectations

- + Minimum 80% quarterly program review meetings are held on time.
- + 97% on-time delivery to commit.
- + Customer support initiated within 24 hours.
- + 1 potential partner engagement.



15 Year Celebration

Take a look at our trip down memory lane...

2006

- + Incorporated as Piezo Resonance Innovations on December 28th.
- + Strategically located in a Keystone Innovation Zone in Bellefonte, PA.



2008

- + Awarded first two SBIRs for the TubeClear System and the IntelliNeedle System.
- + Added Paul Frankhouser, fm. EVP at Arrow Int'l, to the BOD. He's a big PSU fan!



2012

- + Debuted the TubeClear System at ASPEN and found our first investors.
- + Received FDA 510(k) clearance for TubeClear. First TubeClear patient at Walter Reed.



2014

- + Received the SBA's Tibbetts Award for SBIR Commercialization of the TubeClear System.
- + Launched our second product, the GentleSharp Device.



2015

- + Recognized for our entrepreneurial leadership by Ernst & Young and CBICC.
- + Initiated a TubeClear clinical study at the Children's Hospital of Philadelphia.



2017

- + Attended the US Global Entrepreneurship Summit in India.
- + Funded by DARPA to develop the NeuralGlider Inserters.



2018

- + Sold our first NeuralGlider Inserters to Stanford and UNC.
- + Negotiated Vizient, Inc. and Premier Inc. Group Purchasing Organization contracts for the TubeClear System.

2020

- + Quickly brought up a reusable face shield line in response to the Covid PPE shortage, shipping over 85k shields.
- + Received the SBA's Tibbetts Award for SBIR Commercialization of the NeuralGlider Inserters.

2021

- + Expanded our facility enabling a neural devices lab, rapid prototyping & manufacturing lab, and a contract services business unit.
- + Awarded Life Sciences PA 2020 CEO of the Year.

Visit us on social media to see the rest of the posts...

[LinkedIn](#) [Twitter](#) [Facebook](#)



Latest News

Check out our new website:
www.actuatedmedical.com

February 23, 2022:

Actuated Medical Appointed Frederick A. Browne, M.D. as Chief Medical Officer

<https://www.prlog.org/12906402-actuated-medical-appointed-frederick-browne-md-as-chief-medical-officer.html>

October 10, 2021:

Actuated Medical Awarded SBIR Fast Track for Additive Manufacturing of Patient-Specific Masks and Nasal Prongs

<https://www.prlog.org/12890299-actuated-medical-awarded-sbir-fast-track-for-additive-manufacturing-of-patient-specific-masks-and-nasal-prongs>

September 7, 2021:

Actuated Medical Adds Niall Sweeney as COO to Leadership Team

<https://www.prlog.org/12884335-actuated-medical-adds-niall-sweeney-as-coo-to-leadership-team.html>

August 26, 2021:

Maureen L. Mulvihill, Ph.D. Appointed to the Life Sciences Pennsylvania Board of Directors

<https://www.prlog.org/12882723-maureen-mulvihill-phd-appointed-to-the-life-baldino-bioscience-ceo-of-the-year-award.html>

May 24, 2021:

Actuated Medical CEO Honored with Life Sciences Pennsylvania 2020 CEO of the Year Award

<https://www.prlog.org/12870884-actuated-medical-ceo-honored-with-frank-paid-time-off-for-second-covid-19-vaccination.html>



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Innovative motion + Positive outcomes

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