# San Diego Business Journal

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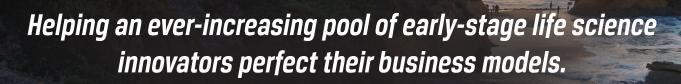
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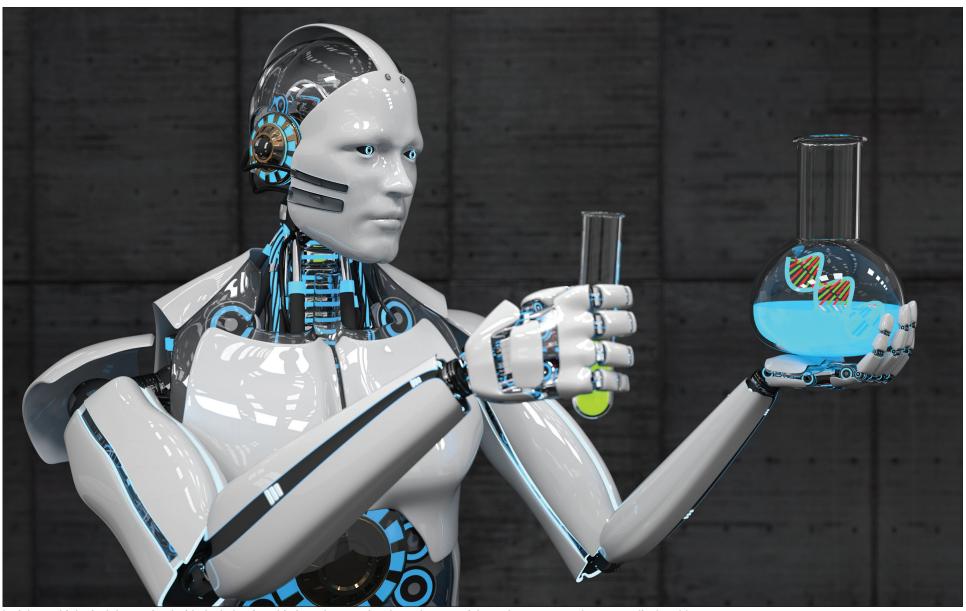
# The State's Most Impactful Life Sciences Membership Organization

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Insights to biological data, gained with the help of sophisticated computing, have the potential to solve some very human medical problems.

#### SPECIAL REPORT: LIFE SCIENCE

# Merging the Biological With the Computational

LIFE SCIENCE: How AI Helps Drive a New Era of Diagnostics and Biomedicine

■ By JEFF CLEMETSON

When scientists began mapping of the human genome, the discoveries in our DNA unleashed an era of biology that advanced breakthroughs in diagnostics and biomedicine beyond what was imaginable when the work began.

Today, with DNA sequencers readily available in many labs around the world, a new technology in computing is quickly becoming an indispensable tool in advancing the work based on the genome.

Artificial intelligence (AI), also referred to as machine learning, is when computers are used to perform tasks that typically require human intelligence. In the case of biomedicine, AI tools are often used to analyze large sets of genomic data and tell the difference between normal and abnormal DNA, for example.

The adoption of AI in medicine is a growing at a massive pace. According to an April 2021 report by **Markets and Markets** titled "Artificial Intelligence in Medical Diagnostics Market," the global market for AI in diagnostics is projected to reach \$3.86 billion by 2025. In 2020, that number was just \$505 million. In the overall healthcare market, Markets and Markets predicts the AI healthcare market will rocket almost ten times higher in the next five years – from \$6.9 billion in 2021 to \$67.4 billion by 2027.

The report lists factors like a need to reduce healthcare costs, improving computing power, more funding for AI-based startups and an "influx of large and complex

datasets" as main drivers for the growing market for AI in healthcare and biomedicine.

#### **Finding Cancer with Computers**

A large part of the influx of complex data in biomedicine is the race to find better diagnostic tools in the treatment of cancer.

Before the advent of genome sequencing, detecting cancer meant taking a tissue sample of a tumor and analyzing it under a microscope. Researchers today are developing tools to detect cancer with blood from a liquid biopsy and using



Dave Mullarkey CEO Bluestar Genomics

AI-enhanced computing to analyze it for signs of the presence of cancers in the body.

"It's the age of biology. DNA sequencing has become mainstream and more cost-effective, but I think

we've only scratched the surface of what's possible to improve in human health when we look at epigenomics," said **Bluestar Genomics** CEO **Dave Mullarkey**.

Epigenomics is the study of the way genes are switched on and off without changing a DNA sequence. Bluestar Genomics is developing a liquid biopsy platform that combines machine learning with a proprietary biomarker analysis technology to precisely screen for epigenomic changes and detect cancer much earlier than existing methods.

"Improved DNA sequencing tools are enabling a new understanding of what happens when genes are turned on and off, proteins are produced, or aren't, or additional molecules attach themselves to DNA and change cellular function," he said. "Understanding all the changes that turn a normal cell into a cancer cell will speed efforts to develop new and better ways of diagnosing, treating and preventing cancer."

#### **AI Fuels Emerging Technologies**

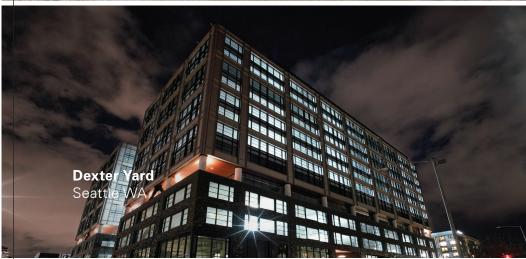
**Micronoma** is taking a similar approach to cancer detection using a different science. The company is also analyzing blood drawn in a liquid biopsy, but instead of looking for epigenomic markers, it is searching for microbes that signal the presence of cancer – a science that is enabled by AI computing.

**→** Biological page 20











## Discover Here®

BioMed Realty is a leading provider of real estate solutions to the life sciences and technology industries. We own and operate high quality life science real estate comprising 14.9 million square feet concentrated in leading innovation markets throughout the United States and the United Kingdom, including Boston/Cambridge, San Francisco, San Diego, Seattle, Boulder and Cambridge, U.K.

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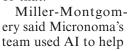


## **Biological**

**→** from page 18

"You can imagine machine learning as helping people doing discovery in the human genome, but the human genome only has 23,000 genes. When you look at a

microbiome, you have 2 million genes to find ... that's a hard endeavor. I think that's part of why microbiome science is only now exploding," said Micronoma CEO Sandrine Miller-Montgomery. "You can't just look at AT-GCs [DNA proteins] in 2 million different combinations and try to get knowledge out of that."





Sandrine Miller-Montgomery CEO Micronomas

analyze microbes found in blood from patients with various forms of cancer.

"From a discovery point of view, it was very interesting for us to be able to use AI to figure out that the cancer tissue in the lung was a different signature on the microbe side than what you'd find in a breast cancer tissue, for example," she said.

Micronoma is now using AI to develop a platform to detect the difference between the DNA of cancerous

microbes and benign microbes to be used commercially as a diagnostics tool.

Epic Sciences is using its diagnostics platform to "transform care for cancer patients by identifying and analyzing circulating tumor cells (CTCs) that can inform treatment decisions," said Epic CEO Lloyd Sanders. The process also informs the AI on how to better learn its function.

Epic's imaging plat-



Lloyd Sanders CEO Epic Sciences

form was innovated to analyze all cells from a patient's blood on each slide in order to avoid making "biased assumptions," Sanders said. The look-at-everything approach over time then "enables AI and machine learning models, coupled with multi-omics methods, to identify cells that matter, while learning and driving more precise data analytics."

"Diagnostic technologies can power a true personalized medicine revolution – but must move faster, unencumbered by existing research frameworks and imperfect standards of care," he added. "We have evolved our technology platform with this purposeful revolution in mind."

Another company revolutionizing diagnostics with a novel approach utilizing machine learning is **Arima Ge-**

nomics – "the market leader in 3D genomics, a technology that provides access to the sequence, structure, and regulatory landscape of genes within the nucleus of a cell," said Anthony Schmitt, senior vice president of science at Arima.

"Coupled with improved machine learning algorithms, 3D genomics can help improve clinical biomarker detection and classification, patient stratification, optimi-



Anthony Schmitt
Senior Vice President of Science
Arima Genomics

zation of epigenetic feature classification, prediction of gene expression and prediction of drug response, among other biological insights," he said.

Schmitt said it can be difficult to explain the impact of any one component of a biological system or to predict effects of interactions between components, but there is "great potential in emerging machine learning capabilities in facilitating an understanding and visualization of these systems."

"I envision that one day there will be diagnostic tests and precision treatments for cancer and other diseases based on 3D genomics data," he added. "Researchers have only begun to scratch the surface of what's possible with this technology."

#### Al and Beyond

Scratching the surface of what's possible with technology is a hallmark of San Diego's innovative life sciences sector. One company that is fusing the world of biology with the world of computing in a real way is **Cardea Bio**.

"Inside your computer, the CPU is the processor that makes the computer work. There is also a GPU that draws the graphics on your screen. We're the first and only company to offer a BPU – a Biosignal Processing Unit," said Cardea CTO **Brett Goldsmith**.

Cardea's BPU, which is still waiting FDA clearance, is designed to run multiple tests on a single blood sample,

potentially allowing doctors and clinicians to do things like track a patient's overall immune system response and test for different cancer markers.

"That means that we can drive a potential paradigm shift in cancer detection - going from the current sporadic testing based on hunches or being so late stage that the cancer manifests physically, to monitoring cancer biosignals," Gold-



Brett Goldsmith CTO Cardea Bio

smith said. "Through regular non-invasive tests, you're always on top of what's going on in your body. Our BPU platform is capable of doing this, and so are others, but our approach is going to be a lot more affordable for people, compared to the costs of current testing."

#### Internet of Biology

In the future, Goldsmith sees an adoption of "biocompatible electronics" to create an "Internet of Biology" similar to how Internet of Things technology works today.

"We will be able to get a step closer to deciphering what's really going on with the most advanced technology on Earth – the biosignals in nature and biology," he said.

Cardea is already taking that step toward an Internet of Biology. The company recently announced a partnership with **The Gates Foundation** to investigate how the body and microbiome all around it communicate information.

"We're going to develop an electronic nose capable of detecting infectious diseases via breath," Goldsmith said.

"These biosignals can be read out with electronics that are compatible with biological environments."

In AI, the future will be in improving data management, according to CRIS-PR-QC President Ross Bundy.

"AI is only as good as the data it gets, so understanding how to get as much data as possible with as small or no burden to actually enter the data and organize it



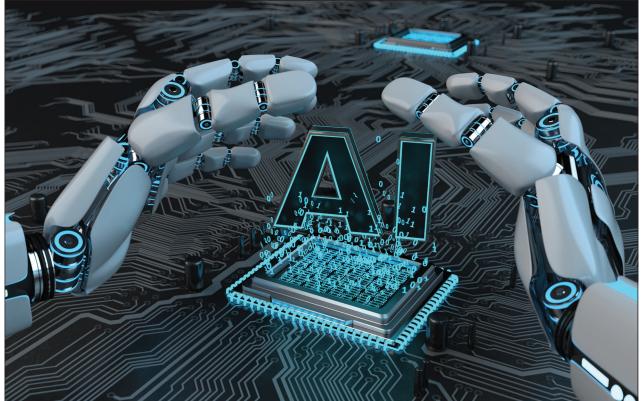
President CRISPR-QC

so the AI can give us those insights is really the thing limiting us," he said. "If useful, well-organized data can be collected without errors in a time-and-cost efficient manner, there are thousands of smart people out there who can build great AI that will unlock the next big breakthroughs in medicine."

Those breakthroughs will come when data can be gathered and organized from across a range of disciplines like genomics, metabolomics and proteomics all at once," he added. "When we're talking about complex issues like long-term degenerative diseases like Alzheimer's, Parkinson's, or just aging in general, real answers are going to be at the intersection of these different fields, as our bodies operate as a system of systems, not siloed fields."

CRISPR-QC is studying how to optimize therapies using CRSPR technology to edit out RNA or DNA from the body.

"CRISPR has this enormous potential to actually cure genetic diseases, like Type 1 Diabetes, liver disease, or even difficult viral infections like HIV. The problem here is that since you're editing people's DNA, every person's unique DNA introduces a unique variable every time," Bundy said. "This isn't diagnostics, rather it's using similar techniques to diagnostics to optimize to the patient's unique situation, which in some ways is just as important, and in gene therapy even more so." ■



Artificial intelligence will help medical doctors and researchers make sense of large data sets.



BCG partners with medical technology, device, and diagnostic companies to address the industry's most pressing challenges, transform enterprises, and improve patient outcomes.

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### **BIOMEDICAL DEVICE MAKERS**

Ranked by number of local full-time employees as of March 1, 2022

Rank	Company Address Website Phone		# of local full-time employees: 2022 2021	# of companywide employees	Description	Top local executive Headquarters Year est. locally	
1	BD (Becton, Dickinson and Co.) 3750 Torrey View Court, San Diego 92130 www.bd.com 858-617-2000	<b>₩</b> BD	4,000 4,000	75,000	Manufactures devices for medication management, diagnostic testing & biomedical research	Michael Garrison Franklin Lakes, N.J. 1997	
2	Thermo Fisher Scientific Inc. 5791 Van Allen Way, Carlsbad 92008 www.thermofisher.com 760-603-7200	Thermo Fisher SCIENTIFIC	3,500 2,400	80,000	Advance discovery, translational research, molecular medicine	John Sos Daniella Cramp Waltham, Mass. 1987	
3	Dexcom Inc. 6340 Sequence Drive, San Diego 92121 www.dexcom.com 858-200-0200	Dexcom	2,773 2,760	6,182	Develops, manufactures & distributes continuous glucose monitoring systems for diabetes mgmt.	Kevin Sayer San Diego 1999	
4	<b>Quidel Corp.</b> 9975 Summers Ridge Road, San Diego 92121 www.quidel.com 800-874-1517	QUIDEL	1,330 866	1,620	Development, manufacturing and marketing of diagnostic tests, assays, instruments	Douglas Bryant San Diego 1979	
5	Hologic Inc. 10210 Genetic Center Drive, San Diego 92121 www.hologic.com 858-410-8000	HOLOGIC°	1,031 974	6,451	Innovative med tech company primarily focused on improving women's health	Kevin Thornal Marlborough, Mass. 1982	
6	Tandem Diabetes Care Inc. 11075 Roselle St., Suite 200, San Diego 92121 www.tandemdiabetes.com 858-366-6900	TANDEM° DIABETES CARE	791 802	2,404	Maker of the t:slim X2 Insulin Pump with Control-IQ	John Sheridan San Diego 2006	
7	ResMed 9001 Spectrum Center Blvd., San Diego 92123 ResMed.com 858-836-5000	ResMed	530 530	8,000	Digital health products to help people sleep, breathe, and live healthier lives outside the hospital	Mick Farrell San Diego 1989	

(NR) Not Ranked

Source: The companies

Source: Ine companies.

In case of a tie, companies are ranked by number of companywide employees.

To the best of our knowledge, this information is accurate as of press time. While every effort is made to ensure the accuracy and thoroughness of

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### **BIOMEDICAL DEVICE MAKERS**

Ranked by number of local full-time employees as of March 1, 2022

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	8	Axelgaard Manufacturing Company Ltd 520 Industrial Way, Fallbrook 92028 www.axelgaard.com 760-451-8000	AXELGAAF MANUFACTURING CO.	RD 137 130	137	Patented medical electrodes, hydrogels	Jens Axelgaard Fallbrook 1985	
	9	ACI Medical LLC 1857 Diamond St., San Marcos 92078 www.acimedical.com 760-744-4400	ACI MEDICAL	35 36	35	Treatment of peripheral artery diseases, venous diagnosis, contract manufacturing, sports recovery	Ed Arkans San Marcos 1995	
	10	Advanced Brain Monitoring Inc. 2237 Faraday Ave., Suite 100, Carlsbad 92008 www.advancedbrainmonitoring.com 760-720-	ADVANCED BRAIN MONITOR	30 30	45	Neurotech company and pioneer in brain science with a platform to tackle a myriad of neurodegenerative issues	Chris Berka Carlsbad 1999	
	11	Aethlon Medical Inc. 11555 Sorrento Valley Road, San Diego 92121 www.aethlonmedical.com 619-941-0360	aethlon MEDICAL, INC.	11 11	13	Devices for medical needs in cancer, infectious disease, and other life-threatening conditions	Charles J. Fisher, Jr., M.D. San Diego 1998	
	12	AVACEN Medical 2365 Camino Vida Roble, Suite C, Carlsbad 92011 www.avacen.com 888-428-2236	AVACEO® Pain Free MEDICAL Is Freedom®	10 10	10	AVACEN 100, AVACEN PRO, AVACEN PRO+ & AVACEN CSS thermotherapy and cardiovascular screening FDA-cleared medical devices	Thomas Muehlbauer Carlsbad 2009	
	40	Advanced Monitors Corp. 7098 Miratech Drive Suite 130	Advanced Monitors	9		Portable endoscopes, video otoscopes, infrared	Rick Ferlito	

(NR) Not Ranked

Source: The companies.

In case of a tie, companies are ranked by number of companywide employees.

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www.admon.com 858-536-8237

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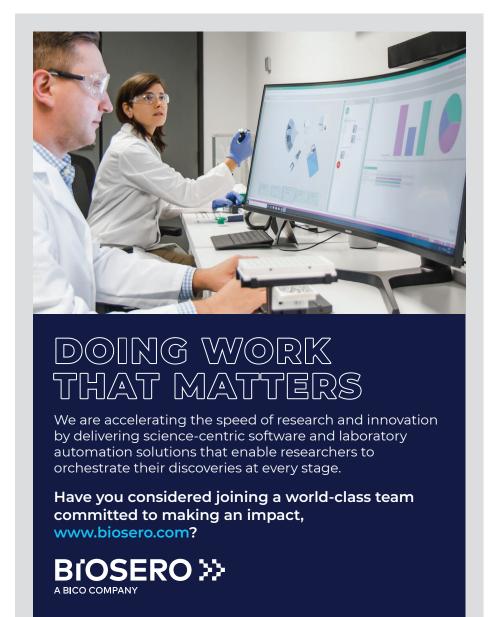
Advanced Monitors

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San Diego

Portable endoscopes, video otoscopes, infrared

thermometers, digital thermometers, surgical lasers





## **Customized Cancer Treatment Options – AI for Oncology**

A cancer diagnosis can feel overwhelming, and working with doctors to quickly identify therapy options that will have the best outcome is complex.

For diagnosed patients, **precision medicine** with the CureMatch Decision Support System helps doctors identify therapies that are tailored to each person's unique molecular profile, supporting the oncology team with options that are 'matched' to an individual's tumor.

If you have cancer or want to help someone who does, find out how you can give *The Gift of CureMatch* for precision medicine – helping the doctor and the patient identify the top matching therapy options.

To find out about the Gift of CureMatch visit <u>Gift of CureMatch</u> Or learn more about advancements in precision medicine digital solutions at <u>www.CureMatch.com</u>

### **DIAGNOSTICS COMPANIES**

Ranked by number of local employees as of March 1, 2022

Rank	Company Address Website Phone		# of local employees: 2022 2021	# of companywide employees	Description	Top local executive Headquarters Year founded	
1	Illumina Inc. 5200 Illumina Way, San Diego 92122 www.illumina.com 858-202-4500	illumına	4,598 3,850	9,100	Improving human health by unlocking the power of the genome	Francis deSouza San Diego 1998	
2	BD (Becton, Dickinson and Co.) 3750 Torrey View Court, San Diego 92130 www.bd.com 858-617-2000	BD	4,000 4,000	wnd	Manufactures devices for medication management, diagnostic testing & biomedical research	Michael Garrison Franklin Lakes, N.J. 1997	
3	Thermo Fisher Scientific Inc. 5791 Van Allen Way, Carlsbad 92008 www.thermofisher.com 760-603-7200	Thermo Fisher SCIENTIFIC	3,500 2,400	100,000	Advance discovery, translational research, molecular medicine	John Sos Daniella Cramp Waltham, Mass. 1987	
4	<b>Quidel Corp.</b> 9975 Summers Ridge Road, San Diego 92121 www.quidel.com 800-874-1517	QUIDEL	1,330 866	1,620	Development, manufacturing and marketing of diagnostic tests, assays, instruments	Douglas Bryant San Diego 1979	
5	Hologic Inc. 10210 Genetic Center Drive, San Diego 92121 www.hologic.com 858-410-8000	HOLOGIC® The Source of Sure	1,031 974	6,541	Innovative med tech company primarily focused on improving women's health	Kevin Thornal Marlborough, Mass. 1982	
6	<b>Biocept Inc.</b> 9955 Mesa Rim Road, San Diego 92121 www.biocept.com 858-320-8200	Biocept Completing the Answer™	165 150	178	Assays, products & services, including its CNSide CSF assay, provide physicians with clinically actionable information for treating and monitoring patients diagnosed with cancer	Samuel Riccitelli San Diego 1993	Missile .
7	Exagen Inc. 1261 Liberty Way, Vista 92081 www.exagen.com 888-452-1522	Exagen®  Patient Focused. Discovery Driven.	150 wnd	222	Commercial-stage life sciences company focused on the diagnosis, prognosis, and management of autoimmune conditions	Ron Rocca Vista 2002	
8	DermTech Inc. 11099 N. Torrey Pines Road, Suite 100, La Jolla 9 www.dermtech.com (858) 450-4222	DermTech	132 96	274	Genomics company in dermatology focused on melanoma detection	John Dobak La Jolla 2012	
9	<b>Helix</b> 9875 Town Centre Drive, San Diego 92121 www.helix.com 415-916-2740	<b>#</b> Helix	100 50	240	Population genomics and viral surveillance company	James Lu San Mateo 2015	
10	Advanced Brain Monitoring Inc. 2237 Faraday Ave., Suite 100, Carlsbad 92008 www.advancedbrainmonitoring.com 760-720-0099	Advanced Brain Monitoring	30 30	44	Neurotech company and pioneer in brain science with a platform to tackle a myriad of neurodegenerative issues	Chris Berka San Diego 1999	

Innominata dba GenBio 15222 Avenue of Science, Suite A, San Diego 92128 www.genbio.com 858-592-9300



13

Develops, manufactures, markets immunoassays for infectious & autoimmune diseases in four formats

Frederick Adler San Diego 1994



PROVIDED BY AVACEN

## **AVACEN Medical® Welcomes Anthony Shimkin** as New Chief Executive Officer

An industry veteran, Shimkin brings more than 25 years of medical and technology commercialization experience to AVACEN.



**Anthony Shimkin** 

"As we continue to expand globally, Anthony's knowledge and deep industry expertise will prove instrumental to our strategic growth," said Thomas G. Muehlbauer, Chairman

and co-founder of AVACEN Medical.

AVACEN Medical, an innovator, manufacturer, and marketer of safe, easy to use, noninvasive drug-free alternatives for pain management, today announced the appointment of Anthony Shimkin as CEO. With more than 25 years of medical and technology commercialization experience, Shimkin will be responsible for driving brand awareness, expanding AVACEN's go-to-market strategy and increasing revenue growth.

"We are thrilled to welcome Anthony to the AVACEN Medical team," said Thomas G. Muehlbauer, Chairman and co-founder of AVACEN Medical. "As we continue to expand globally, Anthony's knowledge and deep industry expertise will prove instrumental to our strategic growth."

Throughout his extensive career, Shimkin held key marketing and innovation leadership roles at several notable companies, including Qualcomm, where he served as senior director of marketing and, later, senior director of business development. Before that, he held senior positions at Lantronix, Quidel, Cardinal Health, Alaris Medical Systems and Neoforma. He also led the health care equity research team at Wedbush Securities and consulted for several leading life sciences companies.

Prior to joining AVACEN Medical, Shimkin served as the senior vice president of marketing at Kajeet, a leading managed IoT connectivity service for remote patient monitoring and telehealth. Prior to Kajeet, he was chief marketing officer at Ready-Set Surgical, a cloud-based coordination platform that consolidates supply chain logistics and communications for surgical teams. Anthony was also a sales and marketing advisor at Farsight Genome Systems, a provider of an innovative SaaS platform for precision medicine, and a principal at Sciencia Consulting, a consulting and interactive content marketing provider for the life sciences industry.

## AVACEN Medical - Pain and Stress Relief in the Palm of Your Hand!

Millions of people live with chronic pain and stress. If you're one of them, you may have tried to manage a deep pain that never really goes away. Pain medication only



Thomas G Muehlbauer, AVACEN Medical Chairman, Danielle Forsgren AVACEN Medical CMO. Photo Courtesy of Pola Allen

masks the pain, doesn't cure anything, and poses the risk of unpleasant side effects. As a result, so many people are resigned to spending their lives in pain.

But what if you could get convenient and safe relief without medication? What if the answer was literally in the palm of your hand?

AVACEN is a unique thermotherapy device that temporarily relieves muscle and joint pain and stiffness including those associated with arthritis, promotes muscular relaxation, and increases circulation. Imagine a walk in the park without fighting the usual jolt of pain! Think about having a sense of calm and relaxation! Picture lifting your child or grandchild pain-free!

This powerful device is noninvasive, drug-free and easy to use. You also get the tremendous healing benefits associated with activating the parasympathetic from placing your hand in this small device and resting the palm of one hand on a heat transfer pad while it is subjected to negative pressure!

AVACEN Medical has just launched its third model, the PRO+. With PRO+, there is new hope on the horizon for more people to experience safe life-changing pain relief.

#### **How Does AVACEN Work?**

AVACEN introduces heat into the circulatory system through high-volume blood vessels located in the palm of the hand.

The heat increases microcirculation and reduces blood thickness. Microcirculation refers to blood flow through the smallest blood vessels which make up approximately 74% of the body's vascular system, which deliver nutrition and oxygen to tissues and helps regulate blood pressure and corebody temperature.

"With poor circulation, the blood can't get to where it's needed, and you may experience pain in your feet, extremities and fingers. AVACEN helps push that blood through those vessels," Forsgren explained.

The hand is simply put in the device, and it warms the blood, relaxes the muscles and increases the delivery of oxygen and nutrients while taking away toxins. It's a simple and safe way to relax the body by activation of the parasympathetic.

The parasympathetic nervous system is responsible for the body's rest and digestion response when the body is relaxed, resting or feeding. It basically undoes the work of sympathetic division after a stressful situation.

"When you meditate or practice yoga, you go into this relaxing parasympathetic state. Muscular relaxation also activates the parasympathetic system. And when you relax, you heal," Muehlbauer said.

It is also quite easy to use.

"Making it as easy as possible for the end-user was especially important for our home device. So, you just push one button and relax. The device does the rest," Muehlbauer added.

#### Launching a New Model: The PRO+

After three years of intensive development AVACEN Medical just launched its new PRO+ at the April 2022 American Academy of Anti-Aging Medicine/Metabolic Medical Institute (A4M) conference. This device is an updated and significantly improved version of the existing practitioner's AVACEN PRO device.

"It's an absolutely hi-tech device," Muehlbauer said. "It improves our existing PRO device by adding: a color touch screen; support for larger hands; Wi-Fi; Bluetooth and RFID support for custom AVACEN Apps. It uses more durable parts that makes it five times more reliable than the current PRO device. The redesign also includes a pop-on/pop-off cuff for easier and less expensive repair of a damaged bladder. In addition, more memory allows support for over 100 languages. With the 10 times faster processor, we were able to add educational and relaxing videos, plus proven deep healing meditation music."

The AVACEN system is a promising device for people living with chronic pain. The new PRO+ model is set to give access to relief to an even larger population. In addition to pain and stress relief, all models benefit users through:

Ease of use: AVACEN device requires only one hand, and there are no complicated instructions or settings.

Convenient size: AVACEN device is small enough to carry easily and operate yourself.

No needles, wires or medications. Brief, 20-to-30-minute sessions. AVACEN Medical



About AVACEN Medical: AVACEN Medical, a rapidly rising INC. 5000 company for the last 3 years, is dedicated to the innovation and design of safe, easy to use, noninvasive drug-free alternatives for the management of pain associated with numerous chronic and acute conditions including the temporary relief of minor muscle and joint pain and stiffness associated with arthritis and potentially other conditions that can cause joint pain, such as CRPS, Raynaud's, and Lyme disease. Founded in 2009, AVACEN Medical is headquartered in Carlsbad, CA. Contact: Danielle Forsgren at (888) 428-2236 x702 or info@AVACEN.com.