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March 15th, 2023

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Happy St. Patrick's Day! Hope everyone has a lot of good luck for this year's celebration.

In this month's newsletter I will cover "What's New in ALS Technology and Treatment?" You can find my article under the Table of Content and click on the link.

If you missed the last month's newsletter "Antibiotic Resistance Crisis: What Can Be Done and Two Different Approaches", click on this <u>link</u> to read the article.

If you need a little inspiration or something to make us laugh to get us through this difficult time, click on the "Inspiration" link to give yourself a few minutes to relax and

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"The Prayer".

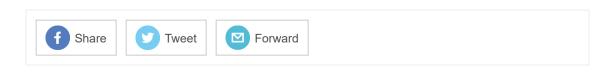
Please read on for other current news in the Table of Content below. The next newsletter will be April 15, 2023.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

Please email me, Regina Au, if you have any questions, comments, or suggestions.



Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
BioMarketing Insight



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## Join my mailing list



Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact <u>me</u> for an appointment. For successful commercial adoption of your product or looking to grow your business, contact <u>me</u> for an appointment.

For more information on our services, click on the links below:

<u>Product Development</u> <u>Market Development</u>

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Save the Date: AAPI Heritage Festival - Saturday, May 20th, 2023

Asian American Pacific Islander (AAPI) Heritage month is a celebration of a diverse group of ethnic heritage within the Asian community who bring a wealth of enriched culture to our society. This celebration will endeavor to build awareness and educate our community on the various cultures and contributions these different Asian ethnic groups have brought to enrich our American Story.

### History you may not know:

- 1. 20,000 Chinese men served in the military during WWII where 40% of the men served without American citizenship due to the "Chinese Exclusion Act". They were later honored in September 2021 with the Congressional Gold Medal for their acts of patriotism, loyalty, and courage for the US.
- 2. 110,000 Japanese American and Japanese were relocated to prison camps during the bombing of Pearl Harbor in 1941. In 1943, Japanese Americans were finally allowed to volunteer for the all-Japanese American 442nd Regiment that fought against the Japanese. These men were awarded the Congressional Gold Medal in 2010.

Examples of Individual Contributions:

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birthright citizenship to all persons born in the United States regardless of race or nationality.

- Har Gobind Khorana, Asian Indian, won the <u>1968 Nobel Prize</u> in Medicine for the United States. He has held professorships at many distinguished universities worldwide.
- Subrahmanyam Chandrasekhar, Asian Indian, a theoretical astrophysicist, won the <u>1983 Nobel Prize</u> in Physics. He has also held professorships at many prestigious institutions.
- 4. Colonel Ellison Onizuka (1946-1986) was the first Asian American, the first Japanese-American, and the first Hawaiian Astronaut in space. His first space mission was aboard Space Shuttle Discovery in 1985. Sadly, Onizuka's life was cut short on January 28, 1986, when Space Shuttle Challenger exploded 73 seconds after launch.

Join us in learning more about contributions from other ethnic groups and celebrating heritage month.

Theme: Contributions Asian American Pacific Islands Have Made to American History

Date: Saturday, May 20, 2023

**Venue**: Woburn Public Library, 45 Pleasant Street, Woburn, MA - program room and outside tent

**Time**: 11am - 3 pm

**Admission**: Free with proof of fully vaccinated (+boosters) or a negative COVID test within 48 hours for the safety of everyone.

Contributions AAPI Have Made to American History Exhibit: On display from May 1 - 31, 2023 at the Woburn Public Library, Lower Level

More information to follow. Hope you can make it.

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I am pleased to announce that I was a speaker at the Westchester Biotech Project for Consortium on Translational Research in the Microbiome on November 11th, 2021. The Topic: General Guidelines to launch and build a clinical trial using microbiome products in an era of personalized medicine. My presentation was on " How to Launch and Market a Successful Microbiome Product: Five Major Considerations". For more information on this event, click here. This webinar it will be available next month, so check back here.

For more information on Westchester Biotech Project and future webinars, click here.

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Fresh Thinking in the Next Normal

I am pleased to announce that I was a speaker at the Institute of Management Consultants event on "What Will the "Next Normal" Be for Productivity, Motivation and Retention of Employees? Four Things Employers Need to Consider." on July 20th, 2021 at 2 pm. For more information and to register click <a href="here">here</a>.

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**Inspirations** 

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.



We Will Get Through It Together

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Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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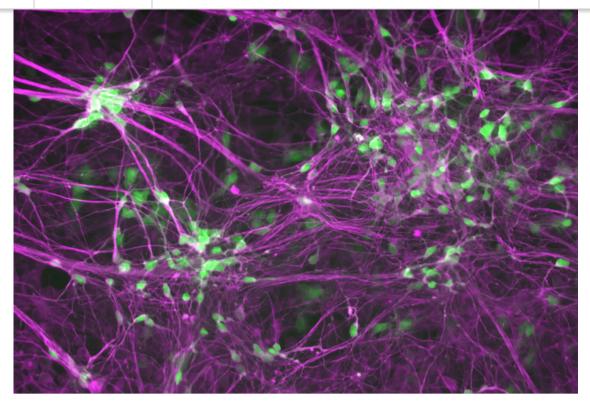


# One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link <a href="here">here</a>.

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What's New in ALS Technology and Treatment?

Most of us knows that ALS or Lou Gehrig's disease, is a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord. This disease progressively destroys the motor neurons, reducing a patient's muscle strength and mobility, until they eventually lose the ability to speak, eat or even breathe.

Unfortunately, the mortality rate is 100% and the average life expectancy after diagnosis is two to five years, but some patients may live for years or even decades. The famous physicist Stephen Hawking lived for more than 50 years after he was diagnosed.

Scientists have been working on treatments for decades but because this disease is so complex in understanding the cause or mechanism of action, currently there is no known cure or treatment that halts or reverses the progression of ALS. The FDA has approved medications such as riluzole (brand names Rilutek, Teglutik) and edaravone (Radicava) but they have proven to have only a modest affect in slowing the progression of ALS.

Despite everything, scientists have not given up and in the last few months, there has been news on scientists discovering new drug targets for treatment and medical devices to improve the quality of life for these patients.

Researchers from the University of Southern California (<u>USC</u>) set out to investigate new drug targets for treating ALS. The scientists started by creating induced pluripotent stem cells from ALS patients, programming them into motor neurons, and then screened

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Using a database called the Connectivity Map, which links drugs to genes and associated diseases, the team identified a gene called SYF2 that seemed to be responsible for ALS. When they suppressed this gene in mice with ALS, they were excited to find that the mice's neurodegeneration, motor dysfunction and other symptoms were reduced.

"What's really exciting is that SYF2 suppression improved symptoms and pathology related to a protein called TDP-43, which can become toxic and is implicated in close to 97% of cases of ALS," said Yichen Li, co-first author of the study.

In a second study, the same methodology using the Connectivity Map identified another culprit: a protein called PIKFYVE. In experiment with fruit flies, roundworms, mice and motor neurons grown from human ALS patients, the team blocked the protein using drugs, genetic engineering and RNA techniques.

Once again, the treatment reduced neurodegeneration, improved motor function and increased the lifespan of the test subjects. On closer inspection, the researchers identified the mechanism behind the improvements – reducing PIKFYVE helped the neurons transport waste to the outside of the cell, which prevents toxic proteins from building up.

"We were able to pinpoint precisely how PIKFYVE inhibition mitigates neurodegeneration, which is important for informing the development of new targeted treatments," said Shu-Ting Hung, co-first author of the study.

There's still plenty of work to do before either of these strategies can ever make it to human trials, but it provides hope of possible paths for treatment.

### **Brain Implants**

Last September, I reported that numerous companies and universities pursuing the Brain Computer Interface (BCI) market because it is the best of both world, healthcare and technology. BCI allow patients to control a computer with their brain which is game changing for patients who have ALS or are paralyzed.

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A 67-year-old ALS patients broke record speed using a brain implant to communicate. The implanted uses neural signals to detect the words she is trying to say and conveying them on a computer screen.

Researchers at Stanford University claimed that a volunteer who lost her power of speech due to ALS received a brain implant and has been able to say "I don't own my home" and "It's just tough" at a rate approaching normal speech. She had smashed previous records by using the brain-reading implant to communicate at a rate of 62 words a minute, three times the previous best.

<u>Philip Sabes</u>, a researcher at the University of California, San Francisco, who was not involved in the project, called the results a "big breakthrough" and said that experimental brain-reading technology could be ready to leave the lab and become a useful product soon.

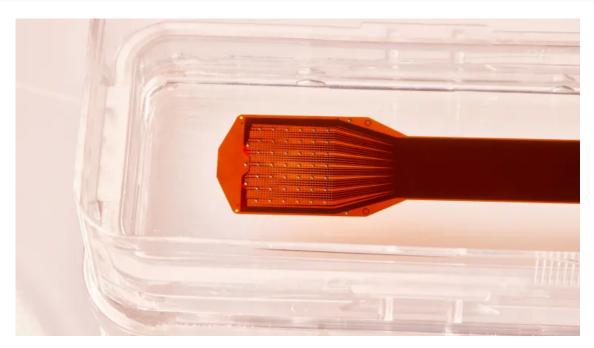
"The performance in this paper is already at a level which many people who cannot speak would want, if the device were ready," says Sabes. "People are going to want this."

Krishna Shenoy, who devoted his career to improving the speed of communication through brain interfaces and her team developed a small pad of sharp electrodes to embed in a person's motor cortex, the brain region most involved in movement. This allows researchers to record activity from a few dozen neurons at once and find patterns that reflect what motions someone is thinking of, even if the person is paralyzed.

Shenoy's recent work looked at useful information about speech movements. A huge discovery was that just a few neurons contained enough information to let a computer program predict, with good accuracy, what words the patient was trying to say. "Our results show a feasible path forward to restore communication to people with paralysis at

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Precision Neuroscience - Layer 7 Cortical Interface

#### More news

Precision Neuroscience is working on developing a brain implant called the <u>Layer 7</u> <u>Cortical Interface</u> to help paralyzed patients and those with severe degenerative diseases, operate digital devices through the use of neural signals alone, the 7th layer. The Layer 7 array looks similar to a piece of scotch tape and thinner than a human hair is capable of conforming to the brain's surface without causing any tissue damaged. The procedure is less invasive where the surgeon makes a very thin slit to implant Layer 7 into the skull without having the patients' head shaved to undergo the procedure.

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**Closing Thoughts** 

As technology advances, scientist are able to use tools, such as the Connectivity Map which links drugs to genes and associated diseases, in developing more targeted treatments faster. This saves a lot of time in the research and discovery phase which is paramount when we are talking about ALS where time is of essence.

The field of BCI has grown and technology has advanced significantly to the point where products being developed are on a nano scale and the technology more sophisticated in letting scientist understand the inner working of how the brain works to develop better products. This also results in products being less invasive than they were previously in for example restoring a patient's speech.

We need both types of technology for patients: drugs to slow or halt the progression and medical devices to improve the quality of life as the patient lives with the disease.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition, target product profile and economic value of your product for reimbursement, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.

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