October 15th, 2023

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

In this month's newsletter I will cover "Two Breakthrough Discoveries". You can find my article under the Table of Content and click on the link.

If you missed the last months newsletter on "Can a New Ultrasound Patch Spot Tiny Breast Abnormalities Early?" click here to read the article.

Save the date: I'll be speaking at the 3rd Annual International Vaccine Congress on October 23 - 25th, 2023 at the Hilton Boston/Woburn, 2 Forbes Road, Woburn, MA 01801. Click on this link to find out more about the conference and my presentation.

If you need a little inspiration or something to make us laugh to get us through this

Needs Now," and ending with Celine Dion and Josh Groban with "The Prayer".

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

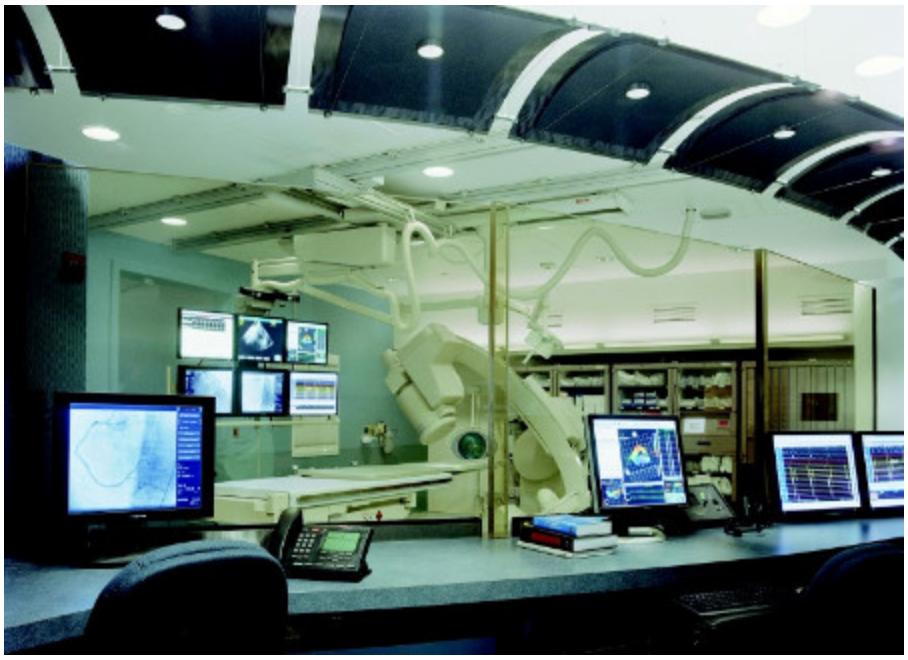
We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

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

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

Table of Contents

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 me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

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

Product Development
Market Development

Top

Save the Date: 3rd Annual International Vaccine Congress (IVC 2023) Conference on October 23 - 25, 2023 in Woburn, MA .

I am pleased to announce that I will be speaking at the IVC 2023 Conference in Woburn, MA on October 23 - 25, 2023. The title of my presentation is "Lessons Learned from the Covid - 19 Vaccine and What is Needed When Developing a Vaccine for a Successful Rollout". For more information on my presentation, click here. For more information on the conference, click here.

Top

Recap of the AAPI Heritage Festival - Saturday, May 20th, 2023

The Asian American Pacific Islander (AAPI) Heritage Festival was a success in celebrating AAPI Heritage Month with both the Asian and nonAsian communities. This celebration was to build awareness and educate our community on the various cultures and contributions the different Asian and Pacific Islanders ethnic groups have brought to enrich our American History.

Our Festival made the front page of the Daily Times Chronicle. See the article and pictures of our speakers, musicians and performers. In addition, we had our "Contributions AAPI Have Made to American History" Exhibit on display in the lobby and continued on into the program room. More pictures will be revealed next month.

Guest Speakers: Massachusetts State Representative Vanna Howard
Mayor Scott Galvin of Woburn
Special Guest Musician: Kevin So
Guest Musician: Entian Lee, Chinese Zither
Guest Performers: Swasti Bhargava & Aanvi Bhargava, Ekam Boston
Anvee Gudipati, Sreshta Mahavadi, Ekam Boston

Home Delivery $1.00 FRIDAY - May 26, 2023 Home

Serving Burlington • Reading • Winchester • Woburn

City Council seeks more info on fil

By PATRICK BLAIS

WOBURN - The City Council wants to consult with the city engineer's office and other department head managers before allowing a Lowell Street landowner to spread out fill in a low-lying depression.

During the elected officials' latest gathering in City Hall, Boxford resident Valentino Tocci Jr. explained that he is looking to bring in more than 100 cubic yards of fill to the back yard of a two-family property at 2 Lowell St., which sits in the city's Central Square area by Main Street.

The council, looking for additional details about the total volume of soil and rocks being brought in and

Lowell St

how the work will i
the site, ultimately
6 meeting.

According to T
nearby professiona
proximate .61-acre
towards that comr
towards Cumming
portedly does not
topography of the
significant storm e

"This is mostly
issue. Since that
unsightly area. O
in that area and m
plained.

"We would ther
still accept rainwa
uation," he contin
likely also be plan

Since the speci
month, both Assis
and Planning Dire
the council cited
water storage volu
situation on abutt

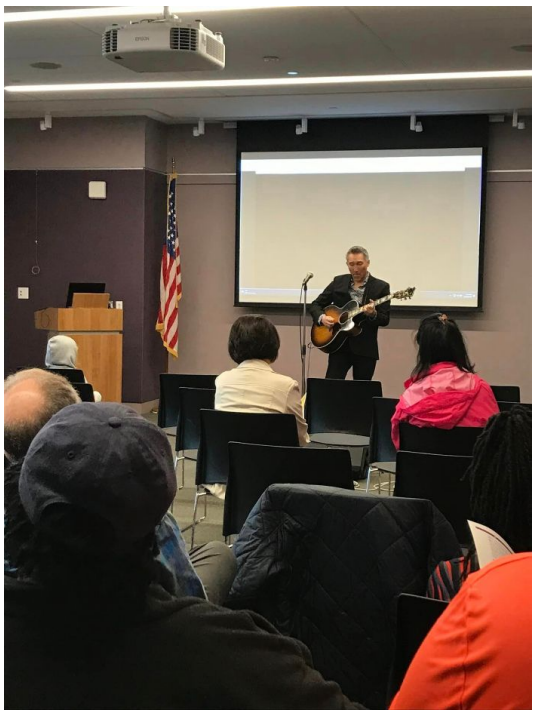
In order to be s
ect doesn't create
experts recomme
ing firm to consul

"There is no ou
shape, other than
soil. Depending o
remain in this
Rheaume noted i

LOWE

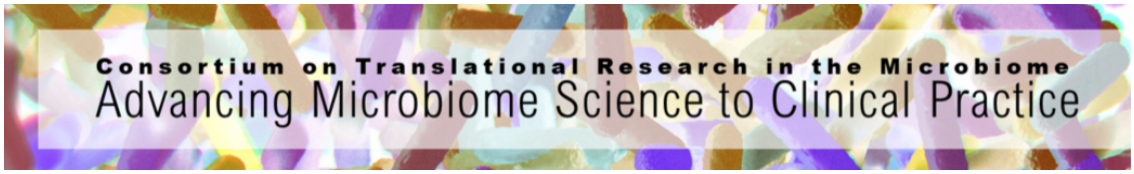
THE ASIAN AMERICAN PACIFIC ISLANDERS HERITAGE FESTIVAL was held at the Woburn Public Library with many posters describing the contributions made to American history. Volunteers and participants in the AAPI Heritage Festival included (l-r) Katherine Jiao, Vicky Wu, AAPIEC Inc. President Regina Au, and Ekam USA-Boston Chapter Director Nagasree Chakka. Some of the entertainment were dancers and musicians inside the library along with food vendors set up outside in the library's parking lot . (KAPAndrewsPhotos)

Board adopts - Burlington middle school ...




Asian American
and Pacific Islander
HERITAGE FESTIVAL

Top



General Guidelines to Launch and Build a Clinical Trial Using Microbiome Products in an Era of Personalized Medicine.

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 Westchester Biotech Project and future webinars, click here.

Top

Inspirations

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

The Pandemic is NOT Over, But We Will Get Through It Together By Taking COVID Precautions: Masking, Regular Testing, Updated Vaccinations and Practice Good Hygiene Every Day.

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

Top

Lioness
FOR THE FEMALE ENTREPRENEUR

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 here.

Top

Two Breakthrough Discoveries

Recently there has been new innovative technologies such as the "New Ultrasound Patch to Detect Tiny Breast Abnormalities Early for diagnoses, and now two (2) discoveries that have stumped scientist for years.

Discovery One:

Scientists in the UK and Belgium think they have figured out how brain cells die in Alzheimer's disease. It has been a mystery and a source of scientific debate for decades. They have found a connection between the abnormal proteins, amyloid and tau that build

It is known that the loss of brain cells or neuron lead to the symptoms of Alzheimer's, including memory loss. Researchers at UK's Dementia Research Institute at University College London and KU Leuven in Belgium state that abnormal amyloid starts to build up in the spaces between neurons, causing inflammation, and in turn starts to change their internal chemistry since neuron don't like inflammation.

Tangles of tau appear and the brain cells start producing a specific molecule, MEG3 that triggers death by necroptosis. Necroptosis is one of the methods our bodies normally use to purge unwanted cells as fresh ones are made.

When the team were able to block MEG3, the brain cells survived.

"This is a very important and interesting finding," said researcher Prof Bart De Strooper, from the UK's Dementia Research Institute.

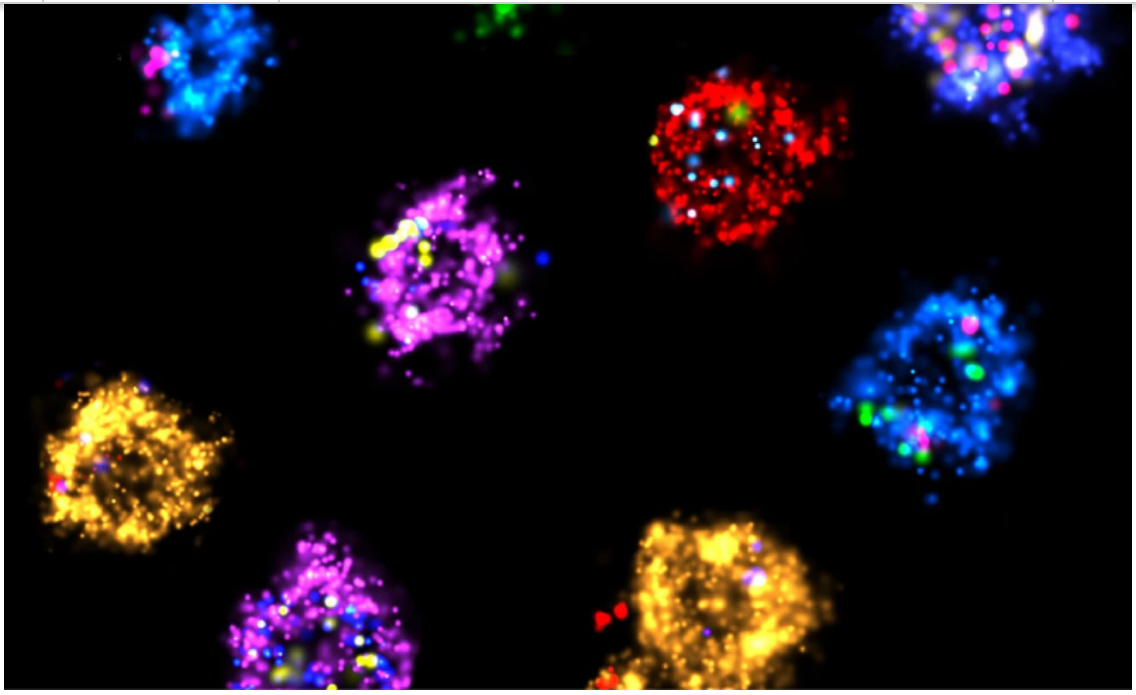
"For the first time we get a clue to how and why neurons die in Alzheimer's disease. There's been a lot of speculation for 30-40 years, but nobody has been able to pinpoint the mechanisms.

"It really provides strong evidence it's this specific suicide pathway."

Prof De Strooper said that the discovery that is blocking the MEG3 molecule can hold off brain cell death could lead to a "whole new line of drugs development". But this will take years of research.

Prof Tara Spires-Jones, from the University of Edinburgh and the president of the British Neuroscience Association, said it "addresses one of the fundamental gaps in Alzheimer's research… these are fascinating results and will be important for the field moving forward."

However, she stressed that "many steps are needed" before knowing whether it could be harnessed as an effective treatment for Alzheimer's.



Tiny bubble-like packages called extracellular vesicles purified from human skin cells. Credit: ONI (Oxford Nanoimaging)

Discovery Two:

Graça Raposo, a scientist from the Netherlands demonstration that extracellular vesicles (EVs, also known as exosomes) might be transmitting information between cells. “We knew that exosomes existed, but at that time they were generally thought to be a way of getting rid of a cell’s trash,” says Raposo. “It was exciting to find that some could have important biological functions — even if not everyone believed it at first.”

Raposo, together with her colleagues at the Curie Institute in Paris, found that exosomes derived from anti-tumor immune cells could be enlisted to suppress cancers in mice.

In 2007, research in this area exploded when researchers discovered that the little packages could contain not only proteins, but also nucleic acids or small RNA molecules. This implied that exosomes might influence gene expression when they reached their destination cells.

Some researcher demonstrated that EVs might be responsible for cancers spreading in the body, or could even be involved in the ageing process. Further research revealed that exosomes could be classified into different classes. Exosomes, with a size range of 30–150 nanometres, are the smallest class. They are produced by machinery inside the cell that traffics molecules and particles to where they need to be. Exosomes are held in larger

Ectosomes pinch off from the edge of the main cell membrane (see Figure 1 on how exosomes and ectsomes travel).

Extracellular vesicles such as exosomes and ectosomes are made in different ways. Exosomes are produced by the cell's internal machinery and loaded into large bubbles. These vesicles are then released at the cell's boundary by exocytosis. Ectosomes are instead 'pinched off' from the membrane. Once a vesicle reaches a recipient cell, it can be taken in by being swallowed, by binding to receptors or by fusing to the membrane.

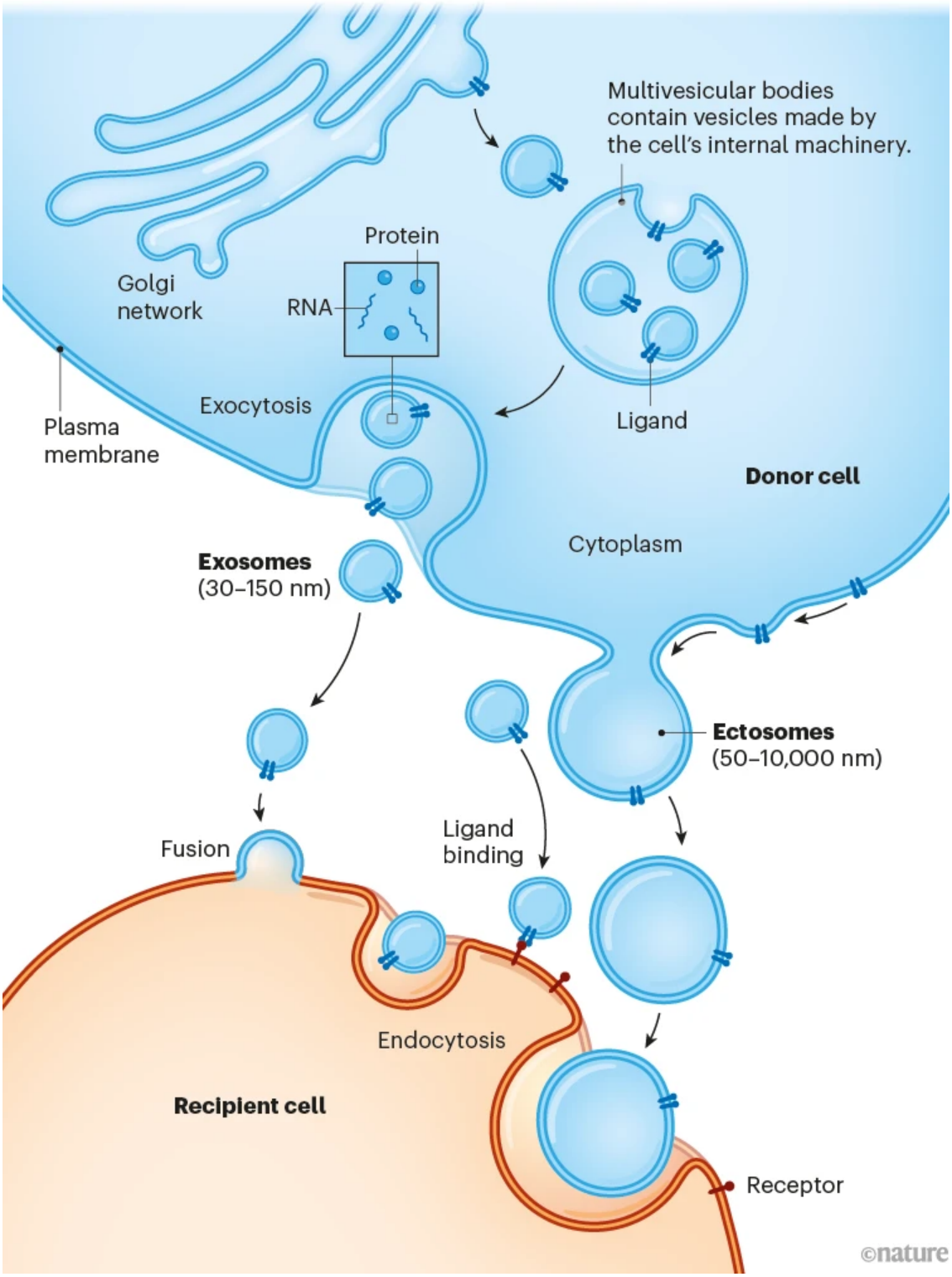


Figure 1: How exocomes and ectosomes travel

1) Many simply carry out the cell's rubbish, by-products and toxins, for instance — and send some of it to the liver for breakdown;

2) Others communicate with cells in the same or different tissues;

3) Some vesicles communicate through signaling molecules on the cells' surface (which Raposo discovered with immune cells);

4) Others do so by entering cells and delivering their cargo internally;

5) Yet, others could be involved in indirect communication such as releasing their contents outside the cells to create a supportive environment for themselves.

It is known that EVs regulate a wide range of physiological processes, from triggering an immune response to maintaining cellular equilibrium in healthy cells. It is hypothesized that EVs from diseased cells might help to spread the disease. For example, EVs from tumor cells carry cancer-promoting proteins and RNA molecules to other sites in the body and metastasize. In neurodegenerative diseases, those associated with misfolded proteins, such as amyloid-β, tau and α-synuclein in Alzheimer's, scientists suspect that EVs secreted by neurons might be responsible for spreading these proteins — and therefore the disease — across the brain.

This inspired many researchers to develop EVs as a delivery system to get proteins and molecules into the cell to treat diseases. Using EVs has important advantages over using whole stem cells for therapy, but EVs has its own challenges in delivering the genetic therapy to the right cells in the right tissue. You will find more details regarding these challenges in the original article.

In 2019, the FDA for the first time granted access to an accelerated approval process for an EV-based diagnostic test, a urine test for prostate cancer developed by Exosome Diagnostic and blood plasma test known as TauSome developed by Exosome Sciences that detects tau protein that is associated with EVs to diagnose chronic traumatic encephalopathy, a neurodegenerative brain disorder that results from repetitive head trauma.

As exciting as this field maybe, to validate this technology in making sure that the treatment is efficacious and safe, there must be standards or regulations in place. However, clinics have been sprouting up around the world offering EV treatments for various conditions, from cosmetic to the life-threatening. "This is all happening without any evidence of safety or efficacy," says stem-cell biologist Darius Widera at the University of Reading, UK.

unproven therapies, which it says could be contaminated or simply ineffective and a waste of money. In 2019, the FDA put out a statement warning of the dangers after several people in Nebraska had serious adverse side effects, including sepsis, following treatment with exosomes. Clinics that claim that they do not need to be regulated are “simply untrue”, said the FDA.

Top

Closing Thoughts

Scientific research takes a long time to make any significant discovery, but once scientists make these discoveries, it can propels the field forward tremendously and be classified as breakthrough discoveries or technologies. Case and point with the CRISPR and mRNA technology, and now the two discoveries I covered in this newsletter.

In addition, the tiny ultrasound patch that could possibly detect microscopic breast cancer covered in last month newsletter could be a game changer in detecting breast cancer very early so treatment can be started in preventing it from progressing. In the long run, it can save the healthcare system money particularly since there are unknown genes that can cause breast cancer that scientist has yet to discover.

Top

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 508-846-9094 or regina@biomarketinginsight.com.
