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October 15th, 2022

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Hope everyone had a great Columbus Day Weekend. Fall is here and activities are resuming again.

This month I will cover "Another Crack at NASH and How is the Liver Involved with Other Diseases?". To read this article, go to the Table of Content and click on the link.

If you missed last month newsletter on "BCI, Why Are Companies Pursuing this Market?", click on this [link](#) to read the article.

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

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Needs Now," other inspirations 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, 2022

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](#)

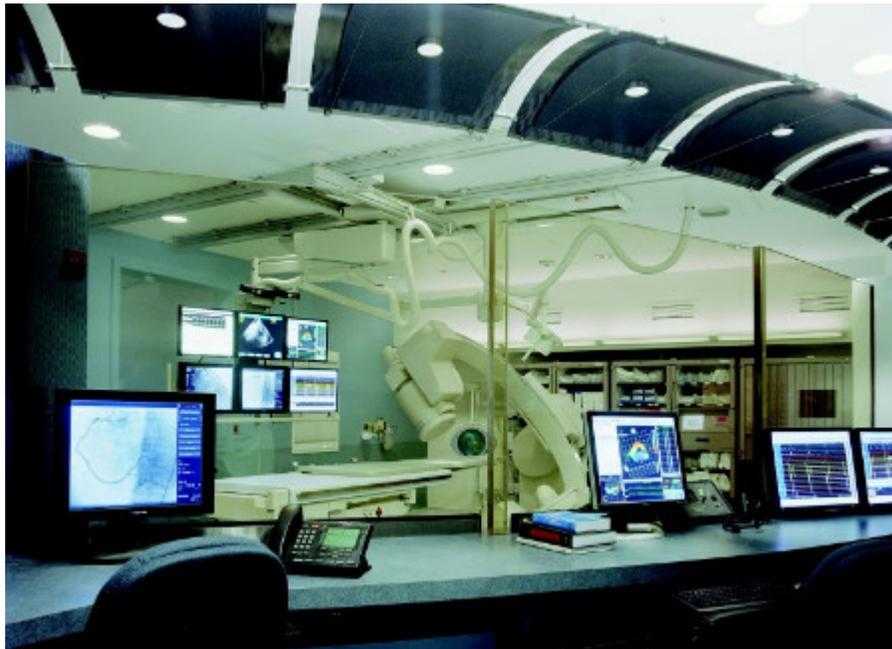


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Developing a Product? Commercializing a Product?

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](#)

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See Photos of the AAPI Heritage Festival - Saturday, May 7th, 2022

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.

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was on display.

The Festival was a huge success with a full agenda of speakers, including State Senator Cindy Friedman and fireside chats with [Shirley Leung](#) from The Boston Globe. We also had a full agenda of performers throughout the festival. We had [Tibetan dancers](#), [Cambodian dancer](#), [Japanese dancers](#), [Lion dance](#), Kung Fu demonstration and many [solo performers](#) playing traditional ethnic instruments. Click [here](#) for the full agenda.

In addition, we had exhibitors from the various ethnic groups displaying items representing their history and culture that complemented the contributions that AAPI have made to American History.

This is AAPI Heritage month, be sure to enjoy all the activities in your area celebrating the diverse group of ethnic heritage within the AAPI community who bring a wealth of enriched culture to our society and American History. It may surprise you the tremendous amount of people who have contributed to our society and American History.

I would like to leave you with this **one thought** "while everyone is unique in their own way, it is important to celebrate our differences and our commonalities. Every person has a vital contribution to make to society - all races, all ethnicities, all religions and all genders together form one human race.

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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 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](#).



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 [here](#).

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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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Lioness
FOR THE FEMALE ENTREPRENEUR

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

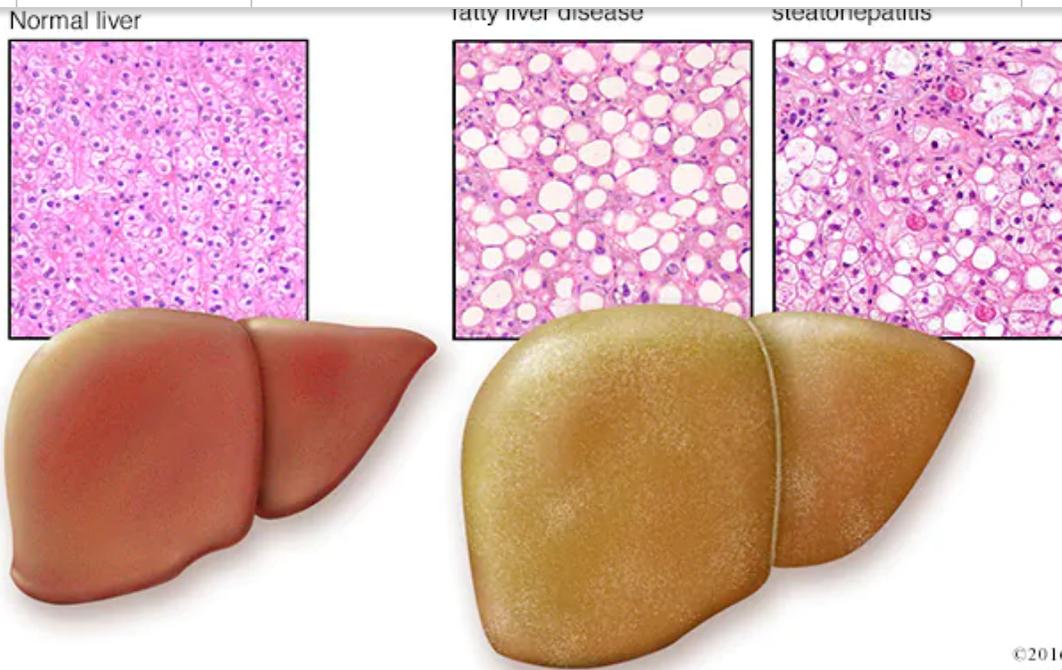
I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link [here](#).

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Another Crack at NASH and How is the Liver Involved with Other Diseases?

Nonalcoholic fatty liver disease

Compared with a normal liver (left), a fatty liver (right) appears enlarged and discolored. Tissue samples reveal fat deposits in nonalcoholic fatty liver disease, while inflammation and advanced scarring (cirrhosis) are visible in nonalcoholic steatohepatitis.

Source: Mayo Clinic

The liver is the largest solid organ in the body. It [removes](#) toxins, waste products, foreign substances-- bacteria, drugs and alcohol from the body's blood supply, maintains healthy blood sugar levels, regulates blood clotting, and performs over 500 vital functions such as produce bile, a fluid that helps digest fats and carry away waste, stores significant amounts of vitamins A, D, E, K, and B12, metals such as iron and copper, and create essential nutrients.

Nonalcoholic fatty liver disease ([NAFLD](#)) is a condition in which excess fat builds up in your liver. This buildup of fat is not caused by heavy alcohol use. When heavy alcohol use causes fat to build up in the liver, this condition is called [alcohol-associated liver disease](#). NASH is the form of NAFLD in which you have inflammation of the liver and liver damage, in addition to fat in your liver. The inflammation and liver damage of NASH can cause fibrosis, or scarring of the liver. NASH may lead to [cirrhosis](#), in which the liver is scarred and permanently damaged. Cirrhosis can lead to liver cancer.

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clinical trials. [Pfizer](#) most recently joined the list of pharmas to call it quits on their NASH project, joining the likes of [Bristol Myers Squibb](#), [Intercept](#) and [Metacrine](#).

But the industry has not given up hope. A collaborations between Alnylam and Regeneron discovered how specific genetic mutations on the CIDEB (Cell Death Inducing DFFA Like Effector B), a Protein Coding gene that is highly expressed in the liver is associated with reductions in liver disease, including NASH.

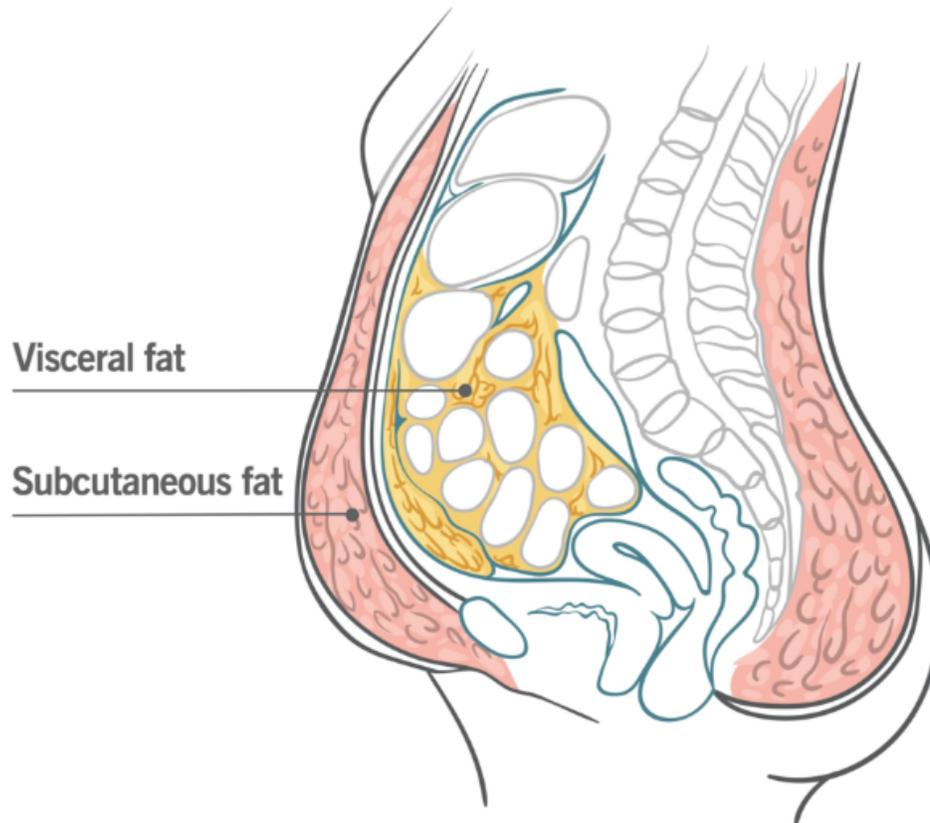
The findings was revealed from a genetic analysis conducted by the [Regeneron](#) Genetics Center of more than 540,000 people. The scientists launched a multistep process of linking genetic clues with disease likelihood.

Through this analysis, [four genes](#)—APOB, ABCB4, SLC30A10 and TM6SF2—were shown to be linked with liver disease. In contrast, tweaks to the CIDEB gene appeared to have a protective effect against liver disease. The association with protection was even stronger against NASH specifically, showing that people who had loss-of-function mutations in one of two copies of CIDEB had a 53% risk reduction for NASH. One important qualifier of the results is that they suffer from a persistent lack of diversity seen in other genetic sequencing studies; the researchers flagged that 96% of genes sequenced were from volunteers of European ancestry.

The researchers also challenged human hepatoma cell lines with oleate, a type of fatty acid, to see how inhibiting the gene impacted the cells. When CIDEB expression was knocked down using siRNA, lipid buildup was prevented.

Luca Lotta, M.D., Ph.D., head of cardiometabolic and musculoskeletal disease genetics at Regeneron, [called the findings](#) a “milestone” in the understanding of the genetic foundation of the disease, which is now informing the company’s own pipeline. The drugmaker already has one phase 1 drug aimed at NASH—HSD17B13—developed in collaboration with Alnylam.

"The unprecedented protective effect that these CIDEB genetic variants have against liver disease provides us with one of our most exciting targets and potential therapeutic approaches for a notoriously hard-to-treat disease where there are currently no approved treatments," said [Aris Baras](#), M.D., head of Regeneron’s genetic center.



Source: Theconversation.com

Another disease tied to mutations in the liver

Amylam is also looking at another rare mutations expressed by the liver call the INHBE (*Inhibin Subunit Beta E*) gene, a growth factor that belongs to the transforming growth factor- β (TGF- β) family, predominantly expressed in the liver. [INHBE](#) is involved in the regulation of liver cell growth and differentiation that are tied to a lower waist-to-hip ratio adjusted for body mass index, which is used as a surrogate measure of abdominal fat and has been linked to [type 2 diabetes and coronary heart disease](#).

The researchers confirmed their thesis, when they noted a higher expression of INHBE in the livers of obese monkeys compared to lean monkeys.

“The results of this exome-wide analysis suggest that targeting INHBE is predicted to have broad beneficial effects on all facets of metabolic syndrome with potential reductions in the risk of type 2 diabetes and coronary heart disease,” Paul Nioi, Ph.D., Vice President of Discovery and Translational Research at Amylam and leader of the company’s Human Genetics Group, said in [a statement](#).

Alnylam and its collaborators searched the database for gene variants associated with a lower waist-to-hip ratio adjusted for body mass index. Their [analysis](#) revealed that a faulty INHBE gene, seen in one in every 587 individuals on the database, was a factor that contributed to a healthier distribution of fat around the body.

In vitro tests showed that the most common variant caused a loss of INHBE function linked to around a 90% reduction in levels of a secreted protein called activin E. Further analysis of individuals with this gene variant then revealed they had a favorable metabolic profile, including lower levels of triglycerides (bad fat due mostly to diet) and increased high-density lipoprotein cholesterol (HDL - good cholesterol), and decreased fasting glucose or sugar.

“Importantly, by reducing abdominal fat, drugs targeting INHBE would have a distinct biological mechanism to existing drugs for coronary heart disease and type 2 diabetes and may complement current therapies,” [Alnylam](#) concluded in its study results.

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Closing Thoughts

Humans can't survive without a liver. Fortunately, the liver is the one organ in the body that can [regenerate](#), replace lost or injured tissue. When a patient's liver completely fails due to disease, a transplant is needed. The donor's liver will soon grow back to normal size after surgery. The part that the recipient receives as a new liver will also grow to normal

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This is the reason, so many companies have invested so much time and money to find a treatment for liver disease particularly NASH. Since the liver is responsible for over 500 vital functions it is no surprise that the liver is involved with many other diseases. However, because the liver is a vital organ, figuring out how the liver is involved can be very complicated.

Despite a number of NASH failures, I'm glad the industry has not given up but taking a break to regroup and start fresh.

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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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