Speaker Stories

Manuel Vega: AGS

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Could you introduce yourself and tell us about your company's unique mission in the exosome space?

I am a biologist with a PhD, a scientist by education and at heart. Life is long and full of adventures. I've been a fellow and researcher at CONICET (Argentina), Würzburg University (Germany), Hosp. Henri Mondor/INSERM (France), and TNO (Netherlands), specializing in molecular virology and gene therapy.

After 10 years of scientific research, I transitioned to entrepreneurship in biotechnology 25 years ago. I co-founded and served as CEO of Nautilus Biotech (France) and Nautilus Technologies (USA), a biotech company dedicated to second-generation therapeutic proteins. Nautilus successfully closed four rounds of VC investment and signed out-licensing deals for its products with global leaders such as Aventis Pasteur (France), Serono (Switzerland), Wyeth (USA), and Hanall Pharmaceuticals (South Korea). Before Nautilus, I was Director of Development & Production at Genethon (France), during the time Genethon began focusing on gene therapy. I am also a co-founding partner at Markets & Listing, a *bureau d'études* dedicated to assisting companies in the life sciences and health sectors.

In 2020, I co-founded AGS Therapeutics, a preclinical-stage biotech company pioneering the use of microalgae extracellular vesicles (MEVs) as a universal delivery system for innovative biologics, vaccines, and gene therapies. I have been AGS's CEO since then, and it has been a scientific and entrepreneurial love story.

So, what is AGS? AGS Therapeutics, based in Paris and Genopole (Evry, France), is a biotechnology company in the human health and biomedicine sector, specifically focused on the development of MEV technology and therapeutic, vaccinal, or gene therapy products delivered by MEVs.

The specificity of our platform technology lies in the delivery system (MEVs), which is highly competitive across a relevant list of parameters compared to other more established delivery systems like lipid nanoparticles (LNPs), AAV viral vectors, or any other extracellular vesicles (EVs), whether mammalian- or plant-derived. MEVs are derived from a particularly interesting unicellular microalgae, Chlorella. Chlorella is a living fossil that appeared on Earth two to three billion years ago, meaning its existence predates any higher plants or animals. We believe this gives the microalgae certain properties that allow its extracellular vesicles to traverse the body and overcome barriers without being detected. This feature is unique among known delivery systems: the vesicles can be transported through distinct routes and enter specific tissues where other systems cannot.

Other astonishing properties include their biocompatibility (non-toxic, non-immunogenic), ideal biodistribution, tissue/cell tropism, and clearance. Thus, the difference between MEVs and other delivery systems isn't about degrees or marginal optimization but a difference in kind: our vesicles can do things that are, again, unique.

AGS Therapeutics is literally pioneering the use of microalgae extracellular vesicles (MEVs) as a universal delivery system for innovative biologics, vaccines, and gene therapies. AGS has demonstrated that MEVs are a safe, targeted, and highly versatile delivery system for RNAs (mRNA, siRNA, miRNA), DNAs (oligos, plasmids), proteins, and peptides, which are relevant to a broad range of human diseases.

The company has two lead therapeutic candidates in development, both addressing multi-billion-dollar markets with significant unmet needs:

- **AGS-1010** for wet age-related macular degeneration (wAMD), with a potential breakthrough in topical administration (eye drops) that could significantly improve patient comfort and compliance compared to the current standard of care (injections into the eye).
- **AGS-2010** for inflammatory bowel disease (IBD), offering a non-systemic oral treatment option.

Manufacturing is another aspect that stands out when comparing MEVs with alternative delivery systems. MEV manufacturing is simple, cost-effective, sustainable, and scalable. MEV production requires only water, light, and minerals—no need for animal components or organic solvents. Within the orbit of AGS Therapeutics is AGS-M, the company's CDMO subsidiary, which produces the MEVs needed to support R&D for AGS and its partnering companies. AGS's MEVs are easy to manufacture in large quantities using eco-friendly and scalable processes, and Chlorella biomass is labeled by the FDA as GRAS (Generally Recognized As Safe) for consumption as a food supplement.

Through strategic partnerships and a commitment to scientific excellence, AGS aims to challenge the delivery landscape and improve the lives of patients across the globe.

What was the pivotal moment or discovery that sparked your personal interest in EVs?

Five years ago, my teammates and I were consulting for a French governmental institution that had asked us to evaluate about 150 patents produced by academia. During this process, we identified one patent that was particularly striking, proposing the use of extracellular vesicles from Chlorella algae to deliver siRNAs. We recognized this as a once-in-a-lifetime opportunity—one whose potential couldn't be ignored, both medically and economically.

We decided to secure an exclusive license for that patent and created AGS. That's how the story began. We then expanded the intellectual property to cover every corner. We were four founders with complementary profiles, most of us having worked together for decades in previous ventures—a solid team that has weathered many storms. We later added new team members with complementary expertise, particularly oriented toward the U.S., as that is the market we are targeting.

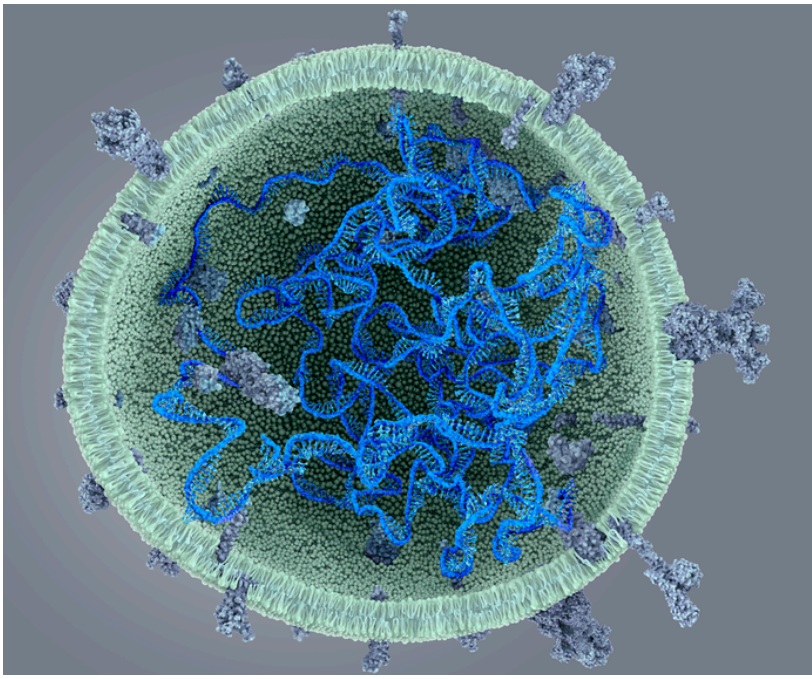
What did we see? Unlike other systems (mammals, including humans) whose development was—and still is—limited by the complexity of mammalian cell cultures, industrial manufacturing of Chlorella had already been ongoing for several decades, making MEV culture easily scalable.

Moreover, while most analogous research focused on the specificity of EVs with native surface markers, MEVs lacked most—if not all—of the canonical and later-developed surface markers found in mammalian or plant EVs. This feature seemed to have the potential to express behavioral versatility.

From then on, every learning step regarding MEV behavior has exceeded our initial expectations. We've been able to load them with any modality we wanted and deliver the loaded vesicles through different routes of administration. For example, orally administered MEVs can pass through the stringent barriers of the mammalian stomach and intestine, deliver an mRNA payload to intestinal epithelial cells, and then express that mRNA to produce the related protein—something no one has demonstrated so far via the oral route.

Another example is how MEVs can "easily" enter the brain: by intranasal administration (a couple of drops of vesicles in the nose), we can enter olfactory neurons without passing through the blood and reach specific parts of the brain relevant to a long list of brain diseases. MEVs can also overcome the retinal barrier, delivering payloads to retinal cells via drop instillation on the eye surface, avoiding the invasive alternative of eye injections.

The cherry on top is that MEVs can be manufactured in large amounts using bioprocesses that require few natural resources (water, light, salt), making them wasteless, riskless, and cost-effective. This ultimately means they can be accessible to patients and sustainable.



From your perspective, what is the single biggest hurdle (be it in manufacturing, clinical translation, or regulation) that the EV field must overcome to realize its full potential?

With distinctive origins (biological kingdoms) shaping their specific biochemical, behavioral, and manufacturing properties and limitations, I wouldn't consider the EV field a unified category of delivery systems.

Instead, I will focus on the kind of EVs we are working with (MEVs) and discuss their interesting particularities, as they represent a fundamentally new class of biogenic biodegradable nanoparticles with unique properties, biocompatibility, scalable production, and sustainable sourcing. Currently at a preclinical stage of development, our MEV technology carries two potential breakthrough innovations. The first concerns the MEVs themselves as a delivery system: biodegradable, universal, and with unique features. The second concerns the manufacturing of MEVs: sustainable, simple, cost-effective, and safe, along with the versatile loading of MEVs for all modalities. If we consider this singular array of features particularly relevant to the field of delivery systems, these innovations could represent a major advancement in biopharmaceutical development.

AGS has advanced the MEV platform (technology and product candidates) by demonstrating safety and efficacy through both in vitro and in vivo studies. These studies have confirmed that MEVs deliver payloads to the correct cellular compartments, where they are expressed and achieve the desired biological activity. Furthermore, consistent data across relevant animal models, including both healthy and disease-simulated conditions, validate the therapeutic effect of loaded MEVs in relevant environments. Confirmatory studies are currently underway. This performance highlights the platform's readiness for regulatory preclinical studies, with promising potential for further clinical testing. From this perspective, the challenge ahead consists of demonstrating the clinical non-toxicity and effectiveness of MEV technology through the upcoming Phases I and II.

Looking ahead, what innovation or breakthrough on the horizon are you most excited about, and how do you see it transforming the development of EV therapies in the next 3-5 years?

EV therapies are, again, diverse in features and limitations, so I will contain my enthusiasm within the innovations powered by MEVs only.

Based on the data obtained from (1) biodistribution studies of MEVs following different routes of administration in vivo (oral, respiratory, intranasal, topical-ocular, intravenous, intramuscular) and (2) functional data on the delivery and expression of different payloads and modalities, AGS has identified a number of focus areas of medical interest for MEVs, which we call Verticals.

These Verticals are: Ophthalmology, Bowel Diseases, Vaccines, Gene Therapy, CNS Disorders, and Respiratory Diseases. Each Vertical represents a somewhat homogenous biological system within the body, meaning a limited number of organs and tissues, as well as specific morphological and physiological determinants and responses, biological barriers, and levels of exposure, tolerance, and sensitivity.

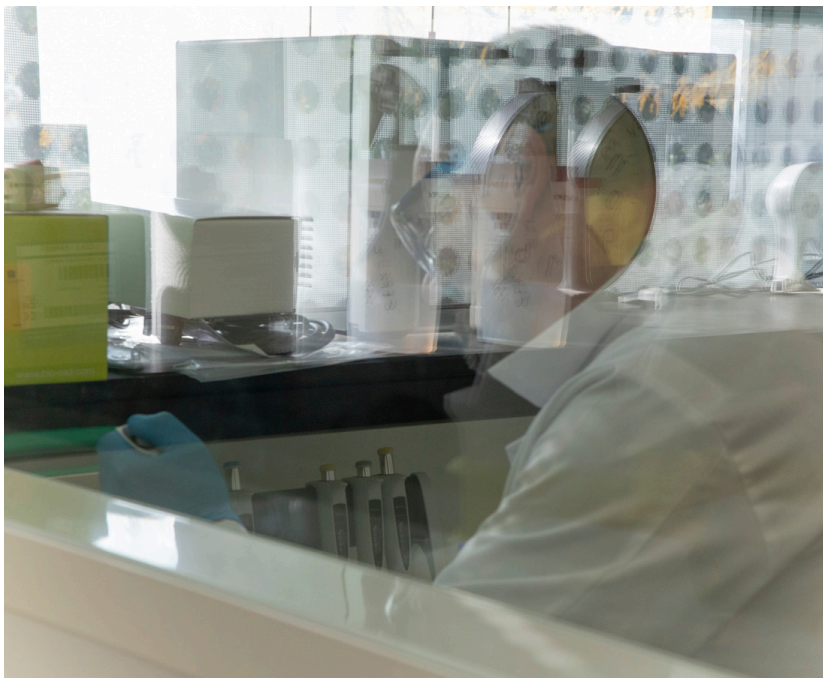
What this actually entails is that each Vertical can be efficiently targeted by a specific route of administration:

- **Ophthalmology** by suprachoroidal injection or drop instillation
- **Bowel Diseases** by oral administration.
- **Vaccines** either by oral-intestinal administration or intramuscular administration
- **CNS Disorders** by intranasal administration
- **Respiratory Diseases** by intratracheal administration or nebulization

Verticals are therefore a biologically relevant means for structuring and focusing our internal research, external collaborations, and further development work.

We are very excited to have two programs (AGS-1010 and AGS-2010) moving toward regulatory preclinical stages—our two lead therapeutic candidates in development—as well as a program (VDS) in partnership with Sanofi.

- **AGS-1010** is designed for wet age-related macular degeneration (wAMD), with a potential breakthrough in topical administration (eye drops) that could significantly improve patient comfort and compliance compared to the current standard of care (injections into the eye)
- **AGS-2010** targets inflammatory bowel disease (IBD), offering a non-systemic oral treatment option



As a baseline idea, AGS products consist of a highly specific payload encapsulated inside a generic MEV. In this way, regardless of the nature of the payload, a MEV traveling through a particular route of administration (whether the olfactory tract in the brain, the digestive tract, the airways, or the eye) remains a generic MEV.

Furthermore, such a MEV will display a specific pattern of tolerance and biological interaction with the surrounding tissues that is expected to be simultaneously (1) particular to each route of administration and (2) independent of the payload.

By following these Verticals and their biologically relevant routes of administration, we can support the view that forward drug development does not need to be limited to or primarily focused on the intravenous route of administration. Intravenous delivery exposes the entire body to the drug, leading to undesired and potentially systemic side effects, and presents many intrinsic obstacles, such as first-pass metabolism in the liver, the blood-brain barrier to access the brain, and filtration in the kidneys, among others. Instead, we can develop biosystems (the MEV carrying the active principle or payload) that are friendly to the logic of the human body—biomedicines that are compliant and accessible to the patient.

Without giving too much away, what is the key takeaway you hope the audience will get from your specific presentation at Exosomes Europe?

My most honest aim is to disseminate the knowledge I have about this technology to other researchers and professionals in the field. I will present what we regard as exciting and major about AGS's ongoing research, as well as our vision, which is to foster a paradigm shift in the field of drug delivery.

We wish to unlock the full medical potential of MEVs, as they may offer solutions to critical and yet unsolved challenges, potentially benefiting a wide spectrum of diseases.

Congresses and events such as **Exosomes Europe** are key to extending our circles of data, thinking, and expertise, and making them intersect.

What are you most looking forward to at the meeting in Amsterdam?

I am eager to weave alliances beyond competitive interests to build a community around the development of MEVs as an alternative and universal delivery system for innovative biologics, vaccines, and gene therapies.

AGS will be joining us at Exosomes Europe this November in Amsterdam. Register Now.

AGS

Extracellular Vesicles from Microalgae, their Use For Vaccines and For Immunomodulation - PTC