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Therapeutic Delivery

September 2019 therapeutic delivery update

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Financial

Development milestone triggers $10 million payment for DURECT

DURECT Corporation (CA, USA) announced on 9 September 2019 that a long-acting injectable HIV investigational product, employing its proprietary SABER® technology, has triggered a $10 million milestone payment from Gilead Sciences (CA, USA). Under the terms of the collaborative agreement, which was signed in July 2019, Gilead was granted the exclusive worldwide rights to develop and commercialize a long-acting injectable HIV product using the SABER technology; an initial upfront payment to DURECT of $25 million was also part of the deal. It is possible that achieving further milestones could trigger up to an additional $65 million as well as up to an additional $70 million in sales-based milestones and tiered royalties on product sales. The agreement also allows Gilead exclusive access to the SABER platform for development of therapeutics for the treatment of HIV and Hepatitis B virus.

DURECT's SABER proprietary technology is based on sucrose acetate isobutyrate and is a platform for developing extended-release, injectable formulations by allowing the active virus to be delivered in a biocompatible matrix depot [1].

Polypid raises $50 million

The Israel-based company Polypid (Petah Tikva, Israel) announced on 5 September 2019 that they had successfully raised $50 million in Series E1 funding, which they intend on using for the development of its pipeline and top conduct, two Phase III, pivotal registration trials of its lead product, a doxycycline conjugate based on the company's proprietary PLEX™ (Polymer-Lipid Encapsulation matriX) platform.

The PLEX platform is based on a matrix made of alternating layers of lipids and biocompatible polymers that encapsulate a therapeutic candidate between them and form a protected reservoir that facilitates localized drug delivery at the target site. The company is developing a range of doxycycline products for the treatment of surgical-site infections [2].

BrightInsight raises $25 million for its connected health software tool

Brightinsight (CA, USA), a spin-off from the medical device manufacturer Flex (CA, USA) announced on 11 September 2019 that it had raised €25 million for Series A funding, to enable the development of its novel software. The software has been designed to enable pharmaceutical and medtech companies' devices and drug-delivery systems to communicate with each other. The company has engaged with the Federal US FDA and other regulatory bodies to ensure that the technology created is regulatory compliant. Some early adopters of the technology include global pharmaceutical companies, such as Novo Nordisk (London, UK) and Roche (Basel, Switzerland). Novo Nordisk has selected BrightInsight to be its global digital health partner, in the development innovative for diabetes-care products. BrightInsight has collaborated with Roche on the development of a novel web-based dosing calculator to treat patients with hemophilia A [3].

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Collaborations & agreements

REGENXBIO to evaluate Clearside's delivery platform for gene therapy candidate

On 4 September 2019, REGENXBio Inc (MD, USA) announced an option and license agreement for exclusive worldwide rights to Clearside Biomedical Inc.'s (GA, USA) proprietary micro-injector delivery platform, for the delivery of REGENRXBio's RGX-314. RGX-314 is a novel, one-time sub-retinal treatment, which treats wet age-related macular degeneration (AMD), diabetic retinopathy and other indications. Clearside's SCS Microinjector™ has been developed for in-office and nonsurgical delivery of therapeutics into the suprachoroidal space.

RGX-314, REGENXBio's lead candidate, is in clinical trials for indications, such as wet AMD and diabetic retinopathy as well as other chronic retinal conditions that have, to date, been treated with antivascular endothelial growth factor. RGX-314 inhibits vascular endothelial growth factor by employing a NAV AAV8 vector encoding an antibody fragment. This modifies the pathway that typically leads to the formation of new leaky blood vessels that can lead to retinal fluid accumulation and, ultimately, vision loss.

Phase IIb clinical trial results, thus far, indicated that subjects with wet AMD experienced dose-dependent increases in protein expression levels across five cohorts tested [4].

Boehringer Ingelheim signs retinal disease deal with Inflammasome

Boehringer Ingleheim (Ingleheim, Germany) and Inflammasome Therapeutics Inc. (MA, USA) disclosed on 20 September 2019 that they had entered into a partnership to develop novel therapies for the treatment of retinal diseases. Under the terms of the agreement, the companies will embark on a program of work, incorporating Inflammasome's intravitreal (IVT) drug-delivery technologies with compounds from Boehringer Ingelheim's retinal disease pipeline portfolio. Under the terms of the agreement disclosed, Inflammasome can potentially receive up to $160 million up-front for R&D support and milestone payments. Additionally, the agreement contains provisions for tiered royalties based on future commercial product sales and other commercialization milestones.

At the announcement of the agreement, CR Wood, from Boehringer Ingelheim, stated *"Boehringer Ingelheim is looking forward to developing Inflammasome's novel technology for the delivery of our first-in-class retinal disease compounds working jointly with Inflammasome's highly experienced scientific team. This will enable us to develop a broad range of novel therapy options for the many patients with retinal diseases waiting urgently for better and new therapy options."*

IVT delivery platform is based on the delivery, via injection, of a long-acting degradable IVT implant to the back of the eye [5].

Wize Pharma signs a deal with Copernicus for ophthalmic nonviral gene therapy technology

Wize Pharma Inc. (Hod Hasharon, Israel) announced on 11 September 2019 that it had signed a deal with the privately held, gene therapy company Copernicus Therapeutics, Inc. (OH, USA) to allow its exclusive rights to license, develop and commercialize products based on a nonviral gene therapy technology, which was developed by Copernicus for the treatment of the rare, degenerative, inherited retinal disorder choroideremia.

Although full financial details of the agreement were not released, Wize has agreed to pay Copernicus an initial one-time license fee and royalty payments in the high single or low double digits, depending on if net sale thresholds are reached. In addition, Wize has also agreed to pay Copernicus to facilitate the completion of a Phase I/II clinical study in subjects with choroideremia.

Copernicus' nonviral delivery platform is based on vectors consisting of DNA nanoparticles (DNPs). The DNP's size (8–11 nm) allows them to diffuse safely and efficiently to the cell nucleus via the nuclear envelope. Studies presented by the company have demonstrated localization of transfected gene expression to injection sites. The company claims that the DNPs elicit fewer inflammatory, toxicity and immune responses when compared with viral vector approaches [6].

University of Maryland grants Spherix option for anthrax-based ovarian cancer drug

Spherix Inc (NY, USA) announced on 17 September 2019 that it had an option to exclusively license an anthrax-based delivery technology platform from the University of Maryland (MD, USA) for the development of PrAg-PAS for the treatment of ovarian cancer. The University of Maryland have granted an exclusive option based on its proprietary technology (currently under patent application) that modifies the anthrax toxin protective antigen to be activated by tumor cell-expressed membrane-anchored serine proteases, thus preferentially targeting cancer cells.

Discussing the option, A Hayes, from Spherix, stated that *"this invention from the University of Maryland, Baltimore is ingenious. In simple terms, they have modified the anthrax toxin so that it kills cancer cells, but not other cells. By using an elegant protein-engineering strategy, the inventors have hijacked the complex anthrax toxin-delivery mechanism to create a highly efficient drug-delivery system specific to ovarian cancer cells. In mouse models tested, the data demonstrated that tumor growth halted following treatment with PrAg-PAS and did not increase compared with the control mice. The inventors also demonstrate that the drug is well-tolerated with no obvious adverse interactions. I believe that PrAg-PAS has the potential to strongly enhance our anticancer clinical development program and we look forward to completing our diligence on this promising anticancer drug"* [7].

Nemaura Pharma & Sparsha announce exclusive strategic collaboration

On 27 September 2019, Nemaura Pharma Ltd (Loughborough, UK) announced that it was forming a strategic partnership with Sparsha USA (CA, USA). The companies have agreed to collaborate on the development and manufacture of transdermal patches and oral thin films at a commercial scale. Under the terms of the agreement disclosed, Nemaura will develop transdermal therapeutic systems up to pilot clinical manufacture scale, for third parties and internally funded programs, at its facilities in Loughborough. Sparsha USA will be the exclusive commercial-scale manufacturer of products for the USA, Latin American and Canadian markets. Nemaura Pharma has a pipeline of 20 drugs in development, of which five are formulated as transdermal patches. Financial details of the agreement were not disclosed [8].

Kiel University & Hovione to develop high-dose inhalation formulations

The Institute of Pharmacy at Kiel University (Kiel, Germany) announced on 3 September 2019 that it had entered into a collaborative agreement with the pharmaceutical company, Hovione (Loures, Portugal). Under the terms of this 3-year agreement, the institute will have access to Hovione's portfolio of large dose dry-powder inhalers to investigate novel formulation approaches for high-dose inhalation applications.

Researchers at Kiel intend to utilize Hovione's TwinMax and 8-shot inhalation devices, which are both large dose dry-powder inhalers, to develop formulations containing soft pellets and nanocrystals for high-dose dry-powder inhaler administration, using model drugs such as clarithromycin and rifampicin.

Speaking at the announcement of the collaboration, R Scherließ, from the Institute of Pharmacy at Kiel University suggested, *"In high-dose drug delivery, the key in inhaled formulation development is to create an active pharmaceutical ingredient-rich formulation, for example, with as little as possible excipients, to deliver the required therapeutic dose with the smallest amount of material as possible"* [9].

Approvals & regulatory updates

FDA approves Novo Nordisk's Oral Semaglutide, first glucagon-like peptide-1 in pill form

It was announced on 20 September 2019 that the FDA has approved Novo Nordisk's (Bagsværd, Denmark) Rybelsus, which contains semaglutide and is the first glucagon-like peptide-1 receptor agonist to be approved in a pill form. According to the company, the once-a-day pill has been approved in two doses, 7 and 14 mg, and is indicated for the treatment of Type 2 diabetes.

Speaking at the announcement of the approval, T Hobbs from Novo Nordisk explained, *"People living with Type 2 diabetes deserve more innovation, research and support to help them achieve their individual (glycated hemoglobin) goals. With Rybelsus, we have the opportunity to expand the use of effective glucagon-like peptide-1 receptor agonist therapy, by providing adults with Type 2 diabetes an oral medication, which was previously only available as an injection, to help with managing their blood sugar"* [10].

FDA clears Insulet's Omnipod DASH™ system as an alternate controller enabled infusion pump

Insulet Inc. (MA, USA) announced on 20 September 2019 that it has received clearance from the FDA for its Omnipod DASH™ system, as an alternate controller enabled infusion pump. This clears the way for the company to market its Omnipod DASH insulin management system, incorporating an automated insulin-delivery system, such as the Insulet's Omnipod Horizon™ system.

Clearance by the FDA for such a system required the company to prove that the pump was capable to reliably and securely communicate with compatible, digitally connected devices and to be capable of receiving, executing and confirming the commands issued by these devices.

Discussing the announcement of the clearance, S Petrovic, from Insulet Inc. reported *"The diabetes industry is a dynamic and evolving landscape with technological and regulatory advancements, enabling more interoperability and more patient choice in treatments and disease management. Omnipod DASH was designed with interoperability in mind and we are thrilled to provide individuals with diabetes with the choice and flexibility to manage their diabetes on their own terms. We commend the FDA's interoperability efforts and look forward to working with the Agency as we continue to deliver our robust innovation pipeline"* [11].

IntelGenx announces resubmission of RIZAPORT® new drug application

It was announced on 26 September 2019 that IntelGenx Corp (QC, Canada) has submitted a new drug application for RIZAPORT® VersaFilm® to the FDA. This is a resubmission of the product in clinical trials for the treatment of migraine and follows on from the company receiving a complete response letter from the FDA in April 2019. Issues cited in the complete response letter relate to the chemistry, manufacturing and controls section of the new drug application and although the FDA requested additional information, no new bioequivalence study was required by the regulatory authority before resubmission.

VersaFilm is a proprietary, buccal film designed to allow buccal or sublingual absorption, facilitated by rapid disintegration, without the need for water that can have the potential for faster onset of action and increased bioavailability. It allows for formulations to have an ease of administration for patients who have problems swallowing, including pediatric and geriatric patients [12].

Orchestra BioMed announces FDA breakthrough device designation for Virtue sirolimus-eluting balloon

Orchestra Biomed (PA, USA) announced on 17 September 2019 that it had secured breakthrough device designation by the FDA for its Virtue Sirolimus-Eluting Balloon (SEB) in the treatment of below-the-knee peripheral artery disease. The company indicated that this breakthrough device designation was due to Virtue SEB being a first-in-class drug/device combination product designed to facilitate the delivery of a sustained-release sirolimus formulation, which can be employed during balloon angioplasty. The sustained release profile obtained is facilitated by bioabsorbable sub-micron particles, which encapsulate the sirolimus and allow for a drug elution profile, comparable to commercially available drug-eluting Orchestra BioMed and its commercial partner Terumo (NY, USA). These companies have planned a global clinical programme to gain regulatory approval for commercial sale of Virtue SEB in multiple markets and further indications [13].

Clinical trials

Genetech announce positive Phase III results

Halozyme Therapeutics, Inc (CA, USA) announced positive results from a Phase III trial, evaluating fixed-dose subcutaneous combination of Genetech's Perjeta® and Herceptin® on 13 September 2019. The clinical trial entitled 'FeDeriCa' investigated the subcutaneous administration of Perjeta and Herceptin (in a fixed-dose combination) employing Halozyme's ENHANZE® drug-delivery technology in combination with the administration of intravenous chemotherapy. Patients with HER2-positive early breast cancer, demonstrated noninferior levels of Perjeta compared with the standard treatment of intravenous infusion of Perjeta plus Herceptin and chemotherapy.

Halozyme's ENHANZE drug delivery technology platform is based on a proprietary, patented, recombinant human hyaluronidase enzyme (rHuPH20), which acts by degrading glycosaminoglycan hyaluronan and plays a role in resistance to bulk fluid flow in the subcutaneous space. Thus, allowing for an increased level of therapeutics that can be delivered subcutaneously [14].

Vascular Therapies announces positive data in Phase II/III trials

Vascular Therapies (NJ, USA) announced on 9 September 2019 that it had received positive initial data in Phase II/III trials, using its proprietary sirolimus formulation, Sirogen™, for intraoperative, local, perivascular drug delivery. The trials aim to investigate if Sirogen can improve arteriovenous fistula outcomes in dialysis patients. The drug development program has received fast track status from the FDA and sirolimus also has 'orphan drug' designation for the dialysis of vascular access indications in both the USA and EU.

Sirogen is a novel bio-resorbable, collagen-based drug-delivery system containing sirolimus, which is implanted during a surgical procedure and provides extended release of the sirolimus. The delivery system is designed to

maintain its cylindrical shape without the need for sutures. This implant then facilitates an increase in vein diameter [15].

Biohaven completes enrollment for pivotal Phase II/III trial of Vazegepant

Biohaven Pharmaceutical Holding Company Ltd (CT, USA) announced on 19 September 2019 that it had completed enrollment for its pivotal Phase II/III trial of intranasally administered vazegepant, for the acute treatment of migraine. Intranasal vazegepant employs the FDA-approved Aptar Pharma's (Milton Keynes, UK) unidose system.

The Phase II/III trial has been designed with end points related to a reduction of migraine associated symptoms at 2 h post-dose and other clinically relevant measures including increased pain relief and the ability to return to normal functioning.

Aptar Pharma's unidose system is designed to deliver both liquid and powder formulations and has been designed to deliver small and very precise amounts of active drug in a single nasal shot. Approved by the FDA for a number of years, over 100 million units have been sold globally [16].

Early stage development

Positive preclinical results for Rapid Dose Technology's film drug-delivery system

On 12 September 2019, Rapid Dose Therapeutics Corp. (Ontario, Canada) announced early preclinical results for its QuickStrip™ technology. QuickStrip is an oral, dispersible, thin-film drug-delivery system designed to rapidly deliver therapeutics directly to the bloodstream via sublingual or buccal routes.

A bioanalytical murine study has been designed to evaluate the oral-thin film of QuickStrip and caffeine for onset time, bioavailability and effects on the central nervous system, compared with direct administration of the active ingredient into the stomach via an oral gavage.

Discussing the results of the study M Upsdell stated, *"We developed QuickStrip as a novel and versatile delivery system with many applications, including nutraceuticals and pharmaceuticals, among others. We are excited to announce the study results from University of Nevada, (Las Vegas, USA) which concluded that, for caffeine, Rapid Dose Therapeutics (RDT) proprietary QuickStrip delivery method, produced greater bioavailability compared with gavage and speed of uptake comparatively. Rapid Dose Therapeutics will continue to expand our research programs to further strengthen our unique delivery leadership position. We are committed to providing consumers in the global medical and personal product markets research-based validation that QuickStrip is a delivery system that is Quick, Convenient, Precise and Discreet™"* [17].

Ultra-long-acting tuneable biodegradable & removable controlled release implants for drug delivery

A study by researchers at the University of North Carolina at Chapel Hill (NC, USA) was reported in *Nature Communications* on 20 September 2019, which described an ultra-long-acting tuneable, biodegradable and removable polymer-based delivery injectable system, that demonstrates sustained drug delivery for up to 1 year for HIV treatment or prophylaxis. The system was studied with six antiretroviral drugs and preclinical results indicated that the drugs were released with concentrations above their protein-adjusted inhibitory concentration. It was also concluded that the formulations allowed the drug candidates to retain their physical and chemical properties upon release.

The formulation was composed of a ternary system: a biodegradable polymer (poly lactide co-glycolide), a biocompatible and water-miscible, solvent N-methyl-2-pyrrolidone and the drug in a homogeneous solution, that becomes a solid implant *in situ* when administered subcutaneously. The results indicated that it was possible to design formulations that could produce release profiles, which revealed the release of actives over periods of up to 1 year with zero order release kinetics [18].

'Nano-diamonds' as a platform for diagnostic & therapeutic approaches for neurodegenerative diseases

An article on 4 September 2019 described work carried out at the Max Planck Institute for Polymer Research (MPI-P) (Munich, Germany) to create tiny diamonds, so-called 'nano-diamonds', which could act as a platform for both the therapy and diagnosis of neurological diseases. Researchers have developed a method of coating nano-diamonds with biocompatible serum albumin. These nanoparticles can be conjugated with drugs and initial

preclinical work has indicated that the diamond-albumin-system can cross the blood–brain barrier both *in vitro* and in murine studies.

Additionally, the researchers have modified the nano-diamond structure by introducing changes to the lattice structure and creating defects that allow the nano-diamonds to be imaged using magnetic resonance tomographs, opening the possibility of the particles being utilized as a diagnostic tool [19].

Alternative viral delivery of gene therapy developed

Researchers at Wisconsin Institute for Discovery at the University of Wisconsin–Madison (WI, USA) have developed a novel nano-capsule that has the potential to deliver gene therapies. A gene-editing tool, CRISPR-Cas9, with guide RNA was encapsulated by the researchers in a thin polymer shell and resulted in the formation of a capsule approximately 25 nm in diameter. This nano-capsule can be modified by the addition of peptides and other targeting functional groups on its surface. When the nano-capsule reaches its target cell its release of its payload is triggered by glutathione. Due to their relatively short lifespan it is anticipated that the nano-capsules may reduce unplanned genetic edits. The researchers claim that the nano-capsules are capable of producing robust gene editing *in vivo* and in murine retinal pigment epithelium tissue and skeletal muscle after local administration [20].

Valeritas presents preclinical CBD Study using h-Patch™

Valeritas Holdings, Inc. (NJ, USA) announced on 19 September 2019 that data from its preclinical pharmacokinetic study of a cannabidiol subcutaneous infusion, which employed its h-Patch™ system, had been accepted for a poster presentation at the CannMed Conference (CA, USA) on 23 and 24 September 2019. Valertis' h-Patch is an FDA-approved technology already utilized in its V-Go® Wearable Insulin Delivery device, to deliver all-in-one basal-bolus delivery of insulin for the treatment of patients with Type 2 diabetes. To date over 20 million V-Go Insulin Delivery devices have been sold in the USA.

The h-Patch system has been designed to provide a continuous basal delivery rate over a period of up to 24 h via subcutaneous delivery of the therapeutic. By avoiding the first-pass effect and eliminating peak/trough variations of drug exposure, the device aims to prolong the half-life of the active ingredient delivered and minimizes the dose necessary to achieve therapeutic levels of the active ingredient [21].

Researchers improve CRISPR-Cas9 delivery efficiency

A team of researchers from the Wake Forest Institute of Regenerative Medicine (NC, USA) reported that they had successfully employed a lentiviral capsid-based bio-nanoparticle system to encapsulate a combination of the Cas9 protein and guide RNA. According to B Lu, this represents a significant advancement to the current state of the art CRISPR-Cas9, as to date, the two components had to be delivered separately. According to the article, this research builds on previously reported work by the group that developed a system capable of packaging up to 100 copies of Cas9 mRNA in each lentivirus-like particle. This encapsulation was mediated via specific interactions between aptamer and aptamer-binding proteins. The work reported that this lentiviral capsid-based bio-nanoparticle system, facilitates more efficient packaging of Cas9/single guide RNA (sgRNA) ribonucleoprotein. The researchers claim that by replacing the Tetraloop of the sgRNA scaffold with a com-aptamer, the functions of guide RNA are preserved. This modified system demonstrated fast reduced off-target rates, thus improving the efficiency of the delivery Cas9 ribonucleoproteins for transient Cas9 expression and improved genome editing efficiency [22].

Innovation Pharmaceuticals report successful formulation of oral Brilacidin tablets

Innovation Pharmaceuticals (MA, USA) announced on 16 September 2019 that its formulation partner, BDD Pharma (Glasgow, UK) had completed nonclinical studies, which demonstrated that their oral dosage form met *in vitro* specifications for selective colonic delivery of oral Brilacidin. This will allow Innovation Pharma to proceed to the first clinical trial of oral Brilacidin for the treatment of Ulcerative Colitis. It is anticipated that this trial will commence in December 2019 and will involve healthy volunteers in the UK.

The Brilacidin tablet design employs BDD Pharma's proprietary OralogiK™ technology, which facilitates controlled release of a therapeutic active agent by programmed erosion of a time-dependent barrier layer, during transit of the small intestine.

Brilacidin has recently completed a Phase II trial as an oral rinse formulation designed for the prevention of severe oral mucositis in patients with head and neck cancer. Innovation Pharma intends to proceed into Phase III clinical development for the oral rinse formulation. Also, the company recently reported positive results for a Phase II

Proof-of-Concept trial treating patients locally with Brilacidin for ulcerative proctitis/ulcerative proctosigmoiditis. Brilacidin was licensed for this indication to the company Alfasigma S.p.A. (Alfasigma, Italy) in July 2019 [23].

Delivery of RIPK4 small interfering RNA for bladder cancer therapy using natural halloysite nanotubes

Researchers from the Central South University (Changsha, China) have reported successful *in vitro* delivery of RIPK4 small interfering RNA using natural halloysite nanotubes in bladder cancer models (T24 bladder cancer cells) in an article recently published in *Science Advances*. The nanotubes are composed of halloysite, an aluminosilicate clay mineral, with the empirical formula $Al_2Si_2O_5(OH)_4$. The manufacture of these nanotubes was achieved via a process of combining a high-speed shear homogenization step followed by a two-step uniform viscosity centrifugation. The resultant nanotubes were typically in the 500 nm size range. Encapsulation of the payload was achieved when negatively charged small interfering RNA was absorbed into the positively charged lumen of the halloysites using vacuum impregnation methods.

The *in vivo* and *in vitro* data presented suggests that the encapsulated formulation enhanced the specific knockdown of RIPK4 in bladder cancer cells and bladder tumors, which effectively suppressed tumor growth and progression in a number bladder tumor models with no observable adverse effects or toxicity. The researchers claim that the use of the nanotube encapsulated RIPK4 could be a novel therapeutic approach to treat bladder cancer [24].

Summary

The present industry update covers the period of September 2019, with information sourced primarily from company press releases, scientific literature and various news websites. This month saw several collaborations announced in the area of delivery of gene therapies, including collaborations between Wize Pharma and Copernicus and REGENXBio and Clearside. Notable approvals by the FDA this month included Novo Nordisk's Oral Semaglutide and Insulet's Omnipod DASH system as an infusion pump for insulin delivery. Halozyme announced positive results from a Phase III trial evaluating fixed-dose subcutaneous combination of Genetech's Perjeta and Herceptin. Vascular Therapies announced that it had received positive initial data in Phase II/III trials using its proprietary sirolimus formulation, Sirogen, which employs a novel bio-resorbable collagen-based drug delivery.

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The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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