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**Pro hac vice applications forthcoming*
Attorneys for Plaintiff Acuitas Therapeutics Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ACUITAS THERAPEUTICS INC.,	)	
	)	Civil Action No. _____
Plaintiffs,	)	
	)	**COMPLAINT FOR**
v.	)	**DECLARATORY JUDGMENT**
	)	**OF NON-INFRINGEMENT**
GENEVANT SCIENCES GMBH, AND	)	**AND INVALIDITY**
ARBUTUS BIOPHARMA CORP.	)	
	)	**Jury Trial Demanded**
Defendants.	)	

Acuitas Therapeutics Inc. ("Acuitas"), for its Complaint against Genevant Sciences GmbH ("Genevant") and Arbutus Biopharma Corp. ("Arbutus") (collectively, "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. COVID-19 presented the worst public-health crisis in a century. Three years later, however, the pandemic is over. That is in large part due to the amazing success story of the mRNA vaccines against the virus that causes COVID-19. Those vaccines exist only because of decades of hard work and ingenuity by Acuitas and others to develop the technology that allowed the rapid development of a vaccine to combat the pandemic.

2. As the pandemic receded, however, litigation proliferated regarding who invented various components of the mRNA vaccines. Despite not having invented or produced any COVID-19 vaccine of their own (or any mRNA vaccine for any virus), Arbutus and Genevant threatened Pfizer and BioNTech (which market an mRNA vaccine for COVID-19, COMIRNATY®) with patent infringement. Acuitas invented and provides an essential component used in COMIRNATY®, a lipid nanoparticle ("LNP") that encapsulates the mRNA payload for delivery, and its constituent lipids. This action arises out of Defendants' threats to sue, and suit against, Pfizer and BioNTech, based in part on their use of Acuitas's LNP and lipids.

THE PROCEDURAL POSTURE

3. This is the second time Acuitas has had to seek a declaratory judgment against Arbutus and Genevant. Acuitas first sued Arbutus and Genevant on March 18, 2022, in the Southern District of New York, seeking a declaratory judgment that Arbutus's patents are invalid and not infringed by COMIRNATY®, after Arbutus and Genevant sent patent-infringement threat letters to Pfizer and BioNTech. *See Acuitas Therapeutics Inc. v. Genevant Scis. GmbH*, Case No. 22-cv-02229-MKV (S.D.N.Y. Mar. 18, 2022) (the "New York Action"). Arbutus and Genevant moved to dismiss the New York Action, arguing that a declaratory-judgment action by Acuitas was unnecessary because Arbutus and Genevant had not, in fact, threatened Pfizer or BioNTech with patent infringement, and might well reach an out-of-court agreement with them.

4. That was not accurate. While Arbutus and Genevant's motion to dismiss Acuitas's New York Action was pending, Arbutus and Genevant did exactly what they implied to the New York Court they had no intention of doing: On April 3, 2023, they sued Pfizer and BioNTech for patent infringement. But rather than doing so in the Southern District of New York, where Acuitas's case was pending, they sued in this Court. *See Arbutus Biopharma Corp. et al v. Pfizer Inc. et al.*, No. 3:23-cv-01876-ZNQ (D.N.J.) ("Arbutus's New Jersey Action"). Arbutus and Genevant explicitly identified Acuitas's lipids and LNP, while studiously not using the word "Acuitas" in their complaint. In answering the complaint in Arbutus's New Jersey Action, Pfizer and BioNTech raised as a defense that Arbutus and Genevant had failed to name or join Acuitas as a "required party." *Arbutus Biopharma Corp. v. Pfizer Inc.*, No. 2:23-cv-01876-ZNQ (D.N.J.) (ECF 17, Fifth Affirmative Defense).

5. Acuitas's declaratory-judgment claim against Arbutus and Genevant being heard in the same Court in which Arbutus's and Genevant's claims against Pfizer and BioNTech are heard will conserve judicial resources and help ensure consistent outcomes.

6. The claims are legally distinct. Acuitas's business model is to develop LNP technology and license it to partners who will use the technology to develop mRNA-based vaccines for pathogens far beyond COVID-19. It is public, for example, that Acuitas is partnering with companies other than Pfizer and BioNTech to investigate therapies directed at a broad range of indications and applications. It is vital to Acuitas's business that its partners and prospective partners can use the licensed Acuitas LNP technology free and clear of interference by threats of suit arising from third party patents. Instead, customers and potential customers of Acuitas must now contend with the risk of avaricious litigation by Arbutus and Genevant, who have demonstrated their willingness to sue Acuitas's customers that use Acuitas LNP technology,

despite the fact that Arbutus and Genevant did not invent and had nothing to do with the success of Acuitas's lipids or vaccines that use them. That threat to other customers and potential customers, and thus the threat to Acuitas itself, would remain even if Arbutus and Genevant were to resolve their dispute with Pfizer and BioNTech. While Acuitas contends that Arbutus and Genevant's claims of infringement are baseless and that their patents are invalid, without a declaratory judgment so holding, Acuitas faces (i) uncertainty with respect to the use of its technology free from the threat of patent infringement, (ii) the possibility of liability under 35 U.S.C. § 271(b) for inducing its customers' infringement or under § 271(c) for contributing to it, or (iii) the possibility of indemnity obligations to its customers under their contracts.

7. There are, however, substantial overlapping legal and factual issues between Arbutus's New Jersey Action and Acuitas's declaratory-judgment claims. Acuitas thus suggested to Arbutus and Genevant that they consent to transfer the New York Action to this Court. Arbutus and Genevant refused. But on August 1, this Tuesday, they wrote to the New York Court to assert—without mentioning their refusal to transfer Acuitas's New York Action to this Court—that Arbutus's New Jersey Action "is uniquely suited to resolve the controversy between Pfizer," BioNTech, and the Defendants. In that letter, Arbutus and Genevant argued that the New York Court should decide their pending motion to dismiss in part because Pfizer and BioNTech did not move "to dismiss" Arbutus's New Jersey Action "on the basis that Acuitas is a necessary party," and that "[t]he closest Pfizer and BioNTech have come" to doing so "is an affirmative defense that states, in its entirety, 'Plaintiffs' Complaint improperly failed to name or join Acuitas Therapeutics, Inc.'" That is not accurate. While Pfizer and BioNTech's Answer and Counterclaims do contain that sentence, it is not the entirety of that defense: The defense is entitled "FAILURE TO JOIN A REQUIRED PARTY." *Arbutus Biopharma Corp. v. Pfizer Inc.*, No.

2:23-cv-01876-ZNQ (D.N.J.) (ECF 17, Fifth Affirmative Defense). And Pfizer and BioNTech included an entire section entitled "BIONTECH'S RELATIONSHIP WITH ACUITAS." *Id*. at ¶¶ 31–34. That Arbutus and Genevant mischaracterize Pfizer and BioNTech's allegations about Acuitas confirms that Arbutus and Genevant recognize the interrelationship between Acuitas's claims and Arbutus's New Jersey Action.

8. Accordingly, Acuitas is withdrawing its New York Action without prejudice, and is filing this declaratory-judgment action in this Court. Acuitas will designate this case as related to Arbutus's New Jersey Action, and is open to working with counsel for all parties in that action to coordinate discovery and case schedules. Acuitas has independent claims that should be adjudicated, but it is logical and efficient to coordinate those claims with the claims and counterclaims in Arbutus's New Jersey Action.

THE SCIENTIFIC CONTEXT

9. Traditional vaccines create immunity by injecting a patient with pieces of the virus, or an inactive form of that virus. The vaccines that Acuitas helped to develop utilize messenger RNA ("mRNA") technology, do not require injection of the virus, and were developed much more quickly than traditional vaccines. All living organisms, including both humans and viruses, make proteins, which are the workhorses that complete the tasks needed by that organism. In humans the "blueprint" for these proteins is carried in genes (i.e., DNA), but that blueprint needs to be converted into an mRNA message that tells the body to make a particular protein.

10. mRNA vaccines work by introducing into a person the mRNA message that instructs the body to make a foreign protein that is itself a piece of a virus. When that viral protein is made, or "expressed," by the person's cells, that person's immune system then recognizes that the protein is foreign and develops an immune response to it. If that person is later infected with

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