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Oragenics Signs Letter of Intent to License CardioDialysis™ Technology from Sigyn Therapeutics to Target TBI-Induced Systemic Inflammation

The Expected License Agreement Would Position Oragenics as the Only Company with Therapeutic Strategies Targeting TBI-Induced Inflammation on Both Sides of the Blood-Brain Barrier

Sarasota, FL and San Diego, CA, May 07, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company"), a clinical-stage biopharmaceutical company pioneering neurological therapeutics, and Sigyn Therapeutics, Inc. (OTCQB: SIGY) (“Sigyn”), a developer of extracorporeal therapies, today announced the signing of a Letter of Intent ("LOI") under which Oragenics expects to license from Sigyn, certain disease indications of CardioDialysis™, a blood purification technology that enables the broad-spectrum clearance of inflammatory and pathogenic molecules from the bloodstream.

Under the terms of the proposed license agreement, Oragenics would receive an exclusive license from Sigyn to develop and commercialize CardioDialysis™ for the treatment of Traumatic Brain Injury (TBI) and other chronic neurodegenerative diseases.

Strategic Rationale: Targeting TBI Inflammation on Both Sides of the Blood-Brain Barrier

Oragenics is currently advancing ONP-002, a first-in-class intranasal neurosteroid in Phase IIa clinical trials for concussion and mild traumatic brain injury (mTBI). ONP-002 is designed to cross the blood-brain barrier and directly address the neuroinflammation and oxidative stress that drive TBI-related damage within the brain.

CardioDialysis™ addresses TBI-induced inflammation from a complementary direction — outside the brain — by purifying the bloodstream of inflammatory and pathogenic molecules that accumulate systemically following a TBI event. Together, the two therapeutic approaches would represent a dual-modality strategy designed to attack the inflammatory cascade of TBI at both the central and peripheral levels simultaneously.

There are currently no FDA-approved pharmacological treatments for concussion or mTBI. Oragenics believes this multi-pronged approach could represent a significant advancement in the standard of care for the estimated 69 million individuals worldwide who suffer a brain

injury each year.

> *"This letter of intent reflects our commitment to building a comprehensive TBI platform — one that addresses the full biology of brain injury, not just symptoms. While ONP-002 targets neuroinflammation directly within the brain, CardioDialysis™ offers a powerful complementary approach to clearing the systemic inflammatory burden that follows a TBI event. We believe combining these two strategies has the potential to redefine recovery outcomes for millions of patients who currently have no approved treatment options." stated Oragenics' Chief Executive Officer, Janet Huffman*
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> *"Beyond the benefit offered to our shareholders, we believe the proposed transaction will position Oragenics as the only Company with therapeutic strategies to directly target TBI-induced inflammation on both sides of the blood-brain barrier," stated Sigyn Therapeutics CEO, Jim Joyce.*
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> *"In the future, we envision the possibility of ONP-002 and CardioDialysis™ being synergistically combined to accelerate TBI recovery and reduce long-term adverse events," concluded Joyce.*

Summary of LOI Terms

The proposed transaction is structured as an exclusive, assignable license of the CardioDialysis™ technology for use in the agreed Target Markets. Key terms of the LOI include:

Consideration: Oragenics expects to issue 3,250,000 shares of a new class of restricted preferred stock to Sigyn, convertible into Oragenics common stock on a one-to-one basis, subject to NYSE American rules and shareholder approval conditions.

Royalty: Oragenics expects to pay a 3% royalty on revenue from sales of the licensed technology following FDA market clearance, for a period of six years from the date of first commercial sale per approved indication and country.

Target Closing: 90 days or sooner from the effective date of the LOI, subject to completion of due diligence, board approvals, an independent third-party valuation, and other customary closing conditions.

Exclusivity: Sigyn has agreed not to license the CardioDialysis™ technology to third parties for the proposed Target Markets during the exclusivity period.

The LOI is non-binding except for certain provisions including exclusivity, confidentiality, and governing law. The completion of a definitive agreement remains subject to due diligence satisfactory to Oragenics, board approvals by both companies, NYSE American continued listing compliance, and other customary closing conditions.

About CardioDialysis™

CardioDialysis™, developed by Sigyn Therapeutics, is an extracorporeal blood purification technology engineered to enable broad-spectrum clearance of inflammatory cytokines, endotoxins, and other pathogenic molecules from the bloodstream. The technology is

designed to leverage naturally occurring pressure dynamics to filter and purify blood plasma through a proprietary cartridge system, with a potential profile that distinguishes it from conventional large-scale plasmapheresis approaches. Sigyn Therapeutics is developing CardioDialysis™ for a range of serious inflammatory conditions.

About Oragenics, Inc.

Oragenics, Inc. (NYSE American: OGEN) is a clinical-stage biopharmaceutical company focused on pioneering neurological therapeutics for patients with unmet medical needs. The Company's lead asset, ONP-002, is a first-in-class intranasal neurosteroid in Phase IIa clinical trials for the treatment of concussion and mild traumatic brain injury — a condition affecting an estimated 69 million people worldwide annually for which no FDA-approved pharmacological treatment currently exists. Delivered via a proprietary intranasal device, ONP-002 is designed to bypass the blood-brain barrier to directly reduce neuroinflammation and oxidative stress at the source of injury. For more information, visit www.oragenics.com.

About Sigyn Therapeutics™

Sigyn Therapeutics is the developer of CardioDialysis, a next-generation blood purification technology that enables continuous broad-spectrum clearance of inflammatory and pathogenic molecules from the bloodstream. Within the emerging field of subtractive medicine, CardioDialysis is the first therapy to integrate plasma separation and therapeutic adsorption within a single device. Therapeutic opportunities for CardioDialysis include sepsis, life-threatening viral infections, neuroinflammatory disorders, and cardiovascular disease. The Company's development pipeline is comprised of ImmunePrep™ to optimize the delivery of therapeutic antibodies to treat cancer; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy. To learn more about Sigyn Therapeutics, visit: www.SigynTherapeutics.com

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding the Company's expectations regarding the proposed transaction with Sigyn Therapeutics, including the execution of a definitive license agreement, the therapeutic potential of CardioDialysis™, the potential clinical benefits of combining ONP-002 and CardioDialysis™, and the Company's broader CNS platform strategy. The words "believe," "expect," "anticipate," "intend," "estimate," "project," "potential," "may," "will," "could," "should," and similar expressions identify forward-looking statements. These statements are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially, including the risk that a definitive agreement may not be executed, that due diligence may reveal unfavorable results, that required approvals may not be obtained, and other risks described in the Company's most recent Form 10-K, Form 10-Q, and other filings with the U.S. Securities and Exchange Commission. The Company does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future developments, or otherwise, except as required by law.

Although the letter of intent provides that certain provisions are binding on the parties, it

does not obligate the parties to consummate the proposed transaction. The consummation of the proposed transaction remains subject to the negotiation, execution and delivery of a definitive license agreement and the satisfaction or waiver of applicable closing conditions. There can be no assurance that any definitive agreements will be entered into or that the proposed transaction will be consummated on the terms described herein or at all. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof and are not guarantees of future performance or outcomes.

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