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Oragenics Partners with DUCK FLATS Pharma to Support FDA IND Readiness and Clinical Trial Design for Concussion Program

Collaboration reinforces regulatory diligence, nonclinical strategy and clinical trial integrity for novel intranasal concussion therapy

Traumatic brain injuries affect more Americans each year than stroke, Alzheimer's disease, Parkinson's disease, multiple sclerosis, and ALS combined

Sarasota, Fla., Feb. 03, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN) ("the "Company"), a clinical-stage biotechnology company focused on developing intranasal therapeutics for neurological disorders, today announced it has engaged DUCK FLATS Pharma as its U.S. Investigational New Drug (IND) readiness and regulatory execution partner to support FDA-facing preparation and clinical trial design as the Company advances its novel intranasal concussion therapy toward U.S.-based development. The engagement is intended to align the Company's upcoming Phase 2a clinical trial in Australia with its U.S regulatory strategy.

"We highly value our collaboration with DUCK FLATS Pharma as we advance our IND strategy for ONP-002 and prepare for future U.S. clinical development," said Janet Huffman, Chief Executive Officer of Oragenics. "By emphasizing regulatory rigor and early preparation, we aim to ensure trial integrity and reduce risk across the U.S. development pathway. DUCK FLATS Pharma's leadership team has contributed to the development and approval of approximately 40 drug programs, including high-impact intranasal therapies such as Narcan® and neffy®, through regulatory submission strategies, nonclinical and clinical development, and FDA engagement. We believe their experience with market-leading drug programs will meaningfully inform Oragenics' regulatory and clinical development strategy as we advance our lead concussion therapy toward a U.S. Phase 2b trial and later-stage development."

DUCK FLATS Pharma supports companies across the full spectrum of size and development stage through a senior leadership-led engagement model, integrating nonclinical, clinical, and regulatory strategies. Drawing on approximately 38 years of regulatory and drug development experience, the team has served as project lead on more than 60 FDA-approved New Drug Applications and managed over 400 regulatory documents across development programs. Team members have served as consultants on several Advisory Committee initiatives for the FDA and other global regulatory authorities. The firm's

Phase 1 and 2 clinical study services include protocol development, case processing, risk management, biomedical literature and medical monitoring. The company also has expertise in nonclinical development to support the clinical indication.

Luana R. C. Pesco Koplowitz, M.D., Ph.D., Founder, President and Chief Scientific Officer of DUCK FLATS Pharma commented, “It is rewarding to engage with Oragenics on overall development strategy for its novel treatment for concussion and mild-traumatic brain injury, a category with no approved therapies for a vast and urgent unmet medical need.”

Traumatic brain injuries affect more Americans each year than stroke, Alzheimer’s disease, Parkinson’s disease, multiple sclerosis, and ALS combined, based on aggregated U.S. incidence estimates—yet no FDA-approved therapy currently exists to treat the underlying injury.

The global concussion market is projected to reach over $9 billion by 2027.[1] As an investigational neuroprotective intranasal drug, ONP-002 if approved by the FDA would join a nasal drug delivery market expected to reach $125+ billion by 2030[2].

About Oragenics, Inc.

Oragenics, Inc. is a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology. The Company's lead candidate, ONP-002, is being advanced as a potential first-in-class treatment for concussion and mild traumatic brain injury. Oragenics is progressing ONP-002 through Phase 2a clinical trials in Australia, with U.S. Phase IIb trials planned to follow. The Company's intranasal delivery platform has potential applications across multiple neurological conditions, including Parkinson's disease, Alzheimer's disease, PTSD, and anxiety disorders. Oragenics is committed to developing innovative therapies that address significant unmet medical needs in neurological care. For more information, visit oragenics.com.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding our future performance, business prospects, expectations and product development plans. These forward-looking statements are not historical facts, but are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. These forward-looking statements include statements about our strategies, objectives, beliefs, goals, and expectations, including those concerning, among other things, our research, development and regulatory activities, our product development timelines, our future products, regulatory matters, our expectations relating to our products candidates, including ONP-002, the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of concussion and mild traumatic brain injury, and the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including ONP-002.These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe," "expect," "anticipate," "intend," "estimate," "project," "potential," "may," "will," "could," "should," and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are

subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to, those described in our most recent Form 10-K, Form 10-Q and other filings we make with the U.S. Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. All information we set forth in this press release is as of the date hereof. We do not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, except as otherwise required by law.

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[1] Grand View Research; Concussion Market (2025 - 2030)

[2] Grand View Research: Nasal Drug Delivery Technology Market (2024 - 2030)

Source: Oragenics, Inc.