November 9, 2023

Ensysce Biosciences Reports Third Quarter 2023 Financial Results

PF614-201 Clinical Study Results Expected by End of Year

SAN DIEGO, CA / ACCESSWIRE / November 9, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, today reported financial results for the third quarter of 2023.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "We continue to execute steps toward meeting our near-term objective of entering Phase 3 evaluation of PF614 with a long-term goal of commercialization. Specifically, we've achieved multiple milestones in the third quarter which began with Institutional Review Board approval of the PF614-201 clinical protocol in August followed by the critically important completion of the Site Initiation Visit to commence our PF614-201 clinical trial, and additionally engagement of the strategic advisory group Alacrita Consulting to enhance our partnering and licensing opportunities. Behind the scenes we are continuing manufacturing activities of both PF614 and the combination product PF614-MPAR for overdose protection. The Company's progress throughout 2023 has further supported our belief that PF614 and PF614-MPAR will become the 'next generation' of analgesics that are equally effective in treating severe pain with a safer outcome for pain management than currently marketed opioids.

Looking forward, we are on track for the important readout from the PF614-201 'time of onset' study prior to year-end. The data will support the design of our Phase 3 protocols and add to the favorable results from the three clinical studies completed over the last year. All data generated to date have contributed to the regulatory submission for our End of Phase 2 discussions with the FDA scheduled for January 30, 2024, in advance of initiating Phase 3 studies in 2024. Lastly, we successfully completed a private placement funding round made possible by the support of our long-term investors signaling continued confidence in Ensysce's PF614 pain management treatment and our mission to improve drug safety," concluded Dr. Kirkpatrick.

TAAP™ (Opioid Abuse Deterrent Program) Updates

Our lead product, PF614, is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone and a potential 'next generation' analgesic for severe pain. The Company's TAAP™ technology is designed to control release, be highly resistant to tampering and reduce abuse through a unique chemical modification. PF614's TAAP™ modification makes it inactive until it is swallowed, following which it is activated or 'turned on' to release oxycodone by the body's owntrypsin, an enzyme in the small intestine. Ensysce completed three clinical trials over the last year and is working to complete enrollment for its latest clinical trial to evaluate the time of onset of pain relief with PF614.

Ensysce believes it has a body of evidence showing that PF614 works as designed, is bioequivalent to OxyContin and has a good safety profile. Our most recent studies demonstrate that PF614 is less liked by recreational drug users when taken orally as compared to regular oxycodone, creating what we believe is a safer analgesic.

Most recently, on September 26, 2023, the Company completed the Site Initiation Visit for the PF614-201 study, ‘A Randomized, Double-Blind, Placebo-Controlled Crossover Study of PF614 on Analgesic Response in the Cold Pressor Test in Healthy Male Subjects' to evaluate time of onset for PF614. The study is being conducted by Dr. George Atiee at Dr. Vince Clinical Research (DVCR) in Overland, KS. The Company expects results from this study in December 2023.

On September 14, 2023, the Company announced that two scale up manufactures had been completed for PF614 in 2023. The success of the scaled manufacturing work positions the Company to begin its strategy of commercial readiness consistent with timeline expectations as it enters the next phase of development, including planning its phase 3 studies.

MPAR® (Opioid Abuse Deterrent and Overdose Protection Program) Updates

PF614-MPAR is a combination product to treat severe pain, designed with overdose protection. MPAR® (Multi-Pill Abuse Resistance) reduces or ‘turns off' the release of the opioid to prevent an overdose, providing an additional layer of protection to Ensysce's TAAP™ medications. We believe that MPAR® is the first technology that may reduce prescription drug overdoses stemming from oral abuse, which can save lives. The clinical data generated over the past year supported the approach that the MPAR® combination technology reduces release and absorption of oxycodone from PF614, when consumed in overdose. A regulatory submission is planned to discuss our MPAR development program with the FDA.

On September 7, 2023, the Company hosted a symposium at PAINWeek 2023 to formally present the recent clinical data for PF614 and PF614-MPAR to a global community of leading pain medical professionals. Ensysce's objectives included conveying an understanding of the current landscape for severe pain treatment and drug use and abuse in America. This overview dovetailed with the Company's thesis of the unmet medical and societal need for the safety and effectiveness of PF614 and PF614-MPAR, the Company's two leading next-generation agents which are designed to reduce opioid abuse and prevent overdose deaths.

The results from our clinical trials are evidence that Ensysce's PF614 and PF614-MPAR analgesics reflect an inflection point in the management of severe pain as a safe and equally effective alternative to prescription opioids that have become less accessible due to the direct correlation to abuse and overdose.

Third Quarter 2023 Financial Results

- **Cash -** Cash and cash equivalents were $1.5 million as of September 30, 2023, as compared to $3.8 million as of June 30, 2023. Subsequent to quarter end, on October 23, 2023, the Company entered into a securities purchase agreement with investors in the form of senior secured convertible notes with a dedicated syndicate of investors for an aggregate investment of $1.7 million to occur in two closings. The initial closing

occurred on October 25, 2023, providing $0.6 million prior to fees and offering expenses. The second closing is anticipated prior to year-end.

- **Federal Grants -** Funding under federal grants totaled to $0.4 million for the third quarter of 2023 compared to $0.3 million in the comparable year ago quarter. The increase is due to the timing of research activities eligible for funding, particularly relative to the MPAR® program.
- **Research & Development Expenses -** R&D expenses decreased to $1.9 million for the third quarter of 2023 compared to $4.8 million for the same period in 2022. The decrease was primarily the result of changes in timing of external research and development costs related to clinical and pre-clinical programs for PF614 and PF614-MPAR.
- **General & Administrative Expenses -** G&A expenses decreased to $1.2 million for the third quarter of 2023 compared to $1.7 million for the same period of 2022. The decrease was primarily a result of reduced stock-based compensation, employee bonus accrual and consulting fees.
- **Other Income (Expense) -** Total other income (expense), net was income of $16,508 for the third quarter of 2023 compared to expense of $3.7 million for the same period of 2022. The change in other income is primarily due to non-cash fair value adjustments for convertible notes and warrants.
- **Net Loss -** Net loss attributable to common stockholders for the third quarter of 2023 was $2.7 million compared to $9.9 million for the third quarter of 2022. As a clinical stage biotech company, our continued research and development efforts toward regulatory approvals for our product candidates are expected to result in losses for the foreseeable future.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Federal grants	$ 435,380	$ 279,351	$ 1,715,488	$ 1,089,920
Operating expenses:				
Research and development	1,914,970	4,756,096	5,354,713	13,393,948
General and administrative	1,227,724	1,686,580	3,923,277	5,717,281
Total operating expenses	3,142,694	6,442,676	9,277,990	19,111,229
Loss from operations	(2,707,314)	(6,163,325)	(7,562,502)	(18,021,309)
Total other income (expense), net	16,508	(3,692,240)	440,588	(708,300)
Net loss	$ (2,690,806)	$ (9,855,565)	$ (7,121,914)	$ (18,729,609)
Adjustments to net loss	1,235	(42,047)	198	(833,979)
Net loss attributable to common stockholders	$ (2,689,571)	$ (9,897,612)	$ (7,121,716)	$ (19,563,588)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (61.58)	$ (3.32)	$ (140.90)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (8,978,107)	$ (14,591,819)
Net cash provided by investing activities	-	4,500
Net cash provided by financing activities	7,294,786	6,825,664
Change in cash and cash equivalents	(1,683,321)	(7,761,655)
Cash and cash equivalents at beginning of period	3,147,702	12,264,736
Cash and cash equivalents at end of period	$ 1,464,381	$ 4,503,081

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,464,381	$ 3,147,702
Prepaid expenses and other current assets	1,293,422	2,151,467
Total current assets	2,757,803	5,299,169
Other assets	460,883	585,883
Total assets	$ 3,218,686	$ 5,885,052
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 916,416	$ 2,943,791
Accrued expenses and other liabilities	763,190	2,253,809
Notes payable and accrued interest	350,932	4,266,610
Total current liabilities	2,030,538	9,464,210
Long-term liabilities	30,473	450,494
Total liabilities	2,061,011	9,914,704
Stockholders' equity (deficit)	1,157,675	(4,029,652)
Total liabilities and stockholders' equity (deficit)	$ 3,218,686	$ 5,885,052

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin-Activated Abuse Protection (TAAP™) and Multi-Pill Abuse Resistance (MPAR®) platforms, the Company is developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. Ensysce's products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without

limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; the ability of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent quarterly report on Form 10-Q and current reports on Form 8-K, which are available, free of charge, at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

Ensysce Biosciences Company Contact:
Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:
Shannon Devine
MZ North America
Main: 203-741-8811
ENSC@mzgroup.us

SOURCE: Ensysce Biosciences Inc.