March 30, 2023

Ensysce Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results

~ Corporate Update Call to be Held Tuesday, April 11, 2023 ~

SAN DIEGO, CA / ACCESSWIRE / March 30, 2023 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety, today reported financial results for the fourth quarter and full year of 2022.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Our focus remains on execution and advancing clinical development plans for our programs that provide strong pain relief using our PF614 and PF614-MPAR drug products. This has been evident in the recently released news regarding completion of enrollment of our first PF614-MPAR study and completion of the clinical stage of two human abuse potential studies for PF614. These studies add to the clinical support demonstrating that Ensysce has a novel approach for delivering effective pain management and safely alleviating severe pain in patients requiring an opioid analgesic. These recent accomplishments move us closer to our Phase 3 plans and toward bringing what we believe is the 'Next Generation of Analgesia' for severe pain to commercialization."

TAAP™ (Opioid Abuse Deterrent Program) Updates

Our lead program, PF614 is a "Trypsin-Activated Abuse Protection" (TAAP™) extended-release oxycodone. The Company's TAAP™ technology is designed to control release, be highly resistant to tampering, and reduce abuse through a unique chemical modification that is activated by trypsin. The achievements highlighted below advance the company toward Phase 3 clinical evaluation.

- On February 28, 2023, the Company announced the database lock for the oral Human Abuse Potential (HAP) study of PF614. With the database lock, no further change to the trial data is permissible.
- On January 4, 2023, the Company announced that it had successfully completed the clinical portion of study PF614-104, 'A Randomized, Double-Blind, Placebo- and Active-Controlled, Crossover Study to Evaluate the Oral Abuse Potential of PF614 Compared with Oxycodone Immediate-Release Tablets, and Placebo in Non-Dependent Recreational Opioid Users' (ClinicalTrials.gov: NCT05571345) conducted by Dr. Vince Clinical Research.
- On November 14, 2022, the Company announced that it received written guidance from the FDA that an acute pain indication may be appropriate for the Company's lead Trypsin Activated Abuse Protection (TAAPTM) product, PF614.

- On October 31, 2022, the Company announced positive topline results from an intranasal human abuse potential (HAP) study for PF614 showing inhalation of PF614 did not produce the ‘drug liking' effects of crushed oxycodone. Ensysce's TAAP™ technology is designed to limit activation to oral administration, be highly resistant to tampering to reduce abuse.

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

PF614-MPAR™ is a combination abuse-protected product designed to overcome prescription drug overdose. MPAR™ (Multi-Pill Abuse Resistance) reduces the release of the opioid in an overdose situation, providing the additional layer of protection to Ensysce's TAAP™ pain medications. The select achievements outlined below demonstrate how Ensysce has progressed, what we believe is the first prescription drug overdose protection technology to be developed.

- On March 22, 2023, the Company announced the completion of enrollment in the final stage of the Phase 1 study, PF614-MPAR-101. This study was conducted by Dr. Maria Bermudez MD, at Quotient Sciences, Miami, Florida.
- On December 19, 2022, the Company announced data from the initial stage of PF614-MPAR-101 successfully demonstrating the overdose protection qualities of its drug product, PF614-MPAR.
    - On December 5, 2022, the Company announced that it had completed the clinical portion of the initial stage of PF614-MPAR-101, entitled ‘Single-Dose Study to Evaluate the Pharmacokinetics of oxycodone and PF614, when PF614 Solution is Co-Administered with Nafamostat, as an Immediate-Release Solution and/or Extended-Release (ER) Capsule Formulations in Healthy Subjects', conducted by Dr. Maria Bermudez MD, at Quotient Sciences, Miami, Florida.

Financial Results

- **Cash -** Cash and cash equivalents were $3.1 million as of December 31, 2022, as compared to $4.5 million as of September 30, 2022, and $12.3 million as of December 31, 2021. Subsequent to year-end, the Company completed a $3.0 million registered direct offering for the sale of 3,571,431 shares of the Company's common stock at a purchase price of $0.84 per share.
- **Federal Grants -** Funding under federal grants was $1.4 million for the fourth quarter of 2022 compared to $1.6 million in the comparable year ago quarter. For the full year 2022, funding from federal grants was $2.5 million compared to $3.5 million for full year 2021. The differences are primarily related to both pre-clinical and clinical activities for the MPAR™ program.
- **Research & Development Expenses -** R&D expenses were $6.4 million for the fourth quarter of 2022 compared to $2.2 million for the same period in 2021 and $19.8 million for the full year of 2022 compared to $4.7 million for the full year of 2021. The increases were primarily the result of increased external research and development costs related to the clinical programs for PF614 and PF614-MPAR.
- **General & Administrative Expenses -** G&A expenses were $1.2 million for the fourth quarter of 2022 compared to $1.5 million for the same period of 2021 and $6.9 million for the full year of 2022 compared to $18.7 million for the full year of 2021. The decrease for the full year period was primarily driven by a one-time $11.6 million non-

cash expense related to warrants issued under a share subscription facility.

- **Other Income (Expense) -** Total other income (expense), net was income of $0.7 million for the fourth quarter of 2022 compared to expense of $8.0 million for the same period of 2021. For the full year periods, total other income (expense), net was income of $0.0 million in 2022 compared to expense of $9.3 million in 2021. The change in other expenses is primarily due to non-cash fair value adjustments for convertible notes and warrants.
- **Net Loss -** Net loss for the fourth quarter of 2022 was $5.5 million compared to $10.0 million for the fourth quarter of 2021. For the full year of 2022, net loss was $24.2 million compared to $29.1 million for the full year of 2021. 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.

Corporate Update Conference Call

As previously announced, CEO, Dr. Lynn Kirkpatrick, CFO, Dave Humphrey, and CMO, Dr. William Schmidt, will host a conference call on Tuesday, April 11, 2023, at 11:00am ET to provide a corporate update and review the recently released results from the oral HAP study of PF614. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Tuesday, April 11, 2023
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Webcast: ENSC Corporate Update Call

Please dial in at least 10 minutes before the start of the call to ensure timely participation. A playback of the call will be available through Tuesday, May 9, 2023. To listen, call 1-844-512-2921 within the United States and Canada or 1-412-317-6671 when calling internationally. Please use the replay pin number 13737179.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	2021	2020	2021	2020
	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Federal grants	$ 1,433,463	$ 1,635,292	$ 2,523,383	$ 3,531,199
Operating expenses:				
Research and development	6,441,927	2,187,850	19,835,875	4,690,082
General and administrative	1,192,322	1,454,187	6,909,603	18,711,548
Total operating expenses	7,634,249	3,642,037	26,745,478	23,401,630
Loss from operations	(6,200,786)	(2,006,745)	(24,222,095)	(19,870,431)

Total other income (expense), net	722,710	(8,030,379)	14,410	(9,275,470)
Net income (loss)	$ (5,478,076)	$ (10,037,124)	$ (24,207,685)	$ (29,145,901)
Adjustments to net income (loss)	(43,832)	(802,926)	(877,811)	(740,950)
Net income (loss) attributable to common stockholders	$ (5,521,908)	$ (10,840,050)	$ (25,085,496)	$ (29,886,851)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (1.52)	$ (8.93)	$ (11.62)	$ (29.64)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	2021	2020
	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (17,887,439)	$ (8,242,177)
Net cash provided by investing activities	4,500	-
Net cash provided by financing activities	8,765,905	20,312,699
Change in cash and cash equivalents	(9,117,034)	12,070,522
Cash and cash equivalents at beginning of period	12,264,736	194,214
Cash and cash equivalents at end of period	$ 3,147,702	$ 12,264,736

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 3,147,702	$ 12,264,736
Prepaid expenses and other current assets	2,151,467	3,397,857
Total current assets	5,299,169	15,662,593
Other assets	585,883	754,756
Total assets	$ 5,885,052	$ 16,417,349
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,943,791	$ 301,104

Accrued expenses and other liabilities	2,253,809	3,432,407
Notes payable and accrued interest	4,266,610	12,748,155
Total current liabilities	9,464,210	16,481,666
Long-term liabilities	450,494	8,093,741
Total liabilities	9,914,704	24,575,407
Stockholders' deficit	(4,029,652)	(8,158,058)
Total liabilities and stockholders' equity	$ 5,885,052	$ 16,417,349

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech company using its proprietary technology platforms to develop safer prescription drugs. Leveraging TAAP™ and MPAR™, the Company is in the process of developing a unique, tamper-proof treatment option for pain that minimizes the risk of both drug abuse and overdoses. 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 annual report on Form 10-K 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.

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