May 15, 2023

Ensysce Biosciences Reports First Quarter 2023 Financial Results

Recently Completed Successful Ground-Breaking Study on Overdose Protection
Recently Completed $7 Million Public Offering

SAN DIEGO, CA / ACCESSWIRE / May 15, 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 first quarter of 2023 following the recently completed, successful PF614-MPAR-101 study.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "As evident in our recently announced completion of PF614-MPAR-101, a clinical study examining the Company's first pain medication with overdose protection, PF614-MPAR, we remain focused on advancing our lead products. The recently completed study serves as a major milestone that brings us one step closer to a first-in-class agent with overdose protection. PF614-MPAR is designed to treat severe pain while reducing the ability to abuse for recreational purposes, with added protection from overdose. Our achievements to date are directly in line with our expectations and we are encouraged by the recent May 2023 financing to advance our development of PF614 and PF614-MPAR."

TAAP™ (Opioid Abuse Deterrent Program) Updates

Our lead program, PF614 is a Trypsin-Activated Abuse Protection (TAAP™) extended-release oxycodone and a potential ‘next generation' analgesic for severe pain designed to reduce abuse. The Company's TAAP™ technology is designed to control release, be highly resistant to tampering, and reduce intranasal and intravenous abuse through a unique chemical modification. The TAAP™ modification of PF614 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 conducted three clinical trials over the last year and has a body of evidence showing that PF614 works as designed and is safe. We believe these trials demonstrate that:

- PF614 is ‘bioequivalent' to OxyContin, meaning it could replace OxyContin in the marketplace, based on our positive bioequivalence study;
- PF614 is less liked by recreational drug users based on our two Human Abuse Potential studies of intranasal and oral administration, so it is less likely to be abused; and
- PF614 has a good safety profile as demonstrated in these three recently completed clinical studies.

On April 3, 2023, the Company announced positive results from a second key study on the human abuse potential of PF614. The study met all key endpoints and showed that oral

administration of PF614 had significantly lower scores of "Drug Liking" than the oxycodone comparator at both the low- and mid-doses studied. The completion of these trials now positions PF614 for an End of Phase 2 meeting with the FDA, anticipated for the second half of 2023, and initiating our Phase 3 strategy in 2024.

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 in an overdose situation providing the 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 and that it can save lives. The clinical data generated over the past year shows that the MPAR™ combination technology reduces activation of the TAAP™ prodrugs, specifically, PF614, in an overdose situation. The outcome of our work of the past year positions us to have a meeting with the FDA to discuss the MPAR™ overdose protection program and we expect will lead to the development of a full dose range of PF614-MPAR drug products moving forward.

On May 9, 2023, the Company announced the successful completion of overdose protection Phase 1 study, PF614-MPAR-101. The final Part B of the study examined dose escalation of PF614-MPAR and successfully showed that PF614-MPAR reduced opioid delivery when three or more doses are consumed simultaneously, yet delivered oxycodone appropriately when one or two doses were consumed.

We believe that the clinical results from Ensysce's programs indicate that both PF614 and PF614-MPAR represent important improvements for pain management, an issue that has greatly impacted the United States in recent years where access to prescriptions of these strong pain medications has been affected by the opioid crisis.

Financial Results

- **Cash -** Cash and cash equivalents were $1.4 million as of March 31, 2023, as compared to $3.1 million as of December 31, 2022. The decrease reflects cash used in operations, partially offset by proceeds from a registered direct offering in February for the sale of 0.3 million shares of common stock at a price of $10.08 per share. On May 12, 2023, we completed a public offering of common stock and warrants for gross cash proceeds of $7.0 million, before deducting placement agent fees and other offering expenses.
- **Federal Grants -** Funding under federal grants was $0.8 million for the first quarter of 2023 compared to $0.6 million in the comparable year ago quarter. Differences are due to the timing of research activities eligible for funding. We expect funding from federal grants to generally remain at current levels.
- **Research & Development Expenses -** R&D expenses were $1.8 million for the first quarter of 2023 compared to $3.1 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™. We do not currently track expenses on a program-by-program basis. We expect future research and development expenses to approximate current levels.
- **General & Administrative Expenses -** G&A expenses were $1.6 million for the first

quarter of 2023 compared to $2.3 million for the same period of 2022. The decrease was primarily a result of reduced stock-based compensation, liability insurance and employee bonus expenses in the 2023 period. We expect future general and administrative expenses to approximate current levels.

- **Other Income (Expense) -** Total other income (expense), net was income of $0.4 million for the first quarter of 2023 compared to income of $3.9 million for the same period of 2022. The change in other expenses is primarily due to non-cash fair value adjustments for convertible notes and warrants.
- **Net Loss -** Net loss attributable to common stockholders for the first quarter of 2023 was $2.2 million compared to $1.7 million for the first 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 March 31,	
	2023	**2022**
Federal grants	$ 789,635	$ 603,098
Operating expenses:		
Research and development	1,796,015	3,140,096
General and administrative	1,554,855	2,265,806
Total operating expenses	3,350,870	5,405,902
Loss from operations	(2,561,235)	(4,802,804)
Total other income (expense), net	369,429	3,851,879
Net loss	$ (2,191,806)	$ (950,925)
Adjustments to net loss	(4,368)	(715,761)
Net loss attributable to common stockholders	$ (2,196,174)	$ (1,666,686)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.08)	$ (14.66)

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

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	$ (3,606,919)	$ (3,437,014)
Net cash provided by investing activities	-	4,500
Net cash provided by (used in) financing activities	1,874,982	(391,270)
Change in cash and cash equivalents	(1,731,937)	(3,823,784)
Cash and cash equivalents at beginning of period	3,147,702	12,264,736
Cash and cash equivalents at end of period	$ 1,415,765	$ 8,440,952

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,415,765	$ 3,147,702
Prepaid expenses and other current assets	1,954,880	2,151,467
Total current assets	3,370,645	5,299,169
Other assets	544,217	585,883
Total assets	$ 3,914,862	$ 5,885,052
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,598,166	$ 2,943,791
Accrued expenses and other liabilities	2,377,802	2,253,809
Notes payable and accrued interest	-	4,266,610
Total current liabilities	3,975,968	9,464,210
Long-term liabilities	91,318	450,494
Total liabilities	4,067,286	9,914,704
Stockholders' equity (deficit)	(152,424)	(4,029,652)
Total liabilities and stockholders' equity	$ 3,914,862	$ 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 in the process of 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.