August 14, 2024

Ensysce Biosciences Reports Second Quarter 2024 Financial Results

PF614-MPAR Progressing to Phase 1b Study to Verify Both Overdose Protection and Effective Delivery of Oxycodone
Opioid Use Disorder Program Advances with Selection of PF9001 as Lead Drug Candidate
PF614 Phase 3 Protocol Being Finalized for Submission to FDA

SAN DIEGO, CA / ACCESSWIRE / August 14, 2024 /Ensysce Biosciences, Inc. (NASDAQ:ENSC) ("Ensysce" or the "Company"), a clinical-stage pharmaceutical company developing innovative solutions for severe pain relief while reducing the potential for opioid abuse and overdose, today reported financial and operational results for the second quarter ended June 30, 2024.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Our FDA-designated Breakthrough Therapy product candidate, PF614-MPAR, is a game-changer for Ensysce as we progress to a second clinical trial, PF614-MPAR-102. We have re-engaged Quotient Sciences to prepare our Phase 1b protocol which will utilize their Translational Pharmaceutics® platform to manufacture and test the PF614-MPAR drug product to expedite the completion of this clinical study.

Additionally, an important breakthrough emerged in our opioid use disorder (OUD) program with the identification of our lead candidate, PF9001. Our OUD program is designed to provide a safer product for those suffering from OUD and is supported by an ongoing multi-year National Institutes of Health (NIH) award."

Dr. Kirkpatrick concluded, "Looking ahead, with our PF614 Phase 3 clinical trial on track to initiate in the second half of this year, we are finalizing the Phase 3 protocol design and preparing for site selection in the coming months. The favorable data generated from our prior PF614 clinical studies verified that PF614 delivers oxycodone in a manner equivalent to a commercially available opioid and provides pain relief with reduced abuse potential. Our goal is to provide safe and effective TAAP™ and MPAR® products and differentiate PF614 and PF614-MPAR from the current slate of extended-release opioid analgesics, as evidenced from the data we have generated over the last year."

TAAP™ (Opioid Abuse Deterrent Program) Update

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 own trypsin, an enzyme in the small intestine. Regulatory submissions and meetings were held in early 2024 and a Phase 3 trial is planned to initiate in the second half of 2024.

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

PF614-MPAR is a combination product of the TAAP™ prodrug PF614 with a trypsin inhibitor, designed to treat severe pain while providing 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. Over the past year, clinical data demonstrated that the MPAR® technology reduces release and absorption of oxycodone from PF614 when consumed in more than a prescribed dose, leading to the FDA's recognition and Breakthrough Therapy designation. The Company's upcoming Phase 1b study, PF614-MPAR-102, will test multiple PF614-MPAR drug products to verify both overdose protection and effective delivery of oxycodone across a dosage range.

Opioid Use Disorder (OUD) Program Update

In June, the Company achieved a critical milestone in the OUD program with the selection of lead drug candidate PF9001, designed to provide a safer and more effective way to help those suffering from the effects of opioid use. PF9001, designed with the application of Ensysce's TAAP™ platform to reduce the abuse profile, has demonstrated a lower potential for cardiovascular side effects associated with traditional methadone OUD treatments. The program is continuing to advance to Investigational New Drug (IND) enabling studies. In coordination with advancement of the OUD program, the Company announced an agreement with Purisys LLC to scale the manufacture of PF9001. This OUD work has been supported by a multi-year Helping to End Addiction Long-Term (HEAL) award of up to $15 million granted by the NIH and the National Institute on Drug Abuse (NIDA).

Q2 2024 Financial Results

Cash - Cash and cash equivalents were $1.0 million as of June 30, 2024, compared to $1.1 million as of December 31, 2023.

Federal Grants - Funding under federal grants totaled to $0.2 million for the second quarter of 2024 compared to $0.5 million in the comparable year ago quarter. The difference is due to the completion of funding under the MPAR grant in December 2023.

Research & Development Expenses - R&D expenses were $0.9 million for the second quarter of 2024 compared to $1.6 million for the same period in 2023. The decrease of $0.7 million was primarily due to reduced external research and development costs related to clinical and pre-clinical programs for PF614 and PF614-MPAR.

General & Administrative Expenses - G&A expenses were $1.2 million in the second quarter of 2024, generally in line with $1.1 million for the second quarter of 2023.

Other Income (Expense) - Total other income (expense), net, was an expense of approximately $12,000 for the second quarter of 2024 compared to income of approximately $55,000 for the same period of 2023. The changes in other expenses were primarily due to

interest expense and non-cash fair value adjustments for warrants.

Net Loss - Net loss attributable to common stockholders for the second quarter of 2024 was $2.0 million compared to $2.2 million for the second quarter of 2023. 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.

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.

Definitions

TAAP: trypsin activated abuse protection - designed to protect against prescription drug abuse.
MPAR: multi-pill abuse resistance - designed to protect against abuse and accidental overdose.

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, possible NASDAQ delisting, 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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Federal grants	$ 181,797	$ 490,472	$ 487,519	$ 1,280,107
Operating expenses:				
Research and development	947,229	1,643,726	1,726,133	3,349,742
General and administrative	1,190,010	1,140,700	2,559,791	2,695,553
Total operating expenses	2,137,239	2,784,426	4,285,924	6,135,295
Loss from operations	(1,955,442)	(2,293,954)	(3,798,405)	(4,855,188)
Total other income (expense), net	(12,351)	54,652	(1,285,951)	424,080
Net loss	$ (1,967,793)	$ (2,239,302)	$ (5,084,356)	$ (4,431,108)
Adjustments to net loss	-	3,331	(216)	(1,037)
Net loss attributable to common stockholders	$ (1,967,793)	$ (2,235,971)	$ (5,084,572)	$ (4,432,145)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.22)	$ (0.98)	$ (0.67)	$ (2.66)

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (5,718,294)	$ (6,715,461)
Net cash provided by financing activities	5,637,921	7,397,241
Change in cash and cash equivalents	(80,373)	681,780
Cash and cash equivalents at beginning of period	1,123,604	3,147,702
Cash and cash equivalents at end of period	$ 1,043,231	$ 3,829,482

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,043,231	$ 1,123,604
Prepaid expenses and other current assets	1,416,506	1,165,264
Total current assets	2,459,737	2,288,868
Other assets	335,883	419,217
Total assets	$ 2,795,620	$ 2,708,085
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 481,971	$ 1,936,007
Accrued expenses and other liabilities	370,186	542,260
Notes payable and accrued interest	454,463	854,697
Total current liabilities	1,306,620	3,332,964
Long-term liabilities	9,615	26,388
Total liabilities	1,316,235	3,359,352
Stockholders' equity (deficit)	1,479,385	(651,267)
Total liabilities and stockholders' equity (deficit)	$ 2,795,620	$ 2,708,085

SOURCE: Ensysce Biosciences, Inc.

View the original press release on accesswire.com