November 12, 2024

Ensysce Biosciences Reports Third Quarter 2024 Financial Results

Awarded $14 Million Multi-Year NIH Grant and Initiated Second Clinical Trial for Breakthrough Therapy PF614-MPAR

Submitted Pivotal PF614 Phase 3 Protocol to the FDA for Review

SAN DIEGO, CA / ACCESSWIRE / November 12, 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 third quarter ended September 30, 2024.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Our team has made significant progress in the third quarter, and we have line of sight to meaningful clinical initiatives to close out the year. The highlight of the third quarter was NIH's recognition of the potential value provided by our overdose protection technology MPAR®, by awarding Ensysce with a $14 million multi-year grant to further the clinical development of PF614-MPAR. The support from the NIH allows the completion of a second Phase 1b trial, PF614-MPAR-102. We believe the data from this study will cement PF614-MPAR as the first opioid with oral overdose protection, a game-changer for those suffering with severe pain while mitigating potential abuse and overdose."

Dr. Kirkpatrick continued, "We also built on FDA feedback from our End of Phase 2 meeting in February to complete our Phase 3 protocol and have submitted it to the FDA. We expect FDA feedback by the end of November to allow us to complete plans to execute the study over the coming year. Our August financing transaction that raised $5 million in gross proceeds allows us to advance to clinical site selection for our pivotal Phase 3 trial for PF614, and the $14 million MPAR® grant has allowed us to rapidly initiate our second trial for PF614-MPAR. We anticipate the results from these clinical studies will continue to build on our prior positive safety data to bring our innovative and premium pain products to market. Lastly, we are applying our TAAP and MPAR technology to our opioid use disorder program and look forward to moving the lead agent into clinical development in the coming years."

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 and exposed to the body's own trypsin in

the small intestine to activate or "switch on" to release oxycodone.

During the third quarter, the Company submitted to the FDA for regulatory review the protocol and statistical analysis plan for its anticipated final Phase 3 study, PF614-301. The study is entitled "A Multicenter, Randomized, Double-Blind, Placebo-and Active-Controlled Study to Evaluate the Efficacy and Safety of PF614 for the Treatment of Moderate to Severe Pain after Abdominoplasty".

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

PF614-MPAR, designed to treat severe pain with added oral overdose protection, is a combination product of the TAAP™ prodrug PF614 with a trypsin inhibitor. MPAR® (Multi-Pill Abuse Resistance) reduces or "switches off" the release of the opioid only in an overdose situation, providing an additional layer of protection to Ensysce's TAAP™ medications. The clinical data from the first clinical trial, PF614-101, 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 Breakthrough Therapy designation in January of this year.

During the third quarter, the Company received approval from the Investigational Review Board ("IRB") of the PF614-MPAR-102 protocol, ‘A Single and Multiple Dose Study to Evaluate the Pharmacokinetics of Oxycodone and PF614 when PF614 capsule is Co-Administered with Nafamostat as a combination Immediate Release solution and Extended-Release Capsule Formulation in Healthy Subjects.' The Site Initiation Visit has been undertaken and the study is on track to initiate subject dosing this quarter. To execute this study, Ensysce has continued its collaboration with Quotient Sciences to use their Translational Pharmaceutics® platform to perfect the drug product. As reported in August, the Company received a $14 million multi-year grant from the NIH, National Institute of Drug Abuse (NIDA) to fund this clinical study as well as the necessary non-clinical studies to support an NDA (New Drug Application) for PF614-MPAR.

Opioid Use Disorder (OUD) Program Update

The Company recently announced the selection of its lead OUD drug candidate PF9001 that has been designed using Ensysce's TAAP™ platform. The intent of the program is to reduce both the abuse profile and the cardiovascular side effects associated with traditional methadone OUD treatments. The program is finalizing required studies supported by a multi-year Helping to End Addiction Long-Term (HEAL) award of up to $15 million granted by the NIH and NIDA and anticipates advancing to Investigational New Drug (IND) enabling studies in the coming year.

Q3 2024 Financial Results

Cash - Cash and cash equivalents were $4.2 million as of September 30, 2024, compared to $1.1 million as of December 31, 2023. A key driver for the increase in cash was cumulative net proceeds of $8.5 million from equity financings in February and August 2024.

Stockholders' Equity - Stockholders' equity was $6.6 million as of September 30, 2024, a level compliant with the $2.5 million stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1).

Federal Grants - Funding under federal grants totaled $3.4 million for the third quarter of 2024 compared to $0.4 million in the comparable year ago quarter. The increase is due to the timing of research activities eligible for funding, with increased activities under the OUD grant following the selection of a lead drug candidate in June. Funding under the current phase of the OUD grant was completed in August 2024. Also contributing to the increase is the recently awarded MPAR grant, with payments for clinical activities for PF614-MPAR initiated during the quarter. With the completion of the OUD grant, funding under federal grants is expected to decline in coming quarters from the level of the third quarter of 2024.

Research & Development Expenses - R&D expenses were $1.7 million for the third quarter of 2024 compared to $1.9 million for the same period in 2023. The decrease of $0.2 million was primarily the result of reduced external research and development costs related to clinical and pre-clinical programs for PF614 in the 2024 period. Increased activities on the OUD and MPAR programs are expected to result in higher research and development expenses in coming quarters.

General & Administrative Expenses - G&A expenses were $1.1 million in the third quarter of 2024, compared to $1.2 million for the third quarter of 2023, a slight decrease of $0.1 million. G&A expenses are expected to approximate current levels in the coming quarters.

Other Income (Expense) - Total other income (expense), net, was consistent with income of $17,023 for the third quarter of 2024 compared to income of $16,508 for the same period of 2023.

Net Income (Loss) - Net income attributable to common stockholders for the third quarter of 2024 was $0.7 million compared to a net loss of $2.7 million for the third quarter of 2023. The Company recorded net income in the third quarter due to the timing of federal grant funding received, with the completion of funding under the OUD grant and the start of funding under the MPAR grant both occurring during the quarter. With only the MPAR grant moving forward, net income for the third quarter is expected to be a one-time event and we do not anticipate net income in coming quarters. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Federal grants	$ 3,418,853	$ 435,380	$ 3,906,372	$ 1,715,488
Operating expenses:				
Research and development	1,690,674	1,914,970	3,416,807	5,354,713
General and administrative	1,083,433	1,227,724	3,643,223	3,923,277
Total operating expenses	2,774,107	3,142,694	7,060,030	9,277,990
Income (loss) from operations	644,746	(2,707,314)	(3,153,658)	(7,562,502)
Total other income (expense), net	17,023	16,508	(1,268,929)	440,588
Net income (loss)	$ 661,769	$ (2,690,806)	$ (4,422,587)	$ (7,121,914)
Adjustments to net income (loss)	-	1,235	(216)	198
Net income (loss) attributable to common stockholders	$ 661,769	$ (2,689,571)	$ (4,422,803)	$ (7,121,716)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ 0.07	$ (0.87)	$ (0.57)	$ (3.32)

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	$ (6,738,610)	$ (8,978,107)
Net cash provided by financing activities	9,768,598	7,294,786
Change in cash and cash equivalents	3,029,988	(1,683,321)
Cash and cash equivalents at beginning of period	1,123,604	3,147,702
Cash and cash equivalents at end of period	$ 4,153,592	$ 1,464,381

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,153,592	$ 1,123,604
Prepaid expenses and other current assets	4,936,915	1,165,264
Total current assets	9,090,507	2,288,868
Other assets	294,217	419,217
Total assets	$ 9,384,724	$ 2,708,085
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,967,573	$ 1,936,007
Accrued expenses and other liabilities	447,035	542,260
Notes payable and accrued interest	387,176	854,697
Total current liabilities	2,801,784	3,332,964
Long-term liabilities	3,213	26,388
Total liabilities	2,804,997	3,359,352
Stockholders' equity (deficit)	6,579,727	(651,267)
Total liabilities and stockholders' equity (deficit)	$ 9,384,724	$ 2,708,085

SOURCE: Ensysce Biosciences, Inc.

View the original press release on accesswire.com