May 13, 2024

Ensysce Biosciences Reports First Quarter 2024 Financial Results

PF614's Phase 3 Clinical Plans Affirm the Path to Regulatory Approval

FDA Breakthrough Therapy Designation of PF614-MPAR Expedites Clinical Program

SAN DIEGO, CA / ACCESSWIRE / May 13, 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 first quarter ended March 31, 2024.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "In the first quarter of 2024, we continued to accelerate the progress of our clinical programs toward regulatory approvals. Early in the quarter, a constructive end of Phase 2 meeting was held with the U.S. Food & Drug Administration (FDA) for our lead opioid product, PF614, providing solid guidance for a Phase 3 clinical trial expected to initiate in the second half of 2024. The FDA also provided guidelines to reduce the regulatory risks for our commercialization plan.

Additionally, in January, the FDA's grant of Breakthrough Therapy designation for PF614-MPAR affirms belief in our novel approach to providing the 'Next Generation' of opioid products. This exclusive designation, granted to fewer than 300 drugs since its introduction in 2012, was based on data generated in our Phase 1 study, PF614-MPAR-101, which demonstrated that the unique combination can add oral overdose protection to our prescription TAAP (Trypsin-Activated Abuse Protection) products. This designation is intended to accelerate product development and provide guidance to aid the design of our PF614-MPAR programs to efficiently move toward a new drug application (NDA) submission and approval of this innovative opioid. Coupled with the previously granted Fast Track designation for PF614, Breakthrough Therapy designation for PF614-MPAR demonstrates the FDA's recognition of these transformational pain medications."

Dr. Kirkpatrick added, "We look forward to beginning our Phase 3 clinical trials in the second half of 2024. We believe the data we have generated to date from multiple clinical studies de-risk our path to commercialization. These studies have verified PF614 delivers oxycodone in an equivalent manner to commercially available opioids and provides pain relief with reduced abuse potential. We believe our TAAP and MPAR (Multi-Pill Abuse Resistance) opioids have a proven safety profile that surpasses the current slate of extended-release opioid analgesics, and we look forward to providing additional milestones and updates in the months ahead," concluded Dr. Kirkpatrick.

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. As mentioned, Ensysce recently received FDA guidance on the strategy and design of its Phase 3 clinical program and expects to commence enrollment for the Phase 3 clinical trial 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.

Ensysce received notice from the FDA that it had granted Breakthrough Therapy designation for PF614-MPAR, specifically acknowledging the potential impact of the innovative MPAR® overdose protection technology. Breakthrough Therapy is an elite designation that expedites the development and review of drugs that are intended to treat a serious condition where the drug may demonstrate substantial improvement over available therapies.

In February, the Company received additional productive guidance from the FDA to aid the execution of our PF614-MPAR programs to efficiently move toward a new drug application (NDA) submission and approval to bring this innovative drug to market.

Q1 2024 Financial Results

Cash - Cash and cash equivalents were $3.4 million as of March 31, 2024, compared to $1.1 million as of December 31, 2023. In January, the Company received cash proceeds of $2.1 million from the exercise of warrants originally issued in the fourth quarter of 2023. Additionally, in February 2024, the Company received gross proceeds of $4.7 million, prior to deducting placement agent fees and offering expenses, from the exercise of warrants originally issued in May 2023.

Federal Grants - Funding under federal grants totaled to $0.3 million for the first quarter of 2024 compared to $0.8 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 $0.8 million for the first quarter of 2024 compared to $1.8 million for the same period in 2023. The decrease of $1.0 million was primarily due to reduced external research and development costs related to pre-clinical programs for PF614 and PF614-MPAR.

General & Administrative Expenses - G&A expenses were $1.4 million in the first quarter of 2024 compared to $1.6 million for the same period of 2023. The decrease of $0.2 million was primarily a result of reduced stock-based compensation and consulting fees in the 2024 period.

Other Income (Expense) - Total other income (expense), net was an expense of $1.3 million for the first quarter of 2024 compared to income of $0.4 million for the same period of 2023. The changes in other expenses were primarily due to interest expense related to convertible notes and non-cash fair value adjustments for convertible notes and warrants.

Net Loss - Net loss attributable to common stockholders for the first quarter of 2024 was $3.1 million compared to $2.2 million for the first 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 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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Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Federal grants	$ 305,722	$ 789,635
Operating expenses:		
Research and development	778,904	1,796,015
General and administrative	1,369,782	1,554,855
Total operating expenses	2,148,686	3,350,870
Loss from operations	(1,842,964)	(2,561,235)
Total other income (expense), net	(1,273,599)	369,429
Net loss	$ (3,116,563)	$ (2,191,806)
Adjustments to net loss	(216)	(4,368)
Net loss attributable to common stockholders	$ (3,116,779)	$ (2,196,174)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.55)	$ (2.08)

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

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (3,408,403)	$ (3,606,919)
Net cash provided by financing activities	5,689,148	1,874,982
Change in cash and cash equivalents	2,280,745	(1,731,937)
Cash and cash equivalents at beginning of period	1,123,604	3,147,702
Cash and cash equivalents at end of period	$ 3,404,349	$ 1,415,765

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,404,349	$ 1,123,604
Prepaid expenses and other current assets	1,292,291	1,165,264
Total current assets	4,696,640	2,288,868
Other assets	377,550	419,217
Total assets	$ 5,074,190	$ 2,708,085
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 981,720	$ 1,936,007
Accrued expenses and other liabilities	408,435	542,260
Notes payable and accrued interest	245,973	854,697
Total current liabilities	1,636,128	3,332,964
Long-term liabilities	17,433	26,388
Total liabilities	1,653,561	3,359,352
Stockholders' equity (deficit)	3,420,629	(651,267)
Total liabilities and stockholders' equity (deficit)	$ 5,074,190	$ 2,708,085

SOURCE: Ensysce Biosciences, Inc.

View the original press release on accesswire.com