March 15, 2024

Ensysce Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results

Corporate Update Call to be Held Thursday, March 21, 2024 at 11:00am ET to Discuss Recent FDA Breakthrough Therapy Designation and Phase 3 Clinical Plans

SAN DIEGO, CA / ACCESSWIRE / March 15, 2024 /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 fourth quarter and full year of 2023.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "We are proud of the significant progress Ensysce has made in 2023 both operationally and clinically for our lead pain therapeutic, PF614, and our overdose protection product, PF614-MPAR. Our advancements were particularly instrumental in providing a foundation for our constructive end of Phase 2 meeting with the U.S. Food & Drug Administration (FDA) for PF614. We believe the FDA's guidance positioned Ensysce favorably and solidified the PF614 Phase 3 clinical study designs to initiate enrollment in the second half of 2024, ultimately reducing regulatory risks that could impede our commercialization plan. Especially encouraging was the FDA grant of Breakthrough Therapy designation to PF614-MPAR in January 2024, acknowledging its unique advantage over current opioids. Breakthrough Therapy, an exclusive designation applied to less than 300 drugs historically, offers Ensysce the opportunity to accelerate our clinical programs and go-to market plans."

"Importantly, the collective empirical data we've received from four completed clinical studies verify PF614's bioequivalence to commercially available opioids but with reduced abuse potential, and reaffirms our belief that Ensysce's PF614 will provide a "next generation" opioid family with the added value proposition of safer products with overdose protection. We have many reasons to remain optimistic on our path to regulatory approval as we advance through our Phase 3 clinical trials beginning in the second half of 2024. Progress in 2023 and early 2024 has provided further evidence that our innovative analgesics will provide prescribers and patients in severe pain with an alternative, effective option with safety advantages to address the opioid epidemic in the United States," concluded Dr. Kirkpatrick.

TAAP™ (Opioid Abuse Deterrent Program) Updates

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. Ensysce recently completed a Phase 2 clinical trial for PF614, 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. Ensysce believes it has a body of evidence showing that PF614 works as designed, has a good safety profile and is bioequivalent to OxyContin providing strong efficacy, yet reduced abuse potential.

As a reaffirmation of the Company's belief in the efficacy of PF614, on February 15, 2024, the Company announced the online publication of its manuscript entitled, "Clinical evaluation of PF614, a novel TAAP™ prodrug of oxycodone, versus OxyContin® in a multi-ascending dose study with a bioequivalence arm in healthy volunteers" by the open-access medical journal Clinical and Translational Science (CTS) sponsored by the American Society of Clinical Pharmacology and Therapeutics (ASCPT). The results from the two-part PF614-102 study demonstrate a clear dose relationship between PF614 and oxycodone, which is the foundation for the FDA submission.

As previously mentioned, on January 31, 2024, the Company completed a successful End of Phase 2 meeting with the FDA regarding PF614 and received guidance on its non-clinical development approach and clinical development plans.

Instrumental to the meeting was the PF614-201 study, "A Randomized, Double-Blind, Placebo-Controlled Crossover Study of PF614 on Analgesic Response in the Cold Pressor Test in Healthy Male Subjects" that concluded in December 2023. This study measured the time-of-onset of pain-relief in healthy volunteers and showed that Ensysce's TAAP™ chemical approach delivers effective analgesia. This study was a meaningful component of the Company's Phase 3 clinical protocol design and a driver of the positive outcome with the FDA.

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

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.

Importantly, in January 2024, Ensysce received notice from the FDA that it had granted Breakthrough Therapy designation for PF614-MPAR, 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 design of our PF614-MPAR programs to efficiently move toward a new drug application (NDA) submission and approval to bring this innovative drug to market.

Financial Results

Cash - Cash and cash equivalents were $1.1 million as of December 31, 2023, as compared to $1.5 million as of September 30, 2023. After year end, the Company received cash proceeds of $2.1 million from the exercise of warrants, originally issued in the fourth quarter of 2023, to purchase 1.3 million shares of common stock. 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 to purchase 3.6 million shares of common stock originally issued in May 2023.

Federal Grants - Funding under federal grants totaled to $0.5 million for the fourth quarter of 2023 compared to $1.4 million in the comparable year ago quarter. For the full year of 2023, funding from federal grants was $2.2 million compared to $2.5 million for the full year of 2022. The decreases are due to the timing of research activities eligible for funding, particularly relative to the MPAR® program.

Research & Development Expenses - R&D expenses were $2.2 million for the fourth quarter of 2023 compared to $6.4 million for the same period in 2022. For the full year of 2023, R&D expenses were $7.6 million compared to $19.8 million for the full year of 2022. The decreases were primarily the result of reduced external research and development costs related to the clinical programs for PF614 and PF614-MPAR, particularly regarding bioequivalence and human abuse potential studies for PF614.

General & Administrative Expenses - G&A expenses were $1.4 million in the fourth quarter of 2023, a slight increase compared to $1.2 million for the same period of 2022. For the full year of 2023, G&A expenses were $5.4 million, a decrease compared to $6.9 million for the full year of 2022. The quarterly increase from the same prior year period was primarily a result of higher non-cash stock-based compensation, while the full year decrease resulted from reduced consulting, legal, liability insurance and employee bonus expenses.

Other Income (Expense) - Total other income (expense), net was an expense of $0.3 million for the fourth quarter of 2023 compared to income of $0.7 million for the same period of 2022. For the full year, total other income (expense), net was income of $91,912 in 2023 compared to income of $14,410 in 2022. The changes in other expenses were primarily due to non-cash fair value adjustments for convertible notes and warrants.

Net Loss - Net loss attributable to common stockholders for the fourth quarter of 2023 was $3.5 million compared to $5.5 million for the fourth quarter of 2022. For the full year of 2023, net loss was $10.6 million compared to $25.1 million for the full year 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.

Corporate Update Conference Call

Ensysce CEO, Dr. Lynn Kirkpatrick, CFO, Dave Humphrey, and CMO, Dr. William Schmidt, will host a conference call on Thursday, March 21, 2024, at 11:00am ET to provide a corporate update and review recent company milestones. The call will conclude with Q&A from participants. An accompanying updated presentation will be posted prior to the call to the Company's investor relations website.

Date: Thursday, March 21, 2024

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 Thursday, April 4, 2024. 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 13744594.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Federal grants	$ 515,032	$ 1,433,463	$ 2,230,520	$ 2,523,383
Operating expenses:				
Research and development	2,232,760	6,441,927	7,587,473	19,835,875
General and administrative	1,437,957	1,192,322	5,361,234	6,909,603
Total operating expenses	3,670,717	7,634,249	12,948,707	26,745,478
Loss from operations	(3,155,685)	(6,200,786)	(10,718,187)	(24,222,095)
Total other income (expense), net	(348,676)	722,710	91,912	14,410
Net loss	$ (3,504,361)	$ (5,478,076)	$ (10,626,275)	$ (24,207,685)
Adjustments to net loss	66	(43,832)	264	(877,811)
Net loss attributable to common stockholders	$ (3,504,295)	$ (5,521,908)	$ (10,626,011)	$ (25,085,496)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.13)	$ (18.30)	$ (4.69)	$ (139.42)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (10,779,982)	$ (17,887,439)
Net cash provided by investing activities	-	4,500
Net cash provided by financing activities	8,755,884	8,765,905
Change in cash and cash equivalents	(2,024,098)	(9,117,034)
Cash and cash equivalents at beginning of period	3,147,702	12,264,736
Cash and cash equivalents at end of period	$ 1,123,604	$ 3,147,702

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 1,123,604	$ 3,147,702
Prepaid expenses and other current assets	1,165,264	2,151,467
Total current assets	2,288,868	5,299,169
Other assets	419,217	585,883
Total assets	$ 2,708,085	$ 5,885,052
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,936,007	$ 2,943,791
Accrued expenses and other liabilities	542,260	2,253,809
Notes payable and accrued interest	854,697	4,266,610
Total current liabilities	3,332,964	9,464,210
Long-term liabilities	26,388	450,494
Total liabilities	3,359,352	9,914,704
Stockholders' deficit	(651,267)	(4,029,652)
Total liabilities and stockholders' equity	$ 2,708,085	$ 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 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, 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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