November 14, 2022

Ensysce Biosciences Reports Third Quarter 2022 Financial Results

Corporate Update Call to be Held Wednesday, November 16, 2022

SAN DIEGO, CA / ACCESSWIRE / November 14, 2022 /Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC)(OTC PINK:ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety to reduce abuse and overdose, today reported financial results for the third quarter of 2022.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "We remain focused on progressing our clinical development plans for our programs and achieving each milestone we have identified. I could not be more pleased with the recently reported positive topline results from our human abuse potential (HAP) study for intranasal administration of PF614. These results were in-line with our expectations and importantly, consistent with the unique properties of PF614 as well as prior findings that we believe demonstrate PF614 will provide advantages over currently marketed products. The highly significant results from this study represent a major accomplishment towards our mission of reducing abuse and overdose, ultimately enhancing drug safety."

Dr. Kirkpatrick continued, "Additionally, we were very happy to provide today's announcement regarding the written guidance we received from the FDA which indicated that a development program for PF614 in acute pain may be appropriate. As a result of this FDA guidance, we believe the non-clinical program for PF614 will be significantly shortened for acute pain. We are pleased we can develop PF614 for acute pain while we also continue with our chronic pain development pathway."

TAAP™ (Opioid Abuse Deterrent Program) Updates

PF614 is the first product in a new class of analgesia, a "Trypsin-Activated Abuse Protection" (TAAP™) oxycodone product. The Company's TAAP™ technology is designed to be highly resistant to tampering and abuse and is a unique chemical modification creating a new generation of opioid pain products as compared to traditional Abuse Deterrent Formulations (ADFs). TAAP™ controls or "turns on" the release of the active ingredient in PF614 providing abuse deterrence.

- On October 31, 2022, the Company announced positive topline results from a human abuse potential (HAP) study, PF614-103, with intranasal administration of PF614 as compared to crushed oxycodone or placebo. PF614 demonstrated significantly reduced "drug liking," the primary endpoint, when compared to intranasal crushed immediate-release oxycodone.
- On October 28, 2022, the Company announced first subjects dosed in its second HAP study, PF614-104, comparing oral administration of PF614 versus oxycodone or

placebo. Data from this study is expected in early 2023. These HAP studies are intended to support abuse-deterrent labeling upon final approval of PF614.
- On July 27, 2022, the Company announced positive date from a bioequivalence (BE) study PF614-102 of its novel TAAP™ opioid PF614 compared to OxyContin which the company believes will support the substitution of PF614 for OxyContin in the market. The Company believes that the BE data from this study will also support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval. This pathway allows reference to available safety and clinical data from an approved product, and the BE data established by this study will move PF614 closer to registration.

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

PF614-MPAR™ is a combination product designed to have overdose protection along with the abuse protection of TAAP™. MPAR™ (Multi-Pill Abuse Resistance) turns off the release of the opioid in an overdose situation, providing the additional layer of protection to Ensysce's TAAP™ pain medications.

- On August 31, 2022, the Company announced a partnership with Quotient Sciences on the Development and Clinical Testing of PF614-MPAR™. Quotient Sciences is currently using its integrated Translational Pharmaceutics® platform to identify a PF614-MPAR combination that allows conversion into oxycodone within the prescribed dose range but reduces conversion to oxycodone at higher than prescribed dose levels in an overdose scenario.
    - On June 27, 2022, the Company announced its notice of award for the 4th year of funding for its MPAR™ platform to support the final part of the ongoing clinical trial PF614-MPAR-101. The amount awarded was $2.8 million and this brings total funding from NIDA under this grant to $10.8 million.

Financial Results

- **Cash -** Cash and cash equivalents were $4.5 million as of September 30, 2022, as compared to $3.7 million as of June 30, 2022.
- **Federal Grants -** Funding from federal grants was $0.3 million for the third quarter of 2022 compared to $1.2 million in the comparable year ago quarter. The decrease is a result of timing of pre-clinical and clinical activities for the MPAR program.
- **Research & Development Expenses -** R&D expenses were $4.8 million for the third quarter of 2022 compared to $1.7 million in the comparable year ago quarter. The increase in expenses results from increased pre-clinical and clinical activities for PF614.
- **General & Administrative Expenses -** G&A expenses were $1.7 million for the third quarter of 2022 compared to $16.4 million for the same period in 2021. The decrease in expenses is largely attributable to significant non-cash expenses recorded in the prior year period related to the valuation of warrants issued.
- **Other Income (Expense) -** Total other income (expense) was expense of $3.7 million in the third quarter of 2022 and expense of $0.3 million in the third quarter of 2021. The change in other expenses is primarily due to non-cash fair value adjustments for convertible notes and warrants.
- **Net Loss -** Net loss for the third quarter of 2022 was $9.9 million compared to net loss

of $17.2 million for the comparable year ago period. 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

As previously announced, CEO, Dr. Lynn Kirkpatrick, CFO, Dave Humphrey, and CMO, Dr. William Schmidt, will host a corporate update conference call on Wednesday, November 16, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results from the HAP study of PF614. The call will conclude with Q&A from participants. An accompanying presentation will be posted prior to the call to the Company's investor relations website.

Date: Wednesday, November 16, 2022
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Conference ID: 13734017
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 Wednesday, November 16, 2022. 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 13734017.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	2021	2020	2021	2020
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Federal grants	$ 279,351	$ 1,200,816	$ 1,089,920	$ 1,895,907
Operating expenses:				
Research and development	4,756,096	1,714,635	13,393,948	2,502,232
General and administrative	1,686,580	16,372,976	5,717,281	17,257,361
Total operating expenses	6,442,676	18,087,611	19,111,229	19,759,593
Loss from operations	(6,163,325)	(16,886,795)	(18,021,309)	(17,863,686)
Total other income (expense), net	(3,692,240)	(312,679)	(708,300)	(1,245,091)
Net loss	$ (9,855,565)	$ (17,199,474)	$ (18,729,609)	$ (19,108,777)
Adjustments to net loss	(42,047)	35,948	(833,979)	61,976

Net loss attributable to common stockholders	$ (9,897,612)	$ (17,163,526)	$ (19,563,588)	$ (19,046,801)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.13)	$ (14.15)	$ (11.74)	$ (20.31)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	2021	2020
	Nine Months Ended September 30,	
	2022	2021
	(Unaudited)	(Unaudited)
Net cash used in operating activities	$ (14,591,819)	$ (4,474,364)
Net cash provided by investing activities	4,500	-
Net cash provided by (used in) financing activities	6,825,664	11,125,822
Change in cash and cash equivalents	(7,761,655)	6,651,458
Cash and cash equivalents at beginning of period	12,264,736	194,214
Cash and cash equivalents at end of period	$ 4,503,081	$ 6,845,672

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 4,503,081	$ 12,264,736
Prepaid expenses and other current assets	3,159,197	3,397,857
Total current assets	7,662,278	15,662,593
Other assets	627,550	754,756
Total assets	$ 8,289,828	$ 16,417,349
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,285,514	$ 301,104
Accrued expenses and other liabilities	3,071,676	3,432,407
Notes payable and accrued interest	7,552,774	12,748,155
Total current liabilities	11,909,964	16,481,666

Long-term liabilities	2,801,796	8,093,741
Total liabilities	14,711,760	24,575,407
Stockholders' deficit	(6,421,932)	(8,158,058)
Total liabilities and stockholders' deficit	$ 8,289,828	$ 16,417,349

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage biotech 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 a unique, tamper-proof treatment option for pain that minimizes the risk of both drug abuse and overdose. Our products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse, reducing the human and economic costs. 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," and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinical development and are 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.

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.

View source version on accesswire.com:
https://www.accesswire.com/725659/Ensysce-Biosciences-Reports-Third-Quarter-2022-Financial-Results