

Ensysce Biosciences Reports Third Quarter 2021 Financial Results and Recent Corporate Updates

SAN DIEGO, Nov. 15, 2021 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company with proprietary technology platforms to reduce the economic and social burden of prescription drug abuse and overdose, today reported financial results for the third quarter of 2021 and recent corporate updates.

"In the third quarter, we successfully completed our convertible note financing of \$15 million that provided us with the necessary proceeds to continue our advancement of our lead clinical trial programs," said Dr. Lynn Kirkpatrick, CEO of Ensysce. "As previously announced, we commenced our second study of our TAAP opioid, PF614, in early September, and through this study, we aim to demonstrate the correlation between PF614 to Oxycontin, and how Ensysce can begin to make this solution readily available for public use. Additionally, we appointed Dr. Linda Pestano as our Chief Development Officer. Linda's extensive expertise in the preclinical drug development area makes her a perfect addition to our team as we work towards commercializing our next-generation opioid products."

Dr. Kirkpatrick concluded, "We're continuing to develop the next generation of innovative solutions to combat the potential for opioid abuse, and we're pleased with our progress to date. We believe we have the necessary resources and bandwidth to continue to progress on our important mission."

Program Updates

TAAP – opioid abuse deterrent program:

- On September 7, 2021, Ensysce enrolled the first cohort of subjects in a clinical study PF614-102 entitled "A Phase 1b, Randomized, 2-Part Single-Center Study to Evaluate the Pharmacokinetics and Safety of Multiple-Ascending Oral Doses of PF614 and the Food Effect and Bioavailability/Bioequivalence of Single Oral Doses of PF614 Relative to OxyContin in Healthy Adult Subjects."
- This study builds on the results of the initial Phase 1 study and is designed to help us understand how PF614 compares to currently available commercial products.

Other Business Highlights

• Ensysce completed a \$15 million convertible note financing, receiving the second tranche of \$10 million on November 5, 2021 after receiving the first tranche of \$5 million on September 24, 2021.

Total gross proceeds from the convertible note financing will be used for general
working capital purposes, allowing for advancement of lead clinical trial programs
including the completion of the PF614-102 bioequivalence study, as well as continuing
the clinical development of the overdose protection platform with our lead product
PF614-MPAR.

Third Quarter 2021 Financial Results

- Cash Cash and cash equivalents were \$6.8 million as of September 30, 2021. On November 5, 2021, Ensysce received additional funding of \$10 million under the convertible note financing.
- **Federal Grants** Funding under federal grants was \$1.2 million for the third quarter of 2021 compared to \$0.8 million for the third quarter of 2020. The increase is attributable to increased clinical development activity with our PF614-MPAR overdose protection product.
- **R&D Expenses** Research and development expenses were \$1.7 million for the third quarter of 2021 compared to \$0.9 million for the same period in 2020. The increase primarily resulted from increased clinical development activity with our PF614 abuse protection product and combination product PF614-MPAR for overdose protection.
- **G&A Expenses** General and administrative expenses were \$16.4 million for the third quarter of 2021 compared to \$0.3 million for the third quarter of 2020. The increase was primarily a result of \$11.6 million of non-cash expenses for warrants issued under a December 2020 share subscription facility following the Company's listing on Nasdaq in July 2021 and \$2.3 million of non-cash expenses related to equity for consultants.
- **Net Loss** Net loss for the third quarter of 2021 was \$17.2 million compared to net income of \$1.6 million for the same period in 2020.

About Ensysce Biosciences (NASDAQ: ENSC)

Ensysce Biosciences, San Diego, CA 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 developing a new class of powerful, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are anticipated to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic cost. 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

This press release contains certain forward-looking statements within the meaning of federal securities laws. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this communication. Such factors can be found 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

<u>www.sec.gov</u>. New risks and uncertainties arise from time to time, and it is impossible for us to predict these events or how they may affect the Company. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made, and Ensysce undertakes no obligation to update or revise the forward-looking statements, whether as a result of new information, changes in expectations, future events or otherwise.

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Ensysce Biosciences, Inc. Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended September 30,				Nine Months Ended September 30,			
		2021		2020		2021		2020
Federal grants	\$	1,200,816	\$	827,639	\$	1,895,907	\$	3,514,720
Operating expenses:								
Research and development		1,714,635		892,991		2,502,232		3,136,207
General and administrative		16,372,976		339,422		17,257,361		898,470
Total operating expenses		18,087,611		1,232,413		19,759,593		4,034,677
Loss from operations		(16,886,795)		(404,774)		(17,863,686)		(519,957)
Total other income (expense), net		(312,679)		1,955,280		(1,245,091)		340,742
Net income (loss)	\$	(17,199,474)	\$	1,550,506	\$	(19,108,777)	\$	(179,215)

Ensysce Biosciences, Inc. Unaudited Condensed Consolidated Balance Sheets

	Se	December 31, 2020		
Assets				
Current assets:				
Cash and cash equivalents	\$	6,845,672	\$	194,214
Prepaid expenses and other current assets		2,075,636		153,662
Total current assets		8,921,308	-	347,876
Other assets		796,423		3,931
Total assets	\$	9,717,731	\$	351,807
Liabilities and stockholders' deficit				
Current liabilities:				
Accounts payable	\$	471,858	\$	1,724,598
Accrued expenses and other liabilities		3,762,429		370,292
Notes payable and accrued interest		2,797,181		4,245,082
Embedded derivative on convertible notes		_		670,262
Total current liabilities		7,031,468		7,010,234
Long-term liabilities		3,071,550		_
Total liabilities		10,103,018		7,010,234
Stockholders' deficit		(385,287)		(6,658,427)
Total liabilities and stockholders' deficit	\$	9,717,731	\$	351,807



Source: Ensysce Biosciences Inc.