August 11, 2022

Ensysce Biosciences Provides Business Update and Reports Second Quarter 2022 Financial Results

Corporate Update Call to be Held Wednesday, August 17, 2022

SAN DIEGO, CA / ACCESSWIRE / August 11, 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 and performance focused on reducing abuse and overdose, today reported financial results for the second quarter 2022.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "With a recently completed $8 million financing, we are well positioned to advance our clinical trials. We also just announced that we achieved our stated milestone of positive bioequivalence (BE) study data from trial PF614-102 of our novel 'TAAP' opioid PF614. This study provides significant evidence of the progress we have made towards seeking to bring to market an important therapeutic option for pain management. Ultimately, the advances in our PF614 clinical development are the building blocks that enable our platforms to fully support our mission of developing a unique pipeline of safer pain products and helping millions who experience severe pain. To conclude, I want to thank all our constituents for their continued support."

TAAP™ (Opioid Abuse Deterrent Program) Updates

- On July 27, 2022, the Company announced positive bioequivalence (BE) study data of its novel TAAP™ opioid PF614 from clinical trial PF614-102.
- Study PF614-102 found that PF614 conformed to the FDA bioequivalence acceptance criteria when compared to OxyContin under both fasted and fed conditions.
- The Company believes that the BE data from this study will 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. This positive BE data should allow the company to meet and communicate its Phase 3 plans with the FDA in 2023.
- This PF614-102 study builds on the safety and pharmacokinetic results of the PF614 Phase 1 and 1b (Part A) studies and demonstrates the advantages we believe PF614 has over OxyContin, including a longer half-life, the limited food effect and the ability to deliver PF614 as an oral solution without losing its abuse deterrent properties for those who may have trouble swallowing.
- This data is critical to understand future prescribing criteria for PF614 as an agent bioequivalent to OxyContin and the ability to substitute the use of PF614 for OxyContin.

- PF614 is designed as an abuse-protected agent with trypsin-activated abuse protection (TAAP™). TAAP™ chemical modification controls the release of the active ingredients in Ensysce's opioid products including PF614, ‘turning on the release' when exposed to trypsin. TAAP™ provides abuse protection and resistance to manipulation and other forms of recreational drug abuse.

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

- On June 27, 2022, the Company announced its notice of award for the 4th year of funding for its Multi-Pill Abuse (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.
- PF614-MPAR™ is a combination product with both trypsin-activated abuse protection (TAAP™) and overdose protection through multi-pill abuse resistance (MPAR™) technology. TAAP™ chemical modification controls the release of the active ingredient in PF614 providing abuse deterrence, and MPAR™ turns off the release in an overdose situation, providing the additional layer of protection.
- Initial clinical data from PF614-MPAR-101 reported previously provided the first human data demonstrating the overdose protection of PF614-MPAR. The ongoing study will allow perfection of the drug product and aid in bringing this first overdose protected opioid to the market.

Financial Results

- **Cash -** Cash and cash equivalents were $3.7 million as of June 30, 2022, as compared to $8.4 million as of March 31, 2022. Cash used in operating activities for the second quarter of 2022 totaled $4.4 million, an increase from $3.4 million in the first quarter of 2022 that primarily resulted from the clinical advancement of our product candidates. In July, we announced completion of a convertible notes financing for $8 million of gross proceeds received in the third quarter of 2022.
- **Federal Grants -** Funding from federal grants was $0.2 million for the second quarter of 2022 compared to $0.4 in the comparable year ago quarter. Funding decreased by $0.2 million under the OUD Grant due to the timing of research activities eligible for funding. Funding under the MPAR grant in the second quarter was reduced because the annual funding limit through June 30, 2022, was reached. A fourth year of funding of the MPAR program was recently approved for $2.8 million covering the annual period through June 30, 2023.
- **Research & Development Expenses -** R&D expenses were $5.3 million for the second quarter of 2022 compared to $0.5 million in the comparable year ago quarter. The increase was primarily the result of increased external research and development costs related to preclinical and clinical programs for PF614 and PF614-MPAR™.
- **General & Administrative Expenses -** G&A expenses were $2.0 million for the second quarter of 2022 compared to $0.4 million for the same period in 2021. The increase was primarily a result of increased expenses related to operating as a public company, including legal and accounting fees, fees incurred in connection with our recent financing, and director and officer insurance expenses.
- **Other Income (Expense) -** Total other income (expense) was expense of $0.9 million in the second quarter of 2022 and expense of $0.5 million in the second quarter of

2021. The expense in the 2022 period is due to non-cash loss on debt conversions into common stock. The 2021 expense primarily reflects non-cash interest expense on notes that were converted on June 30, 2021.

- **Net Income (Loss) -** Net loss for the second quarter of 2022 was $7.9 million compared to net loss of $1.0 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.

Additional Company Highlights

- On July 1, 2022, the Company closed on $4.0 million of an $8.0 million convertible note financing, the remaining $4.0 million closed on August 9, 2022.
- On July 13, 2022, the Company announced initial patients dosed in the first Human Abuse Potential study, PF614-103.

Corporate Update Conference Call

CEO, Dr. Lynn Kirkpatrick, CFO, Dave Humphrey, and CMO, Dr. Nily Osman will host a corporate update conference call on Wednesday, August 17, 2022, at 11:00am ET to provide a corporate update and review the recently discussed results and data from Clinical Trials PF614-102 and PF614-MPAR-101. 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, August 17, 2022
Time: 11:00am ET
U.S. Dial-in: 1-877-407-0792
International Dial-in: 1-201-689-8263
Conference ID: 13731880
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, September 14, 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 13731880.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	2021	2020	2021	2020
	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Federal grants	$ 207,471	$ 444,516	$ 810,569	$ 695,091
Operating expenses:				

Research and development	5,311,298	463,219	8,451,394	787,595
General and administrative	1,951,356	393,914	4,217,161	884,386
Total operating expenses	7,262,654	857,133	12,668,555	1,671,981
Loss from operations	(7,055,183)	(412,617)	(11,857,986)	(976,890)
Total other income (expense), net	(867,937)	(544,994)	2,983,942	(932,413)
Net loss	$ (7,923,120)	$ (957,611)	$ (8,874,044)	$ (1,909,303)
Adjustments to net loss	(76,170)	(22,067)	(791,932)	26,028
Net loss attributable to common stockholders	$ (7,999,290)	$ (935,544)	$ (9,665,976)	$ (1,883,275)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	$ (0.06)	$ (0.32)	$ (0.12)

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	2021	2020
	Six Months Ended June 30,	
	2022	2021
	(Unaudited)	(Unaudited)
Net cash used in operating activities	$ (7,877,508)	$ (649,461)
Net cash provided by investing activities	4,500	-
Net cash provided by (used in) financing activities	(657,082)	8,467,029
Change in cash and cash equivalents	(8,530,090)	7,817,568
Cash and cash equivalents at beginning of period	12,264,736	194,214
Cash and cash equivalents at end of period	$ 3,734,646	$ 8,011,782

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 3,734,646	$ 12,264,736
Prepaid expenses and other current assets	3,460,128	3,397,857
Total current assets	7,194,774	15,662,593

Other assets	754,242	754,756
Total assets	$ 7,949,016	$ 16,417,349
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,048,037	$ 301,104
Accrued expenses and other liabilities	2,680,904	3,432,407
Notes payable and accrued interest	2,519,539	12,748,155
Total current liabilities	8,248,480	16,481,666
Long-term liabilities	498,114	8,093,741
Total liabilities	8,746,594	24,575,407
Stockholders' deficit	(797,578)	(8,158,058)
Total liabilities and stockholders' deficit	$ 7,949,016	$ 16,417,349

About Ensysce Biosciences

Ensysce Biosciences, based in San Diego, CA is a clinical-stage biotech company using its two novel 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 seeking to develop next-generation, tamper-proof opioids that prevent both drug abuse and overdoses. Ensysce's products are expected to provide safer options to treat severe pain and assist in preventing deaths caused by opioid abuse, reducing the human and economic costs. The platforms are covered by an extensive worldwide intellectual property portfolio encompassing a wide array of prescription drugs. 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.

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