March 31, 2022

Ensysce Biosciences Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results

~ Corporate Update Call to be Held Wednesday, April 6, 2022 ~

SAN DIEGO, March 31, 2022 (GLOBE NEWSWIRE) -- Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ: ENSC, OTC: ENSCW), a clinical-stage biotech company applying transformative chemistry to improve prescription drug safety and performance with a current focus on reducing abuse and overdose, today reported financial results for the fourth quarter and full year 2021.

Dr. Lynn Kirkpatrick, Chief Executive Officer of Ensysce, commented, "Following the successful completion of our convertible note financing of $15 million, providing the necessary funds to advance our clinical trials, the year concluded with an exceptional Company milestone as the first patients were enrolled in the Phase 1 study of PF614-MPAR™, the first product utilizing our MPAR™ platform designed to reduce drug overdose.

"Subsequently, we initiated and recently concluded, the final dosing in the Bioequivalence (BE) trial of our TAAP™ opioid, PF614. We believe that the BE study data, expected to be available in the second quarter, will position PF614 as our first commercial candidate, fueling our ability to bring a unique pipeline of products to the market aligned with our mission of helping millions suffering with severe pain."

Dr. Kirkpatrick concluded, "Regarding our financial results, it's important to note that our net loss for the full year consisted of significant non-cash expenses, including $17.9 million related to fair value accounting for warrants and convertible notes. Cash used in operating activities during 2021 totaled $8.2 million."

TAAP™ (Opioid Abuse Deterrent Program) Updates

- On March 21, 2022, the Company concluded the clinical treatment of the Bioequivalence (BE) portion of the PF614-102 trial, which is studying the novel TAAP™ opioid, PF614. This followed the successful completion of the multi-ascending twice daily dosing part of the study in December 2021.
- BE data from the PF614-102 study is expected to be available by the end of the second quarter 2022. The Company believes that the data will support the 505(b)(2) regulatory path for clinical development of PF614, an abbreviated pathway to FDA approval.
- Human abuse liability (HAL) studies to determine labeling claims for PF614 are scheduled to initiate in the second quarter of 2022.

- PF614 is designed using the abuse protective platform TAAP™, a chemical modification which inactivates the active ingredient in Ensysce's opioid products, including PF614, until swallowed and exposed to the enzyme trypsin in the digestive system. Our TAAP™ platform, which we believe provides abuse protection and resistance to manipulation and other forms of recreational drug abuse, should also control the rate of release of the active opioid. The 102 study builds on the safety and pharmacokinetic results of the initial Phase 1 study and is designed to improve the understanding of how PF614 compares to currently available commercial products.

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

- PF614-MPAR-101 Phase 1 study initiated dosing of PF614 in combination with trypsin inhibitor nafamostat and the first subjects successfully completed administration of PF614 followed by PF614 with nafamostat.
- The study is continuing with additional subjects enrolling to receive PF614 and nafamostat in various combinations through the third quarter of 2022. Safety and pharmacokinetic results are expected by the end of the third quarter 2022.

Financial Results

- **Cash –** Cash and cash equivalents were $12.3 million as of December 31, 2021, as compared to $0.2 million for the same period in 2020. In the fourth quarter of 2021, Ensysce received funding of $10 million under the convertible note financing, bringing the total cash provided by financing activities in fiscal year 2021 to $20.3 million. Cash used in operating activities in 2021 totaled $8.2 million.

- **Federal Grants –** Funding under federal grants was $1.6 million for the fourth quarter of 2021 compared to $0.4 million in the comparable year ago quarter. For the full year 2021, funding under federal grants was $3.5 million compared to $3.9 million for the same period in 2020. The Company successfully increased clinical development activity with our PF614-MPAR™ overdose protection product, contributing to an increase in federal grant funding in the fourth quarter of 2021.

- **Research & Development Expenses –** R&D expenses were $2.2 million for the fourth quarter of 2021 compared to $1.3 million in the fourth quarter of 2020 and $4.7 million for the year ended December 31, 2021, compared to $4.4 million for the same period in 2020. The increases for both the quarter and full year were primarily the result of increased external research and development costs related to the clinical programs for PF614 and PF614-MPAR™.

- **General & Administrative Expenses –** G&A expenses were $1.5 million for the fourth quarter of 2021 and $0.3 million for the fourth quarter 2020 and $18.7 million for the year ended December 31, 2021, compared to $1.2 million for December 31, 2020. The quarterly increase reflects increased costs from operating as a public company in the 2021 period. The full year increase was primarily driven by $11.6 million of non-cash expense for warrants issued in July 2021 related to a $60.0 million share subscription facility. Also contributing to the increase was $1.3 million of non-cash expense for consultants and $1.1 million expense for commitment fees for the share subscription

facility.

- **Other Income (Expense) –** Total other income (expense), net was expense of $8.0 million in the fourth quarter of 2021 and income of $1.1 million in the fourth quarter of 2020. For the full year periods, total other income (expense), net was expense of $9.3 million in 2021 and income of $1.5 million in 2020. The increase in net expenses in the 2021 periods results primarily from non-cash fair value adjustments for the convertible notes and related warrants issued in late 2021, which totaled $6.7 million in the fourth quarter of 2021 and $6.3 million for fiscal year 2021.

- **Net Income (Loss) –** Net loss for the fourth quarter was $10.0 million compared to net income of $18,340 for the comparable year ago period. Net loss was $29.1 million for the year ended December 31, 2021, compared to net loss of $0.2 million for the same period in 2020. As noted above, significant components of the net loss are non-cash expenses. For the fourth quarter, $6.7 million of the $10.0 million net loss was for non-cash fair value adjustments related to the convertible notes issued in September and November 2021. For fiscal year 2021, $17.9 million of the $29.1 million net loss resulted from non-cash expenses for fair value of warrants and convertible notes. As we are a clinical stage biotech company, our research and development of, and regulatory approvals for, our product candidates continues, resulting in expected losses for the foreseeable future.

Additional Company Highlights

- Announced the appointment of Dr. Linda Pestano as Chief Development Officer on October 15, 2021, to lead the non-clinical drug development activities.
- The Company further strengthened its Board of Directors with the appointment of Ms. Lee Rauch on February 28, 2022.
- 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.

Corporate Update Conference Call

Management will host a corporate update conference call on Wednesday, April 6, 2022, at 11:00 a.m. Eastern time. The call will conclude with Q&A from participants.

Date:	Wednesday, April 6, 2022
Time:	11:00 a.m. Eastern time
Dial-in:	1-877-407-0792
International Dial-in:	1-201-689-8263
Conference Code:	13727989
Webcast:	ENSC Corporate Update Conference 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 May 6, 2022 on Ensysce's Investor Relations website at ir.ensysce.com.

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Federal grants	$ 1,635,292	$ 416,489	$ 3,531,199	$ 3,931,209
Operating expenses:				
Research and development	2,187,850	1,253,372	4,690,082	4,389,579
General and administrative	1,454,187	256,447	18,711,548	1,154,917
Total operating expenses	3,642,037	1,509,819	23,401,630	5,544,496
Loss from operations	(2,006,745)	(1,093,330)	(19,870,431)	(1,613,287)
Total other income (expense), net	(8,030,379)	1,111,670	(9,275,470)	1,452,412
Net income (loss)	$ (10,037,124)	$ 18,340	$ (29,145,901)	$ (160,875)
Adjustments to net income (loss)	(802,926)	195,655	(740,950)	217,645
Net income (loss) attributable to common stockholders	$ (10,840,050)	$ 213,995	$ (29,886,851)	$ 56,770
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.45)	$ 0.01	$ (1.48)	$ 0.00

Ensysce Biosciences, Inc.
Condensed Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (8,242,177)	$ (1,247,342)
Net cash provided by financing activities	20,312,699	1,100,020
Change in cash and cash equivalents	12,070,522	(147,322)
Cash and cash equivalents at beginning of period	194,214	341,536
Cash and cash equivalents at end of period	$ 12,264,736	$ 194,214

Ensysce Biosciences, Inc.
Condensed Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 12,264,736	$ 194,214
Prepaid expenses and other current assets	3,397,857	153,662
Total current assets	15,662,593	347,876
Other assets	754,756	3,931
Total assets	$ 16,417,349	$ 351,807
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 301,104	$ 1,724,598
Accrued expenses and other liabilities	3,432,407	370,292
Notes payable and accrued interest	12,748,155	4,245,082
Embedded derivative on convertible notes	—	670,262
Total current liabilities	16,481,666	7,010,234
Long-term liabilities	8,093,741	—
Total liabilities	24,575,407	7,010,234
Stockholders' deficit	(8,158,058)	(6,658,427)
Total liabilities and stockholders' equity	$ 16,417,349	$ 351,807

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 developing next-generation, 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 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 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.

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.

Source: Ensysce Biosciences Inc.