

# Ensysce Biosciences Reports Second Quarter 2021 Financial Results and Recent Corporate Updates

SAN DIEGO, Aug. 16, 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 second quarter of 2021 and recent corporate updates.

"In the second quarter, we successfully closed our merger with Leisure Acquisition Corp., providing us with financial resources to advance our lead clinical programs and focus on expanding our pipeline of products in the pain, opioid use disorder (OUD) and ADHD space as a publicly listed company," said Dr. Lynn Kirkpatrick, CEO of Ensysce Biosciences. "We currently have two technology platforms, TAAP and MPAR™, with three clinical-stage product candidates. Our pipeline of candidates provides us with the ability to grow each of these programs. Our focus is on prioritization and resource allocation to maintain an optimal balance between aggressively pursuing our more advanced clinical-stage product candidates, such as PF614, PF614-MPAR™, and nafamostat, while ensuring the continued development of additional potential product candidates. We have partnered with contract development and manufacturing organizations (CDMOs) to bolster our team and facilitate multiple parallel development programs. Our view, based on data so far and feedback from experts, is that our lead assets for chronic and severe pain have the potential to be transformational."

Dr. Kirkpatrick concluded, "Over the long-term, it is our vision to develop the next generation of innovative solutions for severe pain relief while the reducing the fear of and the potential for opioid misuse, abuse and overdose."

## **Program Updates**

## TAAP - opioid abuse deterrent program:

- Ensysce's lead TAAP candidate, PF614, entered Phase 1b/Bioequivalence clinical development.
- Ensysce entered into an agreement for manufacture of PF614 clinical trial material with Recro Pharma.

## MPAR - opioid overdose protection program:

• PF614-MPAR™, our overdose protection program lead product, received an Investigational New Drug (IND) allowance from the U.S. Food and Drug Administration.

- Notice of Award for year 3 of a multi-year grant was received from the National Institute on Drug Abuse (NIDA), providing Ensysce with additional resources to continue its work to bring PF614-MPAR™ into clinical development.
- PF614-MPAR™ entered Phase 1 clinical development utilizing a 'translational pharmaceutics' approach.

### Other programs:

- Ensysce entered into an agreement for manufacture of nafamostat clinical trial material with Recro Pharma for its COVID-19 oral therapy program.
- Ensysce received a Notice of Allowance from the United States Patent and Trademark Office for a patent entitled Compositions Comprising Enzyme-Cleavable Amphetamine Prodrugs and Inhibitors Thereof. This issuance provides the Company with additional pipeline candidates for ADHD indications.

#### **Second Quarter 2021 Financial Results**

- Cash Cash and cash equivalents were \$8.0 million as of June 30, 2021. With the
  public listing of its common stock following the closing of the merger with Leisure
  Acquisition Corp. on June 30<sup>th</sup>, Ensysce now has access to a share subscription facility
  of up to \$60 million which it entered into in December 2020. As such, Ensysce believes
  it has access to sufficient capital to fund its current planned operations for at least the
  next twelve months.
- **Federal Grants** Funding under federal grants was \$0.4 million for the second quarter of 2021 compared to \$1.8 million for the second quarter of 2020. The decrease is attributable to the timing of research activities eligible for funding.
- R&D Expenses Research and development expenses were \$0.5 million for the second quarter of 2021 compared to \$1.4 million for the same period in 2020. The decrease was primarily resulted from reduced external research and development costs related to preclinical programs for PF614-MPAR™ and Phase 1 clinical trial activities of nafamostat.
- **G&A Expenses** General and administrative expenses were \$0.4 million for the second quarter of 2021 compared to \$0.3 million for the second quarter of 2020. The increase was primarily a result of higher legal and other professional services expenses related to post-merger corporate matters.
- **Net Loss** Net loss for the second quarter of 2021 was \$1.0 million compared to \$0.7 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 <u>www.ensysce.com</u>.

### **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 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 <a href="https://www.sec.gov">www.sec.gov</a>. Such factors can also be found in the Form S-4 and Ensysce's definitive proxy statement/prospectus filed on June 16, 2021 and in the Form S-1 filed on August 9, 2021. 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 June 30,				Six Months Ended June 30,			
		2021		2020		2021		2020
Federal grants	\$	444,516	\$	1,824,681	\$	695,091	\$	2,687,081
Operating expenses:								
Research and development		463,219		1,404,246		787,595		2,243,217
General and administrative		393,914		281,354		884,386		559,047
Total operating expenses	<u> </u>	857,133		1,685,600		1,671,981		2,802,264
Income (loss) from operations		(412,617)		139,081		(976,890)		(115,183)
Total other income (expense), net		(544,994)		(845,555)		(932,413)		(1,614,538)
Net loss	\$	(957,611)	\$	(706,474)	\$	(1,909,303)	\$	(1,729,721)

Ensysce Biosciences, Inc.
Unaudited Condensed Consolidated Balance Sheets

	June 30, 2021		December 31, 2020	
Assets				
Current assets:				
Cash and cash equivalents	\$ 8,011,782	\$	194,214	
Prepaid expenses and other current assets	346,286		153,662	
Total current assets	 8,358,068		347,876	
Other assets	838,141		3,931	
Total assets	\$ 9,196,209	\$	351,807	
Liabilities and stockholders' equity (deficit)				
Current liabilities:				
Accounts payable	\$ 3,140,721	\$	1,724,598	
Accrued expenses and other liabilities	422,141		370,292	
Notes payable and accrued interest	466,055		4,245,082	
Embedded derivative on convertible notes	_		670,262	
Total current liabilities	 4,028,917		7,010,234	
Stockholders' equity (deficit)	5,167,292		(6,658,427)	
Total liabilities and stockholders' equity	\$ 9.196.209	\$	351.807	



Source: Ensysce Biosciences Inc.