Protagenic Therapeutics Reports Fourth Quarter and Full Year 2023 Results

- ***Transitioned from Pre-Clinical to Clinical Stage company in FY 2023***
- ***Phase 1/2a trial, designed to assess both healthy volunteers and patients diagnosed with Treatment-Resistant Depression, PTSD or Generalized Anxiety Disorder, progressing through Phase 1 portion***
- ***Plans to enroll final two out of five cohorts into the single dose portion of the Phase 1 trial within the next month***

NEW YORK, NY / ACCESSWIRE / April 1, 2024 / Protagenic Therapeutics, Inc. (NASDAQ:PTIX), a leader in biopharmaceutical innovation, today provided a corporate update and reported financial results for the fourth quarter and full year 2023.

"In 2023, Protagenic Therapeutics achieved a significant milestone as we began enrolling patients for our neuropeptide drug candidate, PT00114," said Dr. Garo Armen, Executive Chairman. "Our primary focus lies in advancing this drug candidate, designed to address the substantial unmet needs across a spectrum of stress-related neuropsychiatric disorders, including Treatment-Resistant Depression, PTSD, Generalized Anxiety Disorder and Addiction withdrawal."

2023 Highlights about PT00114

First Clinical Trial: PT00114, the company's synthetic version of the stress-regulating peptide TCAP, began the single ascending dose (S.A,D,) portion of a Phase 1 clinical trial. Notably, PT00114 has shown excellent tolerability with no adverse safety findings during these ongoing Phase 1 studies. With promising preclinical efficacy in anxiety, depression, PTSD, and addiction models, PT00114 is moving forward in clinical evaluation, representing a key step toward transformative therapies.

Safety Validation: Building on the low dose safety validation announced February 13th, as announced on March 27th, PT00114 has now demonstrated safety at a medium dose of 500 micrograms administered subcutaneously in the third of five planned cohorts of subjects in the single dose portion of the Phase I trial. No adverse reactions were observed among subjects, consistent with the two lower dose cohorts (125 micrograms and 250 micrograms), with no reported injection site reactions or tolerability issues in the week following dosing. Based on preclinical pharmacology, PT00114 is expected to be administered once weekly via subcutaneous injection.

Clinical Protocol Progress: This marks progress in the ongoing Phase 1/2a trial, designed to assess both healthy volunteers and patients diagnosed with Treatment-Resistant Depression, PTSD, or Generalized Anxiety Disorder. The company plans to enroll the final two cohorts into the single dose portion of the Phase 1 trial within the next month.

Comprehensive Approach: In addition to monitoring disease status, the trial incorporates biomarker assessments, including circulating cortisol levels, to measure initial treatment response. Dr. Maurizio Fava, Psychiatrist-in-Chief at Massachusetts General Hospital, serves as the Principal Investigator in Protagenic's Phase 1/2a clinical trial with a basket design.

Strategic Collaboration: Axiom Real-Time Metrics, a CRO/Data Analytics firm, manages the clinical program.

Fourth Quarter and Full Year 2023 Financial Results

Our financial results reflect an increase in research & development spending to pursue our primary objective of developing and commercializing PT00114 during FY 2023, particularly during the fourth quarter. In the fourth quarter of

2023, we spent $1.0 million on R&D, an increase of 301% over our $258,000 R&D spend in the fourth quarter of 2022. This significant increase in R&D expenditures was entirely due to the clinical trial that is now in progress for PT00114, which commenced just as Q4 was starting. Our G&A spend for the fourth quarter of 2023 was just $201,000, down 50% from our G&A spend in the comparable quarter a year ago. Our net loss for Q4 was $1.2 million, compared to a net loss of $656,000 in the year-ago quarter.

For the full year 2023, we spent $3.3 million on R&D, up 109% from the $1.6 million we spent on R&D for the full year 2022. Our full-year G&A of $1.2 million was, similar to the quarter, down almost 40% from the amount spent in the year-ago period.

For full year net income, we lost $4.5 million, which is 27% more loss than we had in 2022, driven primarily by our higher R&D spend because of our clinical trial activities.

For cash, we ended the year with $4.1 million in cash and cash equivalents, down from the $8.0 million we had as of Dec 31, 2022. We believe that our current cash reserves are sufficient to fund all of our Phase I clinical trial.

Profit and Loss Statements

	For the years ended December 31,	
	2023	**2022**
OPERATING AND ADMINISTRATIVE EXPENSES		
Research and development	$3,319,867	$1,589,239
General and administrative	1,207,107	1,968,549
TOTAL OPERATING AND ADMINISTRATIVE EXPENSES	4,526,974	3,557,788
LOSS FROM OPERATIONS	(4,526,974)	(3,557,788)
OTHER INCOME		
Interest income	264,476	185,790
Interest expense	(107,682)	(137,456)
Realized loss on marketable securities	(630,317)	(46,051)
TOTAL OTHER INCOME	(473,523)	2,283
LOSS BEFORE TAX	(5,000,497)	(3,555,505)
INCOME TAX EXPENSE	-	-
NET LOSS	$(5,000,497)	$(3,555,505)
COMPREHENSIVE LOSS	-	-
Other Comprehensive Loss - net of tax		
Net unrealized gain (loss) on marketable securities	16,848	(421,738)
Reclassification of realized losses on debt securities	489,120	-
Foreign exchange translation income (loss)	57,393	(6,820)
TOTAL COMPREHENSIVE LOSS	$(4,437,136)	$(3,984,063)
Net loss per common share - Basic and Diluted	$(1.15)	$(0.82)
Weighted average common shares - Basic and Diluted	4,344,580	4,317,875

Balance Sheet

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash	$1,287,893	$215,189
Marketable securities	2,768,119	7,763,517
Prepaid expenses	144,025	56,939
TOTAL CURRENT ASSETS	4,200,037	8,035,645
Equipment - net	123,332	1,775
TOTAL ASSETS	$4,323,369	$8,037,420
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$439,757	$669,704
Accounts payable and accrued expenses - related party	215,495	105,928
PIK convertible notes payable, net of debt discount	-	150,591
PIK convertible notes payable, net of debt discount - related parties	-	193,639
TOTAL CURRENT LIABILITIES	655,252	1,119,862
TOTAL LIABILITIES	655,252	1,119,862
STOCKHOLDERS' EQUITY		
Preferred stock, $0.000001 par value; 20,000,000 shares authorized; none shares issued and outstanding in the following classes:	-	-
Preferred stock; par value $0.000001; 2,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.000001 par value;18,000,000 shares authorized; 0 and 0 shares issued and outstanding at December 31, 2023, and December 31, 2022	-	-
Preferred stock value	-	-
Common stock, $.0001 par value, 100,000,000 shares authorized, 4,435,132 and 4,321,315 shares issued and outstanding at December 31, 2023, and December 31, 2022	444	434
Additional paid-in-capital	34,559,091	33,371,406
Accumulated deficit	(30,777,872)	(25,777,375)
Accumulated other comprehensive loss	(113,546)	(676,907)
TOTAL STOCKHOLDERS' EQUITY	3,668,117	6,917,558
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$4,323,369	$8,037,420

See accompanying notes to the consolidated financial statements in the company's Form 10-K, filed concurrently.

Conference Call

Date: April 1 , 2024, 4:30 p.m. ET

To access dial-in numbers, please register here.

Participant link (for all regular participants): https://www.webcaster4.com/Webcast/Page/3027/50127.
Or by phone: 888-506-0062
International: 973-528-0011
Participant Access Code: 628544

Webcast
A live webcast and replay of the conference call will be accessible on the company's website at:
https://protagenic.com/investor/press-release/

About Protagenic Therapeutics, Inc.:
Protagenic Therapeutics, Inc. (Nasdaq:PTIX) is dedicated to pioneering therapeutics based on neuro-active peptides to alleviate the negative effects of stress and treat stress-related disorders such as anxiety, depression, PTSD, and addiction. For more information, visit www.protagenic.com.

About PT00114:
PT00114, a 41-amino-acid residue synthetic peptide, shows promise as a novel treatment for serious neuro-psychiatric conditions, including depression, anxiety, and PTSD. It is a synthetic form of the naturally occurring brain peptide TCAP, which counters the negative biochemical and behavioral effects of stress-induced brain hormones Corticotropin Releasing Factor and Arginine-Vasopressin. Among its benefits is the reduction of excessive circulating levels of cortisol often associated with various stressors.

Forward-Looking Statements:
This press release contains forward-looking statements concerning Protagenic Therapeutics' product candidates and clinical trial plans. These statements are subject to various risks and uncertainties. Investors are urged to exercise caution and not place undue reliance on these forward-looking statements.

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