Spyre Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

February 29, 2024

Announced corporate name change to Spyre Therapeutics; appointment of Cameron Turtle, DPhil, as Chief Executive Officer; and began trading on Nasdaq under the symbol "SYRE"

SPY001, an anti-α4β7 antibody engineered for infrequent, subcutaneous dosing, demonstrated an updated half-life of 22 days, a greater than three-fold increase relative to vedolizumab in non-human primate pharmacokinetic data recently presented at ECCO; remains on track to begin first-in-human studies in the first half of 2024, with interim proof-of-concept data expected year-end 2024

SPY002, an anti-TL1A antibody designed for enhanced potency to both TL1A monomers and trimers, and extended half-life compared to existing molecules, remains on track to begin first-in-human studies in the second half of 2024

Raised $180 million in private placement equity financing with participation from new and existing investors

$340 million of cash, cash equivalents, marketable securities, and restricted cash as of December 31, 2023, with expected runway into the second half of 2026, through multiple clinical readouts

WALTHAM, Mass., Feb. 29, 2024 /PRNewswire/ -- Spyre Therapeutics, Inc. ("Spyre" or the "Company") (NASDAQ:SYRE), a biotechnology company advancing a pipeline of investigational antibody therapeutics with the potential to transform the treatment of inflammatory bowel disease ("IBD"), today announced its fourth quarter and full year 2023 financial results and provided program and corporate updates.

"In 2023, we built the foundation required to advance our mission of creating IBD therapies that provide meaningful improvements in both efficacy and convenience compared to today's standard of care. Beginning with a highly unique portfolio of three promising drug candidates to what we consider the most critical targets in IBD, including α4β7, TL1A, and IL-23, we capitalized the company with nearly $400 million from top-tier investors while also attracting a talented and passionate management team and Board of Directors," said Cameron Turtle, DPhil., Chief Executive Officer. "As we look forward to 2024, our ambitions will come into focus as we enter clinical studies across multiple programs and begin to demonstrate potential best-in-class properties of our investigational medicines. We anticipate initiating Phase 2 evaluation of rational therapeutic combinations in IBD patients in 2025."

Development Pipeline Overview and Update

The Company's approach combines best-in-class antibody engineering, rational therapeutic combinations, and precision immunology with the goal of maximizing efficacy, safety, and convenience of its IBD treatments under development. IBD is a chronic condition characterized by inflammation within the gastrointestinal tract, including two main disorders: ulcerative colitis ("UC") and Crohn's disease ("CD"). In the United States, it is estimated that approximately 2.4 million individuals are diagnosed with IBD.

The Company has four programs in preclinical development, three of which are targets in IBD validated by third parties. The fourth program is a novel, undisclosed target. The Company is also researching rational combinations of its therapeutic antibody product candidates to target IBD. All three validated targets offer the potential for effective and safe treatment of UC and CD as a monotherapy or in combination, with the potential advantage of infrequent subcutaneous dosing.

SPY001 – a highly potent and selective investigational anti-α4β7 monoclonal antibody engineered with half-life extension technology and formulated for high concentration and subcutaneous, infrequent dosing.

- In the third quarter of 2023, the Company selected the SPY001 development candidate, which is currently progressing through IND-enabling studies and is expected to enter first-in-human ("FIH") studies in the first half of 2024.
- In February 2024, expanded preclinical data for SPY001 was presented at the 19th Annual Congress of the European Crohn's and Colitis Organisation (ECCO), including head-to-head non-human primate pharmacokinetic data showing an updated half-life of 22 days, a greater than three-fold increase relative to vedolizumab. This data further supports our target human half-life for SPY001 of more than 35 days predicted by allometric scaling.
- Interim data from a healthy volunteer study are expected by the end of 2024. The Company expects pharmacokinetic data to demonstrate proof of concept for SPY001 to potentially be dosed subcutaneously in an every-eight-week or every-twelve-week dosing interval.

SPY002 – a highly potent, selective, half-life extended, anti-TL1A investigational monoclonal antibody with potential best-in-class subnanomolar binding affinity for both the monomer and trimer forms of the target. The Company believes TL1A has emerged as one of the most promising targets in IBD and broader immunology indications.

- The Company has nominated two lead SPY002 development candidates and exercised its option to exclusively license related intellectual property rights under its agreement with Paragon Therapeutics. The Company's lead candidates bind both TL1A monomers and trimers and have *in vitro* subnanomolar potency and pharmacokinetic half-lives that potentially exceed all clinical-stage TL1A antibodies.
- In February 2024, preclinical data for a lead SPY002 development candidate was presented at the 19th Annual ECCO Congress demonstrating subnanomolar binding affinity and potency, as well as a pharmacokinetic half-life of 24 days in non-human primates, which represents a two to three-fold increase compared to clinical-stage anti-TL1As.
- The Company expects to begin FIH studies of one or both SPY002 candidates in the second half of 2024 with healthy volunteer interim data expected in the first half of 2025. If successful, one SPY002 candidate would then advance into additional clinical development.

SPY003 – a highly potent and selective investigational monoclonal antibody targeting the p19 subunit of IL-23 engineered with half-life extension technology.

- The Company continues preclinical development efforts on a potential best-in-class IL-23 monoclonal antibody. Recent data from the Phase 3 SEQUENCE study of risankizumab versus ustekinumab in Crohn's disease validates the Company's targeting of the p19 subunit as it demonstrated superiority to targeting the p40 subunit common to IL-12 and IL-23.
- The Company expects to nominate a development candidate in mid-2024 and move into IND-enabling studies in the second half of 2024.

Recent Corporate Updates

- In February 2024, the Company announced the appointment of Mark C. McKenna, former Chairman, President and CEO of Prometheus Biosciences, Inc., to its Board of Directors. Mr. McKenna's track record of corporate leadership, product development, and value creation will be instrumental to guide the Company as it advances its potentially best-in-class IBD portfolio.
- In December 2023, the Company announced $180 million in gross proceeds from a private placement equity financing with broad participation from both new and existing investors, extending cash runway into the second half of 2026.
- In November 2023, the Company announced its name change to Spyre Therapeutics and the appointment of Cameron Turtle as Chief Executive Officer and also a member of the Company's Board of Directors. The Company also announced the appointments of industry veterans Jeffrey Albers and Laurie Stelzer to its Board of Directors.
- In November 2023, the Company held a Special Meeting of Stockholders wherein all four proposals were approved, including the conversion of the Company's Series A Preferred Stock to common stock and an increase to the Company's authorized shares.

Fourth Quarter 2023 Financial Results

Cash Position: As of December 31, 2023, Spyre had available cash and cash equivalents, marketable securities, and restricted cash of $339.6 million. Net cash used in operating activities was $31.0 million for the fourth quarter of 2023. In December 2023, the Company raised $180.0 million in gross proceeds, before deducting $10.9 million in placement agent fees and other offering costs, from a private placement of equity securities.

Research and Development (R&D) expenses: R&D expenses totaled $33.7 million for the fourth quarter of 2023 and $14.3 million for the fourth quarter of 2022. The increase was primarily related to increases in preclinical development and manufacturing expenses for the Company's IBD pipeline including expenses related to the annual equity grant under our agreement with Paragon, partially offset by a decrease in expenses associated with the Company's legacy rare disease pipeline.

General and Administrative (G&A) expenses: G&A expenses totaled $14.1 million for the fourth quarter of 2023 and $5.1 million for the fourth quarter of 2022. This increase was primarily due to an increase in stock compensation expense, as well as legal and other professional service fees related to the Spyre acquisition.

Gain on Sale of In-Process Research & Development Asset: During the fourth quarter of 2023, the Company recognized an additional $1.8 million gain on the sale of the global rights of pegzilarginase driven by the receipt of a cash reimbursement from Immedica for a previous expenditure.

Other (expense) income: Other (expense) income for the fourth quarter totaled $17.3 million expense primarily driven by an increase in the Company's CVR liability related to the increased likelihood of certain milestone payments related to pegzilarginase reimbursement in European markets, partially offset by interest earned on the Company's cash and marketable securities.

Net Loss: Net loss totaled $63.2 million and $18.8 million for the fourth quarters of 2023 and 2022, respectively, which includes non-cash stock compensation expense of $17.3 million and $1.4 million for the fourth quarters of 2023 and 2022, respectively.

About Spyre Therapeutics
Spyre Therapeutics is a biotechnology company that aims to create the next-generation of inflammatory bowel disease (IBD) products by combining best-in-class antibody engineering, rational therapeutic combinations, and precision medicine approaches. Spyre's pipeline includes investigational extended half-life antibodies targeting α4β7, TL1A, and IL-23.

For more information, please visit http://spyre.com.

Follow Spyre Therapeutics on social media: @spyretx and LinkedIn.

Safe Harbor / Forward Looking Statements
This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. All statements contained in this press release, other than statements of historical fact are forward-looking statements. These forward-looking statements include statements regarding the Company's future results of operations and financial position, business strategy, including the Company's potential success of developing therapeutics for IBD, the sufficiency of the Company's funding to support the development of its assets, the length of time that the Company believes its existing cash resources will fund its operations, its market size, its potential growth opportunities, its preclinical and future clinical development activities, including the expected timing of nomination of development candidates and submission of investigational new drug applications, the efficacy and safety profile of its product candidates, the potential therapeutic benefits and economic value of its product candidates, the timing and results of preclinical studies and clinical trials, including the commencement of FIH studies, the timing of data and whether the data demonstrates proof of concept, and the Company's planned regulatory activities including filing of INDs to support development and potential commercialization of product candidates. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," the negatives of these terms, and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including the expected or potential impact of macroeconomic conditions, including inflationary pressures, rising interest rates, general economic slowdown or a recession, changes in monetary policy, the prospect of a shutdown of the U.S. federal government, volatile market conditions, financial institution instability, as well as geopolitical instability, including the ongoing military conflict in Ukraine, conflict in Israel and surrounding areas, and geopolitical tensions in China on the Company's operations, the potential impacts of the BIOSECURE Act bill if passed into law and those risks described in the Company's Quarterly Reports on Form 10-Q, Annual Reports on Form 10-K, as well as in other filings and reports that the Company makes from time to time with the Securities and Exchange Commission. Moreover, the Company operates in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for the Company's management to predict all risks, nor can the Company assess the impact of all factors on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements it may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. The Company undertakes no obligation to update publicly any forward-looking statement for any reason after the date of this press release to conform these statements to actual results, to reflect changes in the Company's expectations, or otherwise, except as required by law. You should read press release with the understanding that the Company's actual results, levels of activity, performance, events, outcomes, and the timing of results and outcomes, and other circumstances may be materially different from what the Company expects.

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Spyre Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 188,893	$ 34,863
Marketable securities	150,384	20,848
Development receivables	—	375
Prepaid expenses and other current assets	2,251	6,172
Total current assets	341,528	62,258
Restricted cash	322	1,553
Property and equipment, net	—	3,220
Operating lease right-of-use assets	—	3,430
Other non-current assets	9	683
TOTAL ASSETS	$ 341,859	$ 71,144

LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 896	$ 677
CVR liability	1,390	–
Operating lease liabilities	—	625
Deferred revenue	—	517
Accrued and other current liabilities	13,108	12,837
Related party accounts payable and other current liabilities	16,584	–
Total current liabilities	31,978	14,656
Non-current CVR liability	41,310	–
Non-current operating lease liabilities	—	4,004
Deferred revenue, net of current portion	—	2,179
Other non-current liabilities	—	–
TOTAL LIABILITIES	73,288	20,839
Commitments and Contingencies		
Series B non-voting convertible preferred stock, $0.0001 par value; 150,000 and no shares authorized as of December 31, 2023 and December 31, 2022, respectively; 150,000 and no shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	84,555	–
STOCKHOLDERS' EQUITY		
Series A non-voting convertible preferred stock, $0.0001 par value; 1,086,341 and no shares authorized as of December 31, 2023 and December 31, 2022, respectively; 437,037 and no shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	184,927	–
Preferred stock, $0.0001 par value; 8,763,659 shares and 10,000,000 authorized as of December 31, 2023 and December 31, 2022, respectively; no shares issued and outstanding as of December 31, 2023 and December 31, 2022.	—	–
Common stock, $0.0001 par value; 400,000,000 and 20,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; 36,057,109 shares and 2,614,014 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively.	10	6
Additional paid-in capital	763,191	475,971
Accumulated other comprehensive income (loss)	302	(48
Accumulated deficit	(764,414)	(425,624
TOTAL STOCKHOLDERS' EQUITY	184,016	50,305
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY	341,859	71,144

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Spyre Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Development fee and royalty	$ —	$ 168	$ 886	$ 2,3
Total revenue	—	168	886	2,3
Operating expenses:				
Research and development [1]	33,682	14,251	89,504	58,5
General and administrative	14,072	5,079	39,946	28,5
Acquired in-process research and development	—	—	130,188	
Gain on sale of in-process research and development asset	(1,840)	—	(16,449)	

Total operating expenses	45,914	19,330	243,189	87,1
Loss from operations	(45,914)	(19,162)	(242,303)	(84,7
Other (expense) income:				
Interest income	4,126	410	6,147	8
Change in fair value of forward contract liability	—	—	(83,530)	
Other expense, net	(21,392)	(32)	(19,130)	
Total other (expense) income	(17,266)	378	(96,513)	8
Loss before income tax expense	(63,180)	(18,784)	(338,816)	(83,9
Income tax (expense) benefit	—	(38)	26	1
Net loss	$ (63,180)	$ (18,822)	$ (338,790)	$ (83,8
Net loss per share, basic and diluted	$ (4.05)	$ (5.00)	$ (49.12)	$ (24.8
Weighted-average common shares outstanding, basic and diluted	15,607,898	3,764,608	6,897,065	3,371,2

(1) Includes $27.7 million and $48.5 million in related party expenses for the three and twelve months ended December 31, 2023, respectively and no related party expenses for the three and twelve months ended December 31, 2022.

SOURCE Spyre Therapeutics, Inc.