May 10, 2023

Syros Reports First Quarter 2023 Financial Results and Provides a Corporate Update

-- On track to complete enrollment of 190 patients in 4Q 2023, with pivotal complete response (CR) data from SELECT-MDS-1 expected in 3Q 2024 --

-- Amended SELECT-MDS-1 study to add overall survival as key secondary endpoint--

-- Initial data from the randomized portion of SELECT-AML-1 trial expected in 4Q 2023--

-- Management to host conference call at 8:30 a.m. ET today --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Syros Pharmaceuticals (NASDAQ:SYRS), a biopharmaceutical company committed to advancing new standards of care for the frontline treatment of hematologic malignancies, today reported financial results for the quarter ended March 31, 2023 and provided a corporate update.

“In 2023, we are focusing on clinical execution, with the goal of delivering tamibarotene and SY-2101 as new standards of care for the frontline treatment of hematologic malignancies,” said Nancy Simonian, M.D., Chief Executive Officer of Syros. “We are pleased that recent feedback from the FDA on our SELECT-MDS-1 trial continues to support the CR rate as an appropriate primary endpoint for either full or accelerated approval with supporting data on the durability of remission. We have amended our existing trial to add overall survival as a key secondary endpoint, allowing this single trial to efficiently serve as a confirmatory study if needed for full approval.”

Dr. Simonian continued, “In addition, we commenced the randomized portion of the SELECT-AML-1 Phase 2 trial and remain on track to report initial data in the fourth quarter, as well as to provide an update on the development path for SY-2101 in APL in the second half of this year. We are fortunate to operate from a robust financial position, with sufficient capital to fund our efforts into 2025, beyond pivotal CR data from the SELECT-MDS-1 trial and initial data from the randomized portion of SELECT-AML-1.”

UPCOMING MILESTONES

Tamibarotene: Higher-Risk Myelodysplastic Syndrome (HR-MDS)

- Complete enrollment of 190 patients necessary to support complete response (CR) primary endpoint in the SELECT-MDS-1 Phase 3 trial in newly diagnosed HR-MDS patients with *RARA* gene overexpression in the fourth quarter of 2023.
- Report pivotal CR data from the SELECT-MDS-1 Phase 3 trial in the third quarter of 2024.

Tamibarotene: Acute Myeloid Leukemia (AML)

- Report initial data from the randomized portion of the SELECT-AML-1 Phase 2 trial in newly diagnosed unfit AML patients with *RARA* overexpression in the fourth quarter of 2023.
- Report additional data from the SELECT-AML-1 Phase 2 trial in 2024.

SY-2101: Acute Promyelocytic Leukemia (APL)

- Provide an update on the dose confirmation study of SY-2101 and the development path and timing for further evaluation of SY-2101 in a registration-enabling study in APL in the second half of 2023.

RECENT PIPELINE HIGHLIGHTS

- Today, Syros announced that it has amended the protocol for its pivotal Phase 3 SELECT-MDS-1 trial by increasing the number of patients from 190 to 550 to evaluate overall survival (OS) as a key secondary endpoint. This amended study design reflects a more efficient “one-trial” approach and will not affect the timing of our pivotal CR data from SELECT-MDS-1 which is expected in the third quarter of 2024.

First Quarter 2023 Financial Results

- Revenues were $3.0 million for the first quarter of 2023, consisting entirely of revenue recognized under Syros’ collaboration with Pfizer. Syros recognized $5.5 million in revenue in the first quarter of 2022, consisting of $5.1 million in revenue recognized under its collaboration with Pfizer and $0.4 million recognized under its collaboration with Incyte Corporation.
- Research and development expenses were $28.8 million for the first quarter of 2023, as compared to $25.2 million for the first quarter of 2022. This increase was primarily due to the advancement of the Company’s late-stage clinical programs.
- General and administrative (G&A) expenses were $7.4 million for the first quarter of 2023, as compared to $6.9 million for the first quarter of 2022. This increase was primarily due to supporting the advancement of our late-stage clinical programs.
- For the first quarter of 2023, Syros reported a net loss of $23.8 million, or $0.85 per share, compared to a net loss of $25.1 million, or $3.99 per share, for the same period in 2022.

Cash and Financial Guidance

Cash, cash equivalents and marketable securities as of March 31, 2023 were $166 million, as compared with $202 million on December 31, 2022.

Based on its current plans, Syros believes that its existing cash, cash equivalents and marketable securities will be sufficient to fund its anticipated operating expenses and capital expenditure requirements into 2025, beyond pivotal Phase 3 data from the SELECT-MDS-1 trial and initial data from the randomized portion of the SELECT-AML-1 trial.

Conference Call and Webcast

Syros will host a conference call today at 8:30 a.m. ET to discuss these first quarter 2023 financial results and provide a corporate update.

To access the live conference call, please dial (888) 886-7786 (domestic) or (416) 764-8658 (international) and refer to conference ID 19706685. A webcast of the call will also be available on the Investors & Media section of the Syros website at www.syros.com. An archived replay of the webcast will be available for approximately 30 days following the presentation.

About Syros Pharmaceuticals

Syros is committed to developing new standards of care for the frontline treatment of patients with hematologic malignancies. Driven by the motivation to help patients with blood disorders that have largely eluded other targeted approaches, Syros is advancing a robust late-stage clinical pipeline, including tamibarotene, an oral selective RARα agonist in patients with higher-risk myelodysplastic syndrome and acute myeloid leukemia with *RARA* gene overexpression, and SY-2101, a novel oral form of arsenic trioxide in patients with acute promyelocytic leukemia. Syros is also seeking partnerships for SY-5609, a highly selective and potent CDK7 inhibitor in clinical development for the treatment of select solid tumors, and multiple preclinical programs in oncology. For more information, visit www.syros.com and follow us on Twitter (@SyrosPharma) and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding Syros' clinical development plans, including with respect to the progression of its clinical trials, the timing and impact of enrolling study participants and reporting clinical data, the ability to deliver benefit to patients, and the sufficiency of Syros' capital resources to fund its operating expenses and capital expenditure requirements into 2025. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including Syros' ability to: advance the development of its programs, including tamibarotene and SY-2101, under the timelines it projects in current and future clinical trials; demonstrate in any current and future clinical trials the requisite safety, efficacy and combinability of its drug candidates; sustain the response rates and durability of response seen to date with its drug candidates; successfully develop a companion diagnostic test to identify patients with the *RARA* biomarker; obtain and maintain patent protection for its drug candidates and the freedom to operate under third party intellectual property; obtain and maintain necessary regulatory approvals; identify, enter into and maintain collaboration agreements with third parties; manage competition; manage expenses; raise the substantial additional capital needed to achieve its business objectives; attract and retain qualified personnel; and successfully execute on its business strategies; risks described under the caption "Risk Factors" in Syros' Annual Report on Form 10-K for the year ended December 31, 2022 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, each which is on file with the Securities and Exchange Commission; and risks described in other filings that Syros makes with the Securities and Exchange Commission in the future.

Syros Pharmaceuticals, Inc.
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities (current and noncurrent)	$ 165,803	$ 202,304
Working capital[1]	150,093	180,614
Total assets	205,323	244,486
Total stockholders' equity	106,753	127,736

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements for further details regarding its current assets and current liabilities.

Syros Pharmaceuticals, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue	$ 2,954	$ 5,467
Operating expenses:		
Research and development	28,761	25,171
General and administrative	7,405	6,949
Total operating expenses	36,166	32,120
Loss from operations	(33,212)	(26,653)
Interest income	1,775	35
Interest expense	(1,217)	(976)
Change in fair value of warrant liability	8,865	2,448
Net loss applicable to common stockholders	$ (23,789)	$ (25,146)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.85)	$ (3.99)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	27,842,218	6,306,142

View source version on businesswire.com:
https://www.businesswire.com/news/home/20230510005199/en/

Syros
Karen Hunady
Director of Corporate Communications & Investor Relations
1-857-327-7321
khunady@syros.com

Media Relations
Brittany Leigh, Ph.D.
LifeSci Communications, LLC
+1-813-767-7801
bleigh@lifescicomms.com

Investor Relations
Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannah.deresiewicz@sternir.com

Source: Syros Pharmaceuticals