

August 9, 2022



# Syros Reports Second Quarter 2022 Financial Results and Provides a Corporate Update

*Preliminary Data From First Cross-Over Study Directly Comparing PK of SY-2101 to the Approved IV Dose of ATO Demonstrates Comparable PK Exposures; Expect to Initiate Phase 3 Clinical Trial of SY-2101 in APL 2H 2023*

*Definitive Merger Agreement with TYME Technologies and Concurrent PIPE Expected to Close 2H 2022 and Bring Combined Proceeds of Approximately \$190 Million, Extending Cash Runway into 2025*

*On Track to Report Data from Safety Lead-ins of the SELECT-AML-1 Trial and the Phase 1 SY-5609 Trial in Pancreatic Cancer in 2H 2022*

*Advanced SY-12882, an Oral, Potent, and Selective CDK12 Inhibitor, to Development Candidate*

*Management to Host Conference Call at 8:30 a.m. ET Today*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Syros Pharmaceuticals (NASDAQ:SYRS), a leader in the development of medicines that control the expression of genes, today reported financial results for the quarter ended June 30, 2022 and provided a corporate update.

“We are entering the second half of the year in a position of strength with multiple data readouts expected over the next 18 months and, following the anticipated closing of our previously announced merger with TYME Technologies and concurrent PIPE financing, we expect to have a robust balance sheet,” said Nancy Simonian, M.D., Chief Executive Officer of Syros. “The gross proceeds of approximately \$190 million from these transactions, together with the amendment to our existing loan facility, are expected to extend our cash runway into 2025, at least one year beyond expected pivotal data from our ongoing SELECT-MDS-1 trial.”

Dr. Simonian continued, “Today, we reported promising preliminary data from our ongoing dose confirmation trial of SY-2101, our novel oral form of arsenic trioxide. Based on the pharmacokinetic data available to date, SY-2101 achieved exposures comparable to IV arsenic trioxide and demonstrated high oral bioavailability. The totality of data with our oral arsenic trioxide continues to support a favorable safety and tolerability profile, giving us further confidence that SY-2101 has the potential to replace the standard-of-care for acute promyelocytic leukemia patients. Based on recent feedback received from the EMA, Syros plans to conduct a singular registration trial for SY-2101 that could support approval in both the United States and the European Union.”

## UPCOMING MILESTONES

### Tamibarotene: Oral RAR $\alpha$ agonist

#### *Higher-Risk Myelodysplastic Syndrome (HR-MDS)*

- On track to report pivotal data from the SELECT-MDS-1 trial in newly diagnosed RARA-positive patients with HR-MDS in the fourth quarter of 2023 or the first quarter of 2024, with a potential new drug application (NDA) filing expected in 2024.

#### *Acute Myelodysplastic Syndrome (AML)*

- On track to report safety and clinical activity data from the safety lead-in portion of the ongoing SELECT-AML-1 Phase 2 trial in RARA-positive patients with newly diagnosed unfit AML in the second half of 2022.
- Expect to initiate the randomized portion of the SELECT-AML-1 Phase 2 trial in an additional eighty patients evaluating the triplet regimen of tamibarotene, venetoclax and azacitidine compared to venetoclax and azacitidine with data expected in 2023 or 2024.

### SY-2101: Oral arsenic trioxide (ATO)

- Expect to initiate the Phase 3 trial of SY-2101 for the treatment of acute promyelocytic leukemia (APL) in the second half of 2023.

### SY-5609: Oral selective CDK7 inhibitor

- On track to report safety and clinical activity data from the safety lead-in portion of the ongoing Phase 1 trial evaluating SY-5609 in combination with chemotherapy in relapsed/refractory metastatic pancreatic cancer in the second half of 2022.

## RECENT PIPELINE HIGHLIGHTS

- Today, Syros announced promising preliminary data from newly diagnosed APL patients enrolled to date in the dose confirmation trial of SY-2101. This is the first cross-over data directly comparing the pharmacokinetics (PK) of SY-2101 to the approved IV dose ATO. SY-2101 administered at 15 mg achieved comparable PK (AUC and C<sub>max</sub>) exposures to IV ATO administered at 0.15 mg/kg. Additionally, SY-2101 showed high oral bioavailability of approximately 80% and continues to support a favorable tolerability profile.
- In July, Syros received European Medicines Agency (EMA)/ Committee for Medicinal Products for Human Use (CHMP) scientific advice on the SY-2101 Phase 3 trial design in front line APL. The feedback informs Syros' plan for a singular registration trial for SY-2101 that could support approval in both the United States (US) and the European Union (EU).
- In July, the EMA issued a positive opinion on the Company's application for orphan drug designation for tamibarotene for the treatment of MDS. The EMA's orphan designation is available to companies developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the EU. Medicines that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives, including a 10-year period of marketing exclusivity in the EU

after product approval, protocol assistance from the EMA at reduced fees during the product development phase and access to centralized marketing authorization.

- In June, Syros announced that based on results from over 175 MDS patients, the company now estimates that approximately 50% of patients with MDS are RARA-positive, as compared to the previously estimated 30%.
- Roche is now actively enrolling patients in the arm of its ongoing Phase 1/1b INTRINISIC trial evaluating SY-5609 in combination with atezolizumab, its PD-L1 inhibitor, in BRAF-mutant colorectal cancer patients. Under the terms of Syros' agreement with Roche, Roche is the sponsor of the trial and Syros is supplying SY-5609.
- In July, Syros advanced its oral, potent, and selective CDK12 inhibitor, SY-12882, to development candidate. Preclinical data presented at the American Association for Cancer Research (AACR) annual meeting demonstrated that selective CDK12 inhibition resulted in strong anti-tumor activity as a single agent as well as in combination with a DNA damaging agent and in combination with a poly adenosine diphosphate-ribose polymerase (PARP) inhibitor in models of breast, lung, and ovarian cancer.

## **CORPORATE**

- In July, Syros announced that it plans to raise approximately \$190 million through a merger with TYME Technologies and an oversubscribed private investment in public equity (PIPE) financing. The \$130M PIPE was led by a life sciences-focused investment fund, with participation from new and existing investors, including Syros co-founder and founding investor Flagship Pioneering, as well as Avidity Partners, Deep Track Capital, Bain Capital Life Sciences, Invus, Samsara BioCapital, Adage Capital Partners LP, Ally Bridge Group and Cowen Healthcare Investments. The transactions are expected to close concurrently with each other in the second half of 2022, subject to approval by the stockholders of Syros and TYME and the satisfaction of other customary closing conditions.
- Concurrently, Syros amended its senior secured loan facility with Oxford Finance LLC (Oxford) to, subject to certain conditions, extend the interest-only payment period to March 1, 2024 (and, upon the achievement of certain milestones, September 1, 2024), and extend the maturity date to February 1, 2026 (and, upon the achievement of certain milestones, August 1, 2026).
- Also in July, Syros announced that it is seeking partnerships for all its wholly owned discovery programs. The Company will continue to execute on its existing collaborations with Incyte Corporation (Incyte) and Global Blood Therapeutics (GBT), for which its research efforts are fully funded, as provided in each agreement.

## **Second Quarter 2022 Financial Results**

- Revenues were \$6.3 million for the second quarter of 2022, consisting of \$5.7 million in revenue recognized under Syros' collaboration with GBT and \$0.6 million recognized under its collaboration with Incyte. Syros recognized \$5.2 million in revenue in the second quarter of 2021, consisting of \$3.3 million in revenue recognized under its collaboration with GBT and \$1.9 million recognized under its collaboration with Incyte.
- Research and development expenses were \$33.1 million for the second quarter of 2022, as compared to \$25.8 million for the second quarter of 2021. This increase was

primarily due to the increase in costs associated with the continued advancement of our clinical and preclinical programs and employee-related expenses.

- General and administrative (G&A) expenses were \$6.9 million for the second quarter of 2022, as compared to \$5.5 million for the second quarter of 2021. This increase was primarily due to an increase in employee-related expenses.
- For the second quarter of 2022, Syros reported a net loss of \$34.5 million, or \$0.54 per share, compared to a net loss of \$22.5 million, or \$0.36 per share, for the same period in 2021.

## **Cash and Financial Guidance**

Cash, cash equivalents and marketable securities as of June 30, 2022 were \$86.3 million, as compared with \$143.4 million on December 31, 2021. Based on Syros's current operating plan and without giving effect to the merger with TYME, the PIPE financing and the loan amendment with Oxford, the completion of which cannot be assured, Syros anticipates that its cash, cash equivalents and marketable securities of \$86.3 million as of June 30, 2022 will allow it to meet its liquidity requirements into the second quarter of 2023.

If Syros completes the merger with TYME and the PIPE financing and gives effect to certain provisions of the loan amendment with Oxford related to such closings (which is expected to occur in the second half of 2022), Syros anticipates having approximately \$240 million in cash and other capital resources (after transaction expenses), which it believes will be sufficient to fund its planned operating expenses and capital expenditure requirements into 2025.

## **Conference Call and Webcast**

Syros will host a conference call today at 8:30 a.m. ET to discuss these second quarter 2022 financial results and provide a corporate update.

To access the live conference call, please dial (833) 636-1323 (domestic) or (412) 902-4279 (international) and refer to the "Syros Pharmaceuticals Conference Call." A webcast of the call will also be available on the Investors & Media section of the Syros website at [www.syros.com](http://www.syros.com). An archived replay of the webcast will be available for approximately 30 days following the presentation.

## **About Syros Pharmaceuticals**

Syros is redefining the power of small molecules to control the expression of genes. Based on its unique ability to elucidate regulatory regions of the genome, Syros aims to develop medicines that provide a profound benefit for patients with diseases that have eluded other genomics-based approaches. Syros is advancing a robust clinical-stage pipeline, including: tamibarotene, a first-in-class oral selective RAR $\alpha$  agonist in RARA-positive patients with higher-risk myelodysplastic syndrome and acute myeloid leukemia; SY-2101, a novel oral form of arsenic trioxide in patients with acute promyelocytic leukemia; and SY-5609, a highly selective and potent oral CDK7 inhibitor in patients with select solid tumors. Syros also has multiple preclinical and discovery programs in oncology and monogenic diseases. For more information, visit [www.syros.com](http://www.syros.com) and follow us on Twitter ([@SyrosPharma](https://twitter.com/SyrosPharma)) and [LinkedIn](https://www.linkedin.com/company/syros-pharmaceuticals).

## **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the Securities Act) concerning Syros, TYME Technologies, the proposed transactions and other matters, such as Syros' clinical development plans, including with respect to tamibarotene, SY-2101 and SY-5609, Syros' ability to deliver benefit to patients and value to stockholders, the timing and impact of upcoming clinical and preclinical data readouts, the timing for submitting a new drug application to the Food and Drug Administration, the ability to secure additional capital, and the sufficiency of Syros' capital resources to fund its operating expenses and capital expenditure requirements into the second quarter of 2023 or into 2025 upon the completion of the merger, PIPE and after giving effect to certain provision of the loan agreement amendment. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Syros and TYME Technologies, as well as assumptions made by, and information currently available to, management of Syros and TYME Technologies. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation, Syros' ability to: advance the development of its programs, including tamibarotene, SY-2101 and SY-5609, 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. Additional factors that could cause actual results to differ materially from those contained in any forward-looking statement include, without limitation, the risk that the conditions to the closing of the proposed transactions are not satisfied, including the failure to obtain stockholder approval for the transactions or to complete the PIPE financing in a timely manner or at all; uncertainties as to the timing of the consummation of the transactions and the ability of each of Syros and TYME Technologies to consummate the transaction, including the PIPE financing; risks related to TYME Technologies' continued listing on the Nasdaq Stock Market until closing of the proposed transactions; risks related to Syros' and TYME Technologies' ability to correctly estimate their respective operating expenses and expenses associated with the transactions, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; the ability of Syros or TYME Technologies to protect their respective intellectual property rights; competitive responses to the transaction; unexpected costs, charges or expenses resulting from the transaction; potential adverse reactions or changes to business relationships

resulting from the announcement or completion of the transaction; and legislative, regulatory, political and economic developments. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Syros' Annual Report on Form 10-K for the year ended December 31, 2021, Syros' Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and TYME Technologies' Annual Report on Form 10-K for the year ended March 31, 2022, each of which is on file with the Securities and Exchange Commission (SEC). In addition, the extent to which the COVID-19 pandemic continues to impact the proposed transactions will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the pandemic, additional or modified government actions, and the actions that may be required to contain the virus or treat its impact. Syros and TYME Technologies can give no assurance that the conditions to the transactions will be satisfied. Except as required by applicable law, Syros and TYME Technologies undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

### **No Offer or Solicitation**

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed business combination and shall not constitute an offer to sell or a solicitation of an offer to buy any securities nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act.

### **Important Additional Information and Where to Find It**

In connection with the transactions, Syros filed a Registration Statement on Form S-4 (Registration Statement) with the SEC on July 18, 2022, which was subsequently amended on August 1, 2022. The Registration Statement was declared effective by the SEC on August 8, 2022, and Syros and TYME Technologies intend to commence mailing of the joint proxy statement/prospectus contained in the Registration Statement to their respective stockholders on or about August 10, 2022. Syros may also file other relevant documents with the SEC regarding the proposed transactions. Investors and security holders are urged to read the Registration Statement and the joint proxy statement/prospectus carefully before making any voting or investment decision with respect to the proposed transactions. The Registration Statement and the joint proxy statement/prospectus contain important information about Syros, TYME Technologies, the transactions and related matters. Investors and security holders may obtain free copies of the Registration Statement and the joint proxy statement/prospectus and other documents filed with the SEC by Syros and TYME Technologies through the web site maintained by the SEC at [www.sec.gov](http://www.sec.gov). In addition, investors and security holders may obtain free copies of the Registration Statement and the joint proxy statement/prospectus from Syros by contacting [hannahd@sternir.com](mailto:hannahd@sternir.com) or from TYME Technologies by contacting [investorrelations@tymeinc.com](mailto:investorrelations@tymeinc.com).

## Participants in the Solicitation

Syros and TYME Technologies, and their respective directors and executive officers, may be deemed to be participants in the solicitation of proxies in respect of the transactions contemplated by the merger agreement. Information regarding Syros' directors and executive officers and TYME Technologies' directors and executive officers, including their interests in the transactions, is contained in the Registration Statement on file with the SEC. These documents can be obtained free of charge from the sources indicated above.

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities (current and noncurrent)	\$ 86,284	\$ 143,407
Working capital <sup>1</sup>	53,018	105,077
Total assets	126,234	182,935
Total stockholders' equity	31,019	85,218

(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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 6,276	\$ 5,162	\$ 11,743	\$ 9,989
Operating expenses:				
Research and development	33,100	25,786	58,271	45,815
General and administrative	6,945	5,520	13,894	11,260
Total operating expenses	40,045	31,306	72,165	57,075
Loss from operations	(33,769)	(26,144)	(60,422)	(47,086)
Interest income	112	12	147	24
Interest expense	(981)	(969)	(1,956)	(1,937)

Change in fair value of warrant liability	157	4,611	2,604	12,281
Net loss applicable to common stockholders	\$ (34,481)	\$ (22,490)	\$ (59,627)	\$ (36,718)
Net loss per share applicable to common stockholders - basic and diluted	\$ (0.54)	\$ (0.36)	\$ (0.94)	\$ (0.59)
Weighted-average number of common shares used in net loss per share applicable to common stockholders - basic and diluted	63,823,789	62,859,500	63,441,918	62,123,658

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20220809005360/en/>

#### **Media Contact**

Courtney Solberg  
Syros Pharmaceuticals  
917-698-9253  
[csolberg@syros.com](mailto:csolberg@syros.com)

#### **Investor Contact**

Hannah Deresiewicz  
Stern Investor Relations, Inc.  
212-362-1200  
[hannah.deresiewicz@sternir.com](mailto:hannah.deresiewicz@sternir.com)

Source: Syros Pharmaceuticals