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Societal CDMO Reports Second Quarter 2022 Financial Results

Recorded Q2 Revenue of $23.2 Million, a 29% Increase Compared to Prior Year Period

Signed Multiple New Business Agreements Spanning Clinical Trial Support, Commercial Manufacturing and Packaging

Launched Innovative "20/80 Second Source Technical Transfer" Program; New Model Offers Increased Security and Flexibility to Customers

Executed Favorable Amendment to Agreement with Lannett; Provides Improved Overall Economics to Societal

Company to Host Webcast Today at 4:30 p.m. ET

SAN DIEGO and GAINESVILLE, Ga., Aug. 10, 2022 (GLOBE NEWSWIRE) -- Societal CDMO, Inc. ("Societal CDMO"; NASDAQ: SCTL), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development, today reported financial results for the second quarter and six months ended June 30, 2022.

"Second quarter revenues of $23.2 million represent a significant improvement compared to the prior year period. This growth has been supported by the continued expansion and diversification of our customer base; enhancements to our sales and marketing strategies; improvements in the customer engagement process; the optimization of existing facilities and the addition of new capabilities; and finally, the retention and productivity of our employees," stated David Enloe, president and chief executive officer of Societal CDMO.

"One of the company's most significant achievements during the quarter was the launch of our "20/80 Second Source Technical Transfer" service. Through this program, a Societal customer can be "supply ready" approximately a full year sooner than if it commenced these activities at the onset of a supply disruption. This new service offering is just one of the ways that Societal is taking innovative steps to anticipate the future needs of our customers, provide supply security and stability, and do so in a cost-efficient manner.

"Another highly positive development that was achieved subsequent to the quarter end was the successful execution of an amendment to our license and supply agreement with Lannett Company for the marketing of Verapamil PM and Verelan SR products. In recent quarters, Lannett's sales of Verapamil PM declined, prompting Societal management to engage in restructuring discussions with Lannett. In July, we announced that the two companies had agreed upon a mutually beneficial amendment that will provide improved economics to Societal. We are very pleased with the outcome of these negotiations and

believe that the new terms increase the overall value of our partnership.

“The achievements of the first six months of the year reflect our success in executing the company’s strategic plan for 2022, which we believe will continue to deliver growth throughout the year.”

Second Quarter 2022 and Other Recent Developments

Business Development:

- **New and expanded customer projects.** During the quarter, the company signed $3 million in new and expanded project agreements. The new projects span clinical trial support, manufacturing, packaging, and automated fill/finish and lyophilization services, reflecting the company’s wide-ranging appeal to customers at each stage of the development and manufacturing process.

- **Launch of “20/80 Second Source Technical Transfer” program.** Societal created this new service model in response to the growing risks and vulnerabilities associated with the global supply chain that have significantly elevated the importance of second source suppliers within the pharmaceutical industry. Under this model, pharmaceutical companies are able to collaborate with Societal to execute all sourcing and planning phase activities of a standard technical transfer process prior to the time that product supply is needed. By undertaking these activities in advance, Societal customers can complete approximately half of the technical transfer process and position themselves to initiate the transfer of material and commence the batch manufacturing (or execution phase) whenever new and/or additional finished drug product supply is required. Importantly, investing in the initial sourcing and planning phase activities accounts for only 20%, on average, of the total technical transfer costs for a commercial product, whereas the execution/manufacturing phase makes up the remaining 80% of costs.

- **Favorably amended license and supply agreement with Lannett Company for the marketing of Verapamil PM and Verelan SR products.** Societal CDMO owns the new drug application (NDA) and the drug master file for Verapamil, an approved calcium channel blocker for the treatment of hypertension. Lannett has served as the company’s marketing partner for certain formulations of this drug since 2014. As the market for Verapamil is mature, revenues for the entire franchise were expected to remain flat for the duration of the year. However, Lannett’s sales of Verapamil PM have declined in recent quarters, prompting Societal management to engage in restructuring discussions with Lannett. In July, Societal and Lannett agreed to an amendment to the supply agreement. Under terms of the amendment, Societal will now receive improved overall economics, including a 10% increase in the profit share component of revenue from Verapamil PM product sales, as well as immediate and scheduled increases in manufacturing prices. Additionally, the amendment awards Societal potential new GMP manufacturing agreements targeting injectable products for multiple additional Lannett development projects.

Capabilities and Facilities:

- **Expanded capabilities:** During the second quarter, the company completed validation

and commissioning activities for its new aseptic fill/finish services. The new aseptic fill/finish suite features a sterile, automated vial filling system with the capability to fill up to 2,000 presterilized vials per hour at a range of volumes. The company's lyophilization offering incorporates a novel, patented approach to uniformity and instantaneously induces nucleation via pressurization and depressurization. This equipment provides the capacity for lyophilization of approximately 9,000 10 mL vials during each 3-5 day freeze-drying cycle. During the quarter, the company also initiated a new customer project that is the first to utilize these state-of-the-art capabilities. This project is focused on formulation development and sterile GMP manufacturing of a lyophilized novel cancer therapeutic for intravenous infusion. Societal has been contracted by an emerging Japan-based biopharmaceutical company to conduct this work in support of the company's ongoing clinical development of the compound as a potential treatment for solid tumors.

Financial Results for the Three Months Ended June 30, 2022

Revenues for the quarter ended June 30, 2022 were $23.2 million. This represents a 29% increase compared to revenues of $18.0 million recorded during the prior year period. The increase of $5.2 million was primarily driven by an increase in European Ritalin LA demand from the company's new customer InfectoPharm, revenue resulting from the acquisition of IriSys, as well as higher revenues from the company's clinical trial materials business. These increases were partially offset by declining revenues from Lannett's commercial sales of Verapamil PM products compared to the prior year. In an effort to address this decline, the company recently executed an amendment to its license and supply agreement with Lannett for the marketing of Verapamil PM and Verelan products subsequent to the end of the period, which provides overall improved economics for Societal and is expected to strengthen revenues from Lannett in the second half of the year despite the declines experienced in the first half of the year.

Cost of sales for the quarter ended June 30, 2022 was $17.5 million compared to $12.3 million for the comparable period of 2021. The increase of $5.2 million was primarily due to costs associated with operating the San Diego facility acquired from IriSys and increased costs tied to the increased manufacturing revenue during the quarter. In addition, in 2021, the company received certain employment incentive tax credits that were not repeated in 2022 resulting in increased expense in 2022. These increases were partially offset by the reallocation of expenses reflecting the post-acquisition organizational structure.

Selling, general and administrative expenses for the second quarter were $5.2 million, compared to $3.8 million recorded in the 2021 period. The increase of $1.4 million was primarily related to increased personnel costs tied to the reallocation of expenses and integration costs associated with the IriSys integration. Specifically, effective October 1, 2021, certain employees who previously supported the company's plant operations, now support the company's multi-site organization structure and operations. Accordingly, expenses associated with these employees have been reclassified from cost of sales to selling, general and administrative expenses.

Interest expense was $3.4 million for the three months ended June 30, 2022, a decrease compared to $4.0 million for the comparable period of 2021. The decrease of $0.6 million was primarily due to reduced non-cash financing expense and increased capitalized interest. This decrease was partially offset by an increase in interest from the debt portion of the

IriSys acquisition purchase price.

For the quarter ended June 30, 2022, the company recorded a net loss of $3.1 million or $0.06 per diluted share, as compared to a net income of $1.2 million or $0.03 per diluted share, for the comparable period of 2021. EBITDA, as adjusted* for the period was $4.6 million compared to $5.4 million in the prior year period. The prior year period included a one-time $3.4 million gain on extinguishment of debt related to the Paycheck Protection Program note. During the period, lower sales of Verapamil PM by Lannett, negatively impacted EBITDA, as adjusted* by $0.5 million as compared to the 2021 period.

Financial Results for the Six Months Ended June 30, 2022

Revenue for the six months ended June 30, 2022 was $44.3 million, compared to $34.8 million for 2021. The increase of $9.5 million in revenue was primarily driven by revenue resulting from the acquisition of IriSys as well as higher revenues from the company's clinical trial materials business. In addition, there was an increase in European Ritalin LA demand from the company's new customer InfectoPharm, as well as an increase in revenue from the company's largest commercial customer Teva, correlated with pull through in demand resulting from market share gains against the sole competitor for the Verapamil SR products. The increase in revenue was partially offset by a decline in revenue from Lannett's commercial sales of the Verapamil PM products.

Cost of sales for the six months ended June 30, 2022 was $33.6 million, compared to $26.7 million in 2021. The cost of sales increase of $6.9 million was primarily due to the acquisition of the San Diego facility and certain 2021 employment incentive tax credits that were not repeated in 2022 resulting in increased expense in 2022. These increases were partially offset by the reallocation of expenses reflecting the post-acquisition organizational structure.

Selling, general and administrative expenses for the six months ended June 30, 2022 were $10.9 million, compared to $8.5 million in 2021. The increase of $2.4 million was primarily related to increased personnel costs tied to the reallocation of expenses and integration costs associated with the IriSys integration. These increases were offset by lower stock-based compensation expense.

Interest expense was $6.8 million and $7.8 million for the first six months of 2022 and 2021, respectively. The decrease of $1.0 million was primarily due to reduced non-cash financing expense and increased capitalized interest. Also contributing to the reduction in interest was the successful refinancing and reduced term loan borrowings under the Credit Agreement with Athyrium as well as a decrease in the LIBOR base rate of interest on the company's term loans under the Credit Agreement. These decreases were partially offset by an increase in interest from the debt portion of the IriSys acquisition purchase price.

For the six months ended June 30, 2022, Societal reported a net loss of $7.4 million, or $0.13 per diluted share, compared to a net loss of $5.5 million, or $0.16 per diluted share, for 2021. EBITDA, as adjusted* for the first six months was $6.0 million compared to $8.1 million in the prior year period. During the six-month period, lower sales of Verapamil PM by Lannett, negatively impacted EBITDA, as adjusted* by approximately $2.0 million as compared to the 2021 period.

At June 30, 2022, Societal had cash and cash equivalents of $15.5 million compared to

$25.2 million as of the end of the prior fiscal year.

* EBITDA, as adjusted is a non-GAAP financial measure (see reconciliation of non-GAAP financial measures in this release).

Non-GAAP Financial Measures

To supplement Societal's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the company has certain non-GAAP information for the business, including EBITDA, as adjusted. The company believes this non-GAAP financial measure is helpful in understanding the business as it is useful to investors in allowing for greater transparency of supplemental information used by management. This measure is used by investors, as well as management in assessing the company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared. Please see the section of this press release titled "Reconciliation of GAAP to Non-GAAP Financial Measures" for a reconciliation of non-GAAP adjusted EBITDA to its most directly comparable GAAP measure.

Webcast

Societal CDMO management will be hosting a webcast today beginning at 4:30 p.m. ET. The webcast may be accessed via "Investor Events" in the Investor section of the company's website, https://ir.societalcdmo.com/events. An archived webcast will be available on the company's website approximately two hours after the event and will be available for 30 days.

About Societal CDMO

Societal CDMO (NASDAQ: SCTL) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit societalcdmo.com.

Cautionary Statement Regarding Forward Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These

statements, among other things, relate to the company's financial guidance; ability to manage costs and to achieve its financial goals; to operate under increased leverage and associated lending covenants; to pay its debt under its credit agreement; ability to improve its capital structure through real estate transactions; to maintain relationships with CDMO commercial partners and develop additional commercial partnerships; and the company's expectations regarding the benefits of the acquisition of IriSys. The words "anticipate", "believe", "correlate", "could", "estimate", "upcoming", "expect", "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases may be used to identify forward-looking statements in this press release. Our operations involve risks and uncertainties, many of which are outside our control, and any one of which, or a combination of which, could materially affect our results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that could cause the company's actual outcomes to differ materially from those expressed in or underlying these forward-looking statements include, but are not limited to, the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the customer ordering patterns or inventory rebalancing or disruption in raw materials or supply chain; the Company's ability to regain, and maintain, compliance with the Nasdaq continued listing standards; demand for the company's services, which depends in part on customers' research and development and the clinical plans and market success of their products; customers' changing inventory requirements and manufacturing plans; customers and prospective customers decisions to move forward with the company's manufacturing services; the average profitability, or mix, of the products the company manufactures; the company's ability to enhance existing or introduce new services in a timely manner; fluctuations in the costs, availability, and suitability of the components of the products the company manufactures, including active pharmaceutical ingredients, excipients, purchased components and raw materials, or the company's customers facing increasing or new competition; the Company's ability to collect on customers' receivable balances; and risks that the results of the combination of IriSys's business with the company's business may not be as anticipated. These forward-looking statements should be considered together with the risks and uncertainties that may affect our business and future results presented herein along with those risks and uncertainties discussed in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

SOCIETAL CDMO, INC. AND SUBSIDIARIES

Summary of Operating Results

(Unaudited)

(in millions, except per share amounts)	Three months ended June 30, 2022	2021	Change	%
Revenue	$ 23.2	$ 18.0	$ 5.2	29 %
Cost of sales	17.5	12.3	5.2	42 %
Gross margin	*25 %*	*32 %*		
Selling, general and administrative expenses	5.2	3.8	1.4	37 %
Amortization	0.2	0.1	0.1	100 %
Total operating expenses	22.9	16.2	6.7	41 %
Operating income	0.3	1.8	(1.5)	-83 %
Interest expense	(3.4)	(4.0)	0.6	-15 %
Gain on extinguishment of debt	—	3.4	(3.4)	-100 %
Net (loss) income	$ (3.1)	$ 1.2	$ (4.3)	-358 %
(Loss) income per share, diluted	(0.06)	0.03	(0.09)	-300 %
EBITDA, as adjusted*	$ 4.6	$ 5.4	$ (0.8)	-15 %

(in millions, except per share amounts)	Six months ended June 30, 2022	2021	Change	%
Revenue	$ 44.3	$ 34.8	$ 9.5	27 %
Cost of sales	33.6	26.7	6.9	26 %
Gross margin	*24 %*	*23 %*		
Selling, general and administrative expenses	10.9	8.5	2.4	28 %
Amortization	0.4	0.7	(0.3)	-43 %
Total operating expenses	44.9	35.9	9.0	25 %
Operating loss	(0.6)	(1.1)	0.5	-45 %
Interest expense	(6.8)	(7.8)	1.0	-13 %
Gain on extinguishment of debt	—	3.4	(3.4)	-100 %
Net loss	$ (7.4)	$ (5.5)	$ (1.9)	35 %
Loss per share, diluted	(0.13)	(0.16)	0.03	-19 %
EBITDA, as adjusted*	$ 6.0	$ 8.1	$ (2.1)	-26 %

* EBITDA, as adjusted is a non-GAAP financial measure (see reconciliation of non-GAAP financial measures in this release).

SOCIETAL CDMO, INC. AND SUBSIDIARIES

Reconciliation of GAAP to Non-GAAP Measures
(Unaudited)

To supplement the company's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the company has disclosed in the tables below the following non-GAAP information about EBITDA, as adjusted.

EBITDA, as adjusted, is net income or loss as determined under GAAP excluding interest, depreciation, amortization, non-cash stock-based compensation, charges related to reductions in force and costs related to the acquisition and integration of IriSys, as well as the impact of Accounting Standards Update 2014-09 in order to remove the impact of the timing of revenue recognized from profit-sharing arrangements upon transfer of control of the product, which more closely aligns revenue with expected cash receipt.

The company believes that non-GAAP financial measures are helpful in understanding its business as it is useful to investors in allowing for greater transparency of supplemental information used by management. EBITDA, as adjusted, is used by investors, as well as management in assessing the company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

Second quarter results

	Three months ended June 30,		Six months ended June 30,	
(amounts in millions)	2022	2021	2022	2021
Net (loss) income (GAAP)	$ (3.1)	$ 1.2	$ (7.4)	$ (5.5)
Interest expense	3.4	4.0	6.8	7.9
Depreciation	1.8	1.5	3.6	3.0
Amortization of intangible assets	0.2	0.1	0.4	0.7
Stock-based compensation	1.4	2.0	2.9	5.1
Revenue recognition (a)	0.6	—	(0.7)	0.3
Deal and integration costs (b)	0.3	—	0.4	—
Gain on extinguishment of debt (c)	—	(3.4)	—	(3.4)
EBITDA, as adjusted	$ 4.6	$ 5.4	$ 6.0	$ 8.1

Full year results and 2022 guidance

	Year ending / ended December 31,	
(amounts in millions)	2022	2021
	(estimate)	
Net loss (GAAP)	$ (13.3) - (11.3)	$ (11.4)
Interest expense	15.0	15.2
Depreciation	7.5	6.5
Amortization of intangible assets	0.9	1.0
Stock-based compensation	5.6	6.5
Revenue recognition (a)	(0.2)	(0.1)
Deal and integration costs (b)	0.5	2.3
Gain on extinguishment of debt (c)	—	(3.4)
EBITDA, as adjusted	$ 16.0 - 18.0	$ 16.6

a) To exclude the impact of Accounting Standards Update 2014-09, "Revenue Recognition," related to non-cash changes in its contract asset.
b) Costs related to the acquisition and integration of IriSys.
c) In October 2020, the Company submitted a forgiveness application for its note under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020. In June 2021, the note and all accrued interest thereon was forgiven. Upon receiving the decision, the Company recorded a gain on extinguishment of debt for the forgiveness of principal and accrued interest.

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