November 30, 2022

Zacks Small-Cap Research

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Societal CDMO (NASDAQ:SCTL)

SCTL: New Business Trends Illustrate Strong Momentum

Societal's strategy to garner a growing share of the CDMO market appears to be gaining traction, as illustrated by new business trends. SCTL signed a record number of new agreements in 3Q22. The company currently has more than 65 customers, up more than three-fold in just a few short years, fueled by recent growth and diversification initiatives. Nearly 20 of these customers have been signed to-date in 2022.

Current Price (11/29/22)	$1.81
Valuation	**$4.00**

OUTLOOK

SCTL's recently announced new deals includes a MSA (Master Services Agreement) with Cingulate to manufacture all clinical, registration, and commercial batches of Cingulate's lead candidate CTx-1301. We view this deal as another positive underscoring the success of Societal's strategy. In addition to growing and diversifying its customer base, Societal also seeks to refinance debt to extend maturities and lower funding costs. Measures include monetizing non-core real estate assets to pare debt. In August 2022, the company signed a sales and purchase agreement to sell non-core real estate & generate more than $9M to be used for debt repayment. The company also expects to consummate additional asset sales to further address its leverage and strengthen the balance sheet.

SUMMARY DATA

52-Week High	**$2.19**
52-Week Low	**$0.62**
One-Year Return (%)	**22.30**
Beta	**0.70**
Average Daily Volume (sh)	**57,906**
Shares Outstanding (mil)	**57**
Market Capitalization ($mil)	**$99**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**58**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-1.3**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	22 A	16 A	19 A	10 A	66.5 A
2021	17 A	18 A	18 A	22 A	75.4 A
2022	21 A	23 A	22 A	25 E	91.1 E
2023					96.5 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.33 A	-$0.25 A	-$0.09 A	-$0.48 A	-$1.16 A
2021	-$0.23 A	-$0.06 A	-$0.07 A	-$0.04 A	-$0.35 A
2022	-$0.08 A	-$0.06 A	-$0.06 A	-$0.03 E	-$0.22 E
2023					-$0.13 E

Quarters might not sum due to rounding & share counts

Disclosures on page 9

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KEY POINTS: RECENT BUSINESS UPDATE

Solid pipeline of new business supports positive outlook

- Societal's strategy to garner a larger share of the CDMO market appears to be gaining traction, as illustrated by recent new business trends. SCTL signed a quarterly record number of new agreements in 3Q22. Reflecting the company's growth and diversification initiatives, SCTL currently has more than 65 customers, up more than three-fold in just a few short years, with nearly 20 of those new customers signed to-date in 2022.

- The company's customer base includes legacy agreements, companies with early stage assets in development phase and others closer to commercialization implementing tech transfers. This breakdown is consistent with the company's objectives. SCTL also targets doubling the number of proposals in 2022 versus 2021 and believes that its 2022 win-rate on new business exceeds the industry average.

- SCTL recently improved the terms of its agreement with Lannett, which we view as a positive. The modified agreement also now includes scheduled increases in manufacturing prices and awards SCTL potential new manufacturing agreements for additional Lannett development projects.

- Subsequent to 3Q22, the company announced additional new deals, including a MSA (Master Services Agreement) with Cingulate to manufacture all clinical, registration, and commercial batches of Cingulate's lead candidate CTx-1301. We view this deal as another positive that points to the success of Societal's strategy.

- Societal seeks to refinance debt to extend maturities and lower financing costs. The company's measures include monetizing non-core real estate assets to pare debt. In August 2022, the company signed a sales and purchase agreement to sell non-core real estate to generate more than $9 million, which will be used for debt repayment. The company also expects to consummate additional asset sales to further address its leverage and strengthen the balance sheet.

RECENT HIGHLIGHTS

Company believes it is outperforming on new business wins

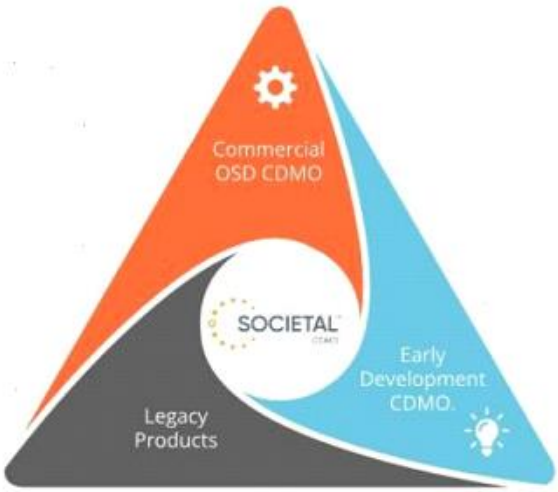
Societal CDMO, an established small-molecule CDMO (contract development and manufacturing organization), is positioning itself as an alternative to larger industry players for established and emerging drug companies. This strategy appears to be gaining traction, as illustrated by new business trends during the company's recently reported 3Q22. Societal believes that its high-touch, customized service offerings will attract clients seeking to partner over the drug development lifecycle. Importantly, management believes that its 2022 win-rate on new business exceeds the industry average.

Societal CDMO 1-3 Year Strategic Plan



Source: Company presentation

Societal's business plan is designed to leverage the expertise, relationships and know-how the company has developed throughout its operating history. Moreover, Societal has expanded its capabilities and capacity in the past year and successfully diversified its customer base, focusing across the pharmaceutical development lifecycle from supplying product for clinical trials, through the regulatory process to commercial scale production. The apparent success of this strategy (in our view) can be seen in the many new contracts the company has signed. In fact, SCTL signed a quarterly record number of new agreements in 3Q22. Reflecting the company's growth and diversification initiatives, SCTL has more than 65 customers, up more than three-fold in just a few short years, with nearly 20 of those in 2022 to-date. The company's customer base includes legacy agreements, companies with early stage assets in development phase and others closer to commercialization implementing tech transfers. The company targets doubling the number of proposals in 2022 versus 2021 and believes that its 2022 win-rate on new business exceeds the industry average.



Source: Company presentation

The company's 3Q22 results illustrate momentum for SCTL's high-touch customer strategy, in our view. Revenue increased 19% from $18.2 million to $21.6 million, primarily reflecting an increase in European Ritalin LA demand from InfectoPharm, a new customer, combined with the integration of IriSys, which SCTL acquired in 2021 and higher revenues from the clinical trial materials business. These improvements offset the decline in revenues from Lannett's lower commercial sales of Verapamil PM products. With the anniversary of the IriSys transaction, year-over-year comparisons are expected to be more apples to apples going forward.

Costs were also higher compared to 3Q21, partially reflecting the integration of IriSys, absence of government subsidies and incentives offered during the pandemic and ongoing wage inflation. The 3Q22 gross margin came in at 25.6% compared to 27.8% in 3Q21. The lower gross margin also reflected higher costs associated with operating the San Diego facility that SCTL acquired from IriSys. SCTL reported a net loss of $3.3 million and a loss per share of ($0.06) compared to a net loss of $3.5 million and ($0.07) in 3Q21.

Adjusted EBITDA was $4.8 million compared to $5.3 million; lower sales of Verapamil PM by Lannett constrained 3Q22 adjusted EBITDA by $0.8 million. Following these solid results, the company reiterated 2022 guidance for revenue of $90.0 million to $95.0 million compared to $75.4 million in 2021 and adjusted EBITDA of $16.0 million to $18.0 million compared to $16.6 million in 2021.

Improved Terms of Lannett Agreement …

Lannett has been one of Societal's largest customers (representing 23% of total revenue in 2021) and a profit sharing partner. In 1H22, Lannett experienced a revenue shortfall. SCTL amended its license and supply agreement with Lannett for the marketing of Verapamil PM and Verelan products, including a 10% increase in the profit share on Verapamil PM sales in order to improve its economics. The modified agreement also now includes scheduled increases in manufacturing prices and awards SCTL potential new manufacturing agreements for additional Lannett development projects.

Record Number of New Contracts Signed …

As noted, SCTL signed a quarterly record number of new business agreements in 3Q22. Specifically, SCTL signed $8.2 million in new and expanded project agreements in 3Q22, which marks the highest number of new contracts the company has signed in any quarter since becoming an independent dedicated CDMO. The agreements cover projects spanning clinical trial services, analytical method, tech transfer, formulation development, cGMP manufacturing, and packaging services.

For example, in early September, Societal announced two new contracts. The first contract supports development of novel immediate and extended-release capsule formulations on an investigational treatment for a range of neurodegenerative disease. Following completion of analytical methods and formulation activities, Societal will manufacture, package, and label the product for phase 1 clinical trials. If the investigational treatment moves ahead, we expect Societal will be well-positioned to continue providing developmental and manufacturing services through the regulatory process, and perhaps through commercialization.

Another contract is to provide developmental/manufacturing services for a topical gel drug candidate to combat hair loss. As with the first contract, Societal will provide analytical and formulation services, as well as clinical trial material manufacturing to support planned Phase 1/2a studies involving the investigational drug candidate. As the company continues to add new contracts, we expect further revenue growth.

Subsequent to 3Q22, the company has announced additional new deals. For example, Cingulate signed a MSA (Master Services Agreement) with Societal for Societal to manufacture all clinical, registration, and commercial batches of Cingulate's lead candidate CTx-1301, which is an investigational medication for the treatment of ADHD (Attention Deficit / Hyperactivity Disorder). Societal CDMO will dedicate a specific manufacturing suite within its Gainesville, Georgia facility to satisfying the Cingulate agreement. SCTL expects to close additional contracts per its segmented sales strategy, as well as to expand agreements with existing customers.

Balance Sheet Initiatives … Include Real Estate Sales & Purchase Agreement …

Societal Company seeks to refinance its debt in order to extend maturities and lower financing costs. At the same time, SCTL also seeks to monetize non-core real estate assets to pare debt. In August 2022, the company signed a sales and purchase agreement to sell roughly 121 acres of non-core real estate to David Weekley Homes, an established homebuilder. The land is located adjacent to Societal's manufacturing facility in Gainesville, Georgia.

… Expected to Generate $9+ Million of Proceeds

The transaction is expected to garner approximately $9.1 million. Subject to standard conditions, Societal expects the sale to close in 2H23. The company has earmarked the proceeds from the sale to strengthen its balance sheet by reducing a portion of its outstanding debt. The company also expects to consummate additional asset sales to further address its leverage and strengthen the balance sheet.

VALUATION

We value SCTL shares based on comparative EV/EBITDA metrics. On an EV/EBITDA basis, the company's peers in the CDMO space trade at average multiples of about 16x to 18x. At a valuation of roughly $4 per SCTL share, based on our 2023 EBITDA forecast and reflecting the company's anticipated steps to reduce debt, SCTL shares would trade at just about 14x on this basis.

Given its anticipated higher growth than peers at this stage in its transformation, we would expect SCTL shares to command a multiple at the high end or even slightly above the range. As the company maintains growth initiatives such as expanding the customer base and boosting capacity utilization, these steps are expected to produce strong adjusted EBITDA expansion over the next few years. Concurrently, the company's deleveraging initiatives are expected to enhance value for equity shareholders, in our view.

We therefore anticipate share price appreciation driven by improving adjusted EBITDA, debt reduction and some slight multiple expansion. We also believe there could be upside to our 2023 adjusted EBITDA estimate, as our forecast incorporates continued headwinds on mature legacy products such as of Verapamil PM and significant lead time during which revenue from new business ramps as the company brings on new agreements with Cingulate and others.

Thus, our valuation, based on the company's current state of development, could change with indications that 2023-24 revenue and adjusted EBITDA growth could beat our current forecast. We note that year-to-date in 2022, Societal's cumulative revenue has grown 24% compared to the same period in 2021 and our 2023 forecast conservatively assumes that growth slows to just under 6% as revenue from new deals ramps. We believe this could be overly conservative, particularly in light of the many new contracts the company has signed and management's confidence in growing its pipeline of new business outlook. We continue to see attractive potential for share price appreciation as the company's balance sheet improves and profit growth momentum accelerates.

RISKS

Risks to Societal achieving its objectives, and to our valuation, include the following.

- The sales and purchase agreement with David Weekley Homes might take longer than expected to close or might not close at all.
- The company might not diversify its customer base as quickly as management expects. Given the historical revenue concentration from a few customers with relatively mature legacy products, this could delay the company's ability to achieve certain operational and financial targets.
- Competition could increase and slow or hinder the company's growth initiatives
- If any of the company's development stage customers fail to obtain sufficient financing to advance their candidates, SCTL could lose customers and revenue.
- Rising cases of COVID-19 or other diseases could further impact global logistics challenges.
- The company might not be able to deleverage as quickly as management anticipates. Given the current interest rate environment, this could impact interest expense and earnings more than currently anticipated.
- SCTL might need to raise additional capital to finance its diversification and growth initiatives.

RECENT NEWS

- SCTL reported 3Q22 results on November 9, 2022.
- Societal announced the signing of multiple agreements with both new and existing customers on September 29, 2022.
- On September 7, 2022, Societal announced that it was awarded two new CDMO service contracts focused on supporting clinical development programs for novel therapeutic candidates.
- Societal signed a Sales and Purchase agreement with David Weekley Homes valued at more than $9 million on August 16, 2022.
- SCTL added three new customers on August 3, 2022, signing agreements to provide CDMO services to support clinical development of several novel therapeutic candidates.

FINANCIAL MODEL

Societal CDMO

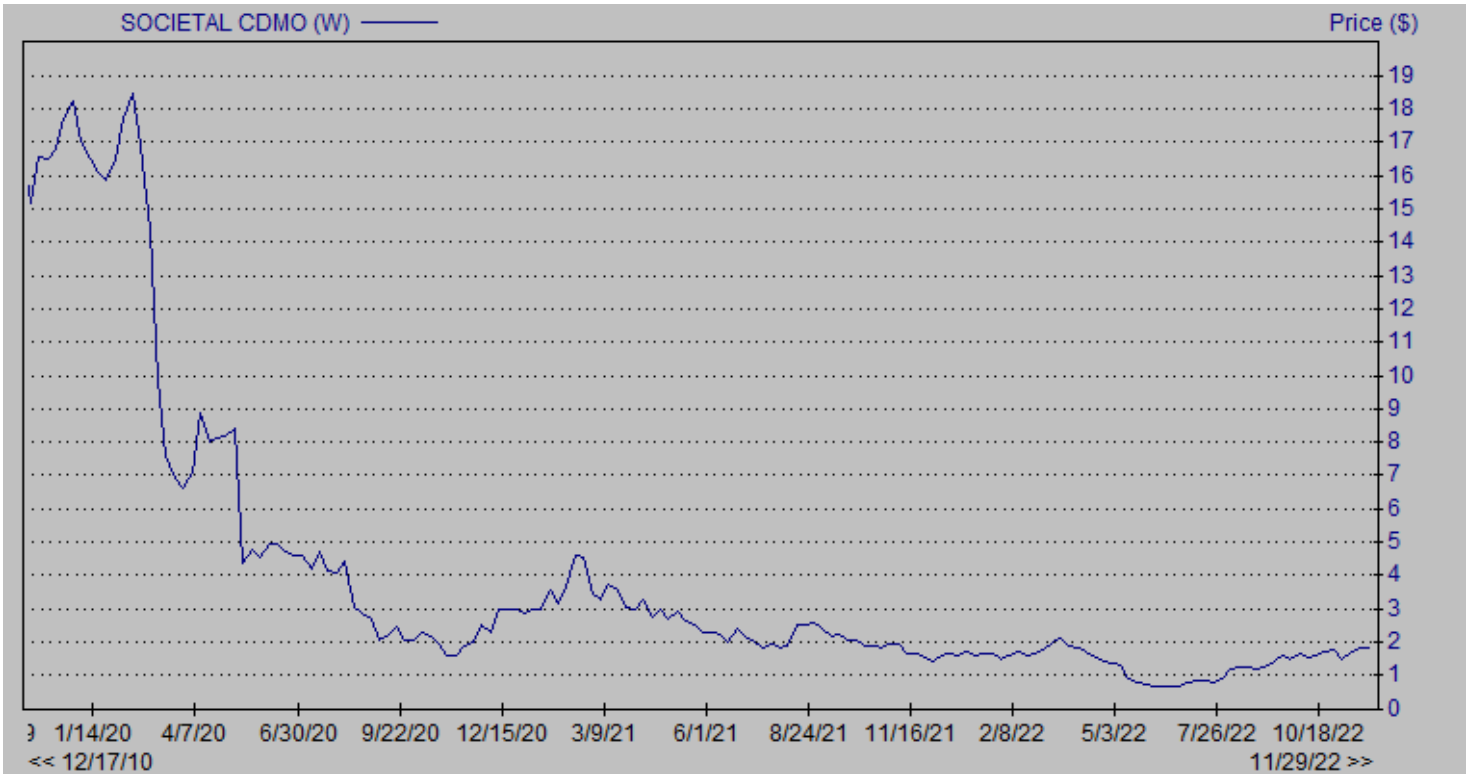
Societal CDMO Income Statement & Projections ($ thousands, except per share data)

	2020	1Q21	2Q21	3Q21	4Q21	2021	1Q22	2Q22	3Q22A	4Q22E	2022E	2023E
Revenue	66,499	16,803	18,017	18,237	22,303	75,360	21,194	23,152	21,589	25,202	91,137	96,542
y/y chg (%)							*26.1%*	*28.5%*	*18.4%*	*13.0%*	*20.9%*	*5.9%*
COGs	54,134	14,337	12,334	13,160	15,706	55,537	16,114	17,470	16,055	18,499	68,138	69,500
Gross profit	12,365	2,466	5,683	5,077	6,597	19,823	5,080	5,682	5,534	6,704	23,000	27,042
Gross margin	18.6%	14.7%	31.5%	27.8%	29.6%	26.3%	24.0%	24.5%	25.6%	26.6%	25.2%	28.0%
S,G&A	18,124	4,683	3,787	4,606	5,298	18,374	5,710	5,160	5,075	4,669	20,614	21,026
Amortization of intangible assets	2,583	646	54	135	202	1,037	221	220	244	244	929	948
Total operating expenses (incl COGs)	74,841	19,666	16,175	17,901	21,206	74,948	22,045	22,850	21,374	23,412	89,681	91,474
Operating income (loss)	(8,342)	(2,863)	1,842	336	1,097	412	(851)	302	215	1,791	1,457	5,067
Interest expense	(19,159)	(3,898)	(3,960)	(3,822)	(3,454)	(15,134)	(3,413)	(3,421)	(3,544)	(3,331)	(13,709)	(12,338)
Gain on extinguishment of debt	-	-	3,352	-	-	3,352	-	-	-	-	-	-
Net loss	(27,501)	(6,761)	1,234	(3,486)	(2,357)	(11,370)	(4,264)	(3,119)	(3,329)	(1,541)	(12,253)	(7,271)
EPS or loss per share	($1.16)	($0.23)	$0.03	($0.07)	($0.04)	($0.26)	($0.08)	($0.06)	($0.06)	($0.03)	($0.22)	($0.13)
Avg shares out (FD)	23,744	29,738	39,352	51,416	55,964	44,117	56,351	56,599	56,666	56,746	56,591	56,911
Stock based comp	10,100	3,100	2,000	1,300	100	6,500	1,500	1,400	1,200	1,207	5,307	5,360
D&A	9,500	2,146	1,554	1,685	1,902	7,287	1,980	2,020	2,154	2,132	8,286	8,369
Other	2,700	300	-	1,800	100	2,200	(1,200)	900	1,200	960	1,860	1,302
Adj EBITDA	13,958	2,683	5,396	5,121	3,199	16,399	1,429	4,622	4,769	6,090	16,910	20,099
Adj EBITDA / share	$0.59	$0.09	$0.14	$0.10	$0.06	$0.37	$0.03	$0.08	$0.08	$0.11	$0.30	$0.35

Source: Company reports & Zacks

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