July 12, 2022

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Elizabeth Senko, CFA
312-265-9484
esenko@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Societal CDMO (NASDAQ:SCTL)

SCTL: An underappreciated opportunity in CDMOs – initiating coverage

Our initial valuation for SCTL is $4.13 per share. The value is based on a 10-year DCF model building to sales of $201 million by 2031. We model terminal sales with an EBIT margin of 14% and a 15% tax rate. We use a terminal growth rate of 2% and an 11% discount rate. We believe the gap between current and our valuation is based on SCTL's less-familiar profile among CDMOs and its relatively high debt burden.

Current Price (07/11/22)	$0.81
Valuation	**$4.13**

OUTLOOK

Societal CDMO is an established small-molecule CDMO taking steps to position itself as alternative to the big industry players for established and emerging drug companies. In the past year, Societal has expanded its capabilities, capacity and diversified its customer base. Societal has a very specific business plan -- built on wisdom, experience, constant operating assessment, and establishing long-term customer relationships – which we believe will mitigate many of the challenges of carving out a bigger share in an industry dominated by large, deep-pocketed companies.

SUMMARY DATA

52-Week High	**$2.55**
52-Week Low	**$0.64**
One-Year Return (%)	**-57.68**
Beta	**1.11**
Average Daily Volume (sh)	**140,354**
Shares Outstanding (mil)	**57**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**59**
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	**-3.0**
P/E using 2023 Estimate	**-3.9**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Value**
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				90.4 E
2023					104.0 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				-$0.24 E
2023					-$0.13 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

INVESTMENT SUMMARY

COMPANY DESCRIPTION. Societal CDMO is an established small-molecule CDMO taking steps to position itself as an alternative to the big industry players for established and emerging drug companies. Societal believes that its high-touch, customized service offerings will attract clients seeking to partner over the drug development lifecycle. In the past year, Societal has expanded its capabilities, capacity and diversified its customer base, focusing across the pharmaceutical development lifecycle from supplying product for clinical trials, through the regulatory process to commercial scale production. Barely a year into its transformation, Societal has a very specific business plan -- built on wisdom, experience, constant operating assessment, and establishing long-term customer relationships – which we believe will mitigate many of the challenges of carving out a bigger share in an industry dominated by large, deep-pocketed companies.

FINANCIALS. Our model is based on SCTL's current business; it does not include any future acquisitions, moves outside of its core small molecule solid-dose oral formulation and injectables business, or the addition of adjacent services (e.g., cGMP consulting). We forecast top line growth of 18% in 2022, based on gains in new business as well as the impact from the IriSys acquisition in 2021. For 2023 – 2031, we forecast top-line growth of 12% slowing to 7%, for a CAGR of 8.6%, slightly ahead of the ~6% top-line growth expected for the CDMO group as a whole. We look for revenues of $90.4 million in 2022, up 20%, We forecast a net loss of $(13.4) million.

By 2026, we forecast revenues of $142.2 million, a 9.5% CAGR. We forecast operating income of $18.2 million in 2026, compared with $0.4 million in 2021. We expect SCTL to be breakeven on a GAAP basis in 2025, as operating income gains offset interest expense.

VALUATION. Our 10-year DCF model builds to sales of approximately $201 million by 2031. We model terminal sales with an EBIT margin of 14% and a 15% tax rate. We assume a terminal revenue growth rate of 2% and a 11% discount rate. Under these assumptions, we arrive at an intrinsic value of $4.13 per share.

SENSITIVITIES. At the most basic level, demand for CDMO services is tied to pharma R&D pipeline trends, and decisions by pharma companies whether to outsource drug development and/or production as part of their corporate strategy. Several factors may affect forecasts and results over the next several years including: outsourcing and asset optimization trends, bio/pharma funding, size and pace of clinical development, supply chain disruptions, etc.

COMPANY OVERVIEW

It's an oft-repeated cycle in healthcare – businesses mature, needs change, and new sectors develop to fulfill those needs. Innovation is alive and well in the pharmaceutical space, and post-COVID, pharmaceutical companies are looking for ways to improve their innovation efficiency – through development partnerships, acquisitions and outsourcing. Contract development management organizations (CDMOs) are a prime beneficiary of these trends.

In particular, investor interest has centered on the largest CDMOs or CRO/CDMOs (e.g., Lonza (SIX: LNN), Catalent (NYSE:CTLT), ThermoFisher (NYSE:TMO)). These companies are seeing record business demand, particularly from demand for bioprocessing/production capacity from both large and emerging biopharmaceutical companies. Over the past two years, shares of the leading players are up anywhere from 15-45%.

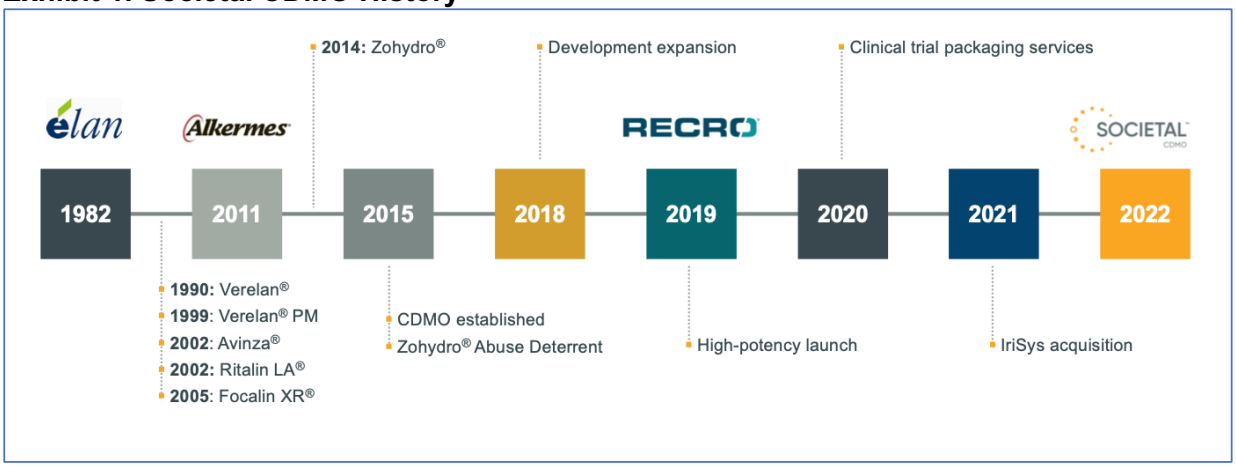
The CDMO industry is diverse both in range of services, and target molecules. While large molecule (e.g., biopharmaceuticals) has garnered much attention, we see opportunities in the small-molecule segment.
We believe that there is an opportunity for mid-cap CDMO companies focusing on specific niches (customer and capabilities) primarily in more mature segments of the business because they will have less exposure to both competitive and innovation risk.

Societal CDMO is an established small-molecule CDMO taking steps to position itself as a high-touch choice compared to the larger CDMOs for both established and emerging drug companies. In the past year, Societal has expanded its capabilities, capacity and diversified its customer base, focusing across the pharmaceutical development lifecycle from supplying product for clinical trials, through the regulatory process to commercial scale production.

Societal began as a contract manufacturing division of Elan, an Irish pharmaceutical company. In 2011, Elan sold its drug formulation and manufacturing business to Alkermes (NASDAQ:ALKS). In 2015, Alkermes sold the CDMO business to Recro Pharmaceuticals, which at the time was a specialty pharmaceutical company in the acute care therapy space**.**

In 2019, Recro Pharmaceuticals separated its acute care therapeutics and CDMO business. The therapeutics business became Baudax Bio (NASDAQ:BXDX), while the CDMO business retained the Recro Pharmaceuticals branding. There is no ongoing relationship between Baudax Bio and Societal CDMO.

Exhibit 1. Societal CDMO History



Source. Societal CDMO.

As a standalone CDMO, Recro (now Societal), reflected years of disengaged leadership and underinvestment. Its business consisted of legacy contracts to manufacture a limited number of mature products - ADHD treatments Ritalin LA and Focalin XR, for Novartis (NYSE:NVS), and two dosage formulations of hypertension treatment verapamil – one for Teva (NYSE:TEVA), and the other for Lannett (NYSE:LCI).

David Enloe joined Recro as CEO in December 2020. Enloe, a veteran in drug development and cGMP manufacturing, brings a CEO-as-owner, hands-on management style that puts him close to customers and employees. In just over a year, Enloe and team have broadened service offerings, completed a major acquisition, signed new clients, and rolled out a "customer-first" segmented sales strategy that emphasizes building out long-term relationships.

Exhibit 2. Societal CDMO capabilities

Source. Societal CDMO.

While Societal doesn't provide detailed revenue breakdown by business segment/customer, management estimated that ~70% of expected sales in 2022 would be from legacy and commercial manufacturing, with the remaining 30% from development contracts. This compares to a 2020 revenue mix of ~90% legacy and ~10% development.

- ***Legacy products.*** Societal's legacy business consists of long-term contracts for small molecule oral solid (e.g., tablet) finished dose commercial manufacturing. Many of these contracts have been in place for 20+ years, and have renewal options in the 2023-2025 timeframe. Some of these contracts include profit-sharing and/or royalty revenues.

- ***Commercial manufacturing.*** In the past year, Societal added several new long-term commercial manufacturing contracts, through the IriSys acquisition (e.g. Donnatal elixir and tablets), and through new client wins, including a long-term tech transfer and commercial production agreement with Otsuka Pharmaceuticals (OTCMKTS: OTSKY), and a a tech transfer/production agreement with Viatris (NASDAQ:VTRS). Generally, these contracts include binding purchase volumes for the first three months, followed by 12 - 24-month volume projections.

- ***Development business.*** Societal's development business covers an array of services, from drug formulation, through clinical trial supply support, pre-commercial manufacturing and project management, and regulatory support.

CDMO INDUSTRY AND OUTLOOK

The pharmaceutical outsourcing industry is large, diverse, and in some aspects, still fragmented. Once distinct "buckets" (e.g., research, clinical trial support, commercial scale manufacturing, market insights), competitors are now best viewed as part of a spectrum. Companies expand up and down the value chain, sometimes while narrowing their focus on particular therapeutic areas or formulations.

The CDMO industry first grew out of less formal arrangements where pharmaceutical companies provided manufacturing services to each other, standalone specialty manufacturers, and chemical companies that provided raw materials/intermediates for APIs. Cooperation between companies was quite common. At the time, API and intermediate production was not distinct from food ingredients, agrichemicals, and other specialized chemicals. Generic APIs were primarily produced in Europe, and custom API manufacturing was generally done in-house by pharma companies.

In the mid-1990s, CDMOs began to emerge as a standalone industry, led by three companies – Patheon (ThermoFisher), Lonza, and Cardinal Health's contract business (now Catalent). Other companies, often backed by private equity, soon emerged.

Several factors drove the development of the CDMO industry:

- **Patent cliff and production right-sizing**. The pharmaceutical companies faced a wave of patent expiries starting in the mid-1990s, reducing the need for in-house manufacturing capacity. In addition, cross-border sales of pharmaceuticals were made easier with the enactment of the European Union and North American Free Trade Agreement, further enabling pharmaceutical companies to right-size their production footprint. Many pharmaceutical companies opted to sell-off production of low-margin, or near-LOE products to CDMO buyers, to retain some control of their supply chain, as well as manage potentially difficult labor settlements.

- **Biotech start-up growth.** The biotech industry grew rapidly in the mid-1990s, as Genentech (SIX:ROC), and other pioneers, created an eco-system of knowledge, external funding, and established technologies. Large pharmaceutical companies and investors looked to early-stage biotech for higher returns. Many biotech startups embraced outsourcing for capital-intensive functions (e.g., manufacturing), as a way to conserve capital, further fueling demand for the CDMO space.

- **Outsourcing viability.** By the mid-1990s, clinical research organizations (CROs) were well established as reliable partners for clinical trial management, data/site monitoring and laboratory services for the pharmaceutical industry.

The CDMO industry grew largely unabated until the 2008 financial crisis. A spate of pharmaceutical mega-mergers in the early 2000s canceled duplicative drug development efforts, the rate of patent expiries moderated, and venture capitalists shifted their focus to tech from biotech, leaving many of the CDMO players without their usually reliable project pipeline. While it was a difficult time for the CDMO players, the low valuations and low interest rates attracted new investors, who saw long-term opportunities in the CDMO industry. The new funders invested to expand capacity (much of it by buying used assets at failed companies) and brought in new capabilities (e.g., bioprocessing) to the CDMO industry, just as funding began to move back into early-stage biotech beginning in 2013.

As demand for CDMO services picked up, so did consolidation. From 2012-2016, M&A activity rose as privately-owned companies sold out to the larger publicly traded companies within the CDMO industry. Patheon, for one, grew through a series of deals starting in 2012, becoming a large key player with $1.9 billion in revenues by 2016. In 2017, the M&A landscape changed, when ThermoFisher, a maker of life-science tools, acquired Patheon for $7.2 billion, moving ThermoFisher into the CDMO services market.

The CDMO market is currently estimated at $90 billion with mid-single digit CAGR through 2030. While there are over 500 CDMOs globally, the top players control ~25% of the market. In the past few years, many players have focused on the large molecule (biotechnology) candidates, with an emphasis on expanding drug development services and production capacity. There are certainly concerns about recent declines in early-stage pharmaceutical (particularly biopharma) funding. If the lull in funding is prolonged, we may see increased competition for new business along the margins as we move past 2023; however, we expect any increase to be primarily among biopharma projects.

To build out a bigger share of the CDMO market, Societal's strategic plan is straightforward. Be the best at the basics. Societal can compete with the top CDMOs in terms of small molecule capability. By virtue of its size, Societal is better positioned to win contracts earlier on in the development lifecycle. The largest CDMOs are often "capacity minded", meaning that smaller clients may have to compete with larger clients in terms of project scheduling and customer service. Societal's clients have regular interactions from the CEO down.

Exhibit 3. Societal CDMO business strategy

Source. Societal CDMO.

Define business scope. As discussed above, many CDMOs and other pharmaceutical outsourcing companies are expanding their scope in an attempt to be all things to all customers. In our view, Societal is taking a more nuanced approach by emphasizing its existing technical expertise in drug delivery (e.g., extended-release fomulation), controlled substance, and complex formulations – all in the small molecule space.

Market-specific sales strategies and client relationship building. One of SCTL's actions was to bolster its business development team by adding six new members. Societal segments its sales strategy into three buckets: legacy profit-sharing accounts (e.g., Teva), commercial oral solid dose production (e.g., Otsuka), and early-stage development clients. Each segment strategy encompasses different drivers, decision processes and performance metrics. SCTL's business development emphasizes regular client engagement. Not only does SCTL view this customer-specific approach as a competitive advantage to grow its business, these interactions also provide information to SCTL so it can optimize its resources and operations.

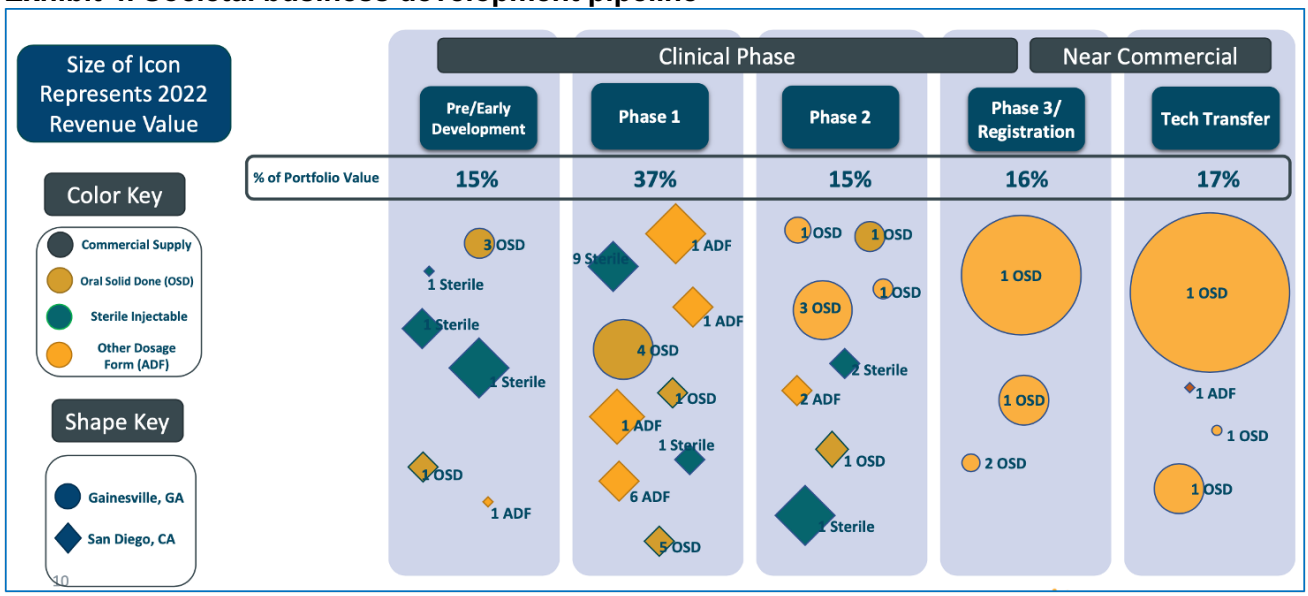
Optimize organization. Expanded sales and service capabilities are useless, if not damaging to a business, without successful execution. Companies often seek to improve their businesses incrementally, through functional or departmental tweaks. Fewer opt for a dynamic 360° view, not only of the organization, but also the ecosystem. SCTL took the latter approach by assessing not only its sales, services, operations, quality and regulatory efforts, and business systems, it looked at how these components work together as a system, both in and outside the organization. The exercise enabled the company to optimize individual processes, while also identifying opportunities for automation and digitalization. In our view, this systems approach creates foundational knowledge for SCTL to execute its strategy, while mitigating potential risks

Expand capabilities and capacity within business scope. In October, 2021, Societal acquired IriSys, a San Diego-based CDMO. IriSys adds a range of new small molecule formulation/delivery (e.g., injectables, capsules, oral liquids, liposomes) drug development and production capabilities to augment the core oral solid-dose business. IriSys also bolsters Societal's clinical trials support services capabilities, which includes preparation of clinical trial supplies, as well as specialized services dedicated to the development and current Good Manufacturing Practices (cGMP).

Financial strength and flexibility. Societal is accomplishing these strategic changes with a heavily-leveraged balance sheet. Much of this debt stems from the Company's 2019 spin-out. At the end of March, SCTL had $2 million in current related party debt, and long-term debt of $93.2 million in a term loan and $3.4 million in related party debt. Despite the current debt levels, management notes that the steps it has taken to build a stronger more diverse business, have created significant opportunities to work non-dilutively on further debt reduction through potential monetization of owned real estate in Gainesville, Georgia as well as position itself for a debt refinancing.

Early results suggest that Societal's revised strategy is working. Throughout 2021, Societal announced new client contracts and expanded service agreements with existing customers. New development agreements include: a development/clinical trial manufacturing for an investigative topical dermal treatment for skin cancer prevention, CMC services for a novel nasal spray analgesic, as well as early development agreements with Astex Pharmaceuticals and Ensysce Biosciences. In October 2021, Otsuka Pharmaceuticals (OTCMKTS: OTSKY) engaged SCTL as second source production for one of its branded drugs. In 2022, Societal has announced a three-year manufacturing and supply agreement with Infectopharm for Ritalin LA, and supply services to upcoming phase III/IV clinical studies in Alzheimer's Disease with AmyriAD pharma.

Exhibit 4. Societal business development pipeline



Source. Societal CDMO.

Societal has provided details for its development business pipeline, by phase, type, location and 2022E revenue potential. While the Company does not specify the revenue opportunity for each project, based on our discussions, we believe pre/early development contracts average in the $3-$4M range (over the life of the project, not in a single year), and that on average, contract size doubles as it advances each step (e.g., $0.5 million Phase 1, $1 million Phase 2, $2 million Phase 3); commercial tech transfer projects are likely in the $3 million+ range. For long-range forecasting, Societal builds in attrition assumptions, based on generally accepted industry metrics (e.g.,10% likelihood for a Phase I candidate to reach commercialization). This conservative approach builds our confidence in SCTL's growth forecasts.

Societal believes that its high-touch, customized service offerings will attract clients seeking to partner over the drug development lifecycle. In the past year, Societal has expanded its capabilities, capacity and diversified its customer base, focusing across the pharmaceutical development lifecycle from supplying product for clinical trials, through the regulatory process to commercial scale production. Barely a year into its transformation, Societal has a very specific business plan -- built on wisdom, experience, constant operating assessment, and establishing long-term customer relationships – which we believe will mitigate many of the challenges of carving out a bigger share in an industry dominated by large, deep-pocketed companies.

SENSITIVITIES

Societal CDMO is barely a year into its transformation. Management has a very specific business plan, one built on wisdom, experience, and building out long-term customer relationships – which we believe will mitigate many of the challenges of carving out a bigger share in an industry dominated by large, deep-pocketed companies. At the most basic level, demand for CDMO services is tied to pharma R&D pipeline trends, and decisions by pharma companies whether to outsource drug development and/or production as part of their corporate strategy. Several factors may affect forecasts and results over the next several years.

- **Outsourcing and asset optimization trends.** The CDMO industry was built on pharmaceutical companies looking to lower the cost of manufacturing older drugs, while divesting excess capacity. Start-up pharmaceutical ventures generally rely on CDMOs to develop/produce their products as a less capital-intensive way to advance their pipelines. Large pharmaceutical companies continue to seek outsourcing opportunities to optimize their assets; however, the pace has slowed in recent years as large pharma companies have made significant investments in new equipment and capacity, particularly for high-margin biotech drugs. Separately, we see a potential new trend related to second source manufacturing and geographic risk from climate change. Otsuka Pharmaceuticals (OTCMKTS: OTSKY) engaged SCTL as second source production for one of its drugs; Otsuka sought a second production line to mitigate weather-related (e.g., tsunami) shut down risk at its primary production line.
- **Early-stage pharmaceutical funding.** Historically, funding for early-stage bio/pharma has been cyclical. Raising funds has been pretty easy in recent years, even for speculative efforts. However, following a recent bolus of clinical-stage disappointments, and the uncertain economic environment, it appears that early-stage investors are more cautious – particularly around newer technologies (e.g., cell therapy). With its small molecule focus, SCTL is largely insulated from biotech funding trends; however, if overall pharmaceutical funding slows, or if biotech-focused CDMOs turn to small molecule opportunities to fill their pipeline, SCTL may see more competition for new business.
- **Clinical development pace.** Alongside funding for early-stage bio/pharma, another issue that affects new business opportunities is the number/size /stage of assets under development. SCTL's strategy is to attract clients in the early stages of development, and grow with those opportunities through clinical trials and commercialization. SCTL's willingness to work on small opportunities with the goal of long-term engagement, may enable SCTL to build a well-diversified project pipeline and relationships which may help it weather business slowdowns, particularly compared with more opportunistic competitors.
- **Supply chain disruption.** It's not enough to have a pipeline of business, a CDMO has to be able to move the business forward. The pandemic continues to disrupt the supply chain for many items, from radiology imaging agents to computer chips and plastics. SCTL notes API supplies have to be ordered way in advance, and when it couldn't get several hundred empty sterile syringes for a clinical trial, it worked client and vendor relationships to fill its need.
- **Competition for talent.** Chemists and other pharmaceutical scientists tend to be nomadic, moving from opportunity to opportunity, in response to projects or reorganizations, and often to follow more senior colleagues. Many professionals were put on hiatus or let go, during the pandemic, and the typical challenging talent hunt is more so in a tight job market. We think it's notable that SCTL puts attracting and *retaining* talent alongside other key goals. While we frequently encounter human capital/social goals as part of overall ESG strategy at large companies, it's much less common at smaller firms.
- **Debt burden.** Reducing leverage is a key goal for SCTL management. At the end of March, SCTL had $15.3 million in cash and equivalents on its balance sheet, down from $25.2 million at the end of 2021. The Company has $2 million in current related party debt, and long-term debt of $93.2 million in a term loan and $3.4 million in related party debt. SCTL is taking steps to reduce its debt burden. It plans to sell 120 acres of land around Lake Lanier, near the Company's Gainesville, GA facility, and complete a sale/leaseback of its Gainesville facility. SCTL expects these moves to generate $35 million - $50 million in cash, which it plans to use to refinance much of its long-term debt (Athyrium). If SCTL successfully completes these transactions in the next year, we believe it will relieve a significant overhang for investors while freeing up new funds for future deals.

VALUATION

While it is tempting to use peer metrics (price-to-earnings or price-to-sales multiples) to value CDMOs, for us, the methodology falls short as the publicly-traded peers differ considerably in terms of scale, business model, strategic priorities, and capital structure. With SCTL's debt burden, cash flows are the most important metric. For these reasons, we opt for a DCF model.

Our 10-year DCF model builds to sales of approximately $201 million by 2031. We model terminal sales with an EBIT margin of 14% and a 15% tax rate. We assume a terminal revenue growth rate of 2% and an 11% discount rate. Under these assumptions, we arrive at an intrinsic value of $4.13 per share.

Exhibit 5. Valuation sensitivity

		Terminal EBIT Margin				
	412.58%	10%	12%	14%	16%	18%
WACC	8%	4.43	4.73	5.02	5.32	5.62
	9%	4.13	4.39	4.64	4.90	5.16
	10%	3.91	4.13	4.36	4.58	4.81
	11%	3.73	3.93	**4.13**	4.34	4.54
	12%	3.59	3.77	3.95	4.14	4.32
	13%	3.48	3.64	3.81	3.97	4.14
	14%	3.38	3.53	3.68	3.83	3.99

Source. Zacks Investment Research estimates.

Our model is based on SCTL's current business; it does not include any future acquisitions, move outside of its core small molecule solid-dose oral formulation and injectables business, or the addition of adjacent services (e.g., cGMP consulting). We forecast top line growth of 18% in 2022, based on gains in new business as well as the impact from the IriSys acquisition in 2021. For 2023 – 2031, we forecast top-line growth of 12% slowing to 7%, for a CAGR of 8.6%, slightly ahead of the ~6% top-line growth expected for the CDMO group as a whole.

We forecast gross margins moving from 26.3% reported in 2021, to 30-32% by 2027. With the acquisition of IriSys' San Diego facilities, SCTL has plenty of excess capacity to support growth. In the interim, this extra overhead is a drag on SCTL's gross margins, and incremental business is highly profitable (management estimates that for every dollar of incremental sales, anywhere from $0.30-$0.40 flows through to the operating line). SG&A should provide some additional operating leverage. We expect the company to continue to invest in its sales/marketing efforts, which is likely to be offset by leveraging largely fixed SG&A expense over a greater revenue base. We anticipate sustainable EBIT margins at 14%.

We've modeled depreciation/amortization at ~$8 million - $9 million each year for the forecast period, and annual capex of $5 million - $6 million (excluding acquisitions). We expect working investment needs to grow each year, but at a declining rate, settling in at a range of $2 million - $3 million year per year.

Our model uses an 11% discount rate, in line with our typical 10-12% rate used for similarly sized companies.

FINANCIALS

Profit and loss

SCTL reported $21 million in revenue in 1Q22, up 26% (YoY). SCTL saw mixed results in its legacy business, where market share gains for Teva's Verapamil SR products were offset by a decline in Lannett's sales of Verapamil PM. COGs totaled $16.2 million compared to $14.4 million for the year-earlier period, driven primarily due to costs related to the San Diego facility (IriSys), partially offset by post-acquisition related restructuring savings. SG&A rose $1 million to $5.7 million, compared to $4.7 million in the year-earlier period. Interest expense was $3.4 million in 1Q22, a decrease compared to $3.9 million in the year-earlier period. In 1Q22, SCTL recorded a net loss of $4.3 million or $0.08 per diluted share, compared to a net loss of $6.8 million or $0.23 per diluted share, for the comparable period of 2021.

In 2021, SCTL reported revenues of $75.4 million, up 13%, from $65.3 million in 2020. Revenue gains were driven by the acquisition of IriSys as well as higher revenues from SCTL's clinical trial materials business including revenue from a commercial product tech transfer project. Organic new business grew by 63% in 2021 (147% including the IriSys acquisition). New business wins in 2021 include a $1.5 million contract from a key department of the US government for formulation development and cGMP manufacturing supporting clinical development of a topical dermal treatment for the prevention of skin cancer.

COGs rose modestly to $55.6 million, compared to $54.1 million for the same period in 2020, due to costs from the San Diego facility (IriSys acquisition) partially offset by workforce reductions (2020) and tax credits. SG&A totaled $18.4 million, largely flat with $18.1 million in 2020. The increase of $0.3 million was primarily related to IriSys deal costs, offset by lower public company costs and stock-based compensation expense.

Interest expense was $15.1 million in 2021 vs. $19.2 million in 2020. The decrease of $4.1 million was primarily due to reduced term loan borrowings and an overall decrease in the rate of interest on term loans partially offset by an increase in interest from the sellers note related to the IriSys acquisition.

For 2021, SCTL reported a net loss of $11.4 million, or $0.26 per diluted share, compared to $27.5 million, or $1.16 per diluted share, for the comparable period in 2020.

In 2022, SCTL is guiding to revenue of $90 to $95 million, net loss to be in the range of $(13.2) million to $(11.2) million, and EBITDA, as adjusted to be in the range of $16 to $18 million. We look for revenues of $90.4 million in 2022, up 20%, We forecast a net loss of $(13.4) million.

By 2026, we forecast revenues of $142 million, a 9.5% CAGR. We forecast operating income of $18.2 million in 2026, compared with $0.4 million in 2021. We expect SCTL to be breakeven on a GAAP basis in 2025, as operating income gains offset interest expense.

Cash flow

SCTL has generated positive operating cash flow in each of the past three years. we forecast SCTL will produce ~$6 million in free cash flow in 2022, growing to $25 million by 2027.

Balance Sheet

At March 31, 2022, SCTL had $15.3 million in cash and equivalents on its balance sheet, down from $25.2 million at the end of 2021. The Company has $2 million in current related party debt, and long-term debt of $93.2 million in a term loan and $3.4 million in related party debt.

Exhibit 6. Summary financial forecast

	2020A	2021A	2022E	2023E	2024E	2025E	2026E	2027E
$ 000								
Revenue								
Service revenues	$ 66,499	$ 75,360	$ 90,432	$ 103,997	$ 117,516	$ 130,443	$ 142,183	$ 153,558
Cost of goods sold (excluding amortization)	(54,134)	(55,537)	(67,372)	(73,838)	(82,261)	(90,006)	(96,684)	(104,419)
Gross profit	12,365	19,823	23,060	30,159	35,255	40,437	45,499	49,138
Operating expenses:								
SG&A	(18,124)	(18,374)	(20,528)	(21,760)	(23,283)	(24,913)	(26,407)	(27,992)
Amortization of intangibles	(2,583)	(1,037)	(985)	(926)	(880)	(880)	(880)	(880)
Net operating income (loss)	**(8,342)**	**412**	**1,547**	**7,473**	**11,092**	**14,645**	**18,211**	**20,267**
Interest expense	(19,159)	(15,134)	(14,983)	(14,683)	(14,389)	(14,102)	(13,820)	(13,543)
Pretax profit	(27,501)	(11,370)	(13,436)	(7,210)	(3,297)	543	4,392	6,724
Income taxes	0	0	0	0	0	0	0	0
Net income (loss)	**(27,501)**	**(11,370)**	**(13,436)**	**(7,210)**	**(3,297)**	**543**	**4,392**	**6,724**
Per share								
Net income (loss) per share - basic	$ (1.16)	$ (0.26)	$ (0.24)	$ (0.13)	$ (0.06)	$ 0.01	$ 0.08	$ 0.12
Net income (loss) per share - diluted	$ (1.16)	$ (0.26)	$ (0.24)	$ (0.13)	$ (0.06)	$ 0.01	$ 0.08	$ 0.12
Weighted shares outstanding - basic (000)	23,744	44,117	56,681	56,681	56,681	56,681	56,681	56,681
Weighted shares outstanding - diluted (000)	23,744	44,117	56,681	56,681	56,681	56,681	56,681	56,681

Source. Company filings, Zacks Investment Research estimates.

KEY EXECUTIVES

J. David Enloe - *President and CEO*

David Enloe brings over two decades of executive leadership experience in biotechnology, clinical drug development, and GMP manufacturing. He recently served as president and chief executive officer of Ajinomoto Bio-Pharma Services, a global, fully integrated CDMO.

Before joining Ajinomoto, David served as Head of Lonza's Viral Therapeutics Business Unit, which resulted from Lonza's acquisition of Vivante GMP Solutions, a gene therapy CDMO that he founded in June 2009 and where he served as president and CEO until its sale to Lonza AG. Under David's leadership, the business experienced rapid expansion, with revenues increasing 500% over three years. Preceding Vivante, Enloe spent 14 years with a biotech company, Introgen Therapeutics, joining as its first employee in 1995 and serving as senior vice president and COO before being named president and CEO. David was an integral part in taking the company through a successful IPO in 2020 and several other significant financial transactions. In addition, he oversaw multiple extensive corporate and academic collaborations and the filing of license applications with both the FDA and European regulatory authorities of Introgen's lead product.

David received a Bachelor of Business Administration, Accounting from the University of Texas at Austin. He is a Certified Public Accountant and started his career in public accounting with Arthur Andersen & Co.

Ryan D. Lake - *CFO*

Ryan Lake has served as SCTL's chief financial officer since January 2018, and he has over 20 years of senior financial and life sciences leadership experience. Ryan joined Societal™ CDMO in June 2017 as the Company's chief accounting officer and senior vice president of finance. He recently served as the chief financial officer of Baudax Bio, Inc.

Before joining Societal, Ryan served as chief financial officer and vice president of finance of Aspire Bariatrics, Inc., a privately held, commercial-stage medical device company. From 2012 to 2015, he has held executive management and senior finance positions, including director of the natural materials division, controller and senior director of finance, at DSM Biomedical (successor to Kensey Nash after its acquisition in 2012), a division of Royal DSM (listed on Euronext Amsterdam), a global science-based company active in health, nutrition, and materials.

From 2002 to 2012, Ryan held various senior financial positions of increasing responsibility, most notably senior director of finance and interim CFO, with Kensey Nash Corporation, a Nasdaq-listed medical device company. Earlier in his career, Ryan worked at Deloitte & Touche, LLP.

Ryan is a Certified Public Accountant, Chartered Global Management Accountant and holds a Bachelor of Science degree in Accounting from the West Chester University of Pennsylvania.

Scott Rizzo – SVP operations

Scott Rizzo brings more than 25 years of leadership experience and operational excellence to Societal™ CDMO as the site's senior vice president of operations. Scott joined Societal in 2015 and has been instrumental in developing a client-focused culture at the Georgia-based CDMO. With full profit and loss (P&L) responsibility of the CDMO business, Scott drives strategic initiatives to yield continued

business growth while prioritizing employee development and community relations through engagements with the Greater Hall Chamber of Commerce and Georgia Bio.

Before joining Societal, Scott held various leadership positions in large and small pharmaceutical businesses and consulting organizations, including Roche Pharmaceuticals, Barrier Therapeutics, J. Knipper, DuPont, and PricewaterhouseCoopers.

Scott is a graduate of Pennsylvania State University, where he earned both his Master of Business Administration and Master of Manufacturing Management degrees. He is currently a board member of Georgia Bio and formerly a member of the Rutgers University Graduate Center for Supply Chain Management and the alumni advisory board for Pennsylvania State University.

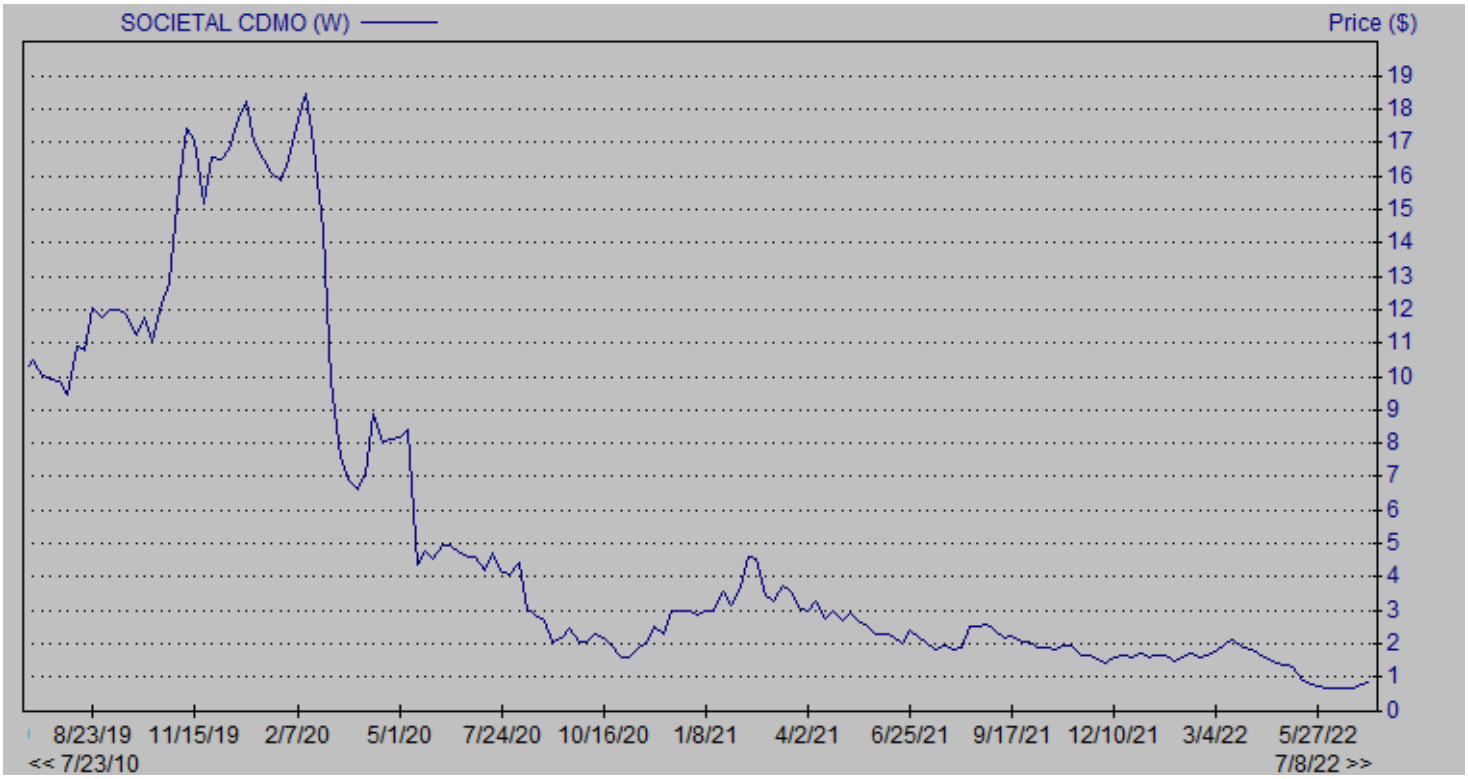
Richard Sidwell, PhD –VP Chief Scientific Officer

Richard Sidwell is responsible for the overall scientific strategy for Societal™ CDMO. He has worked at the Gainesville site since 2003, experiencing its evolution from Elan Drug Technologies to Alkermes in 2011 and finally to Societal in 2015. While at Societal, Richard has been instrumental in leading and building the CDMO's product development team, which focuses on bringing innovative solutions to its clients.

With over 25 years of pharmaceutical development experience, Richard is recognized as a thought leader in pharmaceutical formulation and process development for oral solid dosage forms, multi-particulate, controlled-release formulations, and abuse-deterrent formulations for controlled substances. Richard holds multiple patents and publications in these areas.

Richard earned his Ph.D. in pharmaceutics from the University of Georgia, Master of Science degree in Health Physics from the Georgia Institute of Technology, and Bachelor of Science degree in physics from Oglethorpe University. He is an active member of the American Association of Pharmaceutical Scientists (AAPS).

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Elizabeth Senko, Senior Analyst, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.