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Zacks Small-Cap Research

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Societal CDMO (SCTL-NASDAQ)

SCTL: Business Wins Despite Difficult Economic Environment; Expanding Core Capabilities to Grow Service Offerings

Despite a challenging economic backdrop, SCTL continues to win new business & expand business with existing customers. SCTL also continues to expand core capabilities to increase the range of services it provides. Recently obtained DEA Schedule 1 registration enables SCTL to enter the growing psychedelic drug development vertical.

Current Price (08/15/23)	$0.69
Valuation	**$1.20**

OUTLOOK

SCTL also continues to strengthen its balance sheet and enhance its financial flexibility. Subsequent to 2Q23, the company renegotiated its debt and certain covenants. Important 2022 balance sheet measures contributed to significantly lower interest expense in 2Q23 compared to 2Q22 ($2.3M versus $3.4M). The company believes it has substantial opportunities to continue cross-marketing and cross-selling the broad & growing range of services it offers and diversify its customer base as economic uncertainty abates. We expect the company's progress to lead to share price appreciation over time.

SUMMARY DATA

52-Week High	**$1.86**
52-Week Low	**$0.65**
One-Year Return (%)	**-52**
Beta	**0.90**
Average Daily Volume (sh)	**136,450**
Shares Outstanding (mil)	**90**
Market Capitalization ($mil)	**$62**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**49**
Insider Ownership (%)	**8**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**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	23 A	22 A	24 A	90.2 A
2023	22 A	22 A	24 E	27 E	94.4 E

Earnings/Loss 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	-$0.15 A	-$0.34 A
2023	-$0.06 A	-$0.04 A	-$0.01 E	-$0.01 E	-$0.12 E

Quarters might not sum due to rounding & share counts

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KEY POINTS

- Societal CDMO continues to diversify its customer and revenue base. However, reflecting economic uncertainty and the interest rate environment, many customers have delayed greenlighting or starting new projects. As a result, SCTL expects near-term revenue to skew more heavily towards commercial projects than originally expected, which will likely constrain 2023 EBITDA growth. Revised 2023 EBITDA guidance is $12M to $15M (vs $15M to $18M before). Importantly, the company believes its competitors are experiencing similar trends.

- Societal's 2Q23 revenue of $21.8M declined from $23.2M in 2Q22. Management attributed the decline primarily to lower revenue from Teva, reflecting a planned packaging line shutdown, with Teva orders expected to pick up in the near-term. Tough comps against InfectoPharm's higher-than-quarterly average revenue in 2Q22 also contributed to the decline.

- Nevertheless, new business wins and the company's pipeline remain strong. Societal signed several new customers and expanded business with existing ones in 1H23. We view it as a positive when existing customers expand and / or renew or extend agreements, as we believe it underscores customer satisfaction with the company's services and offerings.

- Societal also continues to expand its core capabilities in order to provide a growing range of services and recently obtained DEA approval to add certain Schedule 1 psychedelic compounds to its manufacturing registration. This enables the company to participate in the growing area of psychedelic drug development with no additional capital investment. SCTL is optimistic about its opportunities in the space.

- Continuing to strengthen its balance sheet and enhance financial flexibility remains a core objective. Subsequent to 2Q23, the company renegotiated its debt and certain covenants. Important balance sheet measures in 2022 contributed to significantly lower interest expense in 2Q23 compared to 2Q22 ($2.3M versus $3.4M).

2Q23 HIGHLIGHTS

Customer diversification strategy continues; near-term focus to expand existing customer relationships

Societal CDMO (NASDAQ: SCTL), an established small-molecule CDMO, reported 2Q23 results this week. Revenue of $21.8 million declined from $23.2 million in 2Q22. Management attributed the decline primarily to lower revenue from Teva, Societal's largest commercial customer, reflecting a planned upgrade and shutdown of a packaging line, as well as tough comps against InfectoPharm's higher-than-quarterly average revenue in 2Q22. The company expects Teva orders to pick up in the near-term.

The company's 2Q23 gross margin of 20.5% declined from about 24.5% in 2Q22, reflecting lower cost absorption, and the revenue mix. With OpEx relatively flat year-over-year – $22.77 million versus $22.85 million last year – cost absorption was lower in 2Q23 compared to the prior year; SCTL recorded an operating loss of $968k compared to an operating profit of $302k.

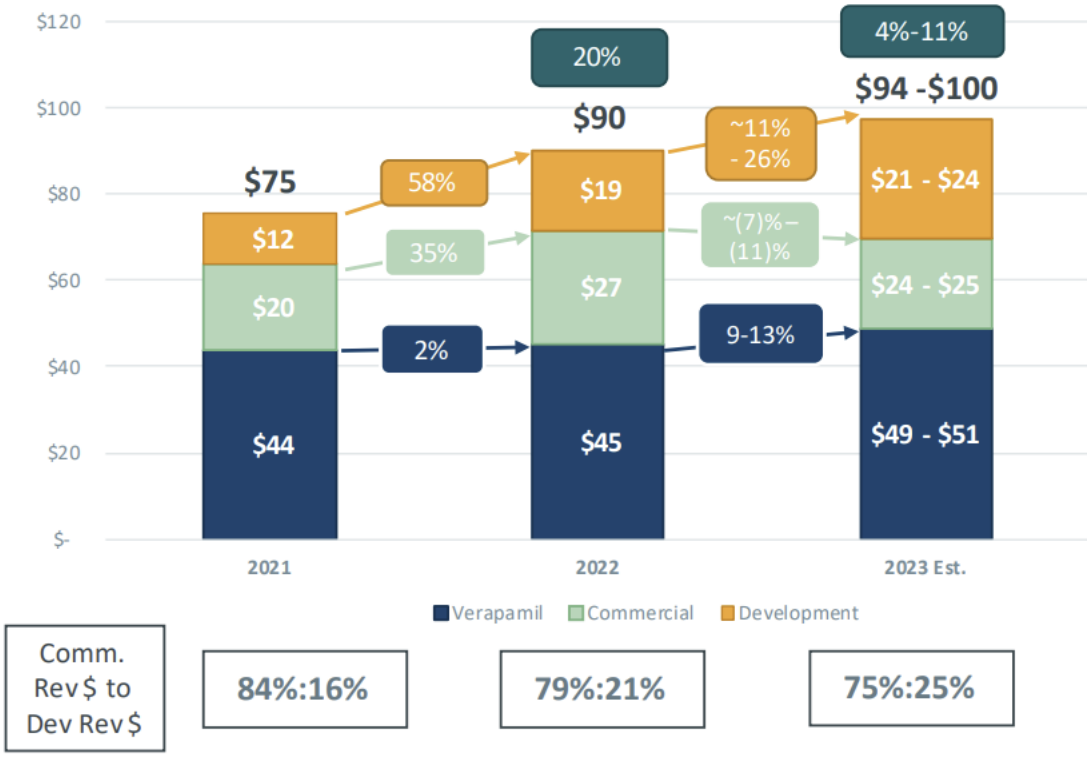
Economic uncertainty could temporary slow SCTL's strong progress growing development revenue …

The company is making progress on its strategy to grow the development component of its revenue mix. This strategy is consistent with SCTL's goal to diversify its customer and revenue base. The company has about 45 active development customers at this point. Although commercial revenue still makes up the greater share of the revenue mix, at roughly 75% of SCTL's total revenue currently, the contribution is down from 84% in 2021, as illustrated below. However, as its customers and prospective customers

continue to encounter tough economic conditions and an unfavorable interest rate environment, many have been delaying greenlighting new projects or starting ones that had already been negotiated. As a result, the company expects near-term revenue to skew more heavily towards commercial projects than originally expected. Importantly, the company believes that this does not reflect market share losses, as it believes its competitors are experiencing similar trends.

Commercial projects generally carry lower margins compared to development ones. Moreover, as the revenue mix continues to skew more heavily towards commercial projects than originally expected, margins could remain under pressure in the near-term. Nevertheless, the company expects margin expansion to resume as capacity utilization ramps and the revenue mix shifts towards higher margin services and projects.

Revenue & Expected Revenue Mix



Source: Company presentation

… leading to reduced EBITDA guidance; revenue guidance unchanged…

On the lower revenue base, 2Q23 adjusted EBITDA was $2.8 million versus $4.0 million. Reflecting the quarterly EBITDA decline and difficult economic backdrop, the company revised its 2023 EBITDA guidance to a range of $12 million to $15 million. Prior guidance was for 2023 EBITDA of $15 million and $18 million. Management noted that the interest rate environment and uncertain economic backdrop could result in delays in initiating some customer programs in the near-term. Thus, margins and EBITDA are expected to be lower than originally anticipated. SCTL's 2023 revenue guidance was unchanged at $94 million to $100 million. This represents an expected 4% to 11% advance compared to 2022.

Interest expense was $2.3 million for 2Q23, compared to $3.4 million for 2Q22. The decrease primarily due reflected significantly lower debt levels and interest rates under the company's refinanced debt. Societal generated a net loss of ($3.2) million or ($0.04) per share, compared to ($3.1) million and ($0.06), respectively, in 2Q22.

Winning new business, expanding programs with existing customers & diversifying customer base …

Even though guidance was reduced, new business wins and the company's pipeline remain strong. Societal signed several new customers and expanded business with existing ones in 1H23. New projects span clinical trial services, tech transfer and formulation development, among other services. Moreover, we view it as a positive when existing customers expand and / or renew or extend agreements. In our view, it underscores customer satisfaction with the company's services and offerings. Gaining expansion projects from current customers is a core objective for the company.

The company believes it has substantial opportunities to continue cross-marketing and cross-selling the broad range of services it offers. For example, Societal has two oral solid dose tech transfers and two development programs with Viatris Inc., as well as proposals for three additional commercial programs. Over the past few weeks, SCTL has won awards from Spinnaker Biosciences for a clinical development project and Atossa Therapeutics to provide a range of services, including analytical method transfer/development and validation, cleaning verification method validation and manufacturing of multiple R&D engineering batches, among others.

SCTL also signed a master service agreement (MSA) with CivicaScript, a PBC (public benefit company) that intends to introduce lower-cost generic medicines in the U.S. The MSA initially supports a generic drug candidate that CivicaScript is advancing through development and registration efforts and potentially could be expanded to include support of additional CivicaScript programs. CivicaScript launched its first product in 2022, with the goal to introduce "six to 10 medicines for which there is currently not enough market competition to drive down price," according to CivicaScript. These business wins follow the addition of 15 new customers in 2022, as the company expands its overall customer base.

… Expanding core capabilities; DEA authorization enables company to participate in fast growing area of psychedelic drug development

Moreover, despite a challenging industry backdrop, Societal continues to expand its core capabilities in order to provide a broad and growing range of services. For example, SCTL recently completed regulatory requirements to obtain U.S. Drug Enforcement Agency (DEA) approval to add certain Schedule 1 psychedelic compounds to its controlled substance manufacturing registration. SCTL has held DEA Schedule 2 manufacturing registration for more than two decades. The new Schedule 1 registration expands the range of CDMO services SCTL can offer and enables the company to participate in the growing area of psychedelic drug development with no additional capital investment.

According to the FDA, "[t]here has been growing interest in the therapeutic potential of psychedelic drugs in recent years. They are being evaluated for use in the potential treatment of conditions such as depression, post-traumatic stress disorder, substance use disorders and other conditions." Societal noted that it is engaged in discussions with multiple drug developers and is optimistic about its opportunities in the space.

Earlier, SCTL had received U.S. FDA approval to manufacture commercial tablet at its Gainesville, Georgia location, the first commercial tablet that SCTL has been approved to manufacture. This also broadens the offerings SCTL can provide to customers. The company is also building upon existing relationships to increase programs and revenue from many current customers. The company has identified several growth opportunities that it intends to pursue in 2023 and beyond and believes it has both sufficient excess production capacity and staff bandwidth to extend its service offerings into complementary areas.

The company believes that these advances, combined with actions taken in 2022, position it well for growth. Societal's objective is to provide a 'concierge' type offering that provides customers access to top management and leverages its broad and growing range of services and capabilities, while concurrently maintaining a relatively agile and smaller operating structure.



Source: Company presentation

Company owns NDA & believes it is well-positioned regarding Lannett

Since 2014, Lannett has been the company's marketing partner for Verapamil, which is a calcium channel blocker to treat hypertension. In 2022, the company improved the terms of its 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 included scheduled increases in manufacturing prices and awards SCTL potential new manufacturing agreements for additional Lannett development projects. Lannett represented 16% of the company's total revenue in 2022 (down from 23% in 2021, in part reflecting SCTL's ongoing diversification and growth initiatives, as well as Lannett's decline in Verapamil PM sales).

Lannett has emerged from Chapter 11 bankruptcy and subsequent reorganization. In the event that SCTL's agreement with Lannett ends, Societal owns the NDA and the drug master file for Verapamil. Recent modifications to their agreement gives SCTL options to engage with other marketing partners under certain conditions and the company expects that if it needs to, it could shift to a different marketing partner with limited disruption to Verapamil PM and Verelan SR sales.

BALANCE SHEET MEASURES

Enhancing financial flexibility; lowering net debt, cost of capital & interest expense

SCTL has focused on strengthening its financial position. Subsequent to 2Q23, the company renegotiated its debt and certain covenants to enhance its financial flexibility. This follows important measures SCTL took in 2022 to strengthen its balance sheet. As noted, the benefits of these measures contributed to significantly lower interest expense in 2Q23 compared to 2Q22 – $2.3 million versus $3.4 million – mirroring substantially lower debt levels and interest rates under the company's refinanced debt.

In 4Q22, the company priced concurrent offerings of 27.8 million shares at $1.10 per share and 450,000 series A convertible preferred shares, raising gross proceeds of about $35.6 million. At the same time, the company negotiated a new credit facility and entered into a sales-leaseback agreement. These measures are steps in the company's strategy to refinance and reduce its debt, extend maturities and lower financing costs. In our view, these refinancing measures help alleviate balance sheet concerns,

enabling management to focus on its growth strategy as SCTL positions itself as an alternative to larger industry players for established and emerging drug companies.

Proceeds from the concurrent transactions were earmarked to fully repay an existing debt facility with Athyrium Capital Management, plus fees and expenses. The Athyrium debt carried a combined interest rate of roughly 13% and was set to mature on December 31, 2023. SCTL entered into an agreement with Royal Bank of Canada (RBC) for a new Term A Loan debt facility for up to $37.5 million. The new facility matures in December 2025 and implies a roughly 9% interest rate. The net impact is expected to reduce SCTL's annual interest expense by about $6.0 million, or by about 50+%.

The RBC credit facility consists of a three-year Term A Loan at SOFR (Secured Overnight Financing Rate) plus an initial base rate of 4.5% per annum that SCTL will immediately use to further reduce its outstanding debt balance with Athyrium. The company has extended debt maturities by two years through these measures.

Another important step towards the goal of strengthening the balance sheet and capital structure includes monetizing non-core real estate assets to pare debt. SCTL also entered into an agreement for a sale and leaseback of its Gainesville, Georgia manufacturing facility with Tenet Equity, a platform that provides capital for real estate transactions. The roughly $39 million in non-dilutive gross proceeds were also earmarked for the elimination of the Athyrium Capital Management debt balance. In addition, Tenet also provided a funding commitment of up to an additional $35 million for renovations and / or expansions in the future. The transaction with Tenet is for the Georgia facility alone and will not impact the company's other manufacturing facilities or development plans.

The sale and leaseback agreement noted above follows the sale and purchase agreement the company announced in 3Q22. 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.

The transaction is expected to garner approximately $9.1 million. Societal expects the sale to close in 2H23 and has earmarked the non-dilutive proceeds from the sale to further strengthen its balance sheet by reducing a portion of its outstanding debt, specifically $10 million on the new term loan facility.

VALUATION

Expect valuation discount to narrow …

SCTL shares have come under increased pressure in 2023 as sector multiples have compressed and Lannett entered bankruptcy protection, as well as reflecting the uncertain economic environment, among other factors impacted share price multiples. Nevertheless, we continue to anticipate higher growth for SCTL than for peers at this stage in its transformation and reflecting its growing numbers of new business wins and expanded customer relationships.

Our valuation is based on the company's current state of development and could change with further potential changes to the 2023-24 outlook. At a valuation of roughly $1.20 per SCTL share, based on our 2023 EBITDA forecast and reflecting the company's deleveraging, SCTL shares would trade at about 8x on this basis on a pro forma (for pending additional debt reduction) basis. By comparison, even after recent multiple compression, peers generally trade at multiples higher than 10x. We expect the multiple gap to narrow.

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. We therefore anticipate share price appreciation driven by improving adjusted EBITDA and multiple expansion. Our 2023 adjusted EBITDA estimate incorporates continued headwinds on factors noted above. As the uncertainty regarding the interest rate environment and economic backdrop subsides, we would anticipate accelerating EBITDA growth for Societal.

RISKS

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

- Economic uncertainty could lead to further delays in customer projects.
- 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.
- 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.
- If it needs to replace Lannett, SCTL might not find a replacement marketing partner as quickly as it anticipates.
- The sales and purchase agreement with David Weekley Homes might take longer than expected to close or might not close at all.

RECENT NEWS

- SCTL reported 2Q23 results on August 14, 2023.
- On July 26, 2023, the company announced its expected expansion into the psychedelic drug development market, with DEA Schedule 2 authorization.
- SCTL was selected by Spinnaker Biosciences to provide CDMO services on July 10, 2023.
- On June 29, 2023, Societal announced an MSA with CivicaScript.
- Societal signed an agreement with Atossa Therapeutics May 23, 2023.

FINANCIAL MODEL

Societal CDMO

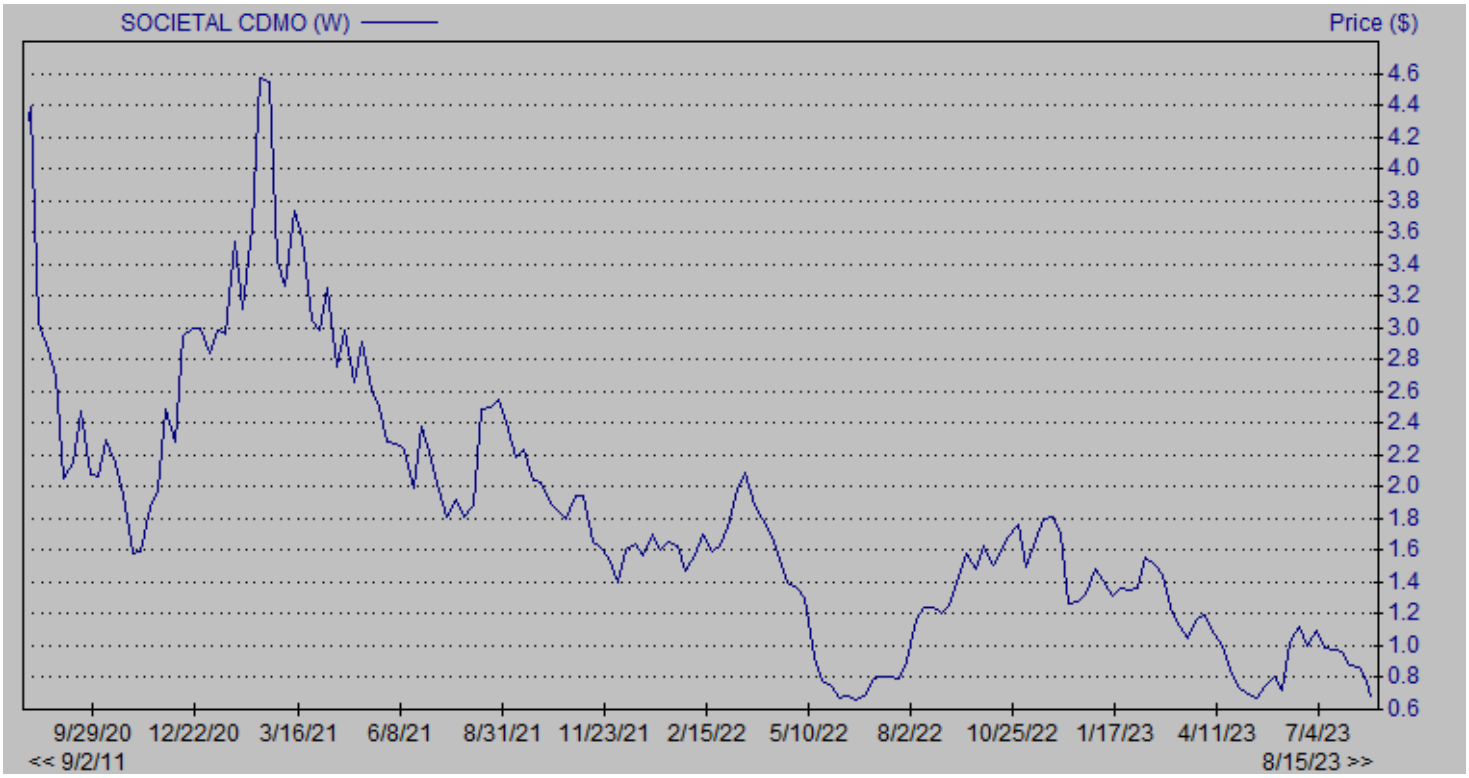
Societal CDMO Income Statement & Projections ($ thousands, except per share data)

	2020	2021	1Q22	2Q22	3Q22	4Q22A	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E
Revenue	66,499	75,360	21,194	23,152	21,589	24,279	90,214	21,527	21,799	24,446	26,585	94,357
y/y chg (%)		*13.3%*	*26.1%*	*28.5%*	*18.4%*	*8.9%*	*19.7%*	*1.6%*	*-5.8%*	*13.2%*	*9.5%*	*4.6%*
COGs	54,134	55,537	16,114	17,470	16,055	17,437	67,076	19,279	17,327	17,381	18,663	72,650
Gross profit	12,365	19,823	5,080	5,682	5,534	6,842	23,138	2,248	4,472	7,065	7,922	21,707
Gross margin	18.6%	26.3%	24.0%	24.5%	25.6%	28.2%	25.6%	10.4%	20.5%	28.9%	29.8%	23.0%
S,G&A	18,124	18,374	5,710	5,160	5,075	6,009	21,954	4,662	5,272	5,771	6,315	22,020
Amortization of intangible assets	2,583	1,037	221	220	244	220	905	184	168	184	184	721
Total operating expenses (incl COGs)	74,841	74,948	22,045	22,850	21,374	23,666	89,935	24,125	22,767	23,337	25,162	95,390
Operating income (loss)	(8,342)	412	(851)	302	215	613	279	(2,598)	(968)	1,109	1,423	(1,033)
Interest expense	(19,159)	(15,134)	(3,413)	(3,421)	(3,544)	(3,681)	(14,059)	(2,014)	(2,314)	(2,141)	(2,131)	(8,600)
Gain / other - debt extinguishment, refin'g	-	3,352	-	-	-	(4,996)	(4,996)	-	109	-	-	109
Pretax loss	(27,501)	(11,370)	(4,264)	(3,119)	(3,329)	(8,064)	(18,776)	(4,612)	(3,173)	(1,031)	(708)	(9,524)
Taxes						1,105	1,105	72	39	49	40	200
Net loss						(9,169)	(19,881)	(4,684)	(3,212)	(1,080)	(748)	(9,724)
EPS or loss per share	($1.16)	($0.26)	($0.08)	($0.06)	($0.06)	($0.15)	($0.34)	($0.06)	($0.04)	($0.01)	($0.01)	($0.12)
Avg shares out (FD)	23,744	44,117	56,351	56,599	56,666	61,895	57,878	84,800	87,330	89,692	89,992	87,954
Stock based comp	10,100	6,514	1,500	1,400	1,200	1,279	5,379	1,044	1,593	1,200	1,212	5,050
D&A	9,500	7,568	1,980	2,020	2,154	2,121	8,275	2,089	2,201	2,262	2,250	8,801
Other	2,700	2,222	(1,200)	900	1,200	2,221	2,868	74	-	-	-	74
Adj EBITDA	13,958	16,716	1,429	4,622	4,769	6,234	16,801	609	2,826	4,571	4,885	12,892
Adj EBITDA / share	$0.59	$0.38	$0.03	$0.08	$0.08	$0.10	$0.29	$0.01	$0.03	$0.05	$0.05	$0.14

Source: Company reports & Zacks

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