



TriSalus Reports Q2 2024 Financial Results and Business Update

August 15, 2024 12:00 PM EDT

- *Reported revenues of \$7.4 million in Q2 2024 and \$13.8 million for six months ended June 30, 2024, up 60% and 82%, respectively, compared to prior year periods*
- *Reported gross margin of 88% in Q2 2024 and 86% for the six months ended June 30, 2024, compared to 83% and 81%, respectively, in the prior year periods*
- *Announces plan to launch the “DELIVER” Program in Q3 2024, clinical trials leveraging the TriNav® Infusion System (TriNav) in complex patient types and aiming to significantly expand the addressable market*
- *Expects to report data from phase 1 trials of nelitolimod in uveal melanoma liver metastases and locally advanced pancreatic cancer via its pancreatic infusion technology in Q4 2024*
- *Following demonstrated tolerability and efficacy in a limited number of patients in the checkpoint doublet cohort studying nelitolimod in hepatocellular cancer and intrahepatic cholangiocarcinoma (PERIO-2), Company intends to proceed with only investigator-initiated studies in combination with regionally delivered chemotherapy or radiation embolic therapies*
- *Closed up to \$50 million of debt financing with OrbiMed to support the TriNav system growth initiatives*
- *Completed warrant exchange offer to simplify capital structure*
- *Management to host earnings conference call on August 15th at 9:00 a.m. EDT*

DENVER--(BUSINESS WIRE)--Aug. 15, 2024-- TriSalus Life Sciences Inc., (Nasdaq: TLSI), an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors, today announced its financial results for the second quarter ended June 30, 2024, and provided a business update.

Mary Szela, President and Chief Executive Officer of TriSalus Life Sciences, stated, "We concluded the second quarter with robust revenue growth and effective execution across our operations. Our sustained revenue growth underscores the critical demand for our Pressure Enabled Drug Delivery™ technology (PEDD™). We are excited to launch the DELIVER program, which will showcase the advantages of our TriNav system in treating a diverse array of complex patients."

"Additionally, we have successfully advanced development of nelitolimod, having treated 100 patients in four indications and three clinical trials using our PEDD technology. Our progress to date indicates that nelitolimod can be delivered to the liver and pancreas with minimal systemic exposure and shows early promise of benefit in heavily pretreated patients with advanced disease," added Ms. Szela. "We anticipate further growth of our PEDD technology and TriNav system and look forward to presenting our final Phase 1 data for uveal melanoma liver metastases and locally advanced pancreatic cancer in the fourth quarter."

Second Quarter Business Update

DELIVER Program

- *TriSalus is excited to unveil the DELIVER program, a series of clinical trials designed to significantly expand the addressable market by evaluating the use of the TriNav system across a diverse range of complex patient populations, with the intent to further validate prior clinical studies that demonstrated the favorable clinical effects of the PEDD technology. This initiative aims to generate comprehensive data and solidify the evidence supporting TriNav's application in patients who might not be suitable candidates for traditional transarterial*

chemotherapy and radioembolization treatments. A key focus of the DELIVER program is to investigate the potential of combining use of the TriNav system with these therapies to enhance effectiveness and address resistance mechanisms in challenging cancers.

- The Company expects to launch the program with its first clinical study, named "PROTECT" (Pressure Enabled Retrograde Occlusive Therapy with Embolization for Control of Thyroid Disease). The goal of the trial is to highlight the advantages of this novel approach compared to conventional surgical methods.

Nelitalimod Clinical Studies in Uveal Melanoma Liver Metastases, Hepatocellular Carcinoma, Intrahepatic Cholangiocarcinoma, and Locally Advanced Pancreatic Cancer via the Pressure-Enabled Regional Immuno-Oncology (PERIO) Clinical Program

- In November 2023, TriSalus presented initial Phase 1 results for the PERIO-01 and PERIO-03 studies at the Society of Immunotherapy for Cancer annual meeting, and in June 2024, it presented top-line results for PERIO-02 at the American Society of Clinical Oncology (ASCO) annual meeting.
- **PERIO-01** is a Phase 1 trial evaluating hepatic arterial delivery of nelitalimod via the PEDD technology in patients with uveal melanoma liver metastases. The trial includes dose-escalation cohorts with monotherapy and in combination with checkpoint inhibitors. The preliminary data show a tolerable safety profile, evidence of liver metastases myeloid-derived suppressor cells (MDSC) depletion with T cell infiltration, and promising indications of activity, including ctDNA responses, disease control, and survival beyond historical benchmarks in predominantly pre-treated patients. The final results for the PERIO-01 Phase 1 trial are expected in Q4 2024.
- **PERIO-02** focuses on the hepatic arterial delivery of nelitalimod via the PEDD technology for patients with hepatocellular carcinoma or intrahepatic cholangiocarcinoma. The study has been completed, and recent findings presented by investigators from MD Anderson Cancer Center at ASCO demonstrated consistent safety and immunologic effects, along with encouraging survival times in a subset of patients treated with a systemic checkpoint inhibitor doublet. The Company expects further investigation into these indications to continue only through investigator-initiated studies.
- **PERIO-03** is a Phase 1 dose-escalation study of nelitalimod in locally advanced pancreatic cancer. Nelitalimod is administered through outpatient interventional radiology procedures using the Pancreatic TriSalus Infusion System™ PEDD device. Phase 1 results for this study are anticipated in Q4 2024.

Closed up to \$50 million of Debt Financing with OrbiMed to support TriNav Growth Initiatives

In April, TriSalus announced the closing of a debt financing facility with OrbiMed, a healthcare investment firm. Under the terms of the credit agreement with OrbiMed, the Company borrowed \$25 million at closing. In addition, an aggregate of up to an additional \$25 million is available in two tranches at the Company's option, subject to the Company's achievement of certain revenue thresholds.

Cash and cash equivalents on hand totaled \$16.5 million on June 30, 2024. Including the Company's Standby Equity Purchase Agreement (SEPA) and other existing sources of liquidity and assuming it achieves the revenue targets and borrow the remaining \$25 million of the debt financing, the Company expects to have sufficient cash runway to fund operations through the end of 2025.

Completion of Warrant Exchange Offer

- On May 24, 2024, TriSalus announced an exchange offer of 0.30 shares of Common Stock for each publicly traded and private warrant tendered.
- The offer's purpose was to simplify the Company's capital structure and reduce the potential dilutive impact of the warrants, thereby providing the Company with more flexibility for financing its operations in the future.
- On July 1st, the Company issued 2,110,366 shares of common stock in exchange for 6,529,954 (or 79%) of its publicly traded warrants and 504,685 (or 10%) of its private warrants.

Financial Results for Q2 2024

Revenue, all of which is from the sale of the TriNav system, was \$7.4 million and \$13.8 million, respectively, for the three and six months ended June 30, 2024, up 60% and 82%, respectively, compared to the same periods in 2023. Revenue growth was driven primarily by increased selling resources and continued market share increases.

Gross margins were 88% and 86% for the three and six months ended June 30, 2024, respectively, compared to 83% and 81%, respectively, for the same periods in 2023. The improvement in the quarter and year-to-date is due to increased factory volumes and improved operational efficiency.

Operating losses were \$8.2 million and \$19.9 million, respectively, for the three and six months ended June 30, 2024, respectively, compared to losses of \$11.4 million and \$21.6 million, respectively, for the same periods in 2023. Current year reductions in operating losses are due to increased sales, improved gross margins, and reduced research and development spending associated with the timing of clinical trial spending.

Net losses available to common stockholders were \$4.3 million and \$17.6 million, respectively, for the three and six months ended June 30, 2024, compared to losses of \$14.0 million and \$22.2 million, respectively, for the same periods in 2023. Net losses in 2024 include non-cash related losses on change in fair value of the Company's SEPA, warrant and revenue base redemption liabilities of \$9.0 million and \$6.5 million, respectively for the three and six months ended June 30, 2024, compared to gains of \$1.1 million and \$3.5 million, respectively, for the same periods in 2023. Net losses in 2023 also include the impact of non-cash related losses on equity issuance of \$4.2 million in the three and six months ended June 30, 2023. These amounts are partially offset in 2024 by the impact of non-cash related gains on the change in fair value of contingent earnout liabilities of \$13.7 million and \$9.7 million, respectively, for the three and six months ended June 30, 2024.

The basic and diluted loss per share for the three and six months ended June 30, 2024, were \$0.21 and \$0.81, respectively, compared to \$35.84 and \$59.79 for the three and six months ended June 30, 2023, respectively.

Conference Call

TriSalus will host a webcast to discuss its second quarter 2024 financial results and business highlights on August 15, 2024 at 9:00 a.m. EDT. The webcast can be accessed on the investor relations section of TriSalus' website at <https://investors.trisaluslifesci.com/news-events/events-presentations>. Following the conclusion of the event, a webcast replay will be available on the website for approximately 90 days. Interested parties participating by phone will need to register using [this online form](#). After registering for the webcast, dial-in details will be provided in an auto-generated e-mail containing a link to the conference phone number and a personal pin.

About TriSalus Life Sciences

TriSalus Life Sciences® is an oncology company integrating novel delivery technology with immunotherapy to transform treatment for patients with liver and pancreatic tumors. The Company's platform includes devices that utilize a proprietary drug delivery technology and a clinical stage investigational immunotherapy. The Company's two FDA-cleared devices use its proprietary Pressure-Enabled Drug Delivery™ (PEDD) approach to deliver a range of therapeutics: the TriNav® Infusion System for hepatic arterial infusion of liver tumors and the Pancreatic Retrograde Venous Infusion System for pancreatic tumors. The PEDD technology is a novel delivery approach designed to address the anatomic limitations of arterial infusion for the pancreas. The PEDD approach modulates pressure and flow in a manner that delivers more therapeutic to the tumor and is designed to reduce undesired delivery to normal tissue, bringing the potential to improve patient outcomes. Nelitolid, the Company's investigational immunotherapeutic candidate, is designed to improve patient outcomes by treating the immunosuppressive environment created by many tumors and which can make current immunotherapies ineffective in the liver and pancreas. Patient data generated during Pressure-Enabled Regional Immuno-Oncology™ (PERIO) clinical trials support the hypothesis that nelitolid delivered via the PEDD technology may have favorable immune effects within the liver and systemically. The target for nelitolid, TLR9, is expressed across cancer types and the mechanical barriers addressed by the PEDD technology are commonly present as well. Nelitolid delivered by the PEDD technology will be studied across several indications in an effort to address immune dysfunction and overcome drug delivery barriers in the liver and pancreas.

In partnership with leading cancer centers across the country – and by leveraging deep immuno-oncology expertise and inventive technology development – TriSalus is committed to advancing innovation that improves outcomes for patients. Learn more at trisaluslifesci.com and follow us on [Twitter](#) and [LinkedIn](#).

Forward Looking Statements

Statements made in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the benefits and potential benefits of the Company's PEDD drug delivery technology, TriNav system and nelitolid investigational immunotherapy, the expected timing for reporting results from the Company's clinical trials for nelitolid, the Company's expectation that the development of nelitolid for the indications covered by PERIO-02 will continue through investigator led trials, the Company's ability to achieve the revenue milestones under the credit facility, the Company's expectations about its cash runway, the Company's expectations about its revenue growth for 2024, the expected benefits from the Company's DELIVER program, the Company's expected timing to launch PROTECT study and any future studies, and the Company's ability to execute on its strategy. Risks that could cause actual results to differ from those expressed in these forward-looking statements include risks associated with clinical development and regulatory approval of drug delivery and pharmaceutical product candidates, including that future clinical results may not be consistent with patient data generated during the Company's clinical trials, the cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, the risks associated with the credit facility, including the Company's ability to remain in compliance with all its obligations thereunder to avoid an event of default, the risk that the Company will continue to raise capital through the issuance and sale of its equity securities to fund its operations, the risk that the Company will not be able to achieve the applicable revenue requirements to access additional financing under the credit facility, changes in expected or existing competition or market conditions, changes in the regulatory environment, unexpected litigation or other disputes, unexpected expensed costs, and other risks described in the Company's filings with the Securities and Exchange Commission under the heading "Risk Factors." All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made except as required by law.

Financials

TriSalus Life Sciences

Condensed Consolidated Statement of Operations (unaudited, in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	\$ 7,364	\$ 4,612	\$ 13,821	\$ 7,596
Cost of goods sold	912	772	1,883	1,434
Gross Profit	6,452	3,840	11,938	6,162
Operating expenses:				
Research and development	4,666	6,886	10,523	12,504
Sales and marketing	6,004	3,492	12,691	6,741
General and administrative	3,956	4,896	8,583	8,472
Loss from operations	(8,174)	(11,434)	(19,859)	(21,555)
Other income (expense):				
Interest income	97	36	189	71
Interest expense	(877)	(4)	(880)	(9)
Loss on equity issuance		(4,225)		(4,189)
Extinguishment of tranche liability		621		
Change in fair value of SEPA, warrant, and revenue base redemption liabilities	(9,016)	1,070	(6,495)	3,491
Change in fair value of contingent earnout liability	13,689		9,701	
Other expense, net	(44)	(25)	(197)	(43)
Loss before income taxes	(4,325)	(13,961)	(17,541)	(22,234)
Income tax expense	(7)	(13)	(10)	(8)
Net loss available to common stockholders	\$ (4,332)	\$ (13,974)	\$ (17,551)	\$ (22,242)
Deemed dividend related to Series B-2 preferred stock down round provision		(2,022)		(2,981)
Undeclared dividends on Series A preferred stock	(801)		(1,602)	
Net loss attributable to common stockholders	\$ (5,133)	\$ (15,996)	\$ (19,153)	\$ (25,223)
Net loss per common share, basic and diluted	\$ (0.21)	\$ (35.84)	\$ (0.81)	\$ (59.79)
Weighted average common shares outstanding, basic and diluted	23,903,659	446,287	23,613,243	421,861

TriSalus Life Sciences

Condensed Consolidated Balance Sheets (unaudited, in thousands)

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	16,481	11,777
Accounts receivable	4,706	3,554
Inventory, net	3,443	2,545
Prepaid expenses	3,311	2,986
Total current assets	27,941	20,862
Property and equipment, net	1,830	2,091
Right-of-use assets	1,123	1,179
Intangible assets, net	1,113	1,127
Other assets	424	466
Total assets	32,431	25,725
Liabilities and Stockholders' Deficit		
Current liabilities:		
Trade payables	1,976	3,391
Accrued liabilities	9,407	10,556
Short-term lease liabilities	323	351
Other current liabilities	291	389
Total current liabilities	11,997	14,687
Long-term debt, net of unamortized discount and debt issuance costs	21,286	
Revenue base redemption feature	715	
Long-term lease liabilities	1,154	1,244
Contingent earnout liability	8,931	18,632
Warrant and SEPA liabilities	12,497	17,100
Total liabilities	56,580	51,663
Stockholders' deficit:		

Preferred Stock, Series A, \$0.0001 par value per share, \$10.00 liquidation value per share. Authorized 10,000,000 shares at June 30, 2024, and December 31, 2023, respectively; issued and outstanding, 4,015,002 shares at June 30, 2024 and December 31, 2023, respectively.

Common stock, \$0.0001 par value per share. Authorized 400,000,000 shares at June 30, 2024 and December 31, 2023, respectively; issued and outstanding, 27,159,463 and 26,413,213 shares at June 30, 2024, and December 31, 2024, respectively

Additional paid-in capital

Accumulated deficit

Total stockholders' deficit

Total liabilities and stockholders' deficit

	2	2
	241,777	222,437
	(265,928)	(248,377)
	(24,149)	(25,938)
	32,431	25,725

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