TriSalus Reports Q4 and Full Year 2023 Financial Results and Business Update

April 1, 2024 12:00 PM EDT

- *Reported revenues of $5.7 million in 4Q23, up 77% over prior year*
- *Full year revenues of $18.5 million, up 49% over prior year*
- *Gross Margin of 90% in 4Q23 and 86% for full year*
- *CMS reimbursement granted for the TriNav® Infusion System via assignment of an HCPCS code*
- *Real-world data published on TriNav system demonstrating significant improvement in the delivery of therapeutics to liver tumors for patients with higher disease burden*
- *Received 510k clearance of TriNav Large and TriGuide systems*
- *Completed enrollment in phase 1 clinical trials (100 patients) in several liver indications; data will be analyzed in the second half of 2024*
- *Initiated first-in-man clinical trial of its novel pancreatic infusion technology (510k cleared), plus nelitolimod, to demonstrate safety and efficacy*

DENVER & SALT LAKE CITY--(BUSINESS WIRE)--Apr. 1, 2024-- TriSalus Life Sciences Inc., (Nasdaq: TLSI), today announced its financial results for the fourth quarter and full year ended December 31, 2023, and provided a business update.

“2023 was a critical year for TriSalus, underscored by significant growth in TriNav revenue, a landmark achievement of permanent reimbursement, and disciplined progress within our technology and clinical pipelines,” said Mary Szela, Chief Executive Officer and President of TriSalus.

“The release of compelling real-world evidence demonstrating the impactful benefits of the TriNav method for complex patients, along with the exploration of nelitolimod in conjunction with the TriNav system through selected phase 1 clinical studies, reinforces our commitment to improving care options for oncology patients. As an example, the phase 1 clinical trial for locally advanced pancreatic patients utilizes our novel pancreatic infusion device in combination with nelitolimod with a goal to demonstrate improved outcomes for pancreatic patients.

Furthermore, receiving 510k clearance of a larger vessel size of the TriNav system, and successfully accessing the public markets underscore our dedication to advancing our company for sustained growth and success. As we reflect on the achievement of the past year, we recognize not only the milestones achieved but also acknowledge the solid foundation for continued future progress across the business, and we remain fully focused and committed to delivering benefit to patients.”

Fourth Quarter 2023 and Subsequent Highlights

CMS Reimbursement for the TriNav Infusion System via Assignment of a New Technology Healthcare Common Procedure Coding System (HCPCS) Code

In December, TriSalus announced that the Centers for Medicare & Medicaid Services (CMS) had created a New Technology Healthcare Common Procedure Coding System (HCPCS) code for procedures involving the TriNav Infusion System. This new code, HCPCS 9797, has been assigned to the Ambulatory Payment Classification (APC) 5194 – Level 4 Endovascular Procedures. The new code became effective on January 1, 2024, and may be reported by hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs).

Real-World Data Demonstrates Ability of TriNav to Successfully Treat Patients with Higher Disease Burden and to Improve Delivery of Therapeutics to Liver Tumors

In February, the Company announced the publication in *Current Medical Research and Opinion* of a manuscript detailing a real-world study of the use of the Pressure-Enabled Drug Delivery™ (PEDD™) method with the TriNav device for trans-arterial chemoembolization (TACE) and trans-arterial radioembolization (TARE) in patients with hepatocellular carcinoma (HCC) and liver metastases. The data presented in the study captured real-world safety and clinical outcomes data for the TriNav system utilizing a large, 300 million patient dataset covering 98% of U.S. payers.

The study data demonstrates that the TriNav method is preferentially selected to treat patients with a higher burden of disease than patients treated with standard catheters, yet these patients show similar results post-treatment compared to patients with a lower disease burden. TriNav patients showed impressive trends toward better outcomes in matched cohort comparisons, including an increased rate of liver transplants.

Completed Enrollment in Multiple Phase 1 Clinical Trials (100 Patients) in Uveal Melanoma Liver Metastases, Hepatocellular Cancer, and Intrahepatic Cholangiocarcinoma in Leading Academic Oncology Centers Across the U.S. to Determine Which Indication to Progress; Full Data Set Will be Analyzed in the Second Half of 2024 to Facilitate the Final Decision

TriSalus presented phase 1 data for the PERIO-01 program, nelitolimod administered via the PEDD method for uveal melanoma liver metastases, at a late-breaking oral session by our lead investigator from The University of Texas MD Anderson Cancer Center at the Society for Immunotherapy for Cancer meeting in November 2023.

Data presented included the following:

- Safety data on 56 uveal melanoma patients with liver metastases, of whom 65% had failed prior therapy.
- Grade 3 or greater treatment related serious adverse event rate was 11% across all doses and cohorts.
- Pharmacokinetic data from the PERIO-01 trial indicate the TriNav system is able to achieve high drug levels in the liver, and systemic exposure is limited with drug undetectable by four hours in more than 95% of patients.
- Amongst patients with available data ctDNA clearance was 59%, with 86% showing reduction in ctDNA.
- Disease control rate (DCR) was 58% across all dose levels, and at the presumed optimal biologic dose (2mg, N=7), there was a DCR of 81%, median progression free survival (PFS) of 11.7 months and 1-year overall survival rate (OS) of 86%.
- The optimal biologic dose assessment was made based on PFS, OS, and immune signals, including MDSC elimination from liver metastases. There was also evidence of systemic immune activation, as measured by serum cytokines and peripheral immune cell activation.

Initiated Phase 1 Study with Nelitolimod via our Novel Pancreatic Infusion Device

The Pancreatic Infusion System with SmartValve® technology is an FDA-cleared device for delivery of therapeutics to the peripheral vasculature. This device is being studied for the delivery of nelitolimod into unresectable pancreatic tumors.

Retrograde venous delivery to the pancreas involves the placement of a PEDD device into the veins draining the pancreas to enable targeted delivery of therapeutics using standard interventional radiology procedures. Unlike the liver, small vessels and extensive collateralization in the pancreas make the arterial route challenging for targeted delivery. Retrograde pancreatic venous infusion provides a potentially more feasible and reliable strategy for targeted delivery of therapeutics through direct venous access.

In November of 2023, TriSalus released study data on three patients receiving nelitolimod via its novel pancreatic infusion device demonstrating immune signals consistent with previous reported data for liver metastases. The Company expects to complete enrollment and report the phase 1 data in the second half of 2024.

Received 510k Clearance for TriNav Large and TriGuide

This year, TriSalus received 510k clearance for a larger vessel size of the TriNav system, TriNav Large, and its dedicated guide catheter, TriGuide. Currently, the Company is in market evaluation for both devices and intends to launch in the second half of 2024. The launch of this TriNav system provides a significant market expansion since the larger vessel size can access an incremental 25% of the embolization market.

Unaudited Financial Results for Q4 and Full Year 2023

Notification of Late Filing

The Company will file a Form 12b-25, Notification of Late Filing, with the SEC related to the Company's Annual Report on Form 10-K for fiscal year 2023. The Company's need to request a 15-day extension is primarily due to errors identified in determining the Company's stock-based compensation expense for 2023 due in part to the Company's transition to a new service provider in 2023 and the use of incorrect assumptions. The Company is working diligently to evaluate the materiality of the errors to determine whether any corrections for the third quarter financial results are required and to complete the Company's year-end 2023 financial statements. As a result, the results below and elsewhere in this press release are unaudited and subject to change pending the completion of the Company's financial statements as of and for the year ended December 31, 2023.

Revenue and Gross Margin

Revenue, all of which is from the sale of the TriNav system, was $5.7 million and $18.5 million, respectively, in the three months and full year ended December 31, 2023. These amounts represent growth vs. prior year of 77% in the fourth quarter and 49% for the full year, primarily due to increased selling resources and continued market share increases.

Gross margins were 90% in the fourth quarter and 86% for the full year ended December 31, 2023, versus 75% and 82%, respectively, in the fourth quarter and full year in 2022. The improvement is due to increased factory volumes and improved operations efficiency.

Operating Results

Operating losses were $14.1 million and $54.2 million, respectively, for the fourth quarter and full year ended December 31, 2023. These amounts include non-recurring professional service fee costs of $7.9 million year to date, primarily related to the completion of the deSPAC process in August 2023. These amounts compare to prior year losses of $11.8 million and $36.4 million, respectively. The Company increased investments in 2023 in R&D to support clinical program progress and in sales and marketing, primarily to expand its sales force to continue to increase market penetration.

Net Results and Earnings per Share

Net losses available to common stockholders were $35.5 million and $59.0 million, respectively, for the fourth quarter and full year ended December 31, 2023. These amounts compare to prior year losses of $22.5 million and $47.2 million, respectively. Net losses include the impact of non-cash related gains/(losses) on revaluation of contingent earnout liabilities of ($9.6) million in the fourth quarter and $10.3 million for the full year period of 2023. In addition, 2023 net losses include the impact of non-cash related losses associated with revaluation of tranche and warrant liabilities of $11.5 million and $10.9 million, respectively, for the fourth quarter and full year ended December 31, 2023. These amounts compare to prior year losses of $2.2 million in the fourth quarter and full year. The fourth quarter and full year ended December 31, 2023, also includes a non-cash related loss on equity issuance of $0.2 million and $4.4 million, respectively. These amounts compare to prior year losses of $8.3 million in the fourth quarter and full year.

Basic and diluted loss per share for the fourth quarter and full year ended December 31, 2023, was $1.56 and $6.73 respectively, compared to a basic and diluted loss per share of $75.01 and $161.55 for the fourth quarter and full year ended December 31, 2022, respectively.

Conference Call

The event will be webcast live 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 along with 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. PEDD 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. SD-101, 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 SD-101 delivered via PEDD may have favorable immune effects within the liver and systemically. The target for SD-101, TLR9, is expressed across cancer types and the mechanical barriers addressed by PEDD are commonly present as well. SD-101 delivered by PEDD 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 and SD-101 investigational immunotherapy, the Company's business strategy and clinical development plans, the safety and efficacy of the Company's product candidates, the Company's plans and expected timing with respect to clinical trials, including the timing for generating and reviewing data from clinical trials, the market opportunity for TriNav Large, and the Company's intention to file Form 12b-25, Notice of Late Filing, with the SEC today. 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 success cost and timing of all development activities and clinical trials, unexpected safety and efficacy data observed during clinical studies, changes in expected or existing competition or market conditions, changes in the regulatory environment, unexpected litigation or other disputes, the Company's ability to timely file its Annual Report on Form 10-K, the risk that the unaudited financials reported in this press release will differ from those in the Company's Annual Report on Form 10-K once filed, the risk the Company will need to make corrections to its previously filed quarterly financial results, 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.

TRISALUS LIFE SCIENCES, INC.
Consolidated Statement of Operations (unaudited, in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenue	$ 5,721	$ 3,226	$ 18,511	$ 12,398
Cost of goods sold	582	816	2,605	2,258
Gross Profit	5,139	2,410	15,906	10,140
Operating expenses:				
Research and development	7,639	6,267	29,510	21,358
Sales and marketing	5,604	3,857	17,034	12,738
General and administrative	6,014	4,058	23,512	12,483
Loss from operations	(14,118)	(11,772)	(54,150)	(36,439)
Interest income	244	105	431	180
Interest expense	(3)	(1)	(16)	(1)
Loss on equity issuance	(182)	(8,312)	(4,353)	(8,312)
Change in fair value of tranche and warrant liabilities	(11,515)	(2,207)	(10,855)	(2,186)
Change in fair value of contingent earnout liability	(9,611)		10,293	
Other expense, net	(323)	(349)	(379)	(420)
Loss before income taxes	(35,508)	(22,536)	(59,029)	(47,178)
Income tax expense	(1)	(6)	(9)	(9)
Net loss available to common stockholders	$ (35,509)	$ (22,542)	$ (59,038)	$ (47,187)
Deemed dividend related to Series B-2 preferred stock down round provision		(2,829)	(2,981)	(2,829)
Undeclared dividends on Series A preferred stock	(800)		(1,258)	

Net loss attributable to common stockholders	$ (36,309)	$ (25,371)	$ (63,277)	$ (50,016)
Net loss per common share, basic and diluted	$ (1.56)	$ (75.01)	$ (6.73)	$ (161.55)
Weighted average common shares outstanding, basic and diluted	23,231,975	338,221	9,395,748	309,609

TRISALUS LIFE SCIENCES, INC.
Consolidated Balance Sheets (unaudited, in thousands)

	December 31, 2023	December 31, 2022
Assets		
Assets		
Cash and cash equivalents	11,777	9,414
Accounts receivable	3,554	1,557
Inventory, net	2,545	1,471
Prepaid expenses	2,986	4,772
Total current assets	20,862	17,214
Property and equipment, net	2,091	2,231
Right-of-use assets	1,179	1,381
Intangible assets, net	1,127	802
Other assets	466	367
Total assets	25,725	21,995
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Trade payables	3,391	4,947
Accrued liabilities	10,556	6,377
Series B-2 tranche liabilities		4,702
Series B-3 warrant liabilities		15,819
Short-term lease liabilities	351	370
Other current liabilities	389	142
Total current liabilities	14,687	32,357
Long-term lease liabilities	1,244	1,593
Contingent earnout liability	18,632	
Warrant liabilities	17,100	369
Total liabilities	51,663	34,319
Convertible preferred stock		164,006
Stockholders' deficit:		
Preferred Stock, Convertible preferred stock, Series A $0.0001 par value per share, $10 liquidation value per share. Authorized 10,000,000 and 0 shares at December 31, 2023 and 2022, respectively; issued and outstanding, 4,015,002 and 0 shares at December 31, 2023 and 2022, respectively		
Common stock, $0.0001 par value per share. Authorized 400,000,000 and 30,898,162 shares at December 31, 2023 and 2022, respectively; issued and outstanding 26,413,324 shares and 347,926 shares at December 31, 2023 and 2022, respectively	2	
Additional paid-in capital	222,437	10,028
Accumulated deficit	(248,377)	(186,358)
Total stockholders' deficit	(25,938)	(176,330)
Total liabilities, convertible preferred stock and stockholders' deficit	25,725	21,995

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Source: TriSalus Life Sciences