TriSalus Reports Q1 2024 Financial Results and Business Update

May 15, 2024 12:00 PM EDT

- *Reported revenues of $6.5 million in 1Q24, up 116% compared to 1Q23*
- *Reported gross margin of 85% in 1Q24*
- *Secured up to $50 million of debt financing with OrbiMed to support TriNav® Infusion System growth initiatives*
- *Announced the appointment of Liselotte Hyveled to the Board of Directors*
- *Full year sales growth expected to exceed 50%*
- *Conference call May 15th at 9:00 a.m. EDT*

DENVER--(BUSINESS WIRE)--May 15, 2024-- TriSalus Life Sciences Inc., (Nasdaq: TLSI), today announced its financial results for the first quarter ended March 31, 2024, and provided a business update.

"I'm proud to highlight our strong start in the first quarter of 2024 with 116% growth in revenues compared to the first quarter of 2023 and significantly improving our financial position with our debt financing facility with OrbiMed," said Mary Szela, Chief Executive Officer of TriSalus. "With our recent positive developments in reimbursement, clinical data, and the dedication of our seasoned executive team, we're confident in our ability to execute our company-building strategy. Our objectives of achieving over 50% top-line revenue growth, advancing our pipeline, and strengthening our operational foundations remain firmly on track."

First Quarter 2024 and Subsequent Highlights

Secured up to $50 million of debt financing with OrbiMed to support TriNav® Infusion System 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.

The $25 million draw, along with cash and cash equivalents on hand of $4 million at March 31, 2024, are expected to provide sufficient cash runway to fund the Company's operations through the end of 2024. Including our SEPA agreement and other existing sources of liquidity and assuming we achieve 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.

Liselotte Hyveled appointed to the Board of Directors

In May, TriSalus announced the appointment of Liselotte Hyveled to its Board of Directors. Ms. Hyveled currently serves as the Chief Patient Officer at Novo Nordisk, where she is responsible for ensuring the integration of patient needs and perspectives into the company's decision-making processes and operations. She brings over two decades of experience stimulating scientific innovation and advancing pharmaceutical pipelines through research and development excellence.

Financial Results for Q1 2024

Revenue, all of which is from the sale of the TriNav® Infusion System, was $6.5 million in the first quarter ended March 31, 2024. This amount represents growth of 116% compared to the first quarter of 2023, primarily due to increased selling resources and continued market share increases.

Gross margins were 85% in the first quarter ended March 31, 2024, versus 78% in the first quarter of 2023. The improvement is due to increased factory volumes and improved operations efficiency.

Operating losses were $11.7 million in the first quarter ended March 31, 2024, versus $10.1 million in the first quarter of 2023. Increased investment in sales and marketing, research and development, as well as general and administrative costs associated with becoming a public company more than offset increased gross profit in 2024.

Net losses available to common stockholders were $13.2 million in the first quarter ended March 31, 2024, versus $8.3 million in the first quarter of 2023. Net losses in 2024 include the impact of non-cash related gains/(losses) on change in fair value of SEPA and warrant liabilities of $2.5 million and change in fair value of contingent earnout liabilities of ($4.0) million. Net losses in 2023 include the impact of non-cash related gains/(losses) on equity issuance of ($1.5) million, extinguishment of tranche liabilities of $0.9 million, and change in fair value of SEPA and warrant liabilities of $2.4 million.

Basic and diluted loss per share for the first quarter ended March 31, 2024, was $0.60 versus $0.57 per share in the first quarter of 2023.

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 on May 15, 2024, at 9:00 a.m. EDT. 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. Nelitolimod, 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 nelitolimod delivered via PEDD may have favorable immune effects within the liver and systemically. The target for nelitolimod, TLR9, is expressed across cancer types and the mechanical barriers addressed by PEDD are commonly present as well. Nelitolimod 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 X [formerly 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 nelitolimod investigational immunotherapy, the Company's ability to achieve the revenue milestones under the credit facility, the Company's expectations about its cash runway, 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 March 31,	
	2024	**2023**
Revenue	$ 6,457	$ 2,984
Cost of goods sold	971	662
Gross Profit	5,486	2,322
Operating expenses:		
Research and development	5,857	5,642
Sales and marketing	6,687	3,249
General and administrative	4,627	3,552
Loss from operations	(11,685)	(10,121)
Other income (expense):		
Interest income	92	35
Interest expense	(3)	(5)
Loss on equity issuance		(1,465)
Extinguishment of tranche liability		881
Change in fair value of SEPA and warrant liabilities	2,521	2,421
Change in fair value of contingent earnout liability	(3,988)	
Other expense, net	(153)	(19)
Loss before income taxes	(13,216)	(8,273)
Income tax (expense) benefit	(3)	5
Net loss available to common stockholders	$ (13,219)	$ (8,268)
Deemed dividend related to Series B-2 preferred stock down round provision		(959)
Undeclared dividends on Series A preferred stock	(801)	
Net loss attributable to common stockholders	$ (14,020)	$ (9,227)
Net loss per common share, basic and diluted	$ (0.60)	$ (0.57)
Weighted average common shares outstanding, basic and diluted	23,323,045	16,166,581

TriSalus Life Sciences

Condensed Consolidated Balance Sheets (unaudited, in thousands)

	March 31, 2024	December 31, 2023
Assets	**(unaudited)**	
Assets		
Cash and cash equivalents	3,970	11,777
Accounts receivable	4,277	3,554
Inventory, net	2,913	2,545
Prepaid expenses	2,031	2,986
Total current assets	13,191	20,862
Property and equipment, net	1,965	2,091
Right-of-use assets	1,196	1,179
Intangible assets, net	1,113	1,127
Other assets	424	466
Total assets	17,889	25,725
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Trade payables	2,348	3,391
Accrued liabilities	11,423	10,556
Short-term lease liabilities	363	351
Other current liabilities	260	389
Total current liabilities	14,394	14,687
Long-term lease liabilities	1,218	1,244
Contingent earnout liability	22,620	18,632
Warrant and SEPA liabilities	14,580	17,100
Total liabilities	52,812	51,663
Stockholders' equity (deficit):		
Preferred Stock, Series A $0.0001 par value per share, $10.00 liquidation value per share. Authorized 10,000,000 and 10,000,000 shares at March 31, 2024, and December 31, 2023, respectively; issued and outstanding, 4,015,002 and 4,015,002 shares at March 31, 2024 and December 31, 2023, respectively		
Common stock, $0.0001 par value per share. Authorized 400,000,000 and 400,000,000 shares at March 31, 2024 and December 31, 2023, respectively; issued and outstanding 26,758,272 and 26,413,213 shares at March 31, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	226,671	222,437
Accumulated deficit	(261,596)	(248,377)
Total stockholders' deficit	(34,923)	(25,938)
Total liabilities and stockholders' deficit	17,889	25,725

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