November 7, 2022

Avalo Reports Third Quarter 2022 Financial Results and Provides Business Updates

- Topline data expected in the first half of 2023 from the Phase 2 PEAK Trial of AVTX-002 in non-eosinophilic asthma (NEA)
- Entered into agreement to sell future economic rights to previously out-licensed assets in consideration for $5 million to be received upon closing
- Progressed BTLA Agonist Fusion Protein (AVTX-008) to IND-enabling studies
- Disclosed cash of approximately $17 million as of September 30, 2022

WAYNE, Pa. and ROCKVILLE, Md., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Avalo Therapeutics, Inc. (Nasdaq: AVTX), today announced business updates and financial results for the third quarter of 2022.

"We have made great operational progress on the enrollment of our Phase 2 PEAK trial of AVTX-002 in NEA. We expect to complete enrollment by the end of the year, which keeps us on track to release topline data in the first half of 2023," said Dr. Garry Neil, Chief Executive Officer and Chairman of the Board. "*Additionally, we expect to further strengthen our balance sheet with the $5 million to be received from the sale of economic rights of previously out-licensed assets upon the transaction closing, which further demonstrates the execution of our strategy to utilize business development to fund our core programs. Once completed, we will have raised $20 million through nondilutive transactions since August. Avalo is focused on closing out the year with further operational and strategic success."*

Business Updates:

- On November 4, 2022, Avalo entered into an agreement with ES Therapeutics, LLC, an affiliate of Armistice Capital LLC (Armistice), to sell its net economic rights to future payments of previously out-licensed assets including AVTX-007, AVTX-501, and AVTX-611 for proceeds of $5 million. The sale is expected to close in November.
- In August 2022, Avalo's Board of Directors appointed Dr. Garry Neil, MD, Avalo's Chief Executive Officer and Director, as Chairman of the Board. Steven Boyd and Keith Maher, MD, both of Armistice, left Avalo's Board of Directors. The former directors expressed that they were pleased with Avalo's strategic progress under Dr. Neil and continued to be supportive of Avalo.
- Avalo sharpened its focus to dysregulated inflammation specifically as it relates to the LIGHT-signaling network. We have two drug candidates that modulate the LIGHT-signaling network, AVTX-002, an anti-LIGHT monoclonal antibody in Phase 2, and AVTX-008, a BTLA agonist fusion protein in lead optimization.

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT monoclonal antibody (mAb) targeting immune-inflammatory diseases.
    - NEA: Topline data expected in the first half of 2023 from the Phase 2 PEAK trial evaluating the safety and efficacy of AVTX-002 in approximately 80 patients with poorly controlled NEA.

- **AVTX-008:** B and T Lymphocyte Attenuator (BTLA) agonist fusion protein targeting immune dysregulation disorders.
    - Avalo identified a lead molecule and is currently evaluating several immune dysregulation disorders, with a target IND submission planned in 2024.

- **AVTX-803:** Fucose replacement for leukocyte adhesion deficiency type II (LAD II, also known as SLC35C1-CDG), a congenital disorder of glycosylation (CDG).
    - Pivotal data expected in the first half of 2023 from the pivotal LADDER trial evaluating the safety and efficacy of AVTX-803 in approximately 2 patients with LAD II.

Third Quarter 2022 Financial Update:

Avalo had $16.9 million in cash as of September 30, 2022, representing a $37.7 million decrease compared to December 31, 2021. The decrease was primarily driven by operating expenditures to fund and support pipeline development and a $15.0 million partial prepayment under its loan and security agreement, partially offset by the $14.5 million upfront payment received from the out-license of AVTX-007 to Apollo Therapeutics ("Apollo") in July 2022. Subsequent to September 30, 2022, Avalo entered into a transaction to sell its net economic rights to future payments of certain previously out-licensed legacy assets for consideration of $5.0 million to be received upon closing, which is expected in November.

Total net revenues increased $12.0 million for the nine months ended September 30, 2022, as compared to the same period in 2021. The increase was mainly driven by the $14.5 million upfront consideration received pursuant to the out-license and transfer of AVTX-007 to Apollo.

Total operating expenses decreased $23.6 million for the nine months ended September 30, 2022. Research and development expenses decreased $23.2 million due to a $10.0 million upfront license fee incurred in the first quarter of 2021, which did not repeat. The remaining $13.2 million decrease was primarily driven by timing of manufacturing and reduced non-clinical and clinical trial activities as a result of pipeline prioritization and the out-license of AVTX-007. Selling, general and administrative expenses decreased $0.9 million due to reduced legal, consulting and marketing expenses from cost savings initiatives, partially offset by increased severance and stock-based compensation expense driven by headcount reductions from the pipeline prioritization plan announced in the first quarter of 2022 and other separations. Cost of product sales increased $1.7 million due to the net profit share of our non-core commercialized product, Millipred®, that began in the third quarter of 2021 and a $1.0 million reserve recognized in the second quarter of 2022 related to a receivable due in December 2024 pursuant to the transition service agreement with the third party that previously managed Millipred®'s commercial operations.

The net loss and change in net loss for the nine months ended September 30, 2022 was largely driven by operating expenses, partially offset by license revenue.

Condensed Consolidated Balance Sheets (Unaudited)
(In thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 16,943	$ 54,585
Accounts receivable, net	—	1,060
Other receivables	1,314	3,739
Inventory, net	22	38
Prepaid expenses and other current assets	1,118	2,372
Restricted cash, current portion	53	51
Total current assets	19,450	61,845
Property and equipment, net	2,507	2,695
Other long-term asset	—	1,000
Intangible assets, net	—	38
Goodwill	14,409	14,409
Restricted cash, net of current portion	181	227
Total assets	$ 36,547	$ 80,214
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 1,447	$ 3,369
Deferred revenue	442	—
Accrued expenses and other current liabilities	13,696	16,519
Notes payable, current	2,564	—
Total current liabilities	18,149	19,888
Notes payable, non-current	16,502	32,833
Royalty obligation	2,000	2,000
Deferred tax liability, net	133	113
Other long-term liabilities	1,791	2,298
Total liabilities	38,575	57,132
Stockholders' (deficit) equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 9,414,104 and 9,399,517 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively[1]	9	9
Additional paid-in capital[1]	291,975	285,239

Accumulated deficit	(294,012)	(262,166)
Total stockholders' (deficit) equity	(2,028)	23,082
Total liabilities and stockholders' (deficit) equity	$ 36,547	$ 80,214

[1] Results for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022.

The unaudited condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021 have been derived from the reviewed financial statements, but do not include all of the information and footnotes required by accounting principles accepted in the United States for complete financial statements.

Condensed Consolidated Statements of Operations (Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product revenue, net	$ 432	$ 1,350	$ 2,638	$ 4,554
License revenue	14,517	—	14,517	625
Total revenues, net	14,949	1,350	17,155	5,179
Operating expenses:				
Cost of product sales	528	908	2,814	1,067
Research and development	7,042	10,551	25,136	48,325
Selling, general and administrative	3,284	5,926	17,752	18,677
Amortization expense	—	428	38	1,281
Total operating expenses	10,854	17,813	45,740	69,350
	4,095	(16,463)	(28,585)	(64,171)
Other expense:				
Interest expense, net	(898)	(985)	(3,221)	(1,207)
Other expense, net	—	(15)	(20)	(20)
Total other expense, net from continuing operations	(898)	(1,000)	(3,241)	(1,227)
Income (loss) from continuing operations before taxes	3,197	(17,463)	(31,826)	(65,398)
Income tax expense (benefit)	5	8	20	(180)
Income (loss) from continuing operations	$ 3,192	$ (17,471)	$ (31,846)	$ (65,218)
Income from discontinued operations	—	76	—	38

Net income (loss)	$ 3,192	$ (17,395)	$ (31,846)	$ (65,180)
Net income (loss) per share of common stock, basic and diluted[1]:				
Continuing operations	$ 0.34	$ (2.09)	$ (3.39)	$ (8.02)
Discontinued operations	0.00	0.01	0.00	0.00
Net income (loss) per share of common stock, basic and diluted	$ 0.34	$ (2.08)	$ (3.39)	$ (8.02)

Net loss per share of preferred stock, basic and diluted[1]:	
Continuing operations	$ (3.34)
Discontinued operations	0.00
Net loss per share of preferred stock, basic and diluted	$ (3.34)

[1] Results for prior periods presented have been retroactively adjusted to reflect the 1-for-12 reverse stock split effected on July 7, 2022.

The unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021 have been derived from the reviewed financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

About AVTX-002

AVTX-002 is a fully human monoclonal antibody, directed against human LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with Herpes Virus **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes). AVTX-002 is currently in Phase 2 development for non-eosinophilic asthma (PEAK trial) with proof-of-concept data in inflammatory bowel diseases and COVID-19 acute respiratory distress syndrome.

About AVTX-002 PEAK Trial

The Phase 2 PEAK trial (n=approximately 80) is a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of AVTX-002 for the treatment of poorly controlled NEA (NCT05288504). The primary endpoint is the proportion of subjects who experience an asthma-related event. At baseline, subjects will be randomized to receive either AVTX-002 or placebo once monthly.

About AVTX-008

AVTX-008 is a fully human B and T Lymphocyte Attenuator (BTLA) agonist fusion protein. IND-enabling activities have been initiated with a target IND submission date in 2024.

About AVTX-803

The active pharmaceutical ingredient (API) in AVTX-803 is fucose. Fucose is a plant-derived, naturally occurring monosaccharide with high solubility in water and is isolated as a white crystalline powder. AVTX-803 is an oral formulation of fucose that enhances fucosylation of proteins in the absence of a functioning GDP-fucose transporter, partially restoring protein function. AVTX-803 was granted Fast Track Designation (FTD), Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD), making it potentially eligible for a Priority Review Voucher (PRV).

About AVTX-803 LADDER Trial

The LADDER trial is a pivotal, randomized, double-blind, two-period crossover, withdrawal study to assess the efficacy and safety of AVTX-803 in patients with LAD II (n=at least 2). The primary endpoint is the comparison of leukocyte function as determined by sialyl Lewis-X (SLx) antigen expression on leukocytes between treatment periods. The trial will conclude with the End of Study/Early Termination Visit at which time subjects will be permitted to enroll into a long-term open-label, safety and efficacy study.

About Avalo Therapeutics

Avalo Therapeutics is a clinical stage biotechnology company focused on the treatment of immune dysregulation by developing therapies that target the LIGHT network.

LIGHT (**L**ymphotoxin-like, exhibits **I**nducible expression, and competes with HSV **G**lycoprotein D for **H**erpesvirus Entry Mediator (HVEM), a receptor expressed by **T** lymphocytes; also referred to as TNFSF14) is an immunoregulatory cytokine. LIGHT and its signaling receptors, HVEM (TNFRSF14), and lymphotoxin β receptor (TNFRSF3), form an immune regulatory network with two co-receptors of herpesvirus entry mediator, checkpoint inhibitor B and T Lymphocyte Attenuator (BTLA), and CD160 (the LIGHT-signaling network). Accumulating evidence points to the dysregulation of the LIGHT network as a disease-driving mechanism in autoimmune and inflammatory reactions in barrier organs. Therefore, we believe reducing LIGHT levels can moderate immune dysregulation in many acute and chronic inflammatory disorders.

For more information about Avalo, please visitwww.avalotx.com.

Forward-Looking Statements

This press release may include forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to significant risks and uncertainties that are subject to change based on various factors (many of which are beyond Avalo's control), which could cause actual results to differ from the forward-looking statements. Such statements may include, without limitation, statements with respect to Avalo's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "might," "will," "could," "would," "should," "continue," "seeks," "aims," "predicts," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," or similar expressions (including their use in the negative), or by discussions of future matters such as: the future financial and operational outlook; the development of product candidates or products; timing and success of trial results and regulatory review; potential attributes and benefits of product candidates; and other

statements that are not historical. These statements are based upon the current beliefs and expectations of Avalo's management but are subject to significant risks and uncertainties, including: Avalo's cash position and the need for it to raise additional capital in the near future; drug development costs, timing and other risks, including reliance on investigators and enrollment of patients in clinical trials, which might be slowed by the COVID-19 pandemic; reliance on key personnel, including as a result of recent management changes; regulatory risks; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic and the war in Ukraine; and those other risks detailed in Avalo's filings with the SEC. Actual results may differ from those set forth in the forward-looking statements. Except as required by applicable law, Avalo expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Avalo's expectations with respect thereto or any change in events, conditions or circumstances on which any statement is based.

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