November 9, 2021

Avalo Reports Third Quarter 2021 Financial Results and Provides Business Updates

- **Topline Phase 1b data for AVTX-002 in moderate to severe Crohn's disease patients expected in the fourth quarter of 2021**
- **Multiple data readouts across programs anticipated within the next six months**
- **Cash and cash equivalents of $71.5 million on hand following recent financing transactions during the quarter**

WAYNE, Pa. and ROCKVILLE, Md., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Avalo Therapeutics, Inc. (Nasdaq: AVTX), a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology, immuno-oncology, and rare genetic diseases today announced business updates and third quarter 2021 financial results.

"The third quarter was focused on execution ahead of a number of data readouts in multiple key pipeline programs anticipated in the coming months," said Mike Cola, Chief Executive Officer of Avalo Therapeutics. *"We further solidified our balance sheet with a successful public offering in September that puts the Company in a position to support the development of our pipeline through multiple catalysts."*

Business Updates:

- In July 2021, the Company reported positive initial results for the low-dose cohort (1.0 mg/kg) of its Phase 1b proof-of-concept study of AVTX-002, an investigational first-in-class fully human anti-LIGHT (tumor necrosis factor superfamily member 14 (TNFSF14)) monoclonal antibody (mAb), in adult patients with moderate to severe Crohn's disease.
- Completed rebranding to Avalo Therapeutics, Inc. from Cerecor Inc., accentuating the Company's transition to developing innovative targeted therapies in immunology, immuno-oncology, and rare genetic diseases.
- In September 2021, the Company raised gross proceeds of approximately $31.5 million through a public offering of common stock, which strengthens and extends the Company's financial resources to advance its clinical pipeline towards key development milestones. Avalo had cash and cash equivalents of $71.5 million as of September 30, 2021.
- During the third quarter of 2021, the Company completed its second drawdown of $10 million and third drawdown of $5 million under its previously announced $35 million venture debt financing agreement with Horizon Technology Finance Corporation. With

the closing of the second and third tranches, the Company has received the full $35 million of gross proceeds under its debt financing agreement.

Program Updates and Milestones:

- **AVTX-002:** Anti-LIGHT mAb targeting immune-inflammatory diseases including acute respiratory distress syndrome (ARDS) and moderate-to-severe inflammatory bowel disease (Crohn's disease and ulcerative colitis).
    - The Company has completed enrollment in Cohort 2 (3.0 mg/kg) of its Phase 1b proof-of-concept trial of AVTX-002 in moderate-to-severe Crohn's disease and anticipates top-line data in the fourth quarter of 2021.
    - Based on the positive data from Cohort 1 (1.0 mg/kg) of its Phase 1b trial of AVTX-002 in moderate-to-severe Crohn's disease, the Company has expanded the IBD program to include patients with moderate-to-severe ulcerative colitis who are refractory to anti-TNF alpha therapies.
    - The Company remains in dialogue with the FDA and is working through feedback to determine the trial design for a registrational study of AVTX-002 in COVID-19 ARDS and accompanying timelines, including the potential expansion to a larger patient population in broader ARDS.

- **AVTX-007:** Anti-IL-18 mAb targeting immuno-oncology and immune-inflammatory diseases including multiple myeloma (MM) and adult onset Still's disease (AOSD).
    - The Company anticipates top-line data from the Phase 1b clinical trial in relapsed or refractory MM patients in the fourth quarter of 2021.
    - The Company anticipates initial data from the Phase 1b clinical trial in AOSD patients in the first quarter of 2022.

- **AVTX-006:** Dual mTORc1/c2 small molecule inhibitor for complex lymphatic malformations.
    - The Company anticipates initial data from the Phase 1b proof-of-concept clinical trial in the first quarter of 2022.

- **AVTX-800 programs (AVTX-801, AVTX-802, and AVTX-803):** Therapeutic doses of monosaccharide therapies for congenital disorders of glycosylation (CDGs).
    - AVTX-801 – In collaboration with the Frontiers in Congenital Disorders of Glycosylation Consortium clinical program, data from the pivotal trial evaluating the safety and efficacy of D-galactose in Phosphoglucomutase-1 deficiency related CDG (PGM1-CDG) patients are anticipated in 2022.
    - AVTX-802 – Data from the pivotal trial evaluating the safety and efficacy of D-mannose in Mannose phosphate isomerase deficiency related CDG (MPI-CDG) patients are anticipated in 2022.
    - AVTX-803 – Data from the pivotal trial evaluating the safety and efficacy of L-fucose in Leukocyte Adhesion Deficiency II (LAD II) patients are anticipated in the first half of 2022.

Third Quarter 2021 Financial Update:

As of September 30, 2021, Avalo had $71.5 million in cash and cash equivalents, representing a $52.6 million increase as compared to December 31, 2020. The increase was primarily driven by gross proceeds of $31.5 million from an underwritten public offering

completed in September 2021, $35 million from a debt financing agreement entered into in June 2021 ($20 million funded in the second quarter and remaining $15 million funded in the third quarter), and gross proceeds of $40.7 million from an underwritten public offering completed in January 2021. Such increases were partially offset by operating expenditures, the majority of which related to pipeline development.

Net product revenue of the Company's non-core commercialized product was $1.4 million for the three months ended September 30, 2021, which was largely consistent with the net product revenue for the three months ended September 30, 2020 of $1.1 million.

Total operating expenses increased $3.4 million for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020, which was the largest driver of the increase in net loss period over period. The increased operating expenses were largely driven by a $1.7 million increase in research and development expenses due to Avalo's continued advancement of its maturing pipeline.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	September 30, 2021 (unaudited) (a)	December 31, 2020 (a)
Assets		
Current assets:		
Cash and cash equivalents	$ 71,506	$ 18,919
Accounts receivable, net	1,435	2,177
Other receivables	2,477	2,208
Inventory, net	16	3
Prepaid expenses and other current assets	1,408	2,660
Restricted cash, current portion	164	38
Total current assets	77,006	26,005
Property and equipment, net	1,410	1,607
Other long-term asset	2,000	—
Intangible assets, net	304	1,585
Goodwill	14,409	14,409
Restricted cash, net of current portion	227	149
Total assets	$ 95,356	$ 43,755
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,568	$ 2,574
Accrued expenses and other current liabilities	15,460	11,310
Current liabilities of discontinued operations	10	1,341
Total current liabilities	19,038	15,225
Notes payable	32,483	—
Royalty obligation	2,000	2,000

Deferred tax liability, net	130	90
Other long-term liabilities	1,396	1,878
Total liabilities	55,047	19,193
Stockholders' equity:		
Common stock—$0.001 par value; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 112,317,829 and 75,004,127 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	112	75
Preferred stock—$0.001 par value; 5,000,000 shares authorized at September 30, 2021 and December 31, 2020; 0 and 1,257,143 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	1
Additional paid-in capital	283,167	202,276
Accumulated deficit	(242,970)	(177,790)
Total stockholders' equity	40,309	24,562
Total liabilities and stockholders' equity	$ 95,356	$ 43,755

(a) The condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020 have been derived from the reviewed and audited financial statements, respectively, 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

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021 (a)	2020 (a)	2021 (a)	2020 (a)
Revenues:				
Product revenue, net	$ 1,350	$ 1,111	$ 4,554	$ 5,202
License revenue	—	—	625	—
Total revenues, net	1,350	1,111	5,179	5,202
Operating expenses:				
Cost of product sales	908	77	1,067	221
Research and development	10,551	8,872	48,325	19,556
Acquired in-process research and development	—	—	—	25,549
General and administrative	5,188	4,573	16,718	13,350
Sales and marketing	738	462	1,959	1,792
Amortization expense	428	404	1,281	1,238
Total operating expenses	17,813	14,388	69,350	61,706

	(16,463)	(13,277)	(64,171)	(56,504)
Other (expense) income:				
Change in fair value of Investment in Aytu	—	—	—	5,208
Other (expense) income, net	(15)	19	(20)	447
Interest (expense) income, net	(985)	—	(1,207)	—
Total other (expense) income, net from continuing operations	(1,000)	19	(1,227)	5,655
Loss from continuing operations before taxes	(17,463)	(13,258)	(65,398)	(50,849)
Income tax expense (benefit)	8	3	(180)	(2,607)
Loss from continuing operations	$ (17,471)	$ (13,261)	$ (65,218)	$ (48,242)
Income (loss) from discontinued operations, net of tax	76	(198)	38	385
Net loss	$ (17,395)	$ (13,459)	$ (65,180)	$ (47,857)
Net (loss) income per share of common stock, basic and diluted:				
Continuing operations	$ (0.17)	$ (0.16)	$ (0.67)	$ (0.68)
Discontinued operations	0.00	(0.01)	0.00	0.00
Net loss per share of common stock, basic and diluted	$ (0.17)	$ (0.17)	$ (0.67)	$ (0.68)
Net (loss) income per share of preferred stock, basic and diluted:				
Continuing operations		$ (0.82)	$ (3.34)	$ (3.40)
Discontinued operations		(0.01)	0.00	0.02
Net loss per share of preferred stock, basic and diluted		$ (0.83)	$ (3.34)	$ (3.38)

(a) The unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020 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 Avalo Therapeutics

Avalo Therapeutics is a leading clinical-stage precision medicine company that discovers, develops, and commercializes targeted therapeutics for patients with significant unmet clinical need in immunology, immuno-oncology, and rare genetic diseases. The Company has built a diverse portfolio of innovative therapies to deliver meaningful medical impact for patients in urgent need. The Company's clinical candidates commonly have a proven mechanistic rationale, biomarkers and/or an established proof-of-concept to expedite and increase the probability of success.

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 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: 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; regulatory risks; Avalo's cash position and the potential need for it to raise additional capital; general economic and market risks and uncertainties, including those caused by the COVID-19 pandemic; 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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