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Clarus Therapeutics Reports Third Quarter 2021 Financial and Operating Results

Third quarter 2021 revenue increased 93% year-over-year to \$4.3 million

Third quarter 2021 total prescription growth for JATENZO® increased 12% sequentially and 132% year-over-year

Conference call and webcast today at 5:15 p.m. ET

NORTHBROOK, Ill., Nov. 18, 2021 (GLOBE NEWSWIRE) -- Clarus Therapeutics Holdings, Inc. (Clarus) (Nasdaq:CRXT), a pharmaceutical company dedicated to providing solutions to unmet medical needs by advancing androgen and metabolic therapies for men and women, today reported financial results for the third quarter of 2021.

"We have achieved some exciting milestones this quarter," said Dr. Robert Dudley, President and Chief Executive Officer of Clarus and founder of its wholly-owned operating subsidiary, Clarus Therapeutics, Inc. "JATENZO continues to grow in prescriptions with positive feedback from both patients and physicians. We remain very enthusiastic and optimistic as we focus on executing our plans to increase awareness about the only FDA-approved oral softgel with flexible dosing options in the testosterone replacement therapy market by educating physicians and patients alike about the attributes of JATENZO."

"September 10 marked our debut as a public combined company trading on Nasdaq," continued Dr. Dudley. "Also in September, we announced the continued diversification and growth of our internal pipeline with the addition of a new technology we licensed from McGill University to potentially treat rare conditions associated with CoQ₁₀ deficiencies. This, in addition to the recent license agreement with HavaH Therapeutics for the worldwide development and commercialization rights to CLAR-121 to potentially treat androgen-dependent inflammatory breast disease and certain forms of breast cancer, positions us well as we focus on our mission to develop androgen and metabolic therapies for men and women. We thank everyone, including our patients, physicians, and stockholders, for their continued support."

Third Quarter 2021 Financial Results

- Third quarter 2021 total revenue increased 92.7% to \$4.3 million from \$2.2 million in the same period last year. For the nine months ended September 30, 2021, total revenue was \$9.4 million, an increase of 138.3% from \$3.9 million for the comparable period in 2020.
- Gross margin percentage was 88.1% for the third quarter of 2021 compared to 88.4% for the prior year period, and 84.8% for the nine months ended September 30, 2021 as compared to a negative margin in the prior year period.
- Third quarter 2021 operating expenses decreased by 7.6% to \$12.2 million from \$13.2 million in the same period last year, primarily attributable to the timing of advertising and promotion costs, offset by slight increases in general and administrative expenses primarily due to increased headcount and financing related costs. For the nine months ended September 30, 2021, operating expenses increased by 16.7% to \$40.4 million from \$34.6 million for the comparable period in 2020, primarily attributable to increased general and administrative expenses, which increased due to higher personnel costs, as well as increased sales and marketing expenses associated with JATENZO advertising and promotion.
- Third quarter 2021 research and development expenses decreased by 11.3% to \$1.3 million (29.7% of revenue) from \$1.4 million in the same period last year primarily due to decreased costs for consulting services during the quarter, offset by increased license fees in the period. For the nine months ended September 30, 2021, research and development expenses increased by 9.8% to \$3.1 million from \$2.8 million in the same period last year, primarily due to clinical costs associated with our lead commercial asset, JATENZO, and licensing fees related to the HavaH and McGill agreements, offset by decreased consulting costs.
- Third quarter 2021 net loss was \$2.8 million, or net loss per common share of \$0.26, compared to net income of \$5.4 million, or net loss per common share of \$0.63 in the same period last year. For the nine months ended September 30, 2021, net loss was \$36.3 million, or net loss per common share of \$5.68, compared to net income of \$4.1 million, or net loss per common share of \$2.03 in the same period last year.
- Cash and cash equivalents as of September 30, 2021 were \$22.0 million.
- In September 2021, the combined company received \$25.3 million in cash upon closing of the business combination between Blue Water Acquisition Corp. (Blue Water) and Clarus Therapeutics, Inc. before transaction expenses. Following completion of the business combination, Blue Water changed its name to Clarus Therapeutics Holdings, Inc.
- As of September 30, 2021, Clarus had 9.2 million weighted-average common shares outstanding for purposes of calculating net (loss) income per share attributable to common stockholders, basic and diluted.

Recent Business Highlights

- Continued total prescription growth for JATENZO in the third quarter of 2021 with an increase of 12% sequentially and 132% year-over-year driven primarily by advertising and promotion and an increase in payer coverage across all payer channels
- Announced a comprehensive settlement of patent litigation with Lipocine, resolving all outstanding claims with payments to Clarus as part of the settlement
- Received two notices of allowance from the United States Patent and Trademark Office (USPTO) covering JATENZO
- Closed the business combination between Blue Water and Clarus Therapeutics, and debuted as a publicly traded combined company focused on androgen and metabolic therapies
- Entered into an exclusive worldwide license agreement with McGill University, Canada's top ranked medical doctoral university, to develop and commercialize technology to treat rare conditions associated with CoQ₁₀ deficiencies
- Entered into an exclusive license agreement with HavaH Therapeutics, an Australia-based biopharmaceutical company developing androgen

therapies for inflammatory breast disease and certain forms of breast cancer

Conference Call and Webcast

Clarus will host a conference call today at 5:15 p.m. ET to discuss the results. The dial-in numbers are (844) 249-2007 for domestic callers and (224) 619-3902 for international callers. The conference ID number is 1354439. A live webcast and replay of the conference call will be accessible through the Investors section of Clarus Therapeutics' website at Investors.ClarusTherapeutics.com.

About Clarus Therapeutics Holdings, Inc.

Clarus Therapeutics Holdings, Inc. is a pharmaceutical company with expertise in developing androgen and metabolic therapies for men and women – including potential therapies for orphan indications. Clarus Therapeutics' first commercial product is JATENZO (testosterone undecanoate). For more information, visit www.clarustherapeutics.com and www.jatenzo.com. Follow us on Twitter ([@Clarus_Thera](https://twitter.com/Clarus_Thera)) and LinkedIn ([Clarus Therapeutics](https://www.linkedin.com/company/clarustherapeutics)).

Clarus Forward-Looking Statements

Certain statements in this press release constitute “forward-looking statements” for purposes of the federal securities laws. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Clarus' forward-looking statements in this press release include, but are not limited to, statements regarding increasing awareness of JATENZO and growing prescriptions, the potential of the technology licensed from McGill University, the potential of CLAR-121, and its ability to execute on its mission, among others. These forward-looking statements are based on current expectations and beliefs concerning future developments and their potential effects. There can be no assurance that future developments affecting us will be those that Clarus has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Clarus' control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risks associated with pharmaceutical development, risks associated with Clarus' financial position, and those factors described under the heading “Risk Factors” in the prospectus filed with the Securities and Exchange Commission (the SEC) under Rule 424(b)(3) on October 7, 2021, and those that are included in any of Clarus' future filings with the SEC, including the 10-Q. Some of these risks and uncertainties may in the future be amplified by the COVID-19 pandemic and there may be additional risks that Clarus considers immaterial, or which are unknown. It is not possible to predict or identify all such risks. Clarus' forward-looking statements only speak as of the date they are made, and Clarus does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

JATENZO® is a registered trademark of Clarus Therapeutics Holdings, Inc.

Clarus Investor Relations Contact:

Kara Stancell
kstancell@clarustherapeutics.com
(847) 562-4300 x 206

The following presents Clarus Therapeutics Holdings, Inc. statements of operations for the three and nine months ended September 30, 2021 and 2020:

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Operations
(Unaudited; in thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Revenue:				
Net product revenue	\$ 4,286	\$ 2,224	\$ 9,395	\$ 3,943
Cost of product sales	510	257	1,431	8,328
Gross profit (loss)	3,776	1,967	7,964	(4,385)
Operating expenses:				
Sales and marketing	7,550	8,733	25,017	23,557
General and administrative	3,384	3,040	12,316	8,261
Research and development	1,275	1,437	3,093	2,818
Total operating expenses	12,209	13,210	40,426	34,636
Loss from operations	(8,433)	(11,243)	(32,462)	(39,021)
Other (expense) income, net:				
Change in fair value of warrant liability and derivative, net	7,610	20,939	7,610	53,854
Interest income	1	1	1	24
Interest expense	(4,447)	(4,291)	(13,964)	(10,790)
Litigation settlement	2,500	—	2,500	—
Total other (expense) income, net	5,664	16,649	(3,853)	43,088
Net (loss) income before income taxes	(2,769)	5,406	(36,315)	4,067
Provision for income taxes	—	—	—	—
Net (loss) income	\$ (2,769)	\$ 5,406	\$ (36,315)	\$ 4,067

Net (loss) income attributable to common stockholders, basic	\$ (2,357)	\$ 5,396	\$ (35,903)	\$ (4,059)
Net loss attributable to common stockholders, diluted	\$ (2,357)	\$ (13,743)	\$ (35,903)	\$ (44,279)
Net (loss) income per common share attributable to common stockholders, basic	\$ (0.26)	\$ 1.10	\$ (5.68)	\$ 0.83
Net loss per common share attributable to common stockholders, diluted	\$ (0.26)	\$ (0.63)	\$ (5.68)	\$ (2.03)
Weighted-average common shares used in net (loss) income per share attributable to common stockholders, basic	9,153,848	4,901,564	6,318,992	4,901,564
Weighted-average common shares used in net loss per share attributable to common stockholders, diluted	9,153,848	21,828,570	6,318,992	21,828,570

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Balance Sheets
(Unaudited; in thousands, except share and per share data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,953	\$ 7,233
Accounts receivable, net	6,932	4,400
Inventory, net	12,480	5,857
Prepaid expenses and other current assets	3,891	1,846
Total current assets	45,256	19,336
Property and equipment, net	66	64
Total assets	\$ 45,322	\$ 19,400
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Senior notes payable	\$ 40,339	\$ 41,902
Accounts payable	15,843	12,107
Accrued expenses	7,373	4,631
Deferred revenue	827	1,172
Total current liabilities	64,382	59,812
Convertible notes payable to related parties	—	77,911
Royalty obligation	—	9,262
Derivative warrant liability	6,465	—
Total liabilities	70,847	146,985
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.001 par value, — and 53,340,636 shares authorized at September 30, 2021 and December 31, 2020, respectively; — and 36,756,498 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	198,195
Stockholders' deficit:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Common stock \$0.0001 par value; 125,000,000 shares authorized; 21,725,817 and 4,901,564 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	291,825	—
Accumulated deficit	(317,352)	(325,781)
Total stockholders' deficit	(25,525)	(325,780)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	\$ 45,322	\$ 19,400