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Clarus Therapeutics Reports First Quarter 2022 Financial and Operating Results

First quarter 2022 net revenue increased 72% year-over-year to \$4.0 million

First quarter 2022 total prescription growth for JATENZO® increased 12% sequentially and increased 75% year-over-year

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

NORTHBROOK, Ill., May 16, 2022 (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 first quarter of 2022.

"We delivered a strong first quarter, as the total number of prescriptions written for JATENZO continued to increase," said Dr. Robert Dudley, President and Chief Executive Officer of Clarus. "With the closing of our recent upsized \$30 million underwritten public offering, we intend to continue our strategic marketing initiatives designed to increase awareness about JATENZO and fuel its further growth. We are excited about additional patent coverage for JATENZO and new patent coverage for CLAR-121, as we recently received a notice of allowance for each. We also applied for Orphan Drug Designation for CLAR-121. Our focus remains on driving long-term stockholder value as we accomplish our business objectives. We thank our employees for their commitment to excellence and our stockholders for their loyalty during these extraordinary times."

Recent Business Highlights

- Increased total prescriptions for JATENZO in the first quarter of 2022 sequentially and year over year by 12% and 75%, respectively, compared to the fourth quarter of 2021 and first quarter of 2021, driven primarily by advertising and promotion and an increase in payer coverage across all payer channels
- Presented new data for JATENZO at the Androgen Society 4th Annual Meeting and at the 2022 American Urological Association Annual Meeting
- Received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for patent claims covering JATENZO; once issued, this will be the eighth patent for JATENZO to be listed in the U.S. Food and Drug Administration's (FDA's) Orange Book
- Received a notice of allowance from the USPTO for patent claims covering CLAR-121, a proprietary combination of testosterone and anastrozole delivered by a subcutaneous implant for the treatment of androgen receptor-mediated inflammatory breast disease that predominantly affects women
- Applied for Orphan Drug Designation from the FDA for CLAR-121 for the treatment of inflammatory periductal mastitis (PDM) for women
- Announced pricing and closing of an upsized \$30 million underwritten public offering, extending cash runway into approximately September 2022
- Continued to explore strategic alternatives to maximize stockholder value

First Quarter 2022 Highlights

First quarter 2022 net revenue increased 72% to \$4.0 million from \$2.3 million in the same period last year, related to the continued growth in sales of JATENZO.

Gross margin was 83% for the first quarter of 2022, compared to 84% for the prior year period.

First quarter 2022 operating expenses increased by 33% to \$16.9 million from \$12.8 million in the same period last year, primarily attributed to an increase in sales and marketing activity associated with the promotion of JATENZO and increases in general and administrative expenses associated with increased headcount, partially offset by decreased research and development expenses.

Included in total operating expenses for first quarter 2022 was an increase in sales and marketing expenses of 35% to \$10.7 million from \$7.9 million in the same period last year, primarily attributed to advertising and promotional spend associated with JATENZO.

Also included in total operating expenses for first quarter 2022 was an increase in general and administrative expenses of 47% to \$5.3 million from \$3.6 million in the same period last year, primarily attributed to an increase in personnel costs associated with a growing business and expenses associated with being a public company.

Total operating expenses for first quarter 2022 also reflect a decrease in research and development expenses of 27% to \$0.9 million from \$1.2 million in the same period last year, primarily attributed to the timing of clinical costs associated with our lead commercial asset.

First quarter 2022 net loss was \$14.9 million, or \$0.61 per common share, compared to net loss of \$15.4 million, or \$0.00 per common share, in the

same period last year.

Major Upcoming Milestones

- Phase 4 clinical trial for JATENZO as testosterone therapy for female-to-male transgender individuals (Investigator-Initiated Study) expected to be initiated in the second half of 2022
- Phase 2 clinical trial for CLAR-121 (testosterone + anastrozole) for the treatment of PDM expected to be initiated in the second half of 2022, subject to availability of funding
- Phase 2 clinical trial for once daily oral testosterone undecanoate for the treatment of male hypogonadism expected to be initiated in the second half of 2022, subject to availability of funding
- Phase 1 clinical trial for CLAR-222 (CoQ₁₀ + caspofungin) for the treatment of primary forms of CoQ₁₀ deficiency and related mitochondrial dysfunction expected to be initiated in the second half of 2022, subject to availability of funding
- Results from the Phase 4 clinical trial of JATENZO for the treatment of hypogonadal men with chronic kidney disease expected in the first half of 2023

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 7677008. A live webcast and replay of the conference call will be accessible through the Investors section of Clarus Therapeutics' website at [Investors.ClarusTherapeutics.com](https://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 its strategic marketing initiatives for JATENZO, potential Orphan Drug Designation for CLAR-121, expectations regarding Clarus' cash runway, exploring strategic alternatives, and the timing of initiation and data from clinical trials for JATENZO and other product candidates, 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 Clarus will be those 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 Clarus' annual report on 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the SEC) on March 31, 2022, and those that are included in any of Clarus' future filings with the SEC. Some of these risks and uncertainties may in the future be amplified by the ongoing 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.

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The following presents Clarus Therapeutics Holdings, Inc. statements of operations for the three months ended March 31, 2022 and 2021:

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

	Three Months Ended March 31,	
	2022	2021
Revenue:		
Net product revenue	\$ 4,011	\$ 2,330
Cost of product sales	664	367
Gross profit	3,347	1,963
Operating expenses:		
Sales and marketing	10,729	7,937
General and administrative	5,285	3,605
Research and development	881	1,210

Total operating expenses	16,895	12,752
Loss from operations	(13,548)	(10,789)
Other (expense) income, net:		
Change in fair value of warrant liability, net	642	—
Interest income	1	—
Interest expense	(1,965)	(4,640)
Total other (expense), net	(1,322)	(4,640)
Net loss before income taxes	(14,870)	(15,429)
Provision for income taxes	—	—
Net loss	<u>\$ (14,870)</u>	<u>\$ (15,429)</u>
Accretion of preferred stock	—	(3,939)
Net loss attributable to common stockholders, basic and diluted	<u>\$ (14,870)</u>	<u>\$ (19,368)</u>
Net loss per common share attributable to common stockholders, basic and diluted	<u>\$ (0.61)</u>	<u>—</u>
Weighted-average common shares used in net loss per share attributable to common stockholders, basic and diluted	<u>24,202,842</u>	<u>—</u>

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

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,137	\$ 26,415
Accounts receivable, net	8,005	6,341
Inventory, net	14,930	14,214
Prepaid expenses	4,383	4,673
Total current assets	<u>36,455</u>	<u>51,643</u>
Property and equipment, net	67	65
Total assets	<u>\$ 36,522</u>	<u>\$ 51,708</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Senior notes payable	\$ 38,485	\$ 42,269
Accounts payable	14,056	13,945
Accrued expenses	11,433	8,261
Deferred revenue	1,980	1,585
Total current liabilities	<u>65,954</u>	<u>66,060</u>
Derivative warrant liability	925	1,567
Total liabilities	<u>66,879</u>	<u>67,627</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.0001 par value; 125,000,000 shares authorized; 24,750,011 and 24,025,817 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	306,166	305,734
Accumulated deficit	(336,525)	(321,655)
Total stockholders' deficit	<u>(30,357)</u>	<u>(15,919)</u>
Total liabilities and stockholders' deficit	<u>\$ 36,522</u>	<u>\$ 51,708</u>