UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-39802

CLARUS THERAPEUTICS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**85-1231852**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
555 Skokie Boulevard, Suite 340 Northbrook, Illinois	**60062**
(Address of principal executive offices)	**(Zip Code)**

(847) 562-4300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common stock, par value $0.0001 per share	**CRXT**	**The Nasdaq Stock Market LLC**
Warrants to purchase one share of common stock at an exercise price of $11.50	**CRXTW**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer, "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 11, 2021, there were 21,725,817 shares of common stock, par value $0.0001 per share, issued and outstanding.

CLARUS THERAPEUTICS HOLDINGS, INC.
Quarterly Report on Form 10-Q

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Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to realize the benefits from the business combination between Blue Water Acquisition Corp. and Clarus Therapeutics, Inc. (the "Business Combination");
- the ability to maintain the listing of our Common Stock on the Nasdaq Global Market;
- our future financial performance;
- the potential liquidity and trading of our securities;
- the impact from the outcome of any known and unknown litigation;
- our ability to forecast and maintain an adequate rate of revenue growth and appropriately plan expenses;
- expectations regarding future expenditures;
- the future mix of revenue and effect on gross margins;
- the attraction and retention of qualified directors, officers, employees and key personnel;
- our ability to compete effectively in a competitive industry;
- our ability to protect and enhance our corporate reputation and brand;
- expectations concerning our relationships and actions with third parties;
- the impact from future regulatory, judicial, and legislative changes in our industry;
- the ability to locate and acquire complementary products or product candidates and integrate those into our business;
- future arrangements with, or investments in, other entities or associations;
- intense competition and competitive pressures from other companies in the industries in which we operate; and
- other economic, business and/or competitive factors, risks and uncertainties,

The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements reflect our current views with respect to future events, are based on assumptions and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, without limitation:

- there is substantial doubt about our ability to continue as a going concern.
- we have incurred significant indebtedness in connection with our business and servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from our operations to satisfy the financial covenants in our debt agreements. We may not receive a waiver of default for outstanding indebtedness for which we may be in default in the future.
- we have identified material weaknesses in our internal control over financial reporting, and we may identify future material weaknesses in our internal control over financial reporting.
- JATENZO is the only product we are commercializing, and we depend almost entirely on its success.
- we have limited experience as a commercial company and the marketing and sale of JATENZO or any future approved drugs may be unsuccessful or less successful than anticipated.
- our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- our reliance on third-party suppliers and distributors could harm our ability to commercialize JATENZO.
- the ongoing COVID-19 pandemic is having, and is expected to have, an adverse impact on our business.
- the U.S. Food and Drug Administration ("FDA") and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.
- even though we have received marketing approval for JATENZO in the United States, we may never receive marketing approval outside of the United States, or receive pricing and reimbursement outside the United States at acceptable levels.
- recent federal legislation may increase pressure to reduce prices of certain pharmaceutical products paid for by Medicare.
- testosterone (T) is a Schedule III (non-narcotic) substance under the Controlled Substances Act and any failure to comply with this act or its state equivalents would have a negative impact on our business.
- if coverage and reimbursement for JATENZO are limited, it may be difficult to profitably sell JATENZO.
- our market is subject to intense competition.

- if we are unable to obtain or protect intellectual property rights related to JATENZO, we may not be able to compete effectively in our market.
- we may be involved in lawsuits and proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.
- we will need to grow our company, and may encounter difficulties in managing this growth.
- our future success depends on our ability to retain our chief executive officer, chief financial officer and chief commercial officer and to attract, retain and motivate qualified personnel.
- our debt agreements contain restrictions that limit our flexibility in operating our business.

Additional discussion of the risks, uncertainties and other factors described above, as well as other risks and uncertainties material to our business, can be found under “Risk Factors” in our prospectus filed pursuant to 424(b)(3) with the SEC on October 7, 2021, and we encourage you to refer to that additional discussion. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this report completely and with the understanding that our actual future results and the timing of events may be materially different from what we expect, and we cannot otherwise guarantee that any forward-looking statement will be realized. We hereby qualify all of our forward-looking statements by these cautionary statements.

Except as required by law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You are advised, however, to consult any further disclosures we make on related subjects.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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 (See Note 12)		
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

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
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 (Note 13)	$ (2,357)	$ 5,396	$ (35,903)	$ (4,059)
Net loss attributable to common stockholders, diluted (Note 13)	$ (2,357)	$ (13,743)	$ (35,903)	$ (44,279)
Net (loss) income per common share attributable to common stockholders, basic (Note 13)	$ (0.26)	$ 1.10	$ (5.68)	$ 0.83
Net loss per common share attributable to common stockholders, diluted (Note 13)	$ (0.26)	$ (0.63)	$ (5.68)	$ (2.03)
Weighted-average common shares used in net (loss) income per share attributable to common stockholders, basic (Note 13)	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 (Note 13)	9,153,848	21,828,570	6,318,992	21,828,570

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
Unaudited
(in thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020 (as previously reported)	36,756,498	$ 198,195	870,263	$ 1	$ —	$ (325,781)	$ (325,780)
Retroactive application of the recapitalization due to the Business Combination (Note 3)	(36,756,498)	(198,195)	4,031,301	—	152,653	37,006	189,659
Adjusted balance at December 31, 2020	—	—	4,901,564	1	152,653	(288,775)	(136,121)
Retroactive application of recapitalization related to 2021 activity (1)	—	—	—	—	(7,737)	7,737	—
Conversion of Series D redeemable convertible preferred stock into common stock, adjusted for retroactive application of the recapitalization	—	—	—	—	11,829	—	11,829
Stock-based compensation	—	—	—	—	176	—	176
Net loss	—	—	—	—	—	(15,429)	(15,429)
Balance at March 31, 2021	—	—	4,901,564	1	156,921	(296,467)	(139,545)
Stock-based compensation	—	—	—	—	177	—	177
Net loss	—	—	—	—	—	(18,117)	(18,117)
Balance at June 30, 2021	—	—	4,901,564	1	157,098	(314,584)	(157,485)
Stock-based compensation	—	—	—	—	207	—	207
Recapitalization on September 9, 2021	—	—	12,984,784	1	117,512	—	117,513
Proceeds from Blue Water Acquisition Corp. in Business Combination	—	—	3,839,469	—	17,008	—	17,008
Net loss	—	—	—	—	—	(2,769)	(2,769)
Balance at September 30, 2021	—	—	21,725,817	$ 2	$291,825	$ (317,352)	$ (25,525)

(1) Relates to reversal of 2021 accretion recorded on the redeemable convertible preferred stock prior to the merger, as the redeemable convertible preferred stock has been retroactively restated to give effect to the reverse recapitalization.

CLARUS THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
Unaudited
(in thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019 (as previously reported)	36,756,498	$ 183,513	870,263	$ 1	$ —	$ (316,269)	$ (316,268)
Retroactive application of the recapitalization due to the Business Combination (Note 3)	(36,756,498)	(183,513)	4,031,301	—	160,363	23,150	183,513
Adjusted balance at December 31, 2019	—	—	4,901,564	1	160,363	(293,119)	(132,755)
Stock-based compensation	—	—	—	—	74	—	74
Net income (loss)	—	—	—	—	—	(11,894)	(11,894)
Balance at March 31, 2020	—	—	4,901,564	1	160,437	(305,013)	(144,575)
Stock-based compensation	—	—	—	—	70	—	70
Net income	—	—	—	—	—	10,555	10,555
Balance at June 30, 2020	—	—	4,901,564	1	160,507	(294,458)	(133,950)
Stock-based compensation	—	—	—	—	90	—	90
Net income	—	—	—	—	—	5,406	5,406
Balance at September 30, 2020	—	—	4,901,564	$ 1	$160,597	$ (289,052)	$ (128,454)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net income (loss)	$ (36,315)	$ 4,067
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash interest expense related to debt financing and royalty obligation	11,137	7,856
Settlement of interest with payment-in-kind note	3,125	—
Non-cash gain on partial extinguishment of senior notes	(296)	—
Change in fair value of warrant liability	(7,610)	(541)
Change in fair value of derivative liability	—	(53,313)
Stock-based compensation expense	560	234
Depreciation	18	14
Changes in operating assets and liabilities:		
Accounts receivable	(2,532)	(3,451)
Inventory	(6,622)	746
Prepaid expenses and other current assets	(2,048)	(734)
Accounts payable	3,736	7,165
Accrued expenses	2,740	1,677
Deferred revenue	(345)	619
Net cash used in operating activities	(34,452)	(35,661)
Investing activities		
Purchases of property and equipment	(20)	(62)
Net cash used in investing activities	(20)	(62)
Financing activities		
Proceeds from business combination, net	17,008	—
Proceeds from issuance of convertible notes payable	23,592	1,611
Proceeds from issuance of senior notes payable	8,592	49,125
Proceeds from PPP loan	—	500
Repayment of PPP loan	—	(500)
Debt issuance costs	—	(3,516)
Net cash provided by financing activities	49,192	47,220
Net increase in cash and cash equivalents	14,720	11,497
Cash and cash equivalents—beginning of period	7,233	1,656
Cash and cash equivalents—end of period	$ 21,953	$ 13,153
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible notes payable into Series D redeemable convertible preferred stock	$ 3,360	$ —
Conversion of Series D redeemable convertible preferred stock into Old Clarus common stock prior to the recapitalization	$ 11,829	$ —
Senior secured note principal and royalty obligation balance conversion to shares of common stock upon merger (Note 3)	$ 28,254	—
Convertible notes principal and accrued interest balance conversion to shares of common stock upon merger (Note 3)	$103,333	—
Conversion of Series D redeemable convertible preferred stock into share of common stock	$189,659	—
Value of warrants assumed upon merger (Note 3)	14,075	—

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

CLARUS THERAPEUTICS HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
Unaudited

1. Organization and Description of Business Operations

Clarus Therapeutics Holdings, Inc. (together with its consolidated subsidiary, the "Company" or "Clarus") formerly known as Blue Water Acquisition Corp. ("Blue Water"), was incorporated in Delaware on May 22, 2020, Blue Water was a Special Purpose Acquisition Company ("SPAC") formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses.

The registration statement for the Company's Initial Public Offering ("IPO") was declared effective on December 15, 2020. On December 17, 2020, the Company consummated its IPO of 5,750,000 units (the "Units" and, with respect to the Class A common stock included in the Units being offered, the "Public Shares"), including 750,000 additional Units to cover over-allotments (the "Over-Allotment Units"), at $10.00 per Unit, generating gross proceeds of $57.5 million, and incurring offering costs of approximately $3.7 million, of which approximately $2.0 million was for deferred underwriting commissions. Simultaneously with the closing of the IPO, the Company consummated the private placement ("Private Placement") of 3,445,000 warrants (each, a "Private Placement Warrant" and collectively, the "Private Placement Warrants") at a price of $1.00 per Private Placement Warrant to Blue Water Sponsor LLC (the "Sponsor"), generating proceeds of approximately $3.4 million. Upon the closing of the IPO and the Private Placement, approximately $58.7 million ($10.20 per Unit) of the net proceeds of the IPO and certain of the proceeds of the Private Placement was held in a trust account ("Trust Account") located in the United States with Continental Stock Transfer & Trust Company acting as trustee, and were invested only in U.S. "government securities" within the meaning of Section 2(a)(16) of the U.S. Investment Company Act of 1940, as amended (the "Investment Company Act") having a maturity of 185 days or less or in money market funds meeting certain conditions under Rule 2a-7 promulgated under the Investment Company Act, which invested only in direct U.S. government treasury obligations, as determined by the Company, until the earlier of: (i) the completion of a business combination and (ii) the distribution of the Trust Account.

Merger

On September 9, 2021 (the "Closing Date"), the Company, and Blue Water Merger Sub Corp., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), consummated the previously announced merger, pursuant to the Agreement and Plan of Merger, dated as of April 27, 2021 (the "Merger Agreement"), with Clarus Therapeutics, Inc., a Delaware corporation ("Old Clarus"), pursuant to which, subject to the terms and conditions set forth in the Merger Agreement, Merger Sub merged with and into Old Clarus, with Old Clarus surviving as a wholly-owned subsidiary of the Company, and with Old Clarus's equity holders' and convertible debt holders equity interests converted into the right to receive shares of the Company's common stock or else be canceled, retired and terminated without consideration, as provided in the Merger Agreement (the "Merger"). Upon the consummation of the business combination, Blue Water changed its name to "Clarus Therapeutics Holdings, Inc."

In connection with the Merger, Old Clarus's convertible noteholders and senior secured noteholders provided $25.0 million in additional capital to Old Clarus following the announcement of the execution of the Merger Agreement. All such proceeds plus accrued interest converted to shares of the Company's common stock at a price of $10.00 per share, resulting in 2,549,939 shares issued on the Closing Date. The additional capital of $25.0 million was received by Old Clarus prior to the Closing Date. Together with Blue Water's cash resources and additional capital, the Company received net proceeds from the Merger (not including the $25.0 million of additional capital) of approximately $17.0 million.

At the effective time of the Merger (the "Effective Time"), shares of Old Clarus's redeemable convertible Series D Preferred Stock issued and outstanding and all principal and accrued interest under Old Clarus's Series D convertible notes immediately prior to the Effective Time converted into 13,431,410 shares of the Company's common stock at a price of $10.20 per share. Additionally, $10.0 million of debt related to Old Clarus' senior secured notes, including certain royalty rights was exchanged for an aggregate of 1,500,000 shares of the Company's common stock. Further, under a share allocation agreement entered into by Blue Water and Old Clarus on September 1, 2021, as part of the Merger, an additional 405,000 shares of the Company's common stock were allocated to the senior secured noteholders (as further described in Note 7), which included 270,000 shares reallocated to the senior secured note holders from Old Clarus's equity holders and 135,000 shares from the Blue Water founder that were transferred from the Sponsor pursuant to the share allocation agreement. All unexpired, outstanding Series D Warrants of Old Clarus remained outstanding and became exercisable for shares of the Company's common stock, subject to adjustment in accordance with the Merger exchange ratio.

All other series of Old Clarus preferred stock, common stock and stock options were cancelled and extinguished upon completion of the Merger. In addition, Old Clarus's existing equity incentive plans were terminated.

For additional information on the business combination, please refer to Note 3, *Business Combination*, to these condensed consolidated financial statements.

Description of Business Following the Merger

The Company operates as a pharmaceutical company post-merger focused on the commercialization of JATENZO® (testosterone undecanoate), the first and only oral testosterone ("T") replacement, or testosterone replacement therapy ("TRT"), of its kind approved by the U.S. Food and Drug Administration ("FDA"). The FDA approved JATENZO for marketing on March 27, 2019, and Old Clarus commercially launched JATENZO on February 10, 2020. JATENZO is the Company's sole source of revenue and sales are exclusively within the United States. Management remains committed to the product's commercial success. In parallel, the broader vision is for the Company to become a profitable pharmaceutical company initially focused on the development and commercialization of T and metabolic therapies for men and women. The Company was founded in 2004 and is located and headquartered in Northbrook, Illinois.

The Company is subject to risks and uncertainties associated with any pharmaceutical company that is transitioning from the development to commercial stage. Since inception, Old Clarus incurred substantial operating losses due to substantial product development and commercialization expenditures. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees and consultants. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of JATENZO, is cash flow positive from operations, or enters into cash flow positive business development transactions.

The Company's U.S. patent portfolio on JATENZO currently includes five issued patents and has recently received two notices of allowance from the United States Patent and Trademark Office (USPTO) for claims that cover its oral testosterone replacement product, JATENZO. The issued U.S. patents contain claims to both pharmaceutical compositions and methods of treatment using the Company's proprietary pharmaceutical composition and all are listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. In addition, the Company has several patent applications pending in the United States and other countries that, if issued, will cover pharmaceutical compositions, methods of treatment and other features of JATENZO, and have the potential to extend patent coverage beyond 2030.

Liquidity and Going Concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed financial statements are issued.

Since its inception, Old Clarus has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Old Clarus, and since the Merger, the Company has incurred significant losses from operations since inception and has an accumulated deficit of $317.3 million as of September 30, 2021. Further, as of September 30, 2021, the Company had a working capital deficit of $19.1 million.

In addition to the consummation of the Merger and the related investment, the Company plans to seek additional funding through the expansion of its commercial efforts to grow JATENZO and its operating cash flow, business development efforts to out-license JATENZO internationally, equity financings, debt financings such as the secured notes described in Note 6, *Debt*, or other capital sources including collaborations with other companies or other strategic arrangements with third parties. There can be no assurance that these future financing efforts will be successful.

If the Company is unable to obtain funding or generate operating cash flow, the Company will be forced to delay, reduce or eliminate some or all of its product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, as of the issuance date of the condensed consolidated financial statements for the nine months ended September 30, 2021, the Company has concluded that its cash and cash equivalents will not be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least twelve months from the date that these condensed consolidated financial statements are available to be issued and that there is substantial doubt about the Company's ability to continue as a going concern.

The accompanying condensed financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Impact of the COVID-19 Pandemic

The business disruptions associated with the COVID-19 pandemic had a significant negative impact on the Company's condensed consolidated financial statements for the nine months ended September 30, 2021. Management expects that the public health actions being undertaken to reduce the spread of the virus, and that may have to be undertaken again in the event of a resurgence of the virus, will create significant disruptions to the Company with respect to: (i) the demand for its products, (ii) the ability of its sales representatives to reach healthcare customers, (iii) its ability to maintain staffing levels to support its operations, (iv) its ability to continue to manufacture certain of its products, (v) the reliability of its supply chain and (vi) its ability to achieve the financial covenants required by the senior secured notes agreement (see Note 6, *Debt*). The extent to which the COVID-19 pandemic will impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The Company is closely monitoring the evolving impact of the pandemic on all aspects of its business. The Company has implemented a number of measures designed to protect the health and safety of its employees, support its customers and promote business continuity. The Company is also actively reviewing and implementing cost-saving measures, including discontinuing or delaying all non-essential services and programs and instituting controls on travel, events, marketing and clinical studies to adapt the business plan for the evolving COVID-19 challenges.

2. Summary of Significant Accounting Policies

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2020 and the notes thereto, which are included in the final prospectus filed with the SEC pursuant to Rule 424(b)(3) on October 7, 2021. Since the date of those consolidated financial statements, there have been no material changes to its significant accounting policies, except as noted below.

Basis of Presentation

The condensed consolidated financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). The unaudited condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). In the opinion of management, all adjustments necessary to fairly present the financial position of the Company as of September 30, 2021 and December 31, 2020, the results of operations for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the nine months ended September 30, 2021 and 2020 have been included and are of a normal, recurring nature except as otherwise disclosed. These condensed consolidated financial statements and notes thereto have been prepared under the presumption that users of the financial information have either read or have access to the audited financial statements for the latest year ended December 31, 2020.

As a result of the Merger, the shares and corresponding capital amounts and loss per share related to Old Clarus's outstanding convertible preferred stock and common stock prior to the Merger have been retroactively restated to reflect the actual shares for which the Series D preferred stock converted into as a result of the conversion terms in the Merger Agreement. For additional information on the Business Combination, please refer to Note 3, *Business Combination*, to these condensed consolidated financial statements.

Use of Estimates

Preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenues and expenses during the reporting period covered by the condensed financial statements and accompanying notes. The most significant estimates relate to determination of fair value of the Company's common stock and common stock warrants, stock-based compensation, notes, royalty obligation and the valuation of embedded derivatives. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and records adjustments when facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from those estimates.

Derivative warrant liabilities

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments, including issued stock purchase warrants, to determine if such instruments are liabilities, derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and ASC 815 *Derivatives and Hedging*, ("ASC 815"). The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

The Private Placement Warrants are recognized as derivative liabilities in accordance with ASC 815. Accordingly, the Company recognizes the warrant instruments as liabilities at fair value and adjusts the instruments to fair value at each reporting period. The fair value of the Private Placement warrants has been estimated using a modified Monte Carlo simulation model at inception and subsequently at each measurement date using the Black-Scholes model. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's statement of operations.

The fair value of warrants issued in connection with the IPO were initially measured at fair value using a Monte Carlo simulation model and have subsequently been measured based on the listed market price of such warrants.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed using the weighted-average number of common shares outstanding during the period and, if dilutive, the weighted-average number of potential shares of common stock. Net income (loss) per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net income (loss) per share for the holders of the Company's common shares and participating securities. The Preferred Stock and warrants to purchase Preferred Stock contain participation rights in any dividend paid by the Company and are deemed to be participating securities. Net income (loss) attributable to common stockholders and participating preferred stock and participating preferred stock warrants is allocated first to preferred stockholders and warrant holders based on dividend rights and then to common and preferred stockholders based on ownership interests on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods in which a net loss is recorded.

When considering the impact of the convertible equity instruments, diluted net income (loss) per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders and warrant holders based on dividend rights and then to common and preferred stockholders and warrant holders based on ownership interests. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, convertible redeemable preferred stock and the potential issuance of common stock upon the conversion of the convertible notes. Common stock equivalent shares are excluded from the computation of diluted net income (loss) per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders because dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

3. Business Combination

On September 9, 2021, the business combination between Blue Water Merger Sub and Old Clarus, was consummated, pursuant to the Merger Agreement dated April 27, 2021 (the "Business Combination"). Upon the closing of the Business Combination, Merger Sub merged with and into Old Clarus, with Old Clarus as the surviving company in the Merger and becoming a wholly-owned subsidiary of the Company. Upon the closing of the Business Combination, Blue Water changed its name to "Clarus Therapeutics Holdings, Inc."

The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles ("GAAP"). Under this method of accounting, Blue Water is treated as the acquired company and Old Clarus is treated as the acquirer for financial statement reporting and accounting purposes. As a result, the historical operations of Old Clarus are deemed to be those of the Company. Therefore, the financial statements included in this report reflect (i) the historical operating results of Old Clarus prior to the Business Combination; (ii) the combined results of the Blue Water and Old Clarus following the Business Combination on September 9, 2021; (iii) the assets and liabilities of Old Clarus at their historical cost; and (iv) the Company's equity structure for all periods presented. The recapitalization of the number of shares of common stock attributable to the Business Combination is reflected retroactively to the earliest period presented and will be utilized for calculating earnings per share in all prior periods presented. No step-up basis of intangible assets or goodwill was recorded in the Business Combination consistent with the treatment of the transaction as a reverse recapitalization of Old Clarus.

The aggregate consideration issued or reserved for issuance to Old Clarus securityholders upon the closing of the Merger was 17,886,349 shares of Company common stock. The 17,886,349 shares includes an aggregate of 1,905,000 shares of common stock (which included the 405,000 shares of the Company's common stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement , as described in Note 7, of which 270,000 shares reallocated to the senior secured note holders from Old Clarus's equity holders and 135,000 shares from the Blue Water founder that were transferred from the Sponsor), which were issued to the holders of Old Clarus' senior secured notes in connection with the Merger Agreement and were in exchange for $18.6 million of aggregate principal amount of the senior secured notes and certain outstanding royalty rights. Within the aggregate shares issued to Old Clarus securityholders is also 2,549,939 shares of common stock at $10.00 per share, that were issued to Old Clarus equity holders for the private placement Additional Closing Shares, of which such noteholders provided gross proceeds of $25.0 million, from the date of Merger Agreement signature through Effective Time. Further, 4,901,564 shares of common stock were issued to the holders of the Series D Preferred Stock and 8,529,846 shares of common stock were issued to the holders of Old Clarus convertible notes that were issued and outstanding prior to the Effective Time.

In connection with the Business Combination, the Company incurred equity issuance costs and other costs considered direct and incremental to the transaction totaling $8.4 million, consisting of legal, accounting, and financial advisory and other professional fees. These amounts are reflected within additional paid in capital in the condensed consolidated balance sheet as of September 30, 2021.

Summary of Net Proceeds

The following table summarizes the elements of the net proceeds from the Business Combination as of September 30, 2021 (in thousands):

Cash – Blue Water Trust Account and cash (net of redemptions)	$25,394
Less: Equity issuance costs and other costs paid prior to September 30, 2021	(8,386)
Net Proceeds from the Business Combination	$17,008

Summary of Shares Issued

The following table summarizes the number of shares of Common Stock outstanding immediately following the consummation of the Business Combination:

Blue Water shares outstanding prior to the Business Combination	3,839,468
Conversion of Old Clarus Series D Preferred Stock	4,901,564
Conversion of Old Clarus convertible notes	8,529,846
Conversion of additional capital provided by Old Clarus convertible note and senior note holders	2,549,939
Conversion of Senior Secured Note principal and royalty rights	1,905,000
Total shares of the Company's common stock outstanding immediately following the Business Combination	21,725,817

The following table summarizes the impact of the transaction on the condensed consolidated statement of stockholder's deficit as of September 9, 2021:

	Additional Paid in Capital
Conversion of senior notes and royalty obligation carrying value	$ 28,254
Conversion of Old Clarus convertible notes carrying value	103,333
Assumption of private placement warrant liabilities	(14,075)
Total reverse recapitalization impact on statement of equity	$ 117,512

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	September 30, 2021			
(in thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$20,001	$20,001	$ —	$ —
Total assets	$20,001	$20,001	$ —	$ —
Liabilities				
Private placement warrant liability	$ 6,465	$ —	$ —	$6,465
Total Liabilities	$ 6,465	$ —	$ —	$6,465

	December 31, 2020			
(in thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash equivalents:				
Money market funds	$7,205	$7,205	$ —	$ —
Total assets	$7,205	$7,205	$ —	$ —

During the nine months ended September 30, 2021 and the year ended December 31, 2020, there were no transfers between levels.

As of September 30, 2021 and December 31, 2020, the Company's cash equivalents consisted of money market funds, classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. There were no transfers or reclassifications between Level 1, Level 2 and Level 3 financial assets during the three and nine months ended September 30, 2021.

As of September 30, 2021 and December 31, 2020, the Company had Level 3 financial liabilities that were measured at fair value on a recurring basis. The Company's Warrant Liabilities and Derivative Liability (defined below) are carried at fair value, determined using Level 3 inputs in the fair value hierarchy. As of September 30, 2021 the Warrant Liabilities were valued at $6.4 million, and as of December 31, 2020, the Warrant Liability and Derivative Liability were valued at zero.

The carrying amounts reported in the accompanying balance sheets for cash, accounts receivable, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these instruments. The carrying value of long-term and short-term debt, taking into consideration debt discounts and related derivative instruments, is estimated to approximate fair value.

Warrant Liabilities

In conjunction with a previous loan agreement of Old Clarus that was fully paid in 2017, certain lenders were granted warrants (or the "Series D Warrants"), to purchase a total of 183,438 shares of Series D Preferred Stock at an exercise price of $4.50 per share. The expiration date of the warrants is the earlier of July 14, 2021 for 122,292 shares and April 9, 2023 for 61,146 shares, or three years from the effective date of a registration statement for an initial public offering of Old Clarus's stock. At December 31, 2020 the Warrant Liability was valued at zero. The Series D Warrants outstanding immediately prior to the Effective Time to purchase 61,146 shares of the Series D Preferred Stock were converted into warrants to purchase 9,246 shares of the Company's common stock at an exercise price of $29.74 per share and the expiration date remains April 9, 2023.

At the Effective Time and immediately following the completion of the Business Combination, 9,195,000 warrants, including 5,750,000 Public Warrants and 3,445,000 Private Placement warrants, previously issued by Blue Water, were assumed by the Company. Upon consummation of the Merger, the Company concluded that the Public Warrants are equity classified and the Private Placement Warrants are liability classified in accordance with ASC 815.

The Private Placement Warrants are a freestanding financial instrument that requires the Company to transfer equity instruments upon exercise by the warrant holder at a strike price equal to $11.50 per share (the "Private Placement Warrant Liability"). The valuation of the private placement warrant liability was determined with the assistance of an independent valuation firm that used a modified Monte Carlo simulation model at inception and subsequently at each measurement date using the Black-Scholes model. The fair value was determined using Level 3 inputs. The Private Placement Warrants to purchase common stock are remeasured at each reporting and settlement date. Changes in fair value for each reporting period are recognized in other income (expense) in the statements of operations. A change in the assumptions related to the valuation of the Warrant Liability could have a significant impact on the value of the obligation.

The following table sets forth a summary of changes in the fair value of the Company's warrant liability for the three and nine months ended September 30, 2021 (in thousands):

Beginning warrant liability balance	$ —
Private placement warrant liability assumed	14,075
Change in fair value of warrant liability	(7,610)
Balance at September 30, 2021	$ 6,465

Derivative Liability

From 2016 through 2020, Old Clarus entered into convertible notes purchase agreements with related parties for a total aggregate borrowing amount of $61.3 million (see Note 7, *Debt*). The convertible notes contained various conversion features including mandatory conversion upon the occurrence of a qualified financing at a 20% discount or shares of Series D Preferred Stock at the Series D Preferred Stock issuance price of $4.50. Upon the occurrence of a non-qualified financing, the noteholders had the option to convert at the same terms as described above for a qualified financing. The Company determined that the acquisition premium and the qualified and non-qualified financing conversion features were embedded derivative instruments requiring bifurcation as separate liabilities with a corresponding debt discount. At December 31, 2020 the derivative liability was valued at zero as the value of the Series D Preferred Stock at December 31, 2020 was less than the Series D Preferred Stock issuance price of $4.50. All of Old Clarus's convertible notes outstanding immediately prior to the Effective Time were converted into shares of the Company's common stock.

5. Inventory

Inventory consisted of the following as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021	December 31, 2020
Raw material	$ 6,738	$ 4,225
Work-in-process	5,778	—
Finished goods	7,865	9,475
Total inventory	20,381	13,700
Inventory reserve	(7,901)	(7,843)
Total inventory, net of reserve	$ 12,480	$ 5,857

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Selling and marketing costs	$ 5,905	$ 3,468
Employee compensation and related benefits	1,074	1,090
Professional fees	388	73
Other	6	—
Total	$ 7,373	$ 4,631

7. Debt

Convertible Notes

From 2016 to 2021, Old Clarus issued several convertible notes (the "Convertible Notes") pursuant to which Old Clarus borrowed an aggregate of $82.3 million from existing investors and related parties. All Convertible Notes accrued interest at a rate of 8% compounded daily and had a maturity date of March 1, 2025. The Convertible Notes contained various conversion features. The Company recorded the notes at the original issuance price, net of the conversion feature discount. The conversion feature discount was accreted to the face value of the notes over the period from the issuance date until the conversion date, offset against interest expense.

At the Effective Time, all principal and accrued interest under Old Clarus' convertible notes and Old Clarus' outstanding warrants immediately prior to the Effective Time converted into 8,529,846 shares of the Company's common stock. As such, there are no Convertible Notes outstanding on September 30, 2021.

As of December 31, 2020, the carrying value of the Convertible Notes consisted of (in thousands):

	December 31, 2020
Principal amount	$ 61,300
Accrued and unpaid interest	17,287
Unamortized debt discount	(676)
Total	$ 77,911

In March 2021, upon an investor's decision to not participate in the next round of Convertible Notes, pursuant to the Convertible Notes' provisions, $3.4 million of the investor's Convertible Notes converted into 747,451 shares of Series D Preferred Stock and such Series D Preferred Stock issued as a result of this conversion was converted into Old Clarus common stock. At the date of conversion, the outstanding principal and accrued interest on the Convertible Notes were $2.6 million and $0.8 million, respectively.

The Company recognized interest expense of $1.5 million during the three months ended September 30, 2021 and 2020, respectively. The Company recognized interest expense of $4.9 million and $4.5 million during the nine months ended September 30, 2021 and 2020, respectively.

Senior Secured Notes

The carrying value of the Company's senior secured notes consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Principal amount	$ 43,125	$ 50,000
Accrued and unpaid interest	1,234	1,278
Unamortized debt discount	(8,062)	(9,376)
Total	$ 40,339	$ 41,902

On March 12, 2020, Old Clarus issued and sold senior secured notes to certain lenders not related to the Company. The aggregate principal amount of the senior secured notes was $50.0 million and Old Clarus received $42.7 million in net proceeds after deducting transaction expenses of $4.4 million and prepaid interest of $2.9 million.

In the second quarter of 2021, Old Clarus added two additional notes to the principal senior secured notes balance, the PIK Note (as defined and further described below) and the Indenture Note (as defined and further described below), totaling $8.1 million. In the third quarter of 2021, the Company added one additional note to the principal senior secured notes balance, the Second Indenture Note (as defined and further described below), totaling $3.6 million.

As part of the Merger (as further described in Note 1), $10.0 million of the principal on the senior secured notes and certain royalty rights were exchanged for an 1,500,000 shares of the Company's common stock and converted at a price of $10.20 per share. Further, under a share allocation agreement entered into by Blue Water and Old Clarus on September 1, 2021, as part of the Merger, an additional 405,000 shares of the Company's

common stock were allocated to the senior secured noteholders (which included 270,000 shares reallocated from Old Clarus's equity holders and 135,000 shares that were transferred from the Sponsor pursuant to the share allocation agreement), and converted at a price of $10.20 per share. Further, an additional $5.0 million of the principal of the senior secured notes balance associated with the Indenture Note and $3.6 million of the principal of the senior secured notes balance associated with the Second Indenture Note, plus related accrued interest, were exchanged for an aggregate 882,318 shares of the Company's common stock, which converted at a price of $10.00 per share.

As a result of the exchange of the principal on the senior secured notes and certain royalty rights for shares of the Company's common stock, the Company wrote off $18.6 million of principal associated with the senior secured notes, $1.5 million of the remaining unamortized debt discount associated with the senior secured notes, and the full carrying value of $11.5 million associated with royalty rights obligation. The Company recorded a gain of approximately $0.3 million during the period ending September 30, 2021 as a result of the extinguishment, representing the difference between the carrying value of the debt exchanged and the value of the shares converted based on the conversion price.

The senior secured notes bear interest at 12.5% and specify semiannual payments on March 1 and September 1 and have a maturity date of March 1, 2025. The first two years provide for interest-only payments with principal payment beginning in 2022. The senior secured notes are governed by an indenture, dated as of March 12, 2020, between Old Clarus and the investors. The interest rate will increase to 14.50% for overdue installments in the event of default. In addition to liquidation preference, the senior secured notes contain a lien on all assets of Old Clarus.

Future principal payments of the senior secured notes are as follows (in thousands):

Years ended December 31,	Amount
2021 (remaining 3 months)	$ —
2022	6,000
2023	15,125
2024	14,000
2025	8,000
Total	$43,125

The senior secured notes had a detachable royalty feature under which the lenders were to receive a royalty of 0.56% to 1.67% on net sales beginning in 2021, with the royalty obligation continuing until the lenders receive total royalty payments of approximately $24.2 million. The value assigned to royalty rights was recorded as a debt discount to the Notes and is amortized to interest expense over the life of the notes. For the three months ended September 30, 2021 and 2020, the Company recorded $0.7 million and $0.6 million, respectively, of interest expense associated with the royalty rights. For the nine months ended September 30, 2021 and 2020 the Company recorded $2.2 million and $1.4 million, respectively, of interest expense associated with the royalty rights. The royalty obligation had a fair value of $7.9 million at issuance in March of 2020. Pursuant to the Merger Agreement and conversion terms, no royalty obligation exists as of September 30, 2021.

During the three months ended September 30, 2021 and 2020, the Company recorded $2.6 million and $2.1 million, respectively in interest expense on the senior secured notes, of which $0.7 million and $0.7 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and debt issue costs. During the nine months ended September 30, 2021 and 2020, the Company recorded $7.2 million and $5.0 million, respectively, in interest expense on the senior secured notes, of which $2.0 million and $1.5 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and issue costs. The Company did not make any cash interest payments during the three and nine months ended September 30, 2021 and 2020.

Pursuant to the indenture governing the senior secured notes, Old Clarus agreed to maintain cash and cash equivalents in an amount of not less than $10.0 million, calculated as of the last day of each calendar month, commencing on March 31, 2020. As of December 31, 2020, Old Clarus' cash and cash equivalents were less than $10.0 million, resulting in a default under the indenture and the negotiation of a forbearance agreement, as noted below. In connection with the Merger, the indenture was amended to require the Company to maintain a balance of not less than $8.0 million in cash and cash equivalents, calculated as of the last day of each calendar month.

The Company has classified the full carrying value of $40.3 million related to the senior secured notes as a current liability within the September 30, 2021 balance sheet as, if the Company is unable to obtain funding or generate operating cash flow, the Company does not expect that it will be in compliance with the covenants under the senior secured notes within one year of the balance sheet date. Refer to Note 1 for further disclosure related to the Company's assessment of the ability to operate as a going concern as of September 30, 2021.

Forbearance Agreement

On March 17, 2021, Old Clarus entered into a forbearance agreement with noteholders in relation to the senior secured notes. Old Clarus was unable to and did not pay interest of $3.1 million due on March 1, 2021. As of March 31, 2021, Old Clarus entered into default on its senior secured notes, and in accordance with the terms of the senior secured notes, the interest increased to 14.5%.

Under the forbearance agreement, in exchange for the investors' agreement not to exercise their rights to retrieve the funds owed, Old Clarus was required to maintain cash and cash equivalents of at least $2.5 million amongst other financial budgeting and reporting requirements until consummation of the Business Combination. Under the forbearance agreement, the forbearance period would not be terminated provided that Old Clarus, amongst other things, executed the Merger Agreement and provided financial reporting requirements by April 27, 2021.

Forbearance Extension

In August 2021, Old Clarus entered into forbearance extensions with the noteholders in relation to the senior secured notes. The latest forbearance extension, entered into on August 26, 2021, extended the forbearance period through September 9, 2021, the Closing Date of the Merger.

On September 28, 2021, the Company entered into a supplemental indenture with the noteholders in relation to the senior secured notes. The supplemental indenture extended the due date of the $3.9 million interest payment due September 1, 2021 to March 1, 2022, and further accrues interest on the past interest due amount at a rate of 18.5% per annum beginning on September 1, 2021 until paid.

PIK Note

In May 2021, Old Clarus entered into a payment-in-kind, or PIK, note (the "PIK Note"), in relation to its missed interest payment (which was due in March 2021) on its senior secured notes, pursuant to which Old Clarus borrowed an aggregate of $3.1 million from senior secured noteholders, to be included in the principal senior secured notes balance. The PIK Note accrues interest at a rate of 14.5%, compounded daily. Pursuant to the PIK Note, on February 1, 2023 the Company is required to make a payment of principal in the amount of $3.1 million, plus accrued and unpaid interest in respect of such principal.

Indenture Note

In June 2021, Old Clarus entered into the Indenture Note (the "Indenture Note"), pursuant to which it borrowed an aggregate of $5.0 million from senior secured noteholders, to be included in the principal senior secured notes balance. The Indenture Note accrues interest at a rate of 14.5%, compounded daily, and was repaid with the Company's common stock upon the closing of the Merger.

Second Indenture Note

In July 2021, Old Clarus entered into an additional note purchase agreement (the "Second Indenture Note") pursuant to which it borrowed an aggregate of $3.6 million from senior secured noteholders. The outstanding balance under the Second Indenture Note accrues interest at a rate of 14.5%, compounded daily, and was repaid with the Company's common stock upon the closing of the Merger.

PPP Loan

In March of 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted to, among other provisions, provide emergency assistance for individuals, families and businesses affected by the COVID-19 pandemic. The CARES Act includes a Paycheck Protection Program ("PPP") administered through the Small Business Association ("SBA"). Under the PPP, beginning April 3, 2020, small businesses and other entities and individuals could apply for loans from existing SBA lenders and other approved regulated lenders that enroll in the program, subject to numerous limitations and eligibility criteria.

In April of 2020, Old Clarus received an unsecured loan of $0.5 million from the SBA. After considering further guidance issued by the SBA, Old Clarus elected to repay the loan in full in May of 2020 with no interest due under safe harbor provisions of the CARES Act.

8. Stockholders' Equity (Deficit)

The condensed consolidated statement of stockholders' equity (deficit) has been retroactively adjusted for all periods presented to reflect the Business Combination and reverse recapitalization as defined in Note 3, *Business Combination*.

Preferred Stock

Pursuant to the terms of the Amended and Restated Certificate of Incorporation dated September 9,2021, the Company authorized 10,000,000 shares of preferred stock with a par value of $0.0001. The Company's Board of Directors has the authority, without further action by the stockholders, to issue such shares of preferred stock in one or more series, to establish from time to time the number of share to be included in each such series, and to fix the designations, powers, voting, and other rights, preferences and privileges of the shares. There were no issued and outstanding shares of preferred stock as of September 30, 2021.

In connection with the closing of the Business Combination, all previously issued and outstanding shares of Series A Preferred Stock, Series B Preferred Stock, and Series C Preferred Stock were cancelled and extinguished. Further, all previously issued and outstanding Series D Preferred Stock was cancelled and exchanged for 4,901,564 shares of the Company's common stock.

Common Stock

Pursuant to the terms of the Amended and Restated Certificate of Incorporation, the Company authorized 125,000,000 shares of common stock with a par value of $0.0001. Immediately following the closing of the Business Combination and as of September 30, 2021, there were 21,725,817 shares of common stock issued and outstanding.

As discussed in Note 3, *Business Combinations*, the Company has retroactively adjusted the shares issued and outstanding prior to September 9, 2021 to give effect to the actual shares for which the Series D preferred stock converted into as a result of the conversion terms in the Merger Agreement.

Voting

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders.

Dividends

Common stockholders are entitled to receive dividends, as may be declared by the board of directors. No dividends have been declared to date.

9. Stock-Based Compensation

2004 Old Clarus Stock Incentive Plan

Effective February 13, 2004, Old Clarus adopted the Clarus Therapeutics 2004 Stock Incentive Plan (the "2004 Plan"). The 2004 Plan was amended on January 28, 2011 to increase the number of shares of Old Clarus's common stock reserved for issuance to employees, directors, and consultants to 1,529,936 shares. Options granted under the 2004 Plan could have been incentive stock options or non-statutory stock options. Restricted stock awards were also granted under the 2004 Plan. Incentive stock options could only be granted to employees. Options generally vested over a four-year period. The exercise price of incentive stock options could be not less than 100% of the fair market value per share of Old Clarus's common stock on the grant date. The awards granted under this plan generally vested over a four-year period and had a 10-year contractual term.

At the Effective Time, the 2004 Plan and all options issued and outstanding, whether vested or unvested, were cancelled and extinguished.

2014 Old Clarus Stock Option and Incentive Plan

Effective February 13, 2014, Old Clarus adopted the Clarus Therapeutics 2014 Stock Option and Incentive Plan (the "2014 Plan") and reserved 1,000,000 shares of Old Clarus common stock for the issuance of awards under the 2014 Plan. The 2014 Plan permitted Old Clarus to make grants of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards, performance share awards and dividend equivalent rights. To qualify as incentive options, stock options must have met additional federal tax requirements, including a $100,000 limit on the value of shares subject to incentive options that first become exercisable in any calendar year, and a shorter term and higher minimum exercise price in the case of certain large stockholders. All full-time and part-time officers, employees, non-employee directors and other key persons, including consultants and prospective employees, were eligible to participate in the 2014 Plan, subject to the sole discretion of the administrator. On December 15, 2017, April 17, 2019 and again on December 18, 2020, the 2014 Plan was amended, increasing the total shares of Old Clarus common stock reserved for issuance by 416,500, 26,140, and 3,000,000 shares, respectively, for a total of 4,442,640 shares of Old Clarus common stock available for award in the 2014 Plan. The awards granted under this plan generally vest over a four-year period and have a 10-year contractual term.

At the Effective Time, the 2014 Plan was terminated and all options issued and outstanding, whether vested or unvested, were cancelled and extinguished.

Clarus Therapeutics Holdings Inc. 2021 Stock Option and Equity Incentive Plan

On August 27, 2021 the Company's stockholders approved the Clarus Therapeutics Holdings Inc. 2021 Stock Option and Equity Incentive Plan (the "2021 Plan"). The 2021 Plan provides for the Company to make equity and equity-based incentive awards to officers, employees, directors and consultants. Pursuant to the 2021 Plan, an initial 3,475,000 shares of the Company's common stock were reserved for issuance (the "Initial Limit"). The 2021 Plan provides that the shares reserved and available for issuance under the 2021 Plan will automatically increase each January 1, beginning on January 1, 2022, by 4% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser amount as determined by the plan administrator (the "Annual Increase"). As of September 30, 2021 no awards have been granted and no shares were issued under the 2021 Plan.

Clarus Therapeutics Holdings, Inc. Employee Stock Purchase Plan

On August 12, 2021 the Company's stockholders approved the Clarus Therapeutics Holdings Inc. Employee Stock Purchase Plan (the "ESPP"). An aggregate of 347,500 shares were reserved and available for issuance under the 2021 ESPP. The 2021 ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 347,500 shares of the Company's common stock, 1.0% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, or such lesser amount as determined by the ESPP administrator. As of September 30, 2021 the Company had not issued any shares under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Selling and marketing	$ 6	$ —	$ 15	$ —
Research and development	19	15	52	54
General and administrative	182	75	491	180
Total stock-based compensation expense	$ 207	$ 90	$ 559	$ 234

As of September 30, 2021, there was no unrecognized stock-based compensation expense related to unvested stock options as no options have been granted under the 2021 Plan. At the Effective Time, the 2004 Plan and 2014 Plan were terminated and all options issued and outstanding, whether vested or unvested, were cancelled and extinguished. As a result, the Company recognized approximately $0.2 million of previously unrecognized stock-based compensation expense related to unvested stock options under the 2004 Plan and 2014 Plan during the period ended September 30, 2021.

10. Income Taxes

The Company did not record a federal or state or income tax provision or benefit for the nine months ended September 30, 2021 or 2020 due to the expected loss before income taxes to be incurred, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss ("NOL") carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed a study to assess whether an "ownership change" has occurred or whether there have been multiple ownership changes since we became a "loss corporation" as defined in Section 382. Future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an "ownership change" has occurred or does occur in the future, utilization of the NOL carryforwards or other tax attributes may be limited, which could potentially result in increased future tax liability to us.

11. License Agreements

Agreement with HavaH

In May 2021, Old Clarus entered into a license agreement (the "HavaH Agreement") with HavaH Therapeutics, or HavaH, an Australia-based biopharmaceutical company developing androgen therapies for inflammatory breast disease and certain forms of breast cancer. Under the HavaH Agreement, the Company will acquire the development and commercialization rights for HavaH T+Ai™, to be renamed CLAR-121.

Under the terms of the licensing agreement, HavaH may be eligible for up to $10.8 million in potential development and regulatory milestone payments. Additionally, HavaH would be eligible for royalty payments and up to $30.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of CLAR-121 in the territory, at a low single digit percentage rate (when there is no patent protection or regulatory exclusivity) or a low teens percentage rate (where CLAR-121 has patent protection or regulatory exclusivity). Additionally, such royalties are payable until the later of ten years or the loss of patent protection or regulatory exclusivity.

To date, pursuant to the HavaH Agreement, the Company has made cash payments of $0.5 million consisting of the upfront payment.

Agreement with The Royal Institution for the Advancement of Learning/McGill University

In September 2021, the Company entered into a license agreement (the "McGill Agreement") with The Royal Institution for the Advancement of Learning/McGill University, or McGill, a Canadian University. Under the agreement, the Company will develop and commercialize McGill's proprietary technology designed to treat conditions associated with CoQ10 deficiencies in humans.

Under the terms of the licensing agreement, McGill may be eligible for up to $10.5 million in potential development and regulatory milestone payments. Additionally, McGill would be eligible for royalty payments and up to $15.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of any licensed products that are covered by the licensed patents in the territory, at a low single digit percentage rate.

To date, pursuant to the McGill Agreement, the Company has made cash payments of $0.4 million consisting of the upfront payment.

12. Commitments and Contingencies

Lease Commitments

The Company leases office space in Northbrook, Illinois and Murfreesboro, Tennessee under non-cancelable operating leases that expire on December 31, 2021 and September 30, 2022, respectively. Total rent expense under the lease agreements was $0.1 million for the nine months ended September 30, 2021 and 2020, respectively.

A summary of the Company's future minimum lease payments required under non-cancellable lease agreements is as follows (in thousands):

Years ended December 31,	Amount
2021 (remaining 3 months)	$ 24
2022	16
2023	—
2024	—
2025	—
Total	$ 40

Purchase Obligation

In July of 2009, Old Clarus entered into a commercial manufacturing agreement, as amended, with Catalent Pharma Solutions, LLC (the "Catalent Agreement"). Pursuant to the terms of the Catalent Agreement, the Company must make minimum annual purchases of JATENZO equal to 7.0 million softgels, through the initial term, or March 2025. Any shortfall between the minimum annual purchase quantities and actual purchases will be multiplied by a unit price, as defined in the Catalent Agreement, and paid to Catalent within 30 days of any year-end that the minimum purchase requirement is not met. The Company has not made any payments to Catalent as a result of a shortfall in minimum purchase quantities. The Catalent Agreement renews automatically for two-year periods and either party may terminate the contract upon twelve months written notice. Purchases under the Catalent Agreement for the three months ended September 30, 2021 and 2020 were $0.9 million and $0.1 million, respectively. Purchases under the Catalent Agreement for the nine months ended September 30, 2021 and 2020 were $6.0 million and $3.1 million, respectively.

Old Clarus entered into a product supply agreement with Pharmacia & Upjohn Company LLC, or Pfizer (the "Pfizer Agreement"), effective January 1, 2021. Pursuant to the terms of the Pfizer Agreement, the Company must make minimum annual purchases of T-undecanoate equal to approximately $1.8 million per year, through the initial term, or January 2024. If there is a shortfall between the minimum annual purchase quantities and actual purchases, the difference between the minimum annual purchase amount and actual purchases will be paid to Pfizer by the Company. There were no purchases under the Pfizer Agreement during the three and nine months ended September 30, 2021.

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations.

On April 2, 2019, an action for patent infringement was filed against Old Clarus by Lipocine in the U.S. District Court for the District of Delaware. The lawsuit (Civil Action No. 19-cv-622, assigned to Judge William Bryson, U.S. Court of Appeals for the Federal Circuit, sitting by designation) sought a declaratory judgement of infringement under 35 U.S.C. § 271(a)-(c) arising from Old Clarus' intent to market and sell JATENZO, based on the FDA's approval of JATENZO in March 2019. Lipocine ultimately alleged that Old Clarus infringed certain claims in each of four U.S. Patents: U.S. Patent No. 9,034,858, U.S. Patent No. 9,205,057, U.S. Patent No. 9,480,690 and U.S. Patent No. 9,757,390. Lipocine sought monetary damages in the form of a reasonable royalty, pre-judgment interest, post-judgment interest, and attorneys' fees, costs and disbursements, and injunctive relief.

Old Clarus asserted defenses of noninfringement and invalidity under 35 U.S.C. §§ 103 and 112, and asserted counterclaims of inequitable conduct, patent misuse and exceptional case. Old Clarus's motion for summary judgment of invalidity under Section 112 was argued on January 15, 2021, and was granted on May 25, 2021, the decision finding all asserted claims invalid for failure to satisfy the written description requirement. On June 15, 2021, Old Clarus requested the Court to schedule a bench trial on Old Clarus's counterclaims of inequitable conduct, patent misuse, and exceptional case at the earliest practicable date, pursuant to the Court's invitation to make such a request.

In July 2021, Old Clarus and Lipocine entered into a settlement agreement that settled all claims between the parties, including the interference matter (described above) and the pending Old Clarus counterclaims against Lipocine, and provides for a payment by Lipocine to Old Clarus of a $4.0 million settlement fee payable as follows: $2.5 million upfront, $1.0 million within 12 months, and the remainder within two years. The Company is recognizing the payments in income as they are received. The Company received payment of $2.5 million of the $4.0 million in July 2021, which is recorded within the litigation settlement line in other income and expense on the statement of operations.

Pursuant to the settlement agreement, a joint stipulation for dismissal was filed, and was so ordered by the Court on July 15, 2021, thereby terminating the district court action. Moreover, and as part of this settlement, Lipocine filed a request for entry of an adverse judgment in Interference No. 106,128 on July 16, 2021. Judgment against Lipocine in Interference No. 106,128 was entered by the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) on July 26, 2021. The Company believes that its '178 application will proceed to issuance following what it believes will be entry of a decision adverse to Lipocine by the PTAB.

13. Net Income (Loss) Per Share

As a result of the Merger, the shares and loss per share related to Old Clarus's outstanding convertible preferred stock and common stock prior to the Merger have been retroactively restated to reflect the actual shares for which the Series D preferred stock converted into as a result of the conversion terms in the Merger Agreement. Basic and diluted earnings (loss) per share attributable to common stockholders are calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss (income)	$ (2,769)	$ 5,406	$ (36,315)	$ 4,067
Earnings attributable to Old Clarus participating warrants (1)	—	(10)	—	(8)
Gain on extinguishment of convertible notes (2)	412	—	412	—
Net (loss) income attributable to common stockholders, basic	(2,357)	5,396	(35,903)	4,059
Effect of convertible notes (3)	—	(19,139)	—	(48,338)
Net loss attributable to common stockholders, diluted	$ (2,357)	$ (13,743)	$ (35,903)	$ (44,279)
Denominator:				
Weighted-average common shares attributable to common stockholders, basic	9,153,848	4,901,564	6,318,992	4,901,564
Effect of convertible notes (4)	—	16,927,006	—	16,927,006
Weighted average number of common shares - diluted	9,153,848	21,828,570	6,318,992	21,828,570
Net loss per common share attributable to common stockholders, basic	$ (0.26)	$ 1.10	$ (5.68)	$ 0.83
Effect of convertible notes	—	(1.73)	—	(2.86)
Net loss per common share attributable to common stockholders, diluted	$ (0.26)	$ (0.63)	$ (5.68)	$ (2.03)

(1) The loss attributable to Old Clarus participating warrants relates to the total earnings attributable to the 9,246 Old Clarus participating warrants using the two-class method.

(2) The gain on extinguishment of convertible notes relates to the difference between the carrying value of the convertible notes upon conversion to shares and the fair value of the shares exchanged which requires adjustment to the numerator when calculating basic EPS.

(3) The effect of the convertible notes on the numerator for the three and nine months ended September 30, 2020 relates to the impact that the convertible notes had on net income during the period, and are removed from net income when calculating net income (loss) attributable to common stockholders diluted using the if-converted method.

(4) The effect of convertible notes on the denominator for the three and nine months ended September 30, 2020 was calculated based on the carrying value of the convertible notes balance at September 30, 2020, converted at the series D price of $4.50 per share and are added back to the denominator when calculating diluted EPS using the if-converted method.

The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of September 30, 2021 and 2020 because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Convertible notes	—	—	—	—
Old Clarus Warrants	9,246	—	9,246	—

The convertible notes including interest for redeemable convertible preferred stock, which as of September 30, 2020 would be convertible into 16,927,006 shares common stock using the as-if converted method, are included in the calculation of diluted earnings per share for the three and nine months ended September 30, 2020. Upon completion of the Merger on September 9, 2021, the convertible notes converted into shares of common stock and thus do not have an impact on diluted EPS for the three and nine months ended September 30, 2021

As of the three months and nine months ended September 30, 2021, the Company's potentially dilutive securities, which include the Old Clarus Series D warrants to purchase common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is not impacted by these securities.

14. Related Party Transactions

In July of 2020, a member of Old Clarus' board of directors, who is now a member of the Company's board of directors, temporarily expanded his director duties as an executive director, at the request of the Company's board of directors. As executive director, this member received a total of $0.2 million in consulting fees during the nine months ended September 30, 2021.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and Old Clarus's audited financial statements and notes thereto for the year ended December 31, 2020 included in the Prospectus as filed with the Securities and Exchange Commission pursuant to Rule 424(b)(3) on October 7, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Unless otherwise indicated or the context otherwise requires, references in this Management's Discussion & Analysis of Financial Condition and Results of Operations section to "Clarus," "we," "us," "our" and other similar terms refer to Old Clarus (as defined below) prior to the Business Combination (as defined below) and to the Company and its consolidated subsidiary after giving effect to the Business Combination.

Overview

We are a pharmaceutical company focused on the commercialization of JATENZO, the first and only oral T-replacement, or T-replacement therapy ("TRT") of its kind that has received final approval by the U.S. Food and Drug Administration ("**FDA**"). We believe that current users of TRT are not satisfied with their current options and desire a therapeutic that is safe, effective and more convenient. Our primary goal for JATENZO is for it to become the preferred choice for TRT among men with hypogonadism — T deficiency accompanied by an associated medical condition. In parallel, our broader vision is for Clarus to become a profitable pharmaceutical company dedicated to providing solutions to unmet medical needs by advancing androgen and metabolic therapies for men and women.

Our corporate objectives include maximizing the commercial success of JATENZO in the United States and internationally by making it the preferred choice for TRT for men with hypogonadism, expanding its research and development portfolio with additional metabolic therapies for men and women and sourcing new technologies through its business development efforts.

We believe JATENZO offers hypogonadal men and prescribing physicians a safe and effective oral replacement option and has a number of advantages over the currently approved replacement therapies, including:

CONVENIENT

- Easy-to-swallow softgel taken BID with food (twice daily)
- Dose adjustable

EFFECTIVE

- 87% of men achieved T levels in normal range
- Restored T levels to mid-normal range

SAFE

- Safety profile consistent with TRT class
- No liver toxicity — JATENZO bypasses first-pass hepatic metabolism; liver toxicity not observed in clinical studies of up to 2 years duration.

In March 2019, our first commercial product, JATENZO, was approved by the FDA as a TRT for the treatment of adult men with hypogonadism due to certain medical conditions. JATENZO is the first oral T therapy approved by the FDA in more than 60 years. JATENZO is a T-ester prodrug created by the linkage of T with the fatty acid undecanoic acid to form T-undecanoate ("**TU**"). Once absorbed, TU, an inactive version of T, is converted by natural enzymes in the body to bioactive T. In February 2020, we commenced U.S. commercial sales of JATENZO and, as of December 31, 2020, JATENZO was available under health plans representing approximately 61% of U.S. commercial insured lives. Of these patients, 65% had access to JATENZO without having to try another T product first (e.g., generic or other branded option). For the three and nine months ended September 30, 2021, JATENZO generated net revenues of approximately $4.3 million, and $9.4 million, respectively, demonstrating consistent prescription and sales growth despite the commercial challenges presented by the COVID-19 pandemic. Total prescription growth for JATENZO for the three months ended September 30, 2021 increased 12% as compared to the prior quarter, and 132% as compared to the prior year period. In August 2019, the FDA granted 3-year Hatch-Waxman market exclusivity to JATENZO, which prevents the FDA from granting full market approval to similar new drugs or generic competitors of JATENZO until March 27, 2022.

We continue to work on several life cycle management projects for JATENZO, including a label expansion to treat hypogonadal men with CKD, development of a once-daily oral TU with Phase 2 clinical trial initiation anticipated in the first half of 2022, and a label expansion to provide T therapy for female-to-male transgender individuals, with a Phase 4 clinical trial initiation anticipated in the first half of 2022.

Our U.S. patent portfolio on JATENZO currently includes five issued patents expiring between March 2029 and December 2030 and we recently received two notices of allowance from the United States Patent and Trademark Office (USPTO) for claims that cover JATENZO. The issued U.S. patents contain claims to both pharmaceutical compositions and methods of treatment using our proprietary pharmaceutical composition and all are listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. In addition, we have several patent applications pending in the United States and other countries that, if issued, will cover pharmaceutical compositions, methods of treatment and other features of JATENZO, and have the potential to extend patent coverage beyond 2030.

We also have issued patents covering JATENZO in Australia, Canada, China, Costa Rica, Europe, Hong Kong, India, Indonesia, Israel, Japan, Mexico, New Zealand, Philippines, Russia, Singapore, South Africa and South Korea.

Since the beginning of Old Clarus's operations in 2004, Old Clarus focused primarily on developing and progressing JATENZO through clinical development, organizing and staffing, research and development activities, raising capital and commercial launch activities. We have one product approved for sale, JATENZO, as of September 30, 2021. Old Clarus funded operations primarily with proceeds from the sale of convertible preferred stock and debt through convertible and senior secured notes, including a royalty obligation. Through September 30, 2021, we have received gross proceeds of $104.2 million from investors in Old Clarus's Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock and Series D Preferred Stock, gross proceeds of $82.3 million from investors in Old Clarus's issued convertible debt, gross proceeds of $61.7 million from investors in issued senior secured notes and related royalty obligation, and net proceeds of $17.0 million from Blue Water in connection with the closing of the Business Combination.

Merger

On the Closing Date, we, together with Blue Water Merger Sub Corp., a Delaware corporation and our wholly-owned subsidiary ("Merger Sub"), consummated the previously announced merger, pursuant to the Agreement and Plan of Merger, dated as of April 27, 2021 (the "Merger Agreement"), with Clarus Therapeutics, Inc., a Delaware corporation ("Old Clarus"), pursuant to which, subject to the terms and conditions set forth in the Merger Agreement, Merger Sub merged with and into Old Clarus, with Old Clarus surviving as our wholly-owned subsidiary, and with Old Clarus's equity holders and convertible debt holders equity interests converted into the right to receive shares of the our common stock or else be canceled, retired and terminated without consideration, as provided in the Merger Agreement (the "Merger"). Upon the consummation of the business combination, Blue Water changed its name to "Clarus Therapeutics Holdings, Inc."

In connection with the Merger, Old Clarus's convertible noteholders and senior secured noteholders provided $25.0 million in additional capital to Old Clarus following the announcement of the execution of the Merger Agreement. All such proceeds plus accrued interest converted to shares of the our common stock at a price of $10.00 per share at the Closing Date, resulting in 2,549,939 shares issued. The additional capital of $25.0 million was received by the Old Clarus prior to the Closing Date. Together with Blue Water's cash resources and additional capital, the combined company received net proceeds from the Merger (not including the $25.0 million of additional capital) of approximately $17.0 million.

At the effective time of the Merger (the "Effective Time"), shares of Old Clarus's redeemable convertible Series D Preferred Stock issued and outstanding and all principal and accrued interest under Old Clarus's Series D convertible notes immediately prior to the Effective Time converted into 13,431,410 shares of our common stock at a price of $10.20 per share. Additionally, $10.0 million of debt related to Old Clarus' senior secured notes including certain royalty rights was exchanged for an aggregate 1,905,000 shares of our common stock (which included 405,000 shares of our common stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement, of which 270,000 shares were reallocated from Old Clarus's equity holders and 135,000 shares that were transferred from the Sponsor). All unexpired, outstanding Series D Warrants of Old Clarus remained outstanding and became exercisable for shares of our common stock, subject to adjustment in accordance with the Merger exchange ratio

All other series of Old Clarus preferred stock, common stock and stock options were cancelled and extinguished upon completion of the Merger. In addition, Old Clarus's existing equity incentive plans were terminated.

As a result of the Merger, we operate under Old Clarus's management team. Dr. Dudley serves as our Chief Executive Officer and President. Frank Jaeger, our Chief Commercial Officer, and the architect of AndroGel 1.62%'s sales and marketing efforts that resulted in annual peak sales of over $1 billion, will continue to lead commercialization efforts for JATENZO. Mr. Jaeger has built a team with vast experience in the TRT field. Kimberly Murphy, former VP, Global Vaccines Commercialization (Influenza) at GSK was named Chairperson of our board after the closing of the business combination.

Risks and Liquidity

Since inception, we have incurred significant operating losses and have experienced negative operating cash flows. Our net losses were $2.7 million and $36.3 million for the three and nine months ended September 30, 2021. As of September 30, 2021, we had an accumulated deficit of $317.3 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future if and as we:

- continue to commercialize JATENZO in the United States for the treatment of adult males with a deficiency or absence of endogenous T;

- incur sales and marketing costs to support the commercialization of JATENZO;
- incur contractual manufacturing costs for JATENZO;
- implement post-approval requirements related to JATENZO;
- actively pursue additional indications and line extensions for JATENZO for the treatment of adult males with a deficiency or absence of endogenous T;
- seek to attract and retain new and existing skilled personnel;
- invest in measures to protect and expand our intellectual property;
- seek to discover and develop additional product candidates;
- seek to in-license or acquire additional product candidates for other medical conditions;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts;
- create additional infrastructure to support operations as a public company and incur increased legal, accounting, investor relations and other expenses; and
- experience delays or encounters issues with additional outbreaks of the pandemic in addition to any of the above.

We expect to incur significant expenses related to developing an internal commercialization capability to support product sales, marketing and distribution. Furthermore, we now expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. To the extent that we raise additional capital through the sale of private or public equity or convertible debt securities, existing ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Private and public equity offerings and debt financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations or other strategic transactions with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the commercialization efforts of our product, JATENZO, and/or any product portfolio expansion.

Because of the numerous risks and uncertainties associated with being a commercial stage pharmaceutical company and our efforts to grow our business by means of product and business development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Old Clarus began product sales in 2020, and if we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. These factors raise substantial doubt about our ability to continue as a going concern. Management believes that our existing cash and cash equivalents of $22.0 million as of September 30, 2021, will not be sufficient to fund our operating expenses and capital expenditure requirements for the next 12 months without additional capital. See “— Liquidity and Capital Resources.”

COVID-19 Business Update

The business disruptions associated with the COVID-19 pandemic had a significant negative impact on our financial statements for the nine months ended September 30, 2021 and for the year ended December 31, 2020. Management expects that the public health actions being undertaken to reduce the spread of the virus, and that will have to be undertaken again in the event of a resurgence of the virus, will create significant disruptions to us with respect to: (i) the demand for our products, (ii) the ability of our sales representatives to reach healthcare customers, (iii) our ability to maintain staffing levels to support our operations, (iv) our ability to continue to manufacture certain of our products, (v) the reliability of our supply chain and (vi) our ability to achieve the financial covenants required by the senior secured notes agreement. The extent to which the COVID-19 pandemic will impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We are closely monitoring the evolving impact of the pandemic on all aspects of our business. We have implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. We are also actively reviewing and implementing cost-saving measures including discontinuing or delaying all non-essential services and programs and instituting controls on travel, events, marketing and clinical studies to adapt the business plan for the evolving COVID-19 challenges.

We expect to have an adequate supply of JATENZO through the end of 2022. We are working closely with our third-party manufacturers, distributors and other partners to manage our supply chain activities and mitigate potential disruptions to product supplies as a result of the COVID-19 pandemic.

Components of Our Results of Operations

Product Revenue

Old Clarus did not generate any product revenue from inception until 2020. Our first commercial product, JATENZO, was approved by the FDA as a treatment for adult males with a deficiency or absence of endogenous testosterone, in March 2019 and became commercially available in February 2020.

Total revenue consists of net sales of JATENZO. Net sales represent the gross sales of JATENZO less provisions for product sales discounts and allowances. These provisions include trade allowances, rebates to government and commercial entities, copay costs and other customary sales discounts. Although we expect net sales to increase over time, the provisions for product sales discounts and allowances may fluctuate based on the mix of sales to different customer segments and/or changes in accrual estimates.

Cost of Product Sales

Cost of product sales includes manufacturing and distribution costs, the cost of the drug substance, FDA program fees, royalties due to third parties on net product sales, freight, shipping, handling, storage costs and salaries of employees involved with production. We began capitalizing inventory upon FDA approval of JATENZO. A portion of the inventory sold during the year ended December 31, 2020 was produced prior to FDA approval and, therefore, expensed previously as research and development expense in 2019 in the amount of $0.7 million.

We expect that our cost of product sales will increase moderately in the near term as we ramp up production to meet anticipated demand for JATENZO.

The shelf life of JATENZO is thirty months from the date of manufacture, with earliest expiration of current inventory expected to be June 2023. Due to the low rate of inventory turnover generated by our commercial launch efforts for JATENZO during a global pandemic, we recorded a reserve for inventory obsolescence of $7.8 million in the nine months ended September 30, 2020. Absent this charge, the gross profit for the nine months ended September 30, 2020 was $3.4 million. We will continue to assess obsolescence in future periods as demand for JATENZO and the rate of inventory turnover evolves.

Operating Expenses

Selling and Marketing Expenses

Sales and marketing expenses consist primarily of commercialization expenses related to JATENZO, commercially launched in February of 2020. Prior to the commercial launch, we had significantly lower selling and marketing expenses. We anticipate that our sales and marketing expenses will increase in 2021 as we continue to expand our commercialization of JATENZO.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, such as salaries, stock-based compensation, benefits and travel expenses for personnel in executive, legal, finance and accounting, human resources, and other administrative departments. General and administrative expenses also consist of office leases, and professional fees, including legal, tax and accounting and consulting fees.

We anticipate that our general and administrative expenses will increase in the future to support continued commercialization efforts, ongoing and future potential research and development activities, and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees paid to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with the requirements of Nasdaq and the SEC, insurance and investor relations costs.

Research and Development Expenses

Research and development expenses have primarily been limited to clinical trials, and chemistry, manufacturing, and controls ("**CMC**"), and CMC activities related to JATENZO. Our research and development costs as incurred, include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- post-marketing requirements of the FDA for JATENZO and pharmaceutical development expense related to our recently in-licensed products; and
- costs of outside consultants, including their fees and related travel expenses engaged in research and development functions.

We currently have one product, JATENZO, and do not currently track internal research and development expenses on an indication-by-indication basis as they primarily relate to personnel, early research and consumable costs, which are deployed across multiple programs. A significant portion of research and development costs are external costs, such as fees paid to consultants, central laboratories, contractors, contract manufacturing organizations, contract research organizations and companies that manufacture clinical trial materials and potential future commercial supplies. We began capitalizing the costs associated with the production of JATENZO after the FDA approval in March 2019.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs will increase as we conduct additional clinical trials for JATENZO and conduct further developmental activities for our research and development pipeline programs.

Total Other Income (Expense), Net

Change in Fair Value of Warrant Liability and Derivative Liability

Change in fair value of warrant liability relates to the change in value of our liability-classified Old Clarus Series D Preferred Stock warrants, and convertible notes derivative liability, which were recognized in connection with our equity financing and certain borrowing arrangements. Such instruments no longer require remeasurement at fair value option due to completion of the Merger.

Subsequent to the completion of the Merger, the change in fair value of the warrant liability relates to the change in fair value of the Private Placement Warrant liabilities, which relate to the Private Placement Warrants issued by Blue Water in its IPO and were assumed by the combined company as part of the Merger. The total change in fair value of the Private Placement Warrants recorded during the three and nine months ended September 30, 2021 was $7.6 million.

Interest Income

Interest income related to our operating bank accounts, including money market funds.

Interest Expense

Interest expense related to Old Clarus's convertible notes, senior secured notes and debt discount amortization.

Litigation Settlement

Litigation settlement relates to cash payment received as a result of the patent infringement lawsuit with Lipocine, as further described in Note 12 in the Notes to the Unaudited Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q. We recognize the cash payments within income as they are received. During the three and nine months ended September 30, 2021, we recognized $2.5 million associated with the first settlement payment received in July 2021.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		
	2021	2020	Change
Net product revenue	$ 4,286	$ 2,224	$ 2,062
Cost of product sales	510	257	253
Gross profit	3,776	1,967	1,809
Operating expenses:			
Sales and marketing	7,550	8,733	(1,183)
General and administrative	3,384	3,040	344
Research and development	1,275	1,437	(161)
Total operating expenses	12,209	13,210	(1,000)
Loss from operations	(8,433)	(11,243)	2,810
Other (expense) income, net:			
Change in fair value of warrant liability and derivative, net	7,610	20,939	(13,329)
Interest income	1	1	—
Interest expense	(4,447)	(4,291)	(156)
Litigation settlement	2,500	—	2,500
Total other (expense) income, net	5,664	16,649	(10,985)
Net (loss) income	$ (2,769)	$ 5,406	$ (8,175)

Net Product Revenue

For the three months ended September 30, 2021, we recorded $4.3 million of net product revenue, which increased by $2.1 million from $2.2 million for the three months ended September 30, 2020. The increase in net revenue is related to the growth of the brand through our sales and marketing efforts. We did not begin commercially selling JATENZO within the United States until February 2020, following FDA approval in March 2019.

Cost of Product Sales

Cost of product sales was $0.5 million for the three months ended September 30, 2021, which increased by $0.2 million, from $0.3 million for the three months ended September 30, 2020. The increase in cost of product sales is related to an increase in product revenue.

Sales and Marketing Expenses

Sales and marketing expenses were $7.5 million for the three months ended September 30, 2021, which decreased by $1.2 million, from $8.7 million for the three months ended September 30, 2020. The decrease in sales and marketing expenses was primarily attributable to the following:

- A $1.7 million decrease in outsourced advertising and promotion costs due to timing of media buys and agency activities;
- a $0.4 million increase in commercial analytic and market research costs, primarily related to prescription and payor data; and
- a $0.1 million decrease in other sales and marketing related costs.

General and Administrative Expenses

General and administrative expenses were $3.4 million for the three months ended September 30, 2021, which increased by $0.3 million, from $3.0 million for the three months ended September 30, 2020. The increase in general and administrative expenses was primarily attributable to the following:

- A $1.0 million increase in personnel costs, including stock-based compensation expense, primarily due to an increase in headcount and external consultants;
- a $0.6 million decrease in consulting and professional fees, primarily due to a decrease in legal fees related to patents; and
- a $0.1 million decrease in other general and administrative costs

Research and Development Expenses

Research and development expenses were $1.3 million for the three months ended September 30, 2021, which decreased by $0.1 million from $1.4 million for the three months ended September 30, 2020. The decrease in research and development expenses was primarily attributable to the following:

- A $1.0 million decrease in costs related to research and development consulting services; offset by
- A $0.9 million increase in license fees related to the License Agreements with HavaH and McGill.

Other (Expense) Income, Net

Total other income, net was $5.6 million for the three months ended September 30, 2021, compared to other income, net of $16.6 million for the three months ended September 30, 2020. The decrease of $10.9 million was primarily related to a $13.3 million decrease in the change in fair value of the warrant liability and derivative, an increase of $2.5 million from a legal settlement received associated with the patent infringement lawsuit with Lipocine, and an increase in interest expense of $0.1 million, related to an increase of $0.2 million in interest incurred with related parties, an increase of $0.2 in interest incurred with third parties, offset by a decrease of $0.3 million associated with a gain on extinguishment of the senior secured notes.

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,		
	2021	2020	Change
Net product revenue	$ 9,395	$ 3,943	$ 5,452
Cost of product sales	1,431	8,328	(6,897)
Gross profit (loss)	7,964	(4,385)	12,349
Operating expenses:			
Sales and marketing	25,017	23,557	1,460
General and administrative	12,316	8,261	4,055
Research and development	3,093	2,818	276
Total operating expenses	40,426	34,636	5,790
Loss from operations	(32,462)	(39,021)	6,559
Other (expense) income, net:			
Change in fair value of warrant liability and derivative, net	7,610	53,854	(46,244)
Interest income	1	24	(23)
Interest expense	(13,964)	(10,790)	(3,174)
Litigation settlement	2,500	—	2,500
Total other (expense) income, net	(3,853)	43,088	(46,941)
Net (loss) income	$(36,315)	$ 4,067	$(40,382)

Net Product Revenue

For the nine months ended September 30, 2021, we recorded $9.4 million of net product revenue, which increased by $5.5 million from $3.9 million for the nine months ended September 30, 2020. The increase in net revenue is related to the timing of when JATENZO became commercially available for sale. We did not begin commercially selling JATENZO within the United States until February 2020, following FDA approval in March 2019.

Cost of Product Sales

Cost of product sales was $1.4 million for the nine months ended September 30, 2021, which decreased by $6.9 million, from $8.3 million for the nine months ended September 30, 2020. The decrease in cost of product sales is related to a reserve for inventory obsolescence of $7.8 million recorded in the nine months ended September 30, 2020, offset by an increase due to increased product revenue sales.

Sales and Marketing Expenses

Sales and marketing expenses were $25.0 million for the nine months ended September 30, 2021, which increased by $1.5 million, from $23.5 million for the nine months ended September 30, 2020. The increase in sales and marketing expenses was primarily attributable to the following:

- A $2.6 million increase in marketing costs, primarily related to the timing of agency activities; and
- a $0.2 million increase in patient assistance costs and other sales and marketing costs; offset by
- a $1.3 million decrease in commercial analytics and market research costs.

General and Administrative Expenses

General and administrative expenses were $12.3 million for the nine months ended September 30, 2021, which increased by $4.1 million, from $8.2 million for the nine months ended September 30, 2020. The increase in general and administrative expenses was primarily attributable to the following:

- A $2.6 million increase in personnel costs, including stock-based compensation expense, primarily due to an increase headcount and external consultants;
- a $0.8 million increase in consulting and professional fees, primarily due to an increase in fees paid to outside accounting and finance consultants and audit fees incurred as a result of becoming a public company;
- a $0.5 million increase in insurance fees, related to directors' and officers' insurance; and
- a $0.2 million increase in other general and administrative expenses.

Research and Development Expenses

Research and development expenses were $3.1 million for the nine months ended September 30, 2021, which increased by $0.3 million from $2.8 million for the nine months ended September 30, 2020. The increase in research and development expenses was primarily attributable to the following:

- A $0.9 million increase in license fees related to the HavaH Agreement and McGill Agreement; and
- a $1.0 million increase in clinical costs related to Phase 4 studies related to the development of JATENZO, our lead commercial product; offset by
- a $1.6 million decrease in costs related to research and development consulting services.

Other (Expense) Income, Net

Total other expense, net was $3.8 million for the nine months ended September 30, 2021, compared to other income of $43.8 million for the nine months ended September 30, 2020. The decrease of $46.9 million was primarily related to a $46.2 million decrease in the change in fair value of the warrant liability and derivative, an increase of $2.5 million associated with a legal settlement received associated with the patent infringement lawsuit with Lipocine, and an increase in interest expense of $3.2 million, related to an increase of $0.4 million in interest incurred with related parties, an increase of $3.1 million in interest incurred with third parties, offset by a decrease of $0.3 million associated with a gain on extinguishment of the senior secured notes.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, Old Clarus has incurred significant operating losses, have experienced negative operating cash flows and have accumulated significant accrued liabilities. Our net loss was $2.7 million and $36.3 million for the three and nine months ended September 30, 2021, respectively. As of September 30, 2021, we had cash and cash equivalents of $22.0 million and an accumulated deficit of $317.3 million. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future. As a result, even with proceeds from the Merger, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions.

Merger

On the Closing Date, we received net proceeds from the Merger of approximately $17.0 million (not including the $25.0 million of additional capital). Further, as a result of the closing of the Merger, approximately $18.6 million of the principal balance of the senior secured notes and the related royalty obligation were exchanged for shares of our common stock, and Old Clarus's equity holders' and convertible debt holders' equity interests converted into the right to receive shares of our common stock or else be canceled, retired and terminated without consideration, as provided in the Merger Agreement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview" for further discussion of the Merger.

Convertible Promissory Notes

On various dates from 2016 to 2021, Old Clarus entered into note purchase agreements, pursuant to which it borrowed an aggregate of $82.3 million from related party investors as of September 30, 2021. The carrying value of all convertible notes prior to conversion into shares of our common stock at the Effective Time was $103.7 million. All Old Clarus convertible notes had the option to convert into Old Clarus Series D Preferred Stock at an exercise price of $4.50.

At the Effective Time, all principal and accrued interest under Old Clarus's convertible notes converted into 8,529,846 shares of our common stock.

Senior Secured Notes

On March 12, 2020, Old Clarus issued and sold senior secured notes to certain lenders not related to it. Gross proceeds from the senior secured notes were $50.0 million, and Old Clarus received $42.7 million in net proceeds after deducting the original issue discount, interest reserve and transaction expenses.

In the second quarter of 2021, Old Clarus added two additional notes to the principal senior secured notes balance, the PIK Note (as defined below) and the Indenture Note (as defined below), totaling $8.1 million. In the third quarter of 2021, we added one additional note to the principal senior secured notes balance, the Second Indenture Note (as defined below), totaling $3.6 million. The PIK Note, the Indenture Note and the Second Indenture Note are further described below.

As part of the Merger (as further described in Note 1 in the Notes to the Unaudited Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q), $10.0 million of the principal on the senior secured notes and certain royalty rights were exchanged for an aggregate 1,905,000 shares of our common stock (which included the 405,000 shares of our common stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement, of which 270,000 shares were reallocated from Old Clarus's equity holders and 135,000 shares that were transferred from the Sponsor) and converted at a price of $10.20 per share. Further, an additional $5.0 million of the principal of the senior secured notes balance associated with the Indenture Note and $3.6 million of the principal of the senior secured notes balance associated with the Second Indenture Note, plus related accrued interest, were exchanged for an aggregate 882,318 shares of our common stock, which converted at a price of $10.00 per share.

As a result of the exchange of the principal on the senior secured notes and certain royalty rights for shares of our common stock, we wrote off $18.6 million of principal associated with the senior secured notes, $1.5 million of the remaining unamortized debt discount associated with the senior secured notes, and the full carrying value of $11.5 million associated with royalty rights obligation. We recorded a gain of approximately $0.3 million during the period ending September 30, 2021 as a result of the extinguishment, representing the difference between the carrying value of the debt exchanged and the value of the shares converted based on the conversion price. As of the September 30, 2021 and following the completion of the Merger, there is approximately $43.125 million of principal (including principal of $3.125 million in respect of the PIK Note), plus accrued interest, outstanding under the senior secured notes.

The senior secured notes bear interest at 12.5% and specify semiannual payments on March 1 and September 1 and have a maturity date of March 1, 2025. The first two years provide for interest-only payments with principal payments beginning in 2022. The senior secured notes are governed by an indenture, dated as of March 12, 2020, between Old Clarus and the investors. The interest rate will increase to 14.50% for overdue installments in the event of default. In addition to liquidation preference, the senior secured notes contain a lien on all assets of Old Clarus.

The senior secured notes had a detachable royalty feature under which the lenders were to receive a royalty of 0.56% to 1.67% on net sales beginning in 2021, with the royalty obligation continuing until the lenders receive total royalty payments of approximately $24.2 million. The value assigned to royalty rights was recorded as a debt discount to the Notes and is amortized to interest expense over the life of the notes. For the three months ended September 30, 2021 and 2020, we recorded $0.7 million and $0.6 million, respectively, of interest expense associated with the royalty rights. For the nine months ended September 30, 2021 and 2020 we recorded $2.2 million and $1.4 million, respectively, of interest expense associated with the royalty rights. The royalty obligation had a fair value of $7.9 million at issuance in March of 2020. Pursuant to the Merger Agreement and conversion terms, no royalty obligation exists as of September 30, 2021.

During the three months ended September 30, 2021 and 2020, we recorded $2.6 million and $2.1 million, respectively in interest expense on the senior secured notes, of which $0.7 million and $0.7 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and debt issue costs. During the nine months ended September 30, 2021 and 2020, we recorded $7.2 million and $5.0 million, respectively in interest expense on the senior secured notes, of which $2.0 million and $1.5 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and issue costs. We did not make any cash interest payments during the three and nine months ended September 30, 2021 and 2020.

Pursuant to the indenture governing the senior secured notes, Old Clarus agreed to maintain cash and cash equivalents in an amount of not less than $10.0 million, calculated as of the last day of each calendar month commencing on March 31, 2020. As of December 31, 2020, Old Clarus' cash and cash equivalents were less than $10.0 million, resulting in a default under the indenture and the negotiation of a forbearance agreement, as noted below. In connection with the Merger, the indenture was amended to require Old Clarus to maintain a balance of not less than $8.0 million in cash and cash equivalents, calculated as of the last day of each calendar month.

We classified the full carrying value of $40.3 million related to the senior secured notes as a current liability within the September 30, 2021 balance sheet as, if we are unable to obtain funding or generate operating cash flow, we do not expect that we will be in compliance with the covenants under the senior secured notes within one year of the balance sheet date. Refer to Note 1 in the Notes to Unaudited Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q for further disclosure related to our assessment of the ability to operate as a going concern as of September 30, 2021.

Forbearance Agreement

On March 17, 2021, Old Clarus entered into a forbearance agreement with noteholders in relation to the senior secured notes. Old Clarus was unable to and did not pay interest of $3.1 million due on March 1, 2021. As of March 31, 2021, Old Clarus entered into default on its senior secured notes, and in accordance with the terms of the senior secured notes, the interest increased to 14.5%.

Under the forbearance agreement, in exchange for the investors' agreement not to exercise their rights to retrieve the funds owed, Old Clarus was required to maintain cash and cash equivalents of at least $2.5 million amongst other financial budgeting and reporting requirements until consummation of the Business Combination. Under the forbearance agreement, the forbearance period would not be terminated provided that Old Clarus, amongst other things, executed the Merger Agreement and provided financial reporting requirements by April 27, 2021.

Forbearance Extension

In August 2021, Old Clarus entered into forbearance extensions with the noteholders in relation to the senior secured notes. The latest forbearance extension, entered into on August 26, 2021, extended the forbearance period through September 9, 2021, the Closing Date of the Merger.

On September 28 2021, we entered into a supplemental indenture with the noteholders in relation to the senior secured notes. The supplemental indenture extended the due date of the $3.9 million interest payment due September 1, 2021 to March 1, 2022, and further accrues interest on the past interest due amount at a rate of 18.5% per annum beginning on September 1, 2021 until paid.

PIK Note

In May 2021, Old Clarus entered into a payment-in-kind, or PIK, note (the "PIK Note"), in relation to its missed interest payment (which was due in March 2021) on its senior secured notes, pursuant to which Old Clarus borrowed an aggregate of $3.1 million from senior secured noteholders, to be included in the principal senior secured notes balance. The PIK Note accrues interest at a rate of 14.5%, compounded daily. Pursuant to the PIK Note, on February 1, 2023 we are required to make a payment of principal in the amount of $3.1 million, plus accrued and unpaid interest in respect of such principal.

Indenture Note

In June 2021, Old Clarus entered into the Indenture Note (the "Indenture Note"), pursuant to which it borrowed an aggregate of $5.0 million from senior secured noteholders, to be included in the principal senior secured notes balance. The Indenture Note accrues interest at a rate of 14.5%, compounded daily, and was repaid with our common stock upon the closing of the Merger.

Second Indenture Note

In July 2021, Old Clarus entered into an additional note purchase agreement (the "Second Indenture Note") pursuant to which it borrowed an aggregate of $3.6 million from senior secured noteholders. The outstanding balance under the Second Indenture Note accrues interest at a rate of 14.5%, compounded daily, and was repaid with our common stock upon the closing of the Merger.

PPP Loan

In March of 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted to, among other provisions, provide emergency assistance for individuals, families and businesses affected by the COVID-19 pandemic. The CARES Act includes a Paycheck Protection Program ("PPP") administered through the Small Business Association ("SBA"). Under the PPP, beginning April 3, 2020, small businesses and other entities and individuals could apply for loans from existing SBA lenders and other approved regulated lenders that enroll in the program, subject to numerous limitations and eligibility criteria.

In April of 2020, Old Clarus received an unsecured loan of $0.5 million from the SBA. After considering further guidance issued by the SBA, Old Clarus elected to repay the loan in full in May of 2020 with no interest due under safe harbor provisions of the CARES Act.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2021 and 2020 (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	(34,452)	(35,661)
Net cash used in investing activities	(20)	(62)
Net cash provided by financing activities	49,192	47,220
Net increase in cash and cash equivalents	$ 14,720	$ 11,497

Operating Activities

Net cash used in operating activities was $34.4 million for the nine months ended September 30, 2021, reflecting net loss of $36.3 million, offset by a net change of $5.0 million in net operating assets and liabilities and non-cash charges of $6.9 million. The non-cash charges primarily consist of non-cash interest expense on debt financings and the royalty obligation, stock-based compensation expense and depreciation. The change in net operating assets and liabilities was primarily due to an increase in inventory of $6.6 million, an increase in accounts receivable of $2.5 million, an increase in prepaid expenses and other current assets of $2.0 million, partially offset by a decrease in deferred revenue of $0.3 million, an increase in accounts payable of $3.7 million and an increase in accrued expenses of $2.7 million.

Net cash used in operating activities was $35.6 million for the nine months ended September 30, 2020, reflecting net income of $4.1 million, offset by a net change of $6.0 million in net operating assets and liabilities and non-cash charges of $45.7 million. The non-cash charges primarily consist of the change in fair value of the warrant liability and derivative liability, non-cash interest expense on debt financings and the royalty obligation, change in fair value of warrant liabilities, stock-based compensation expense and depreciation. The change in net operating assets and liabilities was primarily due to an increase in accounts receivable of $3.5 million, partially offset by an increase in accounts payable of $7.2 million, an increase in accrued expenses of $1.7 million, and an increase in deferred revenue of $0.6 million.

Investing Activities

During the nine months ended September 30, 2021 and 2020, we used approximately $20,000 and $62,000, respectively, of cash in investing activities for purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $49.2 million, related to $23.6 million of proceeds from the issuance of convertible notes payable, $8.6 million of proceeds from the issuance of senior notes payable, and $17.0 million in net proceeds from the Business Combination.

During the nine months ended September 30, 2020, net cash provided by financing activities was $47.2 million, primarily related to $49.1 million of proceeds received from the issuance of senior notes and related royalty obligation, and $1.6 million of gross proceeds received from the issuance of convertible note, partially offset by debt issuance costs paid of $3.5 million.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily related to our selling and marketing activities associated with the commercialization of JATENZO and our research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses. Until such time, if ever, we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If funding permits, we would expect our expenses to increase substantially in connection with its ongoing activities, particularly as we advance the commercialization of our product JATENZO and our research and development pipeline. In addition, we now expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

Going Concern

We evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Since its inception, Old Clarus has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Old Clarus, and since the Merger, we have incurred significant losses from operations since inception and has an accumulated deficit of $317.3 million as of September 30, 2021. Further, as of September 30, 2021, we had a working capital deficit of $19.1 million.

In addition to the consummation of the Merger and the related investment, we plan to seek additional funding through the expansion of our commercial efforts to grow JATENZO and our operating cash flow, business development efforts to out-license JATENZO internationally, equity financings, debt financings such as the secured notes described in Note 6, *Debt*, in the Notes to the Unaudited Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q or other capital sources including collaborations with other companies or other strategic arrangements with third parties. There can be no assurance that these future financing efforts will be successful.

If we are unable to obtain funding or generate operating cash flow, we will be forced to delay, reduce or eliminate some or all of our product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders.

Based on our recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, as of the issuance date of the condensed consolidated financial statements for the nine months ended September 30, 2021, we have concluded that our cash and cash equivalents will not be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through at least twelve months from the date that these condensed consolidated financial statements are available to be issued and that there is substantial doubt about our ability to continue as a going concern.

If we are unable to obtain funding or generate operating cash flow, we will be forced to delay, reduce or eliminate some or all of our product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders.

Working Capital

Because of the numerous risks and uncertainties associated with research, development and commercialization of JATENZO and our research and development portfolio, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- The costs, timing and ability to manufacture JATENZO;
- the costs of future activities, including product sales, marketing, manufacturing and distribution of JATENZO;
- the costs of manufacturing commercial-grade product and necessary inventory to support continued commercial launch;
- the costs of potential milestones related to license agreements;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue from commercial sale of its products;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing its intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 30, 2021, and the effects such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Contractual obligation	Total	Less than 1 year	More than 1 year and less than 3	More than 3 years and less than 5	More than 5 years
Senior secured notes	43,125	6,000	29,125	8,000	—
Interest on senior secured notes (1)	18,226	10,207	7,439	580	—
Operating lease obligations (2)	40	40	—	—	—
Catalent Agreement purchase obligation	12,737	3,639	7,278	1,820	—
Pfizer Agreement purchase obligation	4,719	1,849	2,870	—	—
Total	$78,846	$ 21,734	$ 46,712	$ 10,400	$ 0

(1) We have $43.1 million outstanding aggregate principal on our senior secured notes that bear interest at 12.5% and mature on March 1, 2025.
(2) We have an operating lease agreement for our office space.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts.

Purchase Obligations

In July 2009, Old Clarus entered into a commercial manufacturing agreement, as amended, with Catalent Pharma Solutions, LLC (the “Catalent Agreement”). Pursuant to the terms of the Catalent Agreement, we must make minimum annual purchases of JATENZO softgel capsules, through the initial term, or March 2025. Any shortfall between the minimum annual purchase quantities and actual purchases will be multiplied by a unit price, as defined in the Catalent Agreement, and paid to Catalent within 30 days of any year-end that the minimum purchase requirement is not met. We have not made any payments to Catalent as a result of a shortfall in minimum purchase quantities. The Catalent Agreement renews automatically for two-year periods and either party may terminate the contract upon twelve months, written notice. Purchases under the Catalent Agreement for the three months ended September 30, 2021 and 2020 were $0.9 million and $0.1 million, respectively. Purchases under the Catalent Agreement for the nine months ended September 30, 2021 and 2020 were $6.0 million and $3.1 million, respectively.

Old Clarus entered into a product supply agreement with Pharmacia & Upjohn Company LLC, or Pfizer (the "Pfizer Agreement"), effective January 1, 2021. Pursuant to the terms of the Pfizer Agreement, we must make minimum annual purchases of T-undecanoate equal to approximately $1.8 million per year, through the initial term, or January 2024. If there is a shortfall between the minimum annual purchase quantities and actual purchases, the difference between the minimum annual purchase amount and actual purchases will be paid to Pfizer. There were no purchases under the Pfizer Agreement during the nine months ended September 30, 2021.

Lease Commitments

We have operating leases for rental space in Northbrook, Illinois and Murfreesboro, Tennessee that extend into December 31, 2021 and September 30, 2022, respectively. The table above includes future minimum lease payments under the non-cancelable lease arrangements.

We enter into contracts in the normal course of business with clinical trial sites, clinical and commercial supply manufacturers, and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

Long-Term Debt Commitments

As discussed above and in Note 7 in the Notes to Unaudited Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q, we have senior secured notes that are included in the table above.

License Agreement Commitments

In May 2021, Old Clarus entered into a license agreement (the "HavaH Agreement") with HavaH Therapeutics, or HavaH, an Australia-based biopharmaceutical company developing androgen therapies for inflammatory breast disease ("PDM") and certain forms of breast cancer. Under the HavaH Agreement, we acquired the development and commercialization rights for HavaH T+Ai™, which we renamed CLAR-121, and plan to develop for treatment of PDM and as an adjunctive therapy in ER+/AR+ breast cancer. We believe that HavaH's pharmacokinetic, safety, and early efficacy data will speed our ability to enter into Phase 2 clinical trials. We believe the potential addressable U.S. market for PDM exceeds $400 million and have applied for Orphan Drug status for CLAR-121. We believe even greater opportunities for CLAR-121 exist in the potential treatment for high breast density in women and as adjunctive therapy in women with ER+/AR+ breast cancer, which represents approximately 80% of all breast cancers.

Under the terms of the licensing agreement, we made an upfront payment of $0.5 million and HavaH may be eligible for up to $10.8 million in potential development and regulatory milestone payments. Additionally, HavaH would be eligible for royalty payments and up to $30.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of CLAR-121 in the territory, at a low single digit percentage rate (when there is no patent protection or regulatory exclusivity) or a low teens percentage rate (where CLAR-121 has patent protection or regulatory exclusivity). Additionally, such royalties are payable until the later of ten years or the loss of patent protection or regulatory exclusivity.

To date, pursuant to the HavaH Agreement, we have made cash payments of $0.5 million consisting of the upfront payment.

In September 2021, Old Clarus entered into a license agreement (the "McGill Agreement") with The Royal Institution for the Advancement of Learning/McGill University, or McGill, a Canadian University, which owns the right, title, and interest in licensed patents including the invention of No. 2018-049 titled "A new ubiquinone-10 formulation for the treatment of ubiquinone deficiency and other conditions. Under the McGill Agreement, we acquired the license rights to certain licensed patents for the research, development, and commercialization rights for future products to treat conditions associated with CoQ10 deficiencies. There are currently an estimated one in 5,000 adults worldwide that have a mitochondrial disease, and we believe that our first candidate in this program, CLAR-122, has potential to receive Orphan Drug status in primary CoQ10 deficiency.

Under the terms of the licensing agreement, McGill may be eligible for up to $10.5 million in potential development and regulatory milestone payments. Additionally, McGill would be eligible for royalty payments and up to $15.0 million in potential commercial milestones. Such royalty payments will be based on total aggregate annual net sales of any licensed products that are covered by the licensed patents in the territory, at a low single digit percentage rate.

To date, pursuant to the McGill Agreement, we have made cash payments of $0.4 million consisting of the upfront payment.

Critical Accounting Policies and Significant Judgments and Estimates

There have been no significant changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," disclosed in our most recent annual financial statements included in the Prospectus.

Recently Issued Accounting Pronouncements

See Note 2 to our annual financial statements appearing in our audited financial statements for the year ended December 31, 2020 included in the Prospectus.

Emerging Growth Company Status

We are an "emerging growth company" as defined in the Jobs Act and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until it is no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We expect to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not emerging growth companies, unless it chooses to early adopt a new or revised accounting standard.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks in the ordinary course of its business. Market risk represents the risk of loss that may impact its financial position due to adverse changes in financial market prices and rates. Our market risk exposure primarily relates to changes interest rates.

Interest Rate Risk

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are in the form of money market funds and our long-term debt financings. As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents of $21.9 million and $7.2 million, respectively. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of September 30, 2021 and December 31, 2020, $43.1 million and $111.3 million, respectively, in aggregate principal amount of our outstanding debt obligations were at fixed interest rates, representing approximately 100% of our total debt, on an amortized cost basis. As of September 30, 2021 our outstanding debt obligations at fixed interest rates were comprised of senior notes and at December 31, 2020, our outstanding debt obligations at fixed interest rates were comprised of convertible promissory notes and senior notes.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures as defined in Rules 13a15(e) and 15d-15(e) under the Exchange Act. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were not effective at the reasonable assurance level given the existence of the material weaknesses in our internal control over financial reporting discussed below.

In connection with the audit of our financial statements for the fiscal year December 31, 2020, Old Clarus identified material weaknesses relating to (i) insufficient supervision and review, (ii) a lack of segregation of duties and (iii) a lack of access and input controls related to its financial reporting systems. Management believes these deficiencies are the result of a lack of accounting personnel to provide the necessary segregation and review.

We are committed and are taking steps necessary to remediate the control deficiencies that constituted the above material weakness by implementing changes to our internal control over financial reporting. We have started the process of remediating these deficiencies and will continue to take initiatives to improve our internal control over financial reporting and disclosure controls. Towards this end, we are in the process of hiring additional accounting personnel. Management believes these efforts will address the issues that led to the aforementioned deficiencies. We are committed to appropriately staffing the accounting and reporting functions. However, the implementation of these initiatives is not complete and may not fully address the material weaknesses in our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Other than remediation activities to address the material weaknesses in our internal control over financial reporting discussed above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, in the ordinary course of business, we are subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. We are not currently party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

On April 2, 2019, an action for patent infringement was filed against Old Clarus by Lipocine in the U.S. District Court for the District of Delaware. The lawsuit (Civil Action No. 19-cv-622, assigned to Judge William Bryson, U.S. Court of Appeals for the Federal Circuit, sitting by designation) sought a declaratory judgement of infringement under 35 U.S.C. § 271(a)-(c) arising from our intent to market and sell JATENZO, based on the FDA's approval of JATENZO in March 2019. Lipocine ultimately alleged that Old Clarus infringed certain claims in each of four U.S. Patents: U.S. Patent No. 9,034,858, U.S. Patent No. 9,205,057, U.S. Patent No. 9,480,690 and U.S. Patent No. 9,757,390. Lipocine sought monetary damages in the form of a reasonable royalty, pre-judgment interest, post-judgment interest, and attorneys' fees, costs and disbursements, and injunctive relief.

Old Clarus asserted defenses of noninfringement and invalidity under 35 U.S.C. §§ 103 and 112, and asserted counterclaims of inequitable conduct, patent misuse and exceptional case. Old Clarus's motion for summary judgment of invalidity under Section 112 was argued on January 15, 2021, and was granted on May 25, 2021, the decision finding all asserted claims invalid for failure to satisfy the written description requirement. On June 15, 2021, Old Clarus requested the Court to schedule a bench trial on Old Clarus's counterclaims of inequitable conduct, patent misuse, and exceptional case at the earliest practicable date, pursuant to the Court's invitation to make such a request.

In July 2021, Old Clarus and Lipocine entered into a settlement agreement that settled all claims between the parties, including the interference matter (described above) and the pending counterclaims against Lipocine, and provides for a payment by Lipocine to us of a $4.0 million settlement fee payable as follows: $2.5 million upfront, $1.0 million within 12 months, and the remainder within two years. We received payment of $2.5 million of the $4.0 million in July 2021.

Pursuant to the settlement agreement, a joint stipulation for dismissal was filed, and was so ordered by the Court on July 15, 2021, thereby terminating the district court action. Moreover, and as part of this settlement, Lipocine filed a request for entry of an adverse judgment in Interference No. 106,128 on July 16, 2021. Judgment against Lipocine in Interference No. 106,128 was entered by the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB) on July 26, 2021. We believe that our'178 application will proceed to issuance following entry of this adverse judgement.

Item 1A. Risk Factors

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 16. Exhibits.

Exhibit Number	Description
2.1 †	Agreement and Plan of Merger, dated as of April 27, 2021, by and among Blue Water, Blue Merger Sub and Old Clarus (incorporated by reference to Annex A to the Proxy Statement/Prospectus filed by the Registrant on July 23, 2021).
3.1	Second Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.1#	Form of Indemnification Agreement (Directors) (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.2#	Form of Indemnification Agreement (Officers) (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.3#	Employment Agreement, dated September 9, 2021, by and between Clarus Therapeutics, Inc. and Robert E. Dudley (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.4#	Employment Agreement, dated September 9, 2021, by and between Clarus Therapeutics, Inc. and Richard Peterson(incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.5#	Employment Agreement, dated September 9, 2021, by and between Clarus Therapeutics, Inc. and Steven A. Bourne (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.6#	Employment Agreement, dated September 9, 2021, by and between Clarus Therapeutics, Inc. and Frank Jaeger (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.7#	Clarus Therapeutics Holdings, Inc. 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed by the Registrant on September 30, 2021).
10.8#	Forms of Award Agreements under the 2021 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.9#	Clarus Therapeutics Holdings, Inc. Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 filed by the Registrant on September 30, 2021).
10,10	Office Lease, dated August 18, 2011 by and between Clarus Therapeutics, Inc. and MJH Northbrook LLC, as amended (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-4).
10.11	Form of Warrant to Purchase Stock, issued April 2013, as amended (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).
10.12	Base Indenture, dated March 12, 2020 by and between Clarus Therapeutics, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-4/A filed by the Registrant on June 25, 2021).
10.13	Supplemental Indenture No. 2, dated September 9, 2021 by and between Clarus Therapeutics, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 10.15 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.14	Supplemental Indenture No. 3, dated September 28, 2021 by and between Clarus Therapeutics, Inc. and U.S. Bank National Association (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant on September 29, 2021).
10.15	Registration Rights Agreement, dated September 9, 2021, by and among the Company, Blue Water Sponsor LLC and Old Clarus securityholders party thereto (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by the Registrant on September 15, 2021).
10.16	Form of Stockholder Lock-Up Agreement by and between the Company and the stockholder of Old Clarus party thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, filed by Blue Water on May 3, 2021 and also included as Exhibit I to Annex A to the Proxy Statement/Prospectus filed by the Registrant on July 23, 2021).
10.17	Form of Lender Lock-Up Agreement by and between the Company and the noteholder of Old Clarus party thereto (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, filed by Blue Water on May 3, 2021 and also included as Exhibit J to Annex A to the Proxy Statement/Prospectus filed by the Registrant on July 23, 2021).
10.18	Warrant Agreement, dated December 15, 2020, by and between Blue Water Acquisition Corp. and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed by Blue Water Acquisition Corp. on December 21, 2020).
10.19¥	Softgel Commercial Manufacturing Agreement, dated July 3, 2009 by and between Clarus Therapeutics, Inc. and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).
10.20¥	Amendment No. 1 to Softgel Commercial Manufacturing Agreement, dated October 23, 2012 by and between Clarus Therapeutics, Inc. and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021)
10.21¥	Amendment No. 2 to Softgel Commercial Manufacturing Agreement, dated November 12, 2012 by and between Clarus Therapeutics, Inc. and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).

10.22¥	Amendment No. 3 to Softgel Commercial Manufacturing Agreement, dated June 5, 2017 by and between Clarus Therapeutics, Inc. and Catalent Pharma Solutions, LLC (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).
10.23¥	Commercial Packaging Agreement, dated June 26, 2014 by and between Clarus Therapeutics, Inc. and Packaging Coordinators, LLC (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).
10.24¥	First Amendment to Commercial Packaging Agreement, dated January 14, 2019, by and between Clarus Therapeutics, Inc. and Packaging Coordinators, LLC (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form S-4/A filed by Blue Water Acquisition Corp. on June 25, 2021).
31.1**	Certification of Chief Executive Officer (Principal Executive Officer) Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer (Principal Executive Officer) Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
# Indicates management contract or compensatory plan or arrangement.
¥ Portions of this exhibit (indicated by brackets and asterisks) have been omitted because the Registrant has determined that the information is both not material and is the type that the Registrant treats as private or confidential.
* The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.
** Filed herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 19, 2021

By: /s/ Robert E. Dudley
Name: Robert E. Dudley
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Richard Peterson
Name: Richard Peterson
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert E. Dudley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clarus Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. (Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942);

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 19, 2021

By: /s/ Robert E. Dudley
Robert E. Dudley
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION
PURSUANT TO RULES 13a-14(a) AND 15d-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard Peterson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Clarus Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. (Paragraph intentionally omitted in accordance with SEC Release Nos. 34-47986 and 34-54942);

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: November 19, 2021

By: /s/ Richard Peterson
Richard Peterson
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Clarus Therapeutics Holdings, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert E. Dudley, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 19, 2021

/s/ Robert E. Dudley

Name: Robert E. Dudley
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Clarus Therapeutics Holdings, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Peterson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 19, 2021

/s/ Richard Peterson

Name: Richard Peterson
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)