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

POST-EFFECTIVE AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Clarus Therapeutics Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2836
(Primary Standard Industrial Classification Code Number)

85-1231852
(I.R.S. Employer Identification Number)

555 Skokie Boulevard, Suite 340
Northbrook, Illinois 60062
(847) 562-4300
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Robert E. Dudley, Ph.D.
Chief Executive Officer
555 Skokie Boulevard, Suite 340
Northbrook, Illinois 60062
(847) 562-4300
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, please check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an 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 under the Securities Exchange Act of 1934:
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 7(a)(2)(B) of the Securities Act.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.
On September 30, 2021, we filed a registration statement on Form S-1 (File No. 333-259915) (the “Registration Statement”) with the Securities and Exchange Commission (the “SEC”). The Registration Statement registered for resale (i) up to 19,816,610 shares of Common Stock (including up to 3,445,000 shares of Common Stock that may be issued upon exercise of warrants (the “Placement Warrants”)) and (ii) up to 3,445,000 Placement Warrants held by the selling securityholders named therein. The Registration Statement was declared effective by the SEC on October 7, 2021. This post-effective amendment is being filed to include information from our Annual Report on Form 10-K for the year ended December 31, 2021 that was filed on March 31, 2022. No additional securities are being registered under this post-effective amendment and all applicable registration and filing fees were paid at the time of the original filing of the Registration Statement.
PRELIMINARY PROSPECTUS

Up to 19,816,610 Shares of Common Stock

Up to 9,195,000 Shares of Common Stock Issuable Upon Exercise of Warrants

Up to 3,445,000 Warrants

This prospectus relates to the issuance by us of an aggregate of up to 9,195,000 shares of our common stock, $0.0001 par value per share ("Common Stock"), which consists of (i) up to 3,445,000 shares of Common Stock that are issuable upon the exercise of 3,445,000 warrants (the "Placement Warrants") originally issued in a private placement in connection with the initial public offering of Blue Water Acquisition Corp. ("Blue Water") by the holders thereof and (ii) up to 5,750,000 shares of Common Stock that are issuable upon the exercise of 5,750,000 warrants (the "Public Warrants" and, together with the Placement Warrants, the "Warrants") originally issued in the initial public offering of Blue Water by the holders thereof. We will receive the proceeds from any exercise of any Warrants for cash.

This prospectus also relates to the offer and sale from time to time by the selling securityholders named in this prospectus (the "Selling Securityholders") of (i) up to 19,816,610 shares of Common Stock (including up to 3,445,000 shares of Common Stock that may be issued upon exercise of the Placement Warrants) and (ii) up to 3,445,000 Placement Warrants. We will not receive any proceeds from the sale of shares of Common Stock or Warrants by the Selling Securityholders pursuant to this prospectus. However, we will pay the expenses, other than underwriting discounts and commissions and expenses incurred by the Selling Securityholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Securityholders in disposing of the securities, associated with the sale of securities pursuant to this prospectus.

We are registering the securities for resale pursuant to the Selling Securityholders’ registration rights under certain agreements between us and the Selling Securityholders. Our registration of the securities covered by this prospectus does not mean that the Selling Securityholders will offer or sell any of the shares of Common Stock or Warrants. The Selling Securityholders may offer, sell or distribute all or a portion of their shares of Common Stock or Warrants publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any proceeds from the sale of shares of Common Stock or Warrants by the Selling Securityholders pursuant to this prospectus. We provide more information about how the Selling Securityholders may sell the shares or Warrants in the section entitled “Plan of Distribution.”

We are an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, as amended, and are subject to reduced public company reporting requirements. This prospectus complies with the requirements that apply to an issuer that is an emerging growth company.

The Common Stock and Public Warrants are listed on The Nasdaq Global Market ("Nasdaq") under the symbols “CRXT” and “CRXTW,” respectively. On March 31, 2022, the closing price of the Common Stock was $1.49 and the closing price for the Public Warrants was $0.1471.

See the section entitled “Risk Factors” beginning on page 5 of this prospectus to read about factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2022.
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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference to exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement. Neither we nor the Selling Securityholders have authorized anyone to provide you with different information. Neither we nor the Selling Securityholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.
ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC using the “shelf” registration process. Under this shelf registration process, the Selling Securityholders may, from time to time, sell the securities offered by them described in this prospectus. We will not receive any proceeds from the sale by such Selling Securityholders of the securities offered by them described in this prospectus. This prospectus also relates to the issuance by us of the shares of Common Stock issuable upon the exercise of any Warrants. We will not receive any proceeds from the sale of shares of Common Stock underlying the Warrants pursuant to this prospectus, except with respect to amounts received by us upon the exercise of the Warrants for cash.

Neither we nor the Selling Securityholders have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus or any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. Neither we nor the Selling Securityholders take responsibility for, or provide any assurance as to the reliability of, any other information that others may give you. Neither we nor the Selling Securityholders will make an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

We may also provide a prospectus supplement or post-effective amendment to the registration statement to add information to, or update or change information contained in, this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendment to the registration statement together with the additional information to which we refer you in the sections of this prospectus entitled “Where You Can Find More Information.”

On the Merger Closing Date, Clarus Therapeutics Holdings, Inc., a Delaware corporation (f/k/a Blue Water Acquisition Corp.), consummated the previously announced business combination pursuant to the terms of the Merger Agreement, by and among Blue Water, Blue Water Merger Sub Corp., a Delaware corporation (“Merger Sub”) and Legacy Clarus.

Pursuant to the terms of the Merger Agreement, a business combination between Blue Water and Legacy Clarus was effected through the merger of Merger Sub with and into Legacy Clarus, with Legacy Clarus surviving as the post-merger company and as a wholly owned subsidiary of Blue Water. On the Merger Closing Date, the registrant changed its name from Blue Water Acquisition Corp. to Clarus Therapeutics Holdings, Inc.

Unless the context indicates otherwise, references in this prospectus to the “Company,” “Clarus,” “we,” “us,” “our” and similar terms refer to Clarus Therapeutics Holdings, Inc. (formerly known as Blue Water Acquisition Corp.) and its consolidated subsidiaries (including Legacy Clarus). References to “Blue Water” refer to our predecessor company prior to the consummation of the Merger.

In addition, in this prospectus, unless otherwise stated or the context otherwise requires:

- “Blue Water” means Blue Water Acquisition Corp., a Delaware corporation, which was renamed “Clarus Therapeutics Holdings, Inc.” in connection with the Merger Closing.
- “Blue Water IPO,” “IPO” or “Initial Public Offering” means Blue Water’s initial public offering that was consummated on December 17, 2020.
- “Board” means the board of directors of Clarus.
- “Business Combination” means the Merger and the other transactions contemplated by the Merger Agreement.
- “Bylaws” means the Amended and Restated Bylaws of Clarus Therapeutics Holdings, Inc.
- “Certificate of Incorporation” means the Second Amended and Restated Certificate of Incorporation of Clarus Therapeutics Holdings, Inc.
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- “**Common Stock**” means the common stock, $0.0001 par value per share, of the Company.
- “**DGCL**” means the General Corporation Law of the State of Delaware, as amended.
- “**Effective Time**” means the effective time of the Merger in accordance with the Merger Agreement.
- “**Founder Shares**” means Class B common stock purchased by the Sponsor on June 30, 2020.
- “**Legacy Clarus**” means Clarus Therapeutics, Inc., a Delaware corporation, and a wholly-owned subsidiary of the Company.
- “**Merger**” means the merger of Merger Sub with and into Legacy Clarus, with Legacy Clarus continuing as the surviving corporation and as a wholly-owned subsidiary of the Company, in accordance with the terms of the Merger Agreement.
- “**Merger Agreement**” means the Agreement and Plan of Merger, dated April 27, 2021, and as it may further be amended or supplemented from time to time, by and among Blue Water, Merger Sub and Legacy Clarus.
- “**Merger Closing**” means the closing of the Business Combination.
- “**Merger Closing Date**” means September 9, 2021.
- “**Placement Warrants**” means 3,445,000 warrants to purchase shares of Common Stock issued to the Sponsor in the private placement (including the additional warrants purchased after the Blue Water IPO in connection with the overallotment securities issued to Blue Water’s underwriters). Each Placement Warrant entitles the holder thereof to purchase one share of Common Stock for $11.50 per share.
- “**Public Warrants**” means warrants underlying the units issued in the Blue Water IPO. Each Public Warrant entitles the holder thereof to purchase one share of Common Stock for $11.50 per share.
- “**SEC**” means the U.S. Securities and Exchange Commission.
- “**Securities Act**” means the Securities Act of 1933, as amended.
- “**Sponsor**” means Blue Water Sponsor LLC.
- “**Warrants**” means any of the Placement Warrants and the Public Warrants.
- “**Warrant Agreement**” means that certain Warrant Agreement, dated December 15, 2020, between Blue Water and Continental Stock Transfer & Trust Company, as the warrant agent.
This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. We have based these forward-looking statements on our current expectations and projections about future events. All statements, other than statements of present or historical fact included in this prospectus, our future financial performance, strategy, expansion plans, future operations, future operating results, estimated revenues, losses, projected costs, prospects, plans and objectives of management are forward-looking statements. Any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of such terms or other similar expressions. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of such terms or other similar expressions. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this prospectus. We caution you that these forward-looking statements are subject to numerous risks and uncertainties, most of which are difficult to predict and many of which are beyond our control.

Forward-looking statements in this prospectus may include, for example, statements about:

- our ability to obtain funding for our operations and to grow our business;
- our ability to successfully commercialize and market JATENZO and any future product candidates, if approved, and the timing of any commercialization and marketing efforts;
- the potential market size, opportunity and growth potential for JATENZO and any future product candidates, if approved;
- the benefits of testosterone ("T") replacement therapy in certain populations, patients’ drug administration preferences and acceptance of JATENZO by physicians and patients;
- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- the timing of our product development activities and the initiation, timing, progress and results of our exploratory trials and studies to guide the development of JATENZO for additional potential indications;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- expectations regarding sales of JATENZO and the costs of supplying, manufacturing and continuing to commercialize JATENZO;
- our ability to obtain marketing approval and acceptance for JATENZO in territories outside of the United States;
- our ability to maintain the listing of the Common Stock on the Nasdaq Global Market and the potential liquidity and trading of our securities;
- our future financial performance and expectations regarding future expenditures;
- the accuracy of our estimates regarding expenses, capital requirements and our future needs for additional financing;
our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professional;

developments relating to our competitors and our industry, and our ability to compete effectively in a competitive industry;

our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately and to produce sufficient quantities of clinical and potentially future commercial supplies;

our ability to enter into marketing or co-promotional arrangements and strategic partnerships;

the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;

regulatory, judicial, and legislative developments and their impact on our business;

the impact from the outcome of any known and unknown litigation; and

other risks and uncertainties, including those listed under the section titled “Risk Factors.”

All of these forward-looking statements are subject to a number of risks and uncertainties, including those set forth in this prospectus in the section entitled “Risk Factors.” Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in any accompanying prospectus supplement.

Should one or more of the risks or uncertainties described in this prospectus, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements. Additional information concerning these and other factors that may impact the operations and projections discussed herein can be found in the section entitled “Risk Factors” and in our periodic filings with the SEC. Our SEC filings are available publicly on the SEC’s website at www.sec.gov.

You should read this prospectus and any accompanying prospectus supplement completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.
PROSPECTUS SUMMARY

This summary highlights selected information appearing in this prospectus. Because it is a summary, it may not contain all of the information that may be important to you. To understand this offering fully, you should read this entire prospectus carefully, including the information set forth in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business” and the consolidated financial statements and related notes included elsewhere in this prospectus before making an investment decision.

The Company

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 to become a pharmaceutical company initially focused on the development and commercialization of JATENZO and other metabolic therapies for men and women.

Background

Blue Water was a blank check company incorporated in Delaware on May 22, 2020 and 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.

On September 9, 2021, we consummated the previously announced business combination pursuant to the terms of the Merger Agreement by and among Blue Water, Merger Sub and Legacy Clarus in which Merger Sub merged with and into Legacy Clarus, with Legacy Clarus surviving as the post-merger company and as a wholly owned subsidiary of Clarus Therapeutics Holdings, Inc. On the Merger Closing Date, we changed our name from Blue Water Acquisition Corp. to Clarus Therapeutics Holdings, Inc.

In accordance with the terms and subject to the conditions of the Merger Agreement, at the Effective Time

A. an aggregate of 17,751,348 newly issued shares of Class A common stock, par value $0.0001 per share, of Blue Water (“Blue Water Class A common stock”) were issued to the holders of:
   (i) certain shares of Legacy Clarus preferred stock issued and outstanding immediately prior to the Effective Time (such shares, the “Legacy Clarus Consideration-Receiving Preferred Stock”); and
   (ii) the holders of certain convertible and non-convertible promissory notes of Legacy Clarus outstanding as of the Effective Time (such notes, the “Legacy Clarus Consideration-Receiving Notes”);

B. warrants to purchase an aggregate 61,146 shares of Legacy Clarus stock were converted into warrants to purchase an aggregate 9,246 shares of Common Stock (such converting warrants, the “Legacy Clarus Converting Warrants”)

C. all shares of Legacy Clarus capital stock (other than the Legacy Clarus Consideration-Receiving Preferred Stock), and all outstanding options, warrants or rights to purchase or subscribe for any Legacy Clarus capital stock, securities convertible into or exchangeable for, or that otherwise conferred on the holder any right to acquire any capital stock of Legacy Clarus (in each case, other than the Legacy Clarus Consideration-Receiving Notes and the Legacy Clarus Converting Warrants), whether or not exercised prior to the Effective Time, were cancelled, retired and terminated without any consideration or any liability to Legacy Clarus with respect thereto. In addition, all shares of Class B common stock, par value $0.0001 per share, of Blue Water (“Blue Water Class B common stock”, and together with the Blue Water Class A common stock, the “Blue Water common stock”) were converted into Blue Water Class A common stock in accordance with Blue Water’s amended and restated certificate of incorporation (the “Blue Water Charter”).
Following the Effective Time, upon filing of the Certificate of Incorporation, all shares of Blue Water common stock were redesignated as Common Stock.

The Common Stock and Public Warrants are currently listed on Nasdaq under the symbols “CRXT” and “CRXTW,” respectively.

The rights of holders of the Common Stock and Warrants are governed by the Certificate of Incorporation, the Bylaws and the DGCL, and, in the case of the Warrants, the Warrant Agreement. See the sections entitled “Description of our Securities” and “Certain Relationships and Related Party Transactions.”

Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled “Risk Factors,” following this prospectus summary. These risks include the following, among others:

- We have incurred significant operating losses and there is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to support our operations. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital or address our liquidity needs may force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.
- We have significant indebtedness 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 may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- JATENZO is the only product we are commercializing. If we fail to successfully commercialize JATENZO, we may need to acquire additional product candidates and our business may be impaired.
- 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 or any product candidates that may be approved in the future.
- The ongoing COVID-19 pandemic is having, and is expected to have, an adverse impact on our business.
- The 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, which could materially adversely affect our revenue and our results of operations.
• 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 for us to profitably sell JATENZO.
• Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of JATENZO will be impaired.
• 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 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.
• We will need to grow our company, and we may encounter difficulties in managing this growth, which could disrupt our operations.
• 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.

Corporate Information

The mailing address for our principal executive office is 555 Skokie Boulevard, Suite 340, Northbrook, Illinois 60062, and our telephone number is (847) 562-4300. Our website address is https://clarustherapeutics.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). We will remain an emerging growth company under the JOBS Act until the earliest of (a) the last day of our first fiscal year following the fifth anniversary of Blue Water’s IPO, (b) the last date of our fiscal year in which we have total annual gross revenue of at least $1.07 billion, (c) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding securities held by non-affiliates or (d) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.
## The Offering

**Issuer**

Clarus Therapeutics Holdings, Inc. (formerly known as Blue Water Acquisition Corp.)

### Issuance of Common Stock

**Shares of Common Stock Offered by the Company**

9,195,000 shares of Common Stock, including shares of Common Stock issuable upon exercise of the Warrants, consisting of (i) 3,445,000 shares of Common Stock that are issuable upon the exercise of 3,445,000Placement Warrants by the holders thereof; and (ii) 5,750,000 shares of Common Stock that are issuable upon the exercise of 5,750,000 Public Warrants.

**Shares of Common Stock Outstanding Prior to Exercise of All Warrants**

24,750,011 shares (as of March 24, 2022).

**Shares of Common Stock Outstanding Assuming Exercise of All Warrants**

33,945,011 shares (based on total shares outstanding as of March 24, 2022).

**Exercise Price of Warrants**

$11.50 per share, subject to adjustment as described herein.

**Use of Proceeds**

We will receive up to an aggregate of approximately $105.7 million from the exercise of the Warrants, assuming the exercise in full of all of the Warrants for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. See the section entitled “Use of Proceeds.”

### Resale of Common Stock and Warrants

**Shares of Common Stock Offered by the Selling Securityholders**

19,816,610 shares of Common Stock (including up to 3,445,000 shares of Common Stock that may be issued upon exercise of the Placement Warrants)

**Warrants Offered by the Selling Securityholders**

3,445,000 Placement Warrants.

**Redemption**

The Warrants are redeemable in certain circumstances. See the section entitled “Description of our Securities—Warrants” for further discussion.

**Use of Proceeds**

We will not receive any proceeds from the sale of shares of Common Stock or Warrants by the Selling Securityholders.

**Market for Common Stock and Warrants**

The Common Stock and Public Warrants are currently traded on Nasdaq under the symbols “CRXT” and “CRXTW,” respectively.

**Risk Factors**

See the section entitled “Risk Factors” and other information included in this prospectus for a discussion of factors you should consider before investing in our securities.

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RISK FACTORS

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under “Cautionary Note Regarding Forward-Looking Statements,” you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risks Related to Business Operations and Commercialization

We have incurred significant operating losses and there is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to support our operations.

We have experienced negative operating cash flows and have accumulated significant accrued liabilities. Our net loss was $40.6 million and net income was $4.3 million for the years ended December 31, 2021 and 2020, respectively, and we had an accumulated deficit of $321.7 million as of December 31, 2021. Our revenue generated from the sales of JATENZO along with existing cash and cash equivalents of $26.4 million as of December 31, 2021 is expected to fund our operations into April 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern. Our consolidated financial statements included elsewhere in this prospectus do not include any adjustments that might result from the outcome of this uncertainty. Additionally, our independent registered public accounting firm’s report for the year ended December 31, 2021 and 2020 contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

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 (including potential restructuring of our current indebtedness), 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, or successfully restructure our debt or engage in a strategic transaction, 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. We could also be required to limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

We have significant indebtedness and servicing our debt requires a significant amount of cash. We may not have sufficient cash flow from operations to satisfy the financial covenants in its debt agreements. We may not receive a waiver of default for outstanding indebtedness for which we may be in default in the future.

In March 2020, prior to completion of the Business Combination, Legacy Clarus issued and sold senior secured notes to certain purchasers. The terms of the senior secured notes provide for semi-annual payments on March 1 and September 1. Until March 2022, only interest was payable on the notes. Legacy Clarus did not pay interest of approximately $2.99 million due September 1, 2021. On September 28, 2021, Legacy Clarus and the noteholders entered into Supplemental Indenture No. 3, which supplements the existing indenture, pursuant to which they agreed to defer the September 1, 2021 interest payment to March 1, 2022, at an increased interest rate of 18.5%. Pursuant to Supplemental Indenture No. 3, Legacy Clarus also agreed, among other things, to commence a process to refinance, redeem or repay all notes outstanding under the indenture.
Beginning in September 1, 2022, in addition to interest payments, Legacy Clarus is required to make principal payments of $6 million on each of September 1, 2022, March 1, 2023, September 1, 2023 and March 1, 2024. Thereafter, in addition to interest payments, Legacy Clarus is required to make principal payments of $8 million on each of September 1, 2024 and March 1, 2025. Additionally, on February 1, 2023, Legacy Clarus is required to make a payment of principal in the amount of $3.125 million, which is the amount of a payment-in-kind note Legacy Clarus issued on May 27, 2021, plus accrued and unpaid interest in respect of such principal.

If we are unable to make payments when due or repay these obligations at maturity, and are otherwise unable to extend the maturity dates or refinance these obligations, we would be in default. We cannot provide any assurances that we will be able to generate the necessary amount of capital to make payments as they become due, or to refinance these obligations, or that we will be able to extend the maturity dates or otherwise refinance these obligations. In the event of default on any of these loans, the note holders have the right to exercise all remedies available under the indenture to receive the funds due. Accordingly, a default would have a material adverse effect on our business. In addition, the agreements governing this indebtedness include certain debt service and other financial covenants that Legacy Clarus must satisfy. In the past, Legacy Clarus has defaulted on certain of these covenants and has entered into forbearance agreements to waive Legacy Clarus defaults from the note holders.

We cannot provide any assurance that the note holders would provide us with a consent or enter into a forbearance agreement should Legacy Clarus not be in compliance in the future. A failure to maintain compliance, in the event the note holders do not agree to a consent for the non-compliance, would cause the outstanding borrowings to be in default and payable on demand which would have a material adverse effect on us.

**We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.**

We continue to evaluate all potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

**We depend almost entirely on the success of our product, JATENZO. There is no assurance that our commercialization efforts in the United States with respect to JATENZO will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals.**

Our lead product, JATENZO, was approved by the FDA in March 2019 and became commercially available in the United States in February 2020. Through December 31, 2021, we have generated $20.3 million in net revenues from the sale of JATENZO in the United States.
Our business currently depends heavily on our ability to successfully commercialize JATENZO, an androgen indicated for T-replacement therapy, in the United States to treat adult men with hypogonadism due to certain medical conditions. We may never be able to successfully commercialize the product or meet our expectations with respect to revenues. We may be subject to patent litigation that could materially impact or prevent commercialization. For example, Lipocine, Inc. ("Lipocine") sued us for infringement of their patents. Although we prevailed on our motion for summary judgment in the litigation which invalidated the asserted Lipocine patents, and subsequently entered into a global settlement agreement with Lipocine, additional claims from other third parties could arise in the future. This and other proceedings are discussed in Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus.

Prior to our launch in February 2020, we had never marketed, sold or distributed for commercial use any pharmaceutical product. There is no guarantee that the infrastructure, systems, processes, policies, personnel, relationships and materials we have built to launch and commercialize JATENZO in the United States will be sufficient for us to achieve success at the levels we expect. Additionally, healthcare providers may not prescribe JATENZO due to safety risks posed by T-replacement products. We may also encounter challenges related to the reimbursement of JATENZO, even if we have positive early indications from payors, including potential limitations in the scope, breadth, availability, or amount of reimbursement covering each product. Similarly, healthcare settings or patients may determine that the financial burdens of treatment are not acceptable. Our results may also be negatively impacted if we have not adequately sized our field teams or our targeting strategy is inadequate or if we encounter deficiencies or inefficiencies in our infrastructure or processes. Any of these issues could impair our ability to successfully commercialize JATENZO or to generate substantial revenues or profits or to meet our expectations with respect to the amount or timing of revenue or profits. Any issues or hurdles related to our commercialization efforts may materially adversely affect our business, results of operations, financial condition and prospects. There is no guarantee that we will be successful in our commercialization efforts with respect to JATENZO.

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.

While we have initiated the commercial launch of JATENZO in the United States, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling JATENZO, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive JATENZO and any future products;
- obtain adequate pricing and reimbursement for JATENZO and any future products;
- develop and maintain successful strategic alliances; and
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully commercialize JATENZO and any future product candidates, raise capital, expand our business, or continue our operations.

The sales, marketing and distribution capabilities we have built may not be sufficient to overcome the challenges associated with commercializing JATENZO. We may not be able to build sufficient sales, marketing and distribution capabilities with respect to any of our future product candidates, if successfully developed and approved. If we are unsuccessful in these efforts, or if we are unable to achieve market acceptance for any approved products, our business, results of operations, financial condition and prospects will be materially adversely affected.

JATENZO is the first product we have marketed, sold and distributed for commercial use. There is no guarantee that the systems, processes, policies, relationships and materials we have built will be sufficient to overcome the challenges associated with commercializing JATENZO or for successful commercialization of the product in the United States as a treatment for adult men with hypogonadism due to certain medical conditions.
We have established a specialty sales force to promote JATENZO to endocrinologists and urologists, as well as high-prescribers of T-replacement therapies among primary care physicians (“PCPs”) in the United States. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other pharmaceutical companies to recruit, hire, train and retain sales and marketing personnel. In addition, we plan to explore partnership or co-promotion arrangements with established pharmaceutical companies that have PCP-focused sales forces or contract with an outside sales force to achieve broader penetration into the U.S. PCP market, which may prove costly or difficult to implement. If we are unable to grow our sales force, or enter into agreements with third parties that have existing sales forces, we will not be able to successfully commercialize JATENZO and our ability to generate revenue will be impaired.

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.

During the preparation of our financial statements for the fiscal year ended December 31, 2021, management identified material weaknesses in our internal control over financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Specifically, we identified a combination of deficiencies in our internal controls within the financial reporting function that result from an ineffective design and implementation of an appropriate system of controls. The material weaknesses identified include (i) insufficient supervision and review, (ii) a lack of segregation of duties and (iii) a lack of access and input controls related to our financial reporting systems. Management believes these deficiencies are the result of a lack of accounting personnel to provide the necessary segregation and review.

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 and we cannot assure you that we will not identify other material weaknesses or deficiencies, which could negatively impact our results of operations in future periods.

More generally, the process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that satisfies our reporting obligations. If we are unable to meet the demands placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by law or securities exchange regulations. Failure to comply with the Sarbanes-Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties encountered in their implementation, could result in additional material weaknesses or significant deficiencies, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, and investors could lose confidence in our, reported financial information. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity over a three-year period), the corporation’s ability to use its pre-change net operating loss (“NOL”) carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We have
experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of the Business Combination or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2021, we had U.S. federal and state NOL carryforwards of $231.7 million and $202.7 million, respectively, and our ability to utilize those NOLs could be limited by an “ownership change” as described above, which could result in increased tax liability to us. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As a result, the amount of the NOL and tax credit carryforwards presented in our financial statements could be limited and may expire unutilized. Federal NOL carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such NOL carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020.

**Risk Related to Our Dependence on Third Parties**

Our reliance on third-party suppliers and distributors could harm our ability to commercialize JATENZO or any product candidates that may be approved in the future.

We do not currently own or operate manufacturing facilities for the production of JATENZO or any product candidates that may be approved in the future. We rely on third-party suppliers to manufacture and supply the active pharmaceutical ingredient and drug product required for our commercial supply and clinical studies which may not be able to produce sufficient inventory to meet commercial demand in a cost-efficient, timely manner, or at all. Our third-party suppliers may not be required to, or may be unable to, provide us with any guaranteed minimum production levels or have sufficient dedicated capacity for our drugs. As a result, there can be no assurances that we will be able to obtain sufficient quantities of JATENZO, which could have a material adverse effect on our business as a whole.

If any contract manufacturing organization (“CMO”) with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial distribution could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our products or product candidates. In addition, in the case of the CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Additionally, in March 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was signed into law in response to the COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA’s existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or active pharmaceutical ingredient is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our results could be materially impacted.
We rely on two suppliers for our supply of T-undecanoate (“TU”), the active pharmaceutical ingredient of JATENZO, and the loss of either of these suppliers could impair our ability to procure sufficient amounts of TU to meet demand for JATENZO.

We rely on two third-party suppliers, Pharmacia & Upjohn Company LLC (“Pfizer”) and XIANJU Pharmaceutical Co. LTD (“Xianju”), for our supply of T-undecanoate, the active pharmaceutical ingredient of JATENZO. Because there are only a limited number of TU suppliers in the world, if either of these parties ceases to provide us with TU or materially reduces the amount of TU they can provide us with, including below the minimum supply obligations in the case of our agreement with Pfizer, we may be unable to procure sufficient amounts of TU on commercially favorable terms, or may not be able to obtain it in a timely manner. Furthermore, the limited number of suppliers of TU may provide such companies with greater opportunity to raise their prices. Any increase in price for TU will likely reduce our gross margins.

We depend on Catalent Pharma Solutions, LLC (“Catalent”) for the supply of the softgel capsules for JATENZO and the termination of our agreement with Catalent would hurt our business.

Our JATENZO softgel capsules are manufactured by Catalent pursuant to an exclusive manufacturing agreement under which Catalent will be our sole supplier of JATENZO softgel capsules on a worldwide basis. Reliance on a third-party manufacturer involves risks to which we would not be subject if we manufactured JATENZO ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. The FDA and other regulatory authorities require that JATENZO be manufactured according to current good manufacturing practices (“cGMP”), and we are ultimately responsible for ensuring JATENZO is manufactured in accordance with current cGMP even though we use contract manufacturers. Any failure by our third-party manufacturers to comply with cGMP could be the basis for action by the FDA to withdraw approvals previously granted to us and for other regulatory action.

We are required to purchase a minimum quantity of JATENZO softgel capsules. We are also required to pay to Catalent an annual commercial occupancy fee and an annual product maintenance fee effective January 1 of the year that commercial manufacture of JATENZO occurs. If Catalent terminates the manufacturing agreement, we would need to identify a new supplier of JATENZO softgel capsules, which could result in an interruption of the continued supply of JATENZO. In addition, we would lose the benefits of and rights to use Catalent’s proprietary technology and, to the extent that we were relying upon this technology, would need to negotiate for separate rights to it. The FDA likely will require the facilities of any new manufacturer of JATENZO to pass inspection before approving the change to such new manufacturer and would also potentially require that we run additional studies if we change the softgel formulation of JATENZO. Although it is likely that clinical studies will not be necessary, there is no guarantee of this. Accordingly, the termination of the Catalent manufacturing agreement could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we do not establish successful partnership or co-promotion arrangements, our commercialization plans for JATENZO may be impacted.

We have established our own commercial organization in the United States, however, in order to achieve deeper penetration into the PCP market in the United States; we expect to enter into marketing or co-promotion arrangements with established pharmaceutical companies that have a PCP-focused sales force or contract with an outside sales force. Additionally, we expect to consider strategic partnerships to assist in obtaining marketing approval for and commercialization of JATENZO outside of the United States. We will face significant competition in seeking appropriate partners and these partnership or co-promotion arrangements are complex and time-consuming to negotiate and document. We may not be able to negotiate partnership or co-promotion arrangements on acceptable terms, or at all. If we are unable to enter into partnership or co-promotion arrangements, we may have to curtail or delay commercialization of JATENZO in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake commercialization activities at our own expense. If we elect to increase our expenditures to fund commercialization activities outside of the United States on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.
If we enter into a partnership or co-promotion arrangement and a partner terminates or fails to perform its obligations under an agreement with us, the commercialization of JATENZO could be delayed or negatively impacted.

If we enter into partnership or co-promotion arrangements and any of our partners does not devote sufficient time and resources for a partnership or co-promotion arrangement with us, we may not realize the potential commercial benefits of the arrangement. In addition, if any future partner were to breach or terminate its arrangements with us, the commercialization of JATENZO in countries outside the United States could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue commercialization of JATENZO on our own in such locations.

Competition may negatively impact a partner’s focus on and commitment to JATENZO and, as a result, could delay or otherwise negatively affect the commercialization of JATENZO outside of the United States or in the general PCP market in the United States. If future partners fail to effectively commercialize JATENZO for any of these reasons, our sales of JATENZO may be limited.

The ongoing COVID-19 pandemic is having, and is expected to have, an adverse impact on our business, financial condition and results of operations, including our commercial operations and sales.

The ongoing COVID-19 pandemic may continue to have a negative impact on the global economy which could impact our business and results of operations. The continued spread of COVID-19 could adversely impact our operations. In response to the spread of COVID-19, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including encouraging all employees to work remotely and requiring COVID-19 vaccinations for all employees. Notwithstanding these measures, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on taking similar measures.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the COVID-19 pandemic could also impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

Business interruptions from the current COVID-19, or a future, pandemic may also adversely impact our commercial operations, including:

- adversely impacting the third parties we solely rely on to sufficiently manufacture JATENZO in quantities we require including the availability of raw materials and other supply chain requirements;
- decreasing the demand for JATENZO; and
- the ability of our sales representatives to reach healthcare customers.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and new variants such as the omicron variant the actions taken to contain it or treat its impact and the economic impact on local, regional, and national markets.

Risk Related to Development and Regulation

We may not be able to gain market acceptance for JATENZO.

The commercial success of JATENZO will depend upon the acceptance of the product by the medical community, including physicians, patients and healthcare payors.
Some physicians and patients may determine that the benefits of JATENZO as a T-replacement therapy in adult males do not outweigh the risks, including those risks set forth in the boxed warning for JATENZO. The boxed warning for JATENZO warns physicians that JATENZO can cause blood pressure increases that can increase the risk of major adverse cardiovascular events, including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death. Physicians are recommended to consider the patient’s baseline cardiovascular risk and ensure blood pressure is adequately controlled. Furthermore, physicians are encouraged to monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension.

Physicians may be hesitant to prescribe JATENZO, and patients may be hesitant to take JATENZO, because of the boxed warning. These potential risks may make it more difficult for a patient to decide to begin JATENZO or to stay on JATENZO.

The degree of market acceptance of JATENZO will also depend on a number of other factors, including:

- physicians’ views as to the scope of the approved indication and limitations on use and warnings and precautions contained in JATENZO’s approved labeling;
- the availability, efficacy and safety of competitive therapies;
- pricing and the perception of physicians and payors as to cost effectiveness;
- the existence of sufficient third-party coverage or reimbursement; and
- the effectiveness of our sales, marketing and distribution strategies.

If we are not able to achieve a high degree of market acceptance of JATENZO for T-replacement therapy, we may not be able to achieve our revenue goals or other financial goals or to achieve profitability or cash-flow break-even in the time periods we expect, or at all.

The 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.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as JATENZO. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product’s approved labeling. For instance, we received marketing approval for JATENZO for the treatment of adult men with hypogonadism due to certain medical conditions. Physicians may in their practice prescribe JATENZO to their patients in a manner that is inconsistent with the approved labeling. If we are found to have promoted such off-label uses, we may become subject to public advisory or enforcement letters, reputational damage, and significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion under both the federal Anti-kickback Statute and False Claims Act and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of JATENZO to ensure it remains consistent with its approved labeling, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Even though we have obtained marketing approval for JATENZO in the United States, physicians and patients using other T-replacement therapies may choose not to switch to our product.

Physicians often show a reluctance to switch their patients from existing drug products even when new and potentially more effective and convenient treatments enter the market. Patients also often acclimate to the brand or type of drug product that they are currently taking and do not want to switch unless their physician recommends switching products or they are required to switch drug treatments due to lack of coverage and reimbursement for existing drug treatments. In addition, men who are currently tolerating their current T-replacement therapy may not want to switch to a new product, including our product, particularly given the boxed warning, which includes warnings relating to blood pressure increases, and a limitation of use in the labeling that states that the safety and efficacy of JATENZO in males less than 18 years has not been established. The existence of either or both of physician or patient reluctance in switching to JATENZO, would depress demand for JATENZO and compromise our ability to successfully commercialize it.
We may still face future development and regulatory difficulties, and we will be subject to post-marketing regulatory requirements.

Even though we have received marketing approval, we continue to be subject to conducting required post-marketing studies and clinical trials, and regulatory authorities may still impose significant restrictions on JATENZO’s indicated uses or marketing or impose further ongoing requirements for potentially costly post-approval studies (e.g., FDA post-marketing requirements of which we are required over the next few years to complete: a) Medication Guide comprehension study; b) study to assess impact of chronic JATENZO therapy on adrenal function; c) assessment of JATENZO in pediatric patients who are unable to make sufficient T; and d) a clinical drug-drug interaction study). If we or a regulatory agency discover previously unknown problems with JATENZO, such as adverse events of unanticipated severity or frequency, a regulatory agency may impose restrictions on JATENZO including withdrawal of marketing approval. JATENZO is also subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising and promotion of the product and recordkeeping and submission of safety and other post-market information. The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. The FDA also has the authority to require the submission of a risk evaluation and mitigation strategy (“REMS”), either as part of a New Drug Application (an “NDA”) or after the drug has been approved should FDA become aware of new safety information about a drug and determine that a REMS is necessary to ensure that the benefits of the drug outweigh its risks. A REMS could, for example, limit prescribing to certain physicians or medical centers that have undergone specialized training, limit treatment to patients who meet certain safe-use criteria or require treated patients to enroll in a registry. Any REMS required by the FDA may lead to increased costs to assure compliance with new post-approval regulatory requirements and potential requirements or restrictions on the sale of approved products, all of which could lead to lower sales volume and revenue.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and other regulations. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover previously unknown problems with the facility where JATENZO is manufactured, including the facility where Catalent manufactures JATENZO, a regulatory agency may impose restrictions on JATENZO, the manufacturer or us, including requiring withdrawal of JATENZO from the market or suspension of manufacturing. If we or the operators of the manufacturing facilities for JATENZO fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning or untitled letters or notice of violation letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw marketing approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or request that we initiate a product recall.
If we become subject to adverse regulatory action, the occurrence of such an event or penalty described above may inhibit or diminish our ability to commercialize JATENZO and generate revenue.

**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.**

We may never receive, regulatory approval to market JATENZO or other future product candidates outside of the United States or in any particular country or region, including in the European Union (“EU”). In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional non-clinical studies or clinical trials, additional work related to manufacturing and analytical testing on controls, and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in other countries. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval may require additional studies and data, and can result in substantial delays in bringing products to market in such countries and such investment may not be justified from a business standpoint given the market opportunity or level of required investment. For example, we continue to assess the development and regulatory pathway for JATENZO in the EU and our overall EU strategy in light of our overall portfolio and program priorities. Even if we generate the data and information we believe may be sufficient to file a marketing authorization application for regulatory approval of JATENZO in a region or country outside the United States, the relevant regulatory agency may find that we did not meet the requirements for approval, or even if our application is approved, we may have significant post-approval obligations.

Even if we are able to successfully develop JATENZO and obtain marketing approval in a country outside the United States, we may not be able to obtain pricing and reimbursement approvals in such country at acceptable levels or at all, and any pricing and reimbursement approval we may obtain may be subject to onerous restrictions such as caps or other hurdles or restrictions on reimbursement. Failure to obtain marketing and pricing approval in countries outside the United States without onerous restrictions or limitations related to pricing, or any delay or other setback in obtaining such approval, would impair our ability to market our product candidates successfully or at all in such foreign markets. Any such impairment would reduce the size of our potential market or revenue potential, which could have a material adverse impact on our business, results of operations and prospects.

Any setback or delay in obtaining regulatory approval for our product candidates in a country or region outside the United States where we have decided it makes business sense to proceed or in our ability to commence marketing of our products, if approved, may have a material adverse effect on our business and prospects.

**Recent federal legislation may increase pressure to reduce prices of certain pharmaceutical products paid for by Medicare, which could materially adversely affect our revenue and our results of operations.**

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”) expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors.

Additionally, given the amount of litigation surrounding the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), it is unclear at this time what effect the latest ruling will have on the ACA long term. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business.
Further, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Most recently, on April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit’s decision that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business.

There has also been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, the 340B drug pricing program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase and which suppliers will be included in their prescription drug and other healthcare programs.

We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. It is unclear how the current administration will prioritize and execute initiatives to contain healthcare costs. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for our products and any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

We expect that changes and challenges to the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, and additional downward pressure on the price that we receive for our products and any future approved product.

**Testosterone 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.**

Testosterone is regulated under the Controlled Substances Act of 1970 (“CSA”) as a Schedule III (non-narcotic) substance. The CSA and regulations promulgated by the Drug Enforcement Administration (“DEA”) classify certain substances with a potential for abuse, known as “controlled substances” in either Schedule I, II, III, IV or V, with Schedule I substances considered to present the highest risk of abuse and dependence and Schedule V substances the lowest risk. The CSA establishes a closed chain of distribution for these drugs, and entities or individuals handling controlled substances are subject to DEA regulations relating to manufacturing, distribution, dispensing, importation and exportation. These regulations include requirements for registration, security, storage, recordkeeping and reporting. For example, facilities must maintain certain physical security for storing controlled substances and Schedule III drugs can only be prescribed by an authorized practitioner registered with the DEA and may only be refilled five times within a six-month period from the date of the original prescription.
Entities must register annually with the DEA to manufacture, distribute, import and export controlled substances, and entities prescribing, dispensing or conducting research with controlled substances must register every three years. In addition, the DEA requires entities handling controlled substances to maintain records and file reports related to transactions involving controlled substances follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and criminal penalties and administrative action to revoke a DEA registration. Individual states also have established controlled substances laws. Though state controlled substances laws and regulations often mirror federal law, because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug upon scheduling by DEA, in other states, scheduling requires a rulemaking or legislative action, which could delay commercialization in every state.

Because of the abuse potential, products containing controlled substances may generate public controversy. As a result, reports of diversion or abuse of these products may lead to marketing approvals withdrawn. Moreover, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of JATENZO.

If coverage and reimbursement for JATENZO are limited, it may be difficult for us to profitably sell JATENZO.

Market acceptance and sales of JATENZO will depend, in part, on coverage and reimbursement policies and may be affected by healthcare reform measures. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for JATENZO and, if reimbursement is available, what the level of such reimbursement will be. Limitations on coverage and reimbursement may impact the demand for, or the price of, JATENZO. If coverage is not available or reimbursement is available only at limited levels, we may not be able to successfully commercialize JATENZO.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for JATENZO could hinder our ability to recoup our investment.

The regulations that govern marketing approvals, coverage, and reimbursement for new drug products vary widely from country to country. In some foreign countries, particularly Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. To obtain favorable coverage and reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of JATENZO to other available therapies. If coverage for JATENZO is unavailable in any country in which coverage and reimbursement are sought, or reimbursement for JATENZO is limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenue from JATENZO will be diminished.
There can be no assurance that JATENZO will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that coverage and an adequate level of reimbursement will be available, or that third-party payors’ reimbursement policies will not adversely affect our ability to sell JATENZO profitably.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of JATENZO. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we market, sell and distribute JATENZO. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business.

Applicable federal, state, and foreign healthcare laws and regulations that may affect our ability to operate include: the federal anti-kickback statute, the federal False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) (as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”)), the federal false statements statute, the federal transparency requirements, sometimes referred to as the “Sunshine Act”, under the Patient Protection and ACA, various federal and state health information and data protection laws and regulations and analogous state laws and regulations. These laws and regulations impose a variety of monitoring and reporting obligations as well as civil and criminal penalties and liabilities for noncompliance.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act (the “FCPA”) and other worldwide anti-bribery laws.

We are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We have an ongoing relationship with Xianju, a non-U.S. company, as a third-party supplier of TU and we may commercialize JATENZO outside of the United States in countries where we obtain marketing approval either alone or under a partnership or co-promotion arrangement with a third party. Our significant reliance on a foreign supply of TU demands a high degree of vigilance in preventing our employees and consultants from participation in corrupt activity, because this supplier could be deemed our agent, and we could be held responsible for its actions. The FCPA and similar anti-bribery laws to which we may be subject are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and involve significant costs and expenses, including legal fees. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.
Risks Related to Our Industry and Competition

Our market is subject to intense competition. If we are unable to compete effectively, our opportunity to generate revenue from the sale of JATENZO will be impaired.

The T-replacement therapies market is highly competitive and dominated by the sale of T-gels and injectable forms of T, which accounted for 95% of all prescriptions written in the United States for T-replacement therapies in 2020. Our success will depend, in part, on our ability to obtain and retain an appreciable share of the market. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms and other drug discovery organizations. JATENZO or its use may infringe competitors’ patents, and if any patent infringement suit against us is successful, it could materially impact commercialization of JATENZO. Competitors may attack our patent portfolio, see Lipocine’s interferences under “Business—Legal Proceedings” and in the “—Risks Related to Our Intellectual Property” subsection below. Other pharmaceutical companies may develop oral T-replacement therapies that would compete with JATENZO that do not infringe the claims of our pending patent applications or other proprietary rights, and these therapies may have competitive advantages over JATENZO. For example, because T and TU are not patented compounds and are commercially available to third parties, it is possible that competitors may design methods of T or TU administration that would be outside the scope of the claims of our issued patents and patent applications. This would enable their products to compete with JATENZO.

T-replacement therapies currently on the market that would compete with JATENZO, include the following:

- T-gels, such as AndroGel, marketed by AbbVie Inc. (“AbbVie”); Testim, marketed by Endo Pharmaceutical (“Endo”); and Fortesta, marketed by Endo in the United States;
- generic T-injectables;
- oral methyl-T;
- transdermal patches, such as Androderm, marketed by Allergan Sales, LLC, a subsidiary of AbbVie; buccal patches, such as Striant, marketed by Endo;
- implanted subcutaneous pellets, such as Testopel, marketed by Endo;
- Aveed, a long-acting T-injectable marketed by Endo;
- Xyosted, a sub-cutaneous weekly auto-injector T-therapy marketed by Antares Pharma, Inc.; and
- Natesto, an intranasal T-therapy, marketed by Acerus Pharmaceuticals.

Several other pharmaceutical companies have T-replacement therapies, including oral formulations, and other therapies that are either pending approval of an NDA or in clinical development, which may be approved for marketing in the United States or outside of the United States. Based on publicly available information, we believe that current therapies in development that would be competitive with JATENZO include:

- TLANDO, an oral TU formulation developed by Lipocine, and tentatively approved by the FDA pending the expiration on March 27, 2022 of JATENZO’s three-year Hatch-Waxman exclusivity;
- KYZATREX, an oral TU formulation as a T-replacement therapy being developed by Marius Pharmaceuticals with a Prescription Drug User Fee Act (“PDUFA”) date of October 31, 2021. To date, the status of the NDA for KYZATREX is unknown but it has not received FDA approval. If the FDA rules favorably on KYZATREX, tentative approval would be granted pending the expiration on March 27, 2022 of JATENZO’s three-year Hatch-Waxman exclusivity;
- a once weekly aromatase inhibitor, for first-line therapy for the treatment of obese men with hypogonadotropic hypogonadism, which has completed its Phase 2b trials, currently being developed by Mereo BioPharma Group Ltd; and
• an oral bio-identical testosterone, which has completed its Phase 2 clinical studies, being developed by TesoRx LLC.

In addition, Andriol, an oral TU formulation, has been marketed by Merck & Co, Inc. in Europe or other international markets since the early 1970s, but is not nor has it ever been approved in the United States.

Many of our potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other marketing approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors’ drugs may be more effective, less expensive or more effectively marketed and sold than JATENZO and may render JATENZO obsolete or non-competitive before we can recover the expenses of developing and commercializing it. We anticipate that we will face intense and increasing competition as new drugs, both generic and branded, enter the market and advanced technologies become available.

Several companies have obtained approval for Section 505(b)(2) NDAs that cite existing T-gel products as their listed drugs. The entrance of any generic T-gel into the market might create downward pricing pressure on all T-replacement therapies and therefore could hurt our business.

Three Section 505(b)(2) NDAs citing to approved T-gel products have been approved for marketing in the United States. Teva Pharmaceuticals USA (“Teva”) and Perrigo Israel Pharmaceuticals Ltd (“Perrigo”) have obtained approval from the FDA to market T-gel products in the United States that are versions of AndroGel 1%. In addition, Upsher-Smith Laboratories, Inc. (“Upsher-Smith”) received approval to market its T-gel product, a version of Auxilium’s Testim 1%, in the United States. The entrance of any generic T-gel into the market might cause downward pressure on the pricing of all T-replacement therapies, and which could negatively affect the level of sales and price at which we can sell JATENZO.

Further, the Creating and Restoring Equal Access to Equivalent Samples Act (“CREATES Act”) was enacted in 2019 requiring sponsors of approved NDAs to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to responding to such requests or any legal challenges under this law, our business could be adversely impacted.

The introduction of generic T-gels may also affect the reimbursement policies of government authorities and third-party payors, such as private health insurers and health maintenance organizations. These organizations determine which medications they will pay for and establish reimbursement levels. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for branded medications when there is a generic version available. If generic T-gels are available in the market, that may create an additional obstacle to the availability of coverage and reimbursement for JATENZO or lead to reduction in the level of such reimbursement, and our ability to generate revenue could be compromised.

We face potential product liability exposure, and, if claims are brought against us, we may incur substantial liability.

The use of JATENZO in past clinical trials and the sale of JATENZO, expose us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with JATENZO. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

• substantial monetary awards to patients from our clinical trials or other claimants;
• decreased demand for JATENZO;
• damage to our business reputation and exposure to adverse publicity;
• increased FDA warnings on product labels;
• costs of related litigation;
• distraction of management’s attention from our primary business;
• loss of revenue; and
• the inability to successfully commercialize JATENZO.

We have obtained product liability insurance coverage for commercial sales of JATENZO in the United States with a $10.0 million annual aggregate coverage limit. However, our insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain or obtain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial. A product liability claim or series of claims brought against us could cause our stock price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, business and prospects could be materially adversely impacted.

JATENZO is the only product we are commercializing. If we fail to successfully commercialize JATENZO, we may need to acquire additional product candidates and our business may be impaired.

We have no other compounds beyond JATENZO in clinical testing, preclinical testing, lead optimization or lead identification stages. If we fail to successfully commercialize JATENZO as a T-replacement therapy, our ability to generate revenue will be impaired and we may need to develop other sources of revenues. If this occurs, we may seek out opportunities to discover, develop, acquire or license additional promising product candidates or drug compounds to expand our product candidate pipeline beyond JATENZO; however, this would constitute a significant change in our strategy and would likely require substantial additional capital. We would also be exposed to numerous additional risks related to our ability to identify, select and acquire the right product candidates and products on terms that are acceptable to us, and there is no guarantee that we would be successful in these efforts.

Risks Related to Our Intellectual Property

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 rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to JATENZO. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover JATENZO in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against JATENZO. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent application from issuing as a patent. In particular, because the active pharmaceutical ingredient in JATENZO has been on the market as an ingredient in separate products for many years, it is possible that these products have previously been used off-label in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or not infringed. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold with respect to JATENZO fail to issue, or if the breadth or strength of protection of our patent portfolio is threatened, it could dissuade companies from partnering with us to commercialize JATENZO. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable or will go unthreatened by third parties. For several of our patents and patent applications, Lipocene suggested patent interferences, which can invalidate a patent or preclude issuance of a patent application; two interferences were decided against us, another was declared but
resolved in our favor as part of the global settlement agreement with Lipocine, and several more were suggested by Lipocine but not instituted to date, see below and see Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus. Further, if we encounter delays in regulatory approvals, the period of time during which we could market JATENZO under patent protection could be reduced. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to JATENZO. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us or the U.S. Patent and Trademark Office (“USPTO”) to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. The outcome of an interference can invalidate one or both involved patents, and a license may be needed to practice the claims of the prevailing patent. Such license may not be available on favorable terms.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market and our ability to achieve profitability could be impaired.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on JATENZO in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with JATENZO and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement in, a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could hurt our ability to successfully commercialize JATENZO.

Further, many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement
of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and post-grant review, inter partes review and inter party reexamination proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are commercializing JATENZO. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that JATENZO may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of JATENZO. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that JATENZO may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of JATENZO, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize JATENZO unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize JATENZO unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. See, for example, Lipocine’s patent infringement suit filed against us, and past patent interferences under “Business—Legal Proceedings” below.

Third parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize JATENZO; see Lipocine’s patent infringement suit filed against us under “Business—Legal Proceedings” below. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing product, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize JATENZO, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against JATENZO, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may be involved in lawsuits and proceedings to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from
using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other contentious proceedings involving our patents or patent applications could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party is awarded one or more claims that cover JATENZO and does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

We have recently been involved in a number of interference proceedings and an infringement lawsuit with Lipocine regarding JATENZO, which consumed time and resources. In May 2021, our motion for summary judgment against Lipocine for failure to provide adequate written description of Lipocine’s asserted patent claims was granted, and we subsequently entered into a global settlement agreement with Lipocine that settled all patent-related claims, including the sole pending interference, and provided for a payment by Lipocine to us as a settlement fee. For more information regarding the disputes with Lipocine, see Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus. There is no guarantee that additional interference or infringement proceedings will not be filed by other third parties in the future.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the price of Common Stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering JATENZO, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees’ former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.
We will need to grow our company, and we may encounter difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth in the number of employees and the scope of our operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects. Our future financial performance and our ability to successfully commercialize JATENZO and compete effectively will depend, in part, on our ability to effectively manage any future growth. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy.

Our future success depends on our ability to retain our chief executive officer, chief financial officer, chief commercial officer and chief administrative officer and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Robert E. Dudley, our chief executive officer, Richard Peterson, our chief financial officer, Steven A. Bourne, our chief administrative officer, and Frank Jaeger, our chief commercial officer. We have entered into employment agreements with these individuals, but any of them may terminate his employment with us at any time. Although we do not have any reason to believe that we may lose the services of any of these individuals in the foreseeable future, the loss of their services might impede the achievement of our research, development and commercialization objectives. We rely on consultants and advisors to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may expand through acquisitions of, or investments in, other companies, each of which may divert our management's attention, result in additional dilution to our stockholders and consume resources that are necessary to sustain and grow our business.

An element of our growth strategy is to expand our product candidate pipeline beyond JATENZO. To pursue this strategy, we will need to acquire androgen and metabolic therapies for men and women or other complementary products, product candidates or businesses. We also may enter into relationships with other businesses in order to expand our product offerings, which could involve preferred or exclusive licenses, additional channels of distribution or discount pricing or investments in other companies.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies. Moreover, we will face significant competition in seeking to acquire or license promising product candidates or drug compounds. Other companies, including some with significantly greater financial, marketing and sales resources and more extensive experience in preclinical studies and clinical trials, obtaining marketing approval and manufacturing and marketing pharmaceutical products, may compete with us for the license or acquisition of product candidates and drug compounds. If we are unable to acquire or license additional promising product candidates or drug compounds, we will not be able to expand our product candidate pipeline and our prospects for future growth and our ability to sustain profitability will continue to be entirely dependent upon the success of JATENZO.

In addition, the process of proposing, negotiating and implementing these transactions can be time consuming, difficult and expensive, and our ability to close these transactions may be subject to third-party approvals, such as government regulation, which are beyond our control. Consequently, we can make no assurance that these transactions, once undertaken and announced, will close.

An acquisition or investment may result in unforeseen operating difficulties and expenditures. In particular, we may encounter difficulties assimilating or integrating the businesses, products, personnel or operations of the
acquired companies, particularly if the key personnel of the acquired business choose not to work for us, and we may have difficulty retaining the customers of any acquired business. Acquisitions may also disrupt our ongoing business, divert our resources and require significant management attention that would otherwise be available for development of our business. Any acquisition or investment could expose us to unknown liabilities. Moreover, we cannot assure you that the anticipated benefits of any acquisition or investment would be realized or that we would not be exposed to unknown liabilities. An acquisition could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses or the write-off of goodwill.

Our debt agreements contain restrictions that limit our flexibility in operating our business.

In March 2020, Legacy Clarus entered into an indenture and certain collateral agreements that places a lien on our assets and a negative pledge on our intellectual property. These loan documents contain various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- sell, transfer, lease or dispose of certain assets;
- encumber or permit liens on certain assets;
- make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, Common Stock; and
- enter into certain transactions with affiliates.

A breach of any of the covenants under the loan agreements could result in a default under the loan. Upon the occurrence of an event of default under the loan, the lenders could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay those amounts, the lenders could proceed against the collateral granted to them to secure such indebtedness.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in cyber security.

Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. While we have not, to our knowledge, experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture and supply of the ingredients required for our commercial supply and clinical studies of JATENZO or any future product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of JATENZO or any future product candidates could be hindered or delayed.

Increasing scrutiny and changing expectations from investors, lenders and other market participants with respect to our Environmental, Social and Governance, (“ESG”), policies may impose additional costs on us or expose us to additional risks.

Increasing scrutiny and changing expectations from investors, lenders and other market participants with respect to our ESG policies may impose additional costs on us or expose us to additional risks. Companies across all industries are facing increasing scrutiny relating to their ESG policies. Investors, lenders and other market participants are increasingly focused on ESG practices and in recent years have placed increasing importance on the implications and social cost of their investments. The increased focus and activism related to ESG may hinder our access to capital, as investors and lenders may reconsider their capital investment allocation as a result of their
assessment of our ESG practices. If we do not adapt to or comply with investor, lender or other industry shareholder expectations and standards, which are evolving, or if we are perceived to have not responded appropriately to the growing concern for ESG issues, regardless of whether there is a legal requirement to do so, we may suffer from reputational damage and the business, financial condition and the price of our company’s shares could be materially and adversely affected.

Risks Related to Ownership of our Securities

An active market for our securities may not develop, which would adversely affect the liquidity and price of our securities.

The price of our securities may vary significantly due to factors specific to us as well as to general market or economic conditions. Furthermore, an active trading market for our securities may never develop or, if developed, it may not be sustained. You may be unable to sell your securities unless a market can be established and sustained.

Our securities may be delisted from the Nasdaq and begin trading in the over-the-counter markets if we are not successful in regaining compliance with the Nasdaq’s continued listing standards, which may negatively impact the price of our securities and our ability to access the capital markets.

On February 18, 2022, we received two written notifications from the Listing Qualifications Department of The Nasdaq Stock Market LLC. The first notification indicated that as of February 18, 2022, we did not meet the $15,000,000 minimum market value of publicly held shares required to maintain continued listing as set forth in Nasdaq Marketplace Rule 5450(b)(2)(C) (the “MVPHS Rule”) for the 33-business day period ended February 17, 2022. The second notification indicated that as of February 18, 2022, we did not meet the $50,000,000 minimum market value of listed securities required to maintain continued listing as set forth in Nasdaq Marketplace Rule 5450(b)(2)(A) (the “MVLS Rule” and together with the MVPHS Rule, the “Rules”) for the 30-business day period ended February 17, 2022. Under Nasdaq rules, we will have 180 calendar days from the date of the notifications to regain compliance by meeting the continued listing requirements, namely the market value of publicly held shares closes at $15,000,000 or more for a minimum of 10 consecutive business days and the market value of listed securities closes at $50,000,000 or more for a minimum of 10 consecutive business days. If we are unable to regain compliance with the Rules during the 180-day period, and we receive a delisting determination from Nasdaq, we may, at that time, request a hearing to remain on the Nasdaq, which request will ordinarily suspend such delisting determination until a decision is issued by Nasdaq subsequent to the hearing.

We intend to actively monitor and assess the market value of our publicly held shares and publicly listed securities and may, as appropriate, consider available options to regain compliance with the Rules. However, there can be no assurance that we will be successful in regaining compliance with the Rules and maintaining the listing of our securities on the Nasdaq Stock Market.

If Nasdaq delists our securities from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

• a limited availability of market quotations for our securities;
• reduced liquidity for our securities;
• a determination that the Common Stock is a “penny stock,” which will require brokers trading in Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
• a limited amount of news and analyst coverage;
• a decreased ability to issue additional securities or obtain additional financing in the future.
• potential loss of confidence by partners and employees; and
• loss of institutional investor interest and fewer business development opportunities.
The price of the Common Stock may change significantly and you could lose all or part of your investment as a result.

The trading price of the Common Stock is likely to be volatile. The stock market recently has experienced extreme volatility. This volatility often has been unrelated or disproportionate to the operating performance of particular companies. You may not be able to resell your shares of common stock at an attractive price due to a number of factors such as those listed elsewhere in this section and the following:

- results of operations that vary from the expectations of securities analysts and investors;
- results of operations that vary from those our competitors;
- changes in expectations as to our future financial performance, including financial estimates and investment recommendations by securities analysts and investors;
- declines in the market prices of stocks generally;
- strategic actions by us or our competitors;
- announcements by us or our competitors of significant contracts, acquisitions, joint ventures, other strategic relationships or capital commitments;
- any significant change in our management;
- changes in general economic or market conditions or trends in our industry or markets;
- changes in business or regulatory conditions, including new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- future sales of Common Stock or other securities;
- investor perceptions of the investment opportunity associated with the Common Stock relative to other investment alternatives;
- the public’s response to press releases or other public announcements by our or third parties, including our filings with the SEC;
- litigation involving our, our industry, or both, or investigations by regulators into our operations or those of our competitors;
- guidance, if any, that we provide to the public, any changes in this guidance or our failure to meet this guidance;
- the development and sustainability of an active trading market for the Common Stock;
- actions by institutional or activist stockholders;
- changes in accounting standards, policies, guidelines, interpretations or principles; and
- other events or factors, including those resulting from pandemics, natural disasters, war, acts of terrorism or responses to these events.

These broad market and industry fluctuations may adversely affect the market price of the Common Stock, regardless of our actual operating performance. In addition, price volatility may be greater if the public float and trading volume of the Common Stock is low.

In the past, following periods of market volatility, stockholders have instituted securities class action litigation. If we are involved in securities litigation, it could have a substantial cost and divert resources and the attention of executive management from our business regardless of the outcome of such litigation.
Because there are no current plans to pay cash dividends on the Common Stock for the foreseeable future, you may not receive any return on investment unless you sell your Common Stock at a price greater than what you paid for it.

We intend to retain future earnings, if any, for future operations, expansion and debt repayment and there are no current plans to pay any cash dividends for the foreseeable future. The declaration, amount and payment of any future dividends on shares of Common Stock will be at the sole discretion of the Board. The Board may take into account general and economic conditions, our financial condition and results of operations, our available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions, implications of the payment of dividends by us to our stockholders or by our subsidiaries to us and such other factors as the Board may deem relevant. As a result, you may not receive any return on an investment in the Common Stock unless you sell your Common Stock for a price greater than that which you paid for it.

Our stockholders may experience dilution in the future.

The percentage of shares of Common Stock owned by current stockholders may be diluted in the future because of equity issuances for acquisitions, capital market transactions or otherwise, including, without limitation, equity awards that we may grant to our directors, officers and employees, or exercise of our outstanding warrants. Such issuances may have a dilutive effect on our earnings per share, which could adversely affect the market price of the Common Stock.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for the Common Stock to decline.

The sale of shares of Common Stock in the public market, or the perception that such sales could occur, could harm the prevailing market price of shares of Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We issued a significant number of shares in the Business Combination to Legacy Clarus’ stockholders, all of which are freely tradable following expiration of the lock-up agreements other than by our “affiliates.” In addition, we adopted a new equity plan and an employee stock purchase plan, all of which could result in the issuance of additional shares into the market.

In the future, we may also issue securities in connection with investments or acquisitions. The amount of shares issued in connection with an investment or acquisition could constitute a material portion of the then-outstanding common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

We account for the private warrants issued in a private placement concurrent with the Blue Water IPO as a liability and record changes in fair value each period reported in earnings, which may have an adverse effect on the market price of the Common Stock.

We classify the private warrants issued in a private placement concurrent with Blue Water’s IPO as a liability as opposed to equity. Accordingly, this results in the application of derivative liability accounting, which entails a quarterly valuation of these liabilities with any change in value reflected in our quarterly and annual financial statements. The impact of changes in fair value on earnings may have an adverse effect on the market price of the Common Stock.

If securities or industry analysts do not publish research or reports about our business, if they change their recommendations regarding the Common Stock or if our operating results do not meet their expectations, the price of the Common Stock and trading volume could decline.

The trading market for Common Stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no securities or industry analysts commence coverage of us, the trading price for Common Stock could be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover or downgrade our securities or publish unfavorable research about our business, or if our operating results do not meet analyst expectations, the trading price of the Common Stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for Common Stock could decrease, which might cause the price of the Common Stock and trading volume to decline.
We are an emerging growth company within the meaning of the Securities Act, and we if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies.

We are an “emerging growth company” within the meaning of the Securities Act, as modified by the JOBS Act. We intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We cannot predict whether investors will find securities issued by us less attractive because we rely on these exemptions. If some investors find those securities less attractive as a result of its reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. As an emerging growth company, we can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the closing of the Blue Water IPO, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of the Common Stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We may redeem certain of our outstanding warrants prior to their exercise at a time that is disadvantageous for warrant holders.

We will have the ability to redeem outstanding warrants issued as part of the units in the Blue Water IPO at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last reported sales price of the Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date we send the notice of redemption to the warrant holders. If and when such warrants become redeemable, we may exercise our redemption right if there is a current registration statement in effect with respect to the shares of Common Stock underlying such warrants. Redemption of such outstanding warrants could force you to: (i) exercise your warrants and pay the related exercise price at a time when it may be disadvantageous for you to do so; (ii) sell your warrants at the then-current market price when you might otherwise wish to hold your warrants; or (iii) accept the nominal redemption price that, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants. None of the warrants issued in the private placement by Blue Water will be redeemable by us for cash so long as they are held by our former sponsor or its permitted transferees.
U.S. federal income tax reform could adversely affect us and holders of our securities.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service ("IRS"), and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of Common Stock. In recent years, many changes have been made and changes are likely to continue to occur in the future. Additional changes to U.S. federal income tax law are currently being contemplated, and future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

This prospectus does not discuss any such tax legislation or the manner in which it might affect holders of our securities. We urge holders of our securities to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of their ownership of our securities.

Delaware law and our current Certificate of Incorporation and Bylaws contain certain provisions, including anti-takeover provisions, that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

Our current Certificate of Incorporation and Bylaws, as amended in connection with the Business Combination, and the DGCL contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition deemed undesirable by the Board and therefore depress the trading price of the Common Stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of the Board or taking other corporate actions, including effecting changes in our management. Among other things, our Certificate of Incorporation and Bylaws include provisions regarding:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board;
- opting out of Section 203 of the DGCL to allow us to establish our own rules governing business combinations with interested parties;
- the ability of the Board to issue shares of preferred stock, including “blank check” preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the limitation of the liability of, and the indemnification of, our directors and officers;
- the exclusive right of the Board to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on the Board;
- the requirement that directors may only be removed from the Board for cause;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of stockholders and could delay the ability of stockholders to force consideration of a stockholder proposal or to take action, including the removal of directors;
- the requirement that a special meeting of stockholders may be called only by the Board, the chairperson of the Board, our chief executive officer or our president (in the absence of a chief executive officer), which could delay the ability of stockholders to force consideration of a proposal or to take action, including the removal of directors;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings;
the requirement for the affirmative vote of holders of at least 2/3 of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend, alter, change or repeal any provision of the Certificate of Incorporation and Bylaws, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board and also may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt;

• the ability of the Board to amend the bylaws, which may allow the Board to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend the bylaws to facilitate an unsolicited takeover attempt; and

• advance notice procedures with which stockholders must comply to nominate candidates to the Board or to propose matters to be acted upon at a stockholders’ meeting, which could preclude stockholders from bringing matters before annual or special meetings of stockholders and delay changes in the Board and also may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer’s own slate of directors or otherwise attempting to obtain control of our company.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in the Board or management.

Any provision of our Certificate of Incorporation and Bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for Common Stock.

Our Bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, each of which could limit the ability of our stockholders to choose the judicial forum for disputes with us or our directors, officers, or employees.

Our current Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the DGCL, or our Certificate of Incorporation or the Bylaws or (iv) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware), in all cases subject to the court having jurisdiction over indispensable parties named as defendants. Our current Bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The exclusive forum provision is applicable to the fullest extent permitted by applicable law, subject to certain exceptions. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision does not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities is deemed to have notice of and consented to this provision. This exclusive-forum provision may limit a stockholder’s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find the exclusive-forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations.
USE OF PROCEEDS

All of the Common Stock and Warrants offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective accounts. We will not receive any of the proceeds from these sales.

We will receive up to an aggregate of approximately $105.7 million from the exercise of the Warrants, assuming the exercise in full of all of the Warrants for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. We will have broad discretion over the use of proceeds from the exercise of the Warrants. There is no assurance that the holders of the Warrants will elect to exercise any or all of such Warrants. To the extent that the Warrants are exercised on a “cashless basis,” the amount of cash we would receive from the exercise of the Warrants will decrease.

DETERMINATION OF OFFERING PRICE

The offering price of the shares of Common Stock underlying the Warrants offered hereby is determined by reference to the exercise price of the Warrants of $11.50 per share. The Public Warrants are listed on Nasdaq under the symbol “CRXTW.”

We cannot currently determine the price or prices at which shares of the Common Stock or Warrants may be sold by the Selling Securityholders under this prospectus.
The Common Stock and Public Warrants are currently listed on the Nasdaq Global Market under the symbols “CRXT” and “CRXTW,” respectively. Prior to the consummation of the Merger, the Common Stock, units and Public Warrants were listed on the Nasdaq Capital Market under the symbols “BLUW,” “BLUWU” and “BLUWW,” respectively. We currently do not intend to list the Placement Warrants offered hereby on any stock exchange or stock market.

As of March 24, 2022, we had approximately 24,750,011 shares of Common Stock issued and outstanding held of record by 27 registered holders and approximately 5,750,000 Public Warrants outstanding held of record by two registered holders. The actual number of holders of these securities is greater than this number of record holders, as the actual number includes holders who are beneficial owners whose securities are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose securities may be held in trust by other entities.

Dividend Policy

We have not paid any cash dividends on the Common Stock to date. We may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. We do not anticipate declaring any cash dividends to holders of the Common Stock in the foreseeable future.
The following discussion and analysis provides information which our management believes is relevant to an assessment and understanding of our results of operations and financial condition. This discussion and analysis should be read together with our financial statements and notes thereto included elsewhere in this prospectus. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. See the section entitled “Cautionary Note Regarding Forward-Looking Statements.” Our actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under “Risk Factors” and elsewhere in this prospectus.

Overview

We are a pharmaceutical company focused on the commercialization of JATENZO, the first and only oral T-replacement, or T-replacement therapy of its kind that has received final approval by the 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 to become a pharmaceutical company initially focused on the development and commercialization of JATENZO and other metabolic therapies for men and women.

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 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, 2021, JATENZO was available under health plans representing approximately 70% of all covered lives in the United States. Of those lives, 77% of the commercial lives had access to JATENZO. For the years ended December 31, 2021 and 2020, JATENZO generated net revenues of approximately $14.0 million, and $6.4 million, respectively, demonstrating consistent prescription and sales growth despite the commercial challenges presented by the ongoing COVID-19 pandemic. Total prescription growth for JATENZO for the year ended December 31, 2021 increased 81% 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 chronic kidney disease (“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.

Since the beginning of Legacy’s Clarus’ operations in 2004, we have 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 December 31, 2021. Legacy Clarus funded its operations primarily with proceeds from the sale of convertible preferred stock and debt through convertible and senior secured notes, including a royalty obligation. Through December 31, 2021, we have received gross proceeds of $104.2 million from investors in our 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 our 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 the closing of the Business Combination, and net proceeds of $13.8 million from investors in a December 2021 private placement.

Merger

On the Closing Date, we consummated the previously announced merger, pursuant to the Merger Agreement, with Clarus Therapeutics, Inc., a Delaware corporation, pursuant to which, subject to the terms and conditions set forth therein, Clarus Therapeutics, Inc. survived as our wholly-owned subsidiary, and its equity holders and convertible debt holders equity interests converted into the right to receive shares of Common Stock or else were canceled, retired and terminated without consideration, as provided in the Merger Agreement. Upon the consummation of the Business Combination, we changed our name to “Clarus Therapeutics Holdings, Inc.”
In connection with the merger, Legacy Clarus’ then convertible noteholders and senior secured noteholders provided $25.0 million in additional capital to it following the announcement of the execution of the Merger Agreement. All such proceeds plus accrued interest converted to shares of 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 Legacy Clarus prior to the Closing Date. Together with our 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, shares of Legacy Clarus’ redeemable convertible Series D Preferred Stock issued and outstanding and all principal and accrued interest under its Series D convertible notes immediately prior to the Effective Time converted into 13,431,410 shares of Common Stock at a price of $10.20 per share. Additionally, $10.0 million of debt related to its senior secured notes including certain royalty rights was exchanged for an aggregate 1,905,000 shares of Common Stock (which included 405,000 shares of Common Stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement, of which 270,000 shares were reallocated from its equity holders and 135,000 shares that were transferred from our former sponsor). All unexpired, outstanding Series D Warrants of Legacy Clarus remained outstanding and became exercisable for shares of Common Stock, subject to adjustment in accordance with the merger exchange ratio.

All other series of preferred stock, common stock and stock options of Clarus Therapeutics, Inc. were cancelled and extinguished upon completion of the merger. In addition, its existing equity incentive plans were terminated.

As a result of the Merger, we operate under Clarus Therapeutics Inc.’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 GlaxoSmithKline (“GSK”) was named Chairperson of the Board after the closing of the Business Combination.

The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. generally accepted accounting principles (“GAAP”). Under this method of accounting, we are treated as the acquired company and Clarus Therapeutics, Inc. is treated as the acquirer for financial statement reporting and accounting purposes. As a result, the historical operations of Clarus Therapeutics, Inc. are deemed to be our financial statements. Therefore, the audited consolidated financial statements included elsewhere in this prospectus reflect (i) the historical operating results of Clarus Therapeutics, Inc. prior to the Business Combination; (ii) the combined results following the Business Combination on the Closing Date; (iii) the assets and liabilities of Clarus Therapeutics, Inc. at their historical cost; and (iv) our 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 Clarus Therapeutics, Inc.

Risks and Liquidity

Since inception, we have incurred significant operating losses and have experienced negative operating cash flows. For the year ended December 31, 2021 our net loss was $40.6 million. For the year ended December 31, 2020 we had net income of $4.3 million, primarily due to a non-cash gain of $66.9 million as a result in a change in the warrant liability valuation. As of December 31, 2021, we had an accumulated deficit of $321.7 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 encounter 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. We 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 operations at planned levels and be forced to reduce or terminate our operations.

In light of our current liquidity, we need to raise additional capital to support our operations and debt obligations and concurrently, we are exploring strategic alternatives for the purpose of maximizing stockholder value. We expect to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Board has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, fall into forbearance on our debt obligations, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

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 $26.4 million as of December 31, 2021 and revenue generated from sales of JATENZO will fund our operations into April 2022. See “— Liquidity and Capital Resources.”

COVID-19 Business Update

The business disruptions associated with the ongoing COVID-19 pandemic had a significant negative impact on our financial statements for the years ended December 31, 2021 and 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 the COVID-19 pandemic worsens, such as by the omicron variant or other variants that may surface, 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 ongoing 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, vaccine rates and mandates, 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 its 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

Legacy 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. For further discussion of the components of revenue see “— Critical Accounting Policies and Significant Judgments and Estimates.”

Cost of Product Sales

Cost of product sales includes manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, salaries of employees involved with production and a reserve for short-dated, obsolete inventory. 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 30 months from the date of manufacture. Due to the low rate of inventory turnover generated by our commercial launch efforts for JATENZO during a global pandemic, we recorded a charge for inventory obsolescence of $0.7 million and $7.8 million in the years ended December 31, 2021 and 2020, respectively. Absent the charges for inventory obsolescence, gross profit for the years ended December 31, 2021 and 2020 was $11.9 million and $5.5 million, respectively. We will continue to assess obsolescence in future periods as demand for JATENZO and the rate of inventory turnover evolves. We will continue to assess obsolescence in future periods as demand for JATENZO and the rate of inventory turnover evolves.

Operating Expenses

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of commercialization expenses related to JATENZO, commercially launched in February of 2020, and FDA program fees. Prior to the commercial launch, we had significantly lower sales and marketing expenses. We anticipate that our sales and marketing expenses will increase in 2022 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 internally -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. Inventory acquired prior to receipt of the marketing approval of JATENZO was recorded as research and development expense as incurred. 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 Legacy 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. As the fair value of Legacy Clarus’ Series D convertible notes and Series D warrants at December 31, 2020 was less than the Series D Preferred Stock issuance price of $4.50, the fair value of the derivative liability and warrant liability was reduced to zero.

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 warrants issued in a private placement concurrent with Blue Water’s IPO. The total change in fair value of the private placement warrants recorded during the year ended December 31, 2021 was $12.5 million.

Interest Income

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

Interest Expense

Interest expense is related to Legacy Clarus’ 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 13 to our audited consolidated financial statements included elsewhere in this prospectus. We recognize the cash payments within income as they are received. During the year ended December 31, 2021, we recognized $2.5 million associated with the first settlement payment received in July 2021.
## Results of Operation

### Comparison of the years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020 (in thousands):

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2021</th>
<th>2020</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net product revenue</td>
<td>$13,957</td>
<td>$6,369</td>
<td>$7,588</td>
</tr>
<tr>
<td>Cost of product sales</td>
<td>2,720</td>
<td>8,687</td>
<td>(5,967)</td>
</tr>
<tr>
<td>Gross profit</td>
<td>11,237</td>
<td>(2,318)</td>
<td>13,555</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>30,677</td>
<td>30,524</td>
<td>153</td>
</tr>
<tr>
<td>General and administrative</td>
<td>16,662</td>
<td>11,937</td>
<td>4,725</td>
</tr>
<tr>
<td>Research and development</td>
<td>3,630</td>
<td>2,398</td>
<td>1,232</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>50,969</td>
<td>44,859</td>
<td>6,110</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(39,732)</td>
<td>(47,177)</td>
<td>7,445</td>
</tr>
<tr>
<td>Other (expense) income, net:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability and derivative, net</td>
<td>12,508</td>
<td>66,891</td>
<td>(54,383)</td>
</tr>
<tr>
<td>Interest income</td>
<td>2</td>
<td>25</td>
<td>(23)</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(15,895)</td>
<td>(15,394)</td>
<td>(501)</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>2,500</td>
<td>—</td>
<td>2,500</td>
</tr>
<tr>
<td>Total other (expense) income, net</td>
<td>(885)</td>
<td>51,522</td>
<td>(52,407)</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (40,617)</td>
<td>$ 4,345</td>
<td>(44,962)</td>
</tr>
</tbody>
</table>

### Net Product Revenue

For the year ended December 31, 2021, we recorded $14.0 million of net product revenue, which increased by $7.6 million from $6.4 million for the year ended December 31, 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 $2.7 million for the year ended December 31, 2021, which decreased by $6.0 million, from $8.7 million for the year ended December 31, 2020. The decrease in cost of product sales is primarily due to the fact that 2020 includes a $7.8 million inventory obsolescence charge whereas such charge was $0.7 million in 2021, offset by an increase due to increased product revenue sales.

### Sales and Marketing Expenses

Sales and marketing expenses were $30.7 million for the year ended December 31, 2021, which increased by $0.2 million, from $30.5 million for the year ended December 31, 2020. The increase in sales and marketing expenses was primarily attributable to the following:

- a $1.8 million increase in in commercial analytic and market research costs, primarily related to prescription and payor data;
- a $1.5 million decrease in outsourced advertising and promotion costs due to timing of media buys and agency activities; and
- a $0.1 million increase in other sales and marketing related costs.

### General and Administrative Expenses

General and administrative expenses were $16.6 million for the year ended December 31, 2021, which increased by $4.7 million, from $11.9 million for the year ended December 31, 2020. The increase in general and administrative expenses was primarily attributable to the following:
• a $2.8 million increase in personnel costs, including stock-based compensation expense, primarily due to an increase in headcount and external consultants;
• a $1.0 million increase in insurance fees, related to directors’ and officers’ insurance;
• a $0.6 million increase in in consulting and professional fees, primarily in connection with operating as a public company; and
• a $0.3 million increase in in other general and administrative costs.

Research and Development Expenses

Research and development expenses were $3.6 million for the year ended December 31, 2021, which increased by $1.2 million from $2.4 million for the year ended December 31, 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 license agreements with HavaH Therapeutics (“HavaH”) and McGill University (“McGill”);
• a $0.7 million increase in clinical costs related to Phase 4 studies related to the development of JATENZO, our lead commercial product; offset by
• a $0.4 million decrease in costs related to research and development consulting services.

Other (Expense) Income, Net

Total other expense, net was $0.9 million for the year ended December 31, 2021, compared to income of $51.5 million for the year ended December 31, 2020. The decrease of $52.4 million was primarily related to a $54.4 million decrease in the change in fair value of the warrant liability and derivative, a $2.5 million increase from a legal settlement received associated with the patent infringement lawsuit with Lipocine, and an increase in interest expense of $0.5 million. The increase in interest expense is driven by an increase of $1.1 million in interest incurred with related parties offset by a decrease of $1.9 million in interest incurred with third parties and an increase of $0.3 million associated with a gain on extinguishment of the senior secured notes.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, Legacy Clarus has incurred significant operating losses, experienced negative operating cash flows and has accumulated significant accrued liabilities. Our net loss was $40.6 million and net income was $4.3 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had cash and cash equivalents of $26.4 million and an accumulated deficit of $321.7 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 and our December private placement, 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.

We are exploring strategic alternatives for the purpose of maximizing stockholder value. We expect to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Board has not approved a definitive course of action. Additionally, there
can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

Merger

On the Closing Date, we received net proceeds of approximately $17.0 million (not including the $25.0 million of additional capital provided prior thereto). 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 Common Stock, and Legacy Clarus’ equity holders’ and convertible debt holders’ equity interests converted into the right to receive shares of Common Stock or were canceled, retired and terminated without consideration as provided in the Merger Agreement. See “— Overview” for further discussion of the Merger.

Private Placement

In December 2021, we issued and sold 3,024,194 units in a private placement at a purchase price of $4.96 per unit, resulting in net proceeds of $13.8 million, after deducting offering expenses. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), and a five-year warrant to purchase one share of common stock at an exercise price of $5.25 per share. In connection with the private placement, we filed a resale registration statement with the SEC in December 2021 to register the resale of the common stock (including shares underlying the pre-funded warrants and other warrants) by the purchaser in the private placement.

Convertible Promissory Notes

On various dates from 2016 to 2021, Legacy Clarus entered into note purchase agreements, pursuant to which it borrowed an aggregate of $82.3 million from related party investors as of December 31, 2021. The carrying value of all convertible notes prior to conversion into shares of Common Stock at the Effective Time was $103.7 million. All such convertible notes had the option to convert into Legacy Clarus’ Series D Preferred Stock at an exercise price of $4.50.

At the Effective Time, all principal and accrued interest under such convertible notes converted into 8,529,846 shares of Common Stock.

Senior Secured Notes

On March 12, 2020, Legacy 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 it received $42.7 million in net proceeds after deducting the original issue discount, interest reserve and transaction expenses.

In the second quarter of 2021, Legacy 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 3 to our audited consolidated financial statements included elsewhere in this prospectus), $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 Common Stock (which included the 405,000 shares of Common Stock that were allocated to the senior secured noteholders pursuant to the share allocation agreement, of which 270,000 shares were reallocated from Legacy Clarus’ equity holders and 135,000 shares that were transferred from our former 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 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 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 December 31, 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 December 31, 2021 and following the completion of the merger, there is approximately $45.4 million of principal (including principal of $3.1 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. 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 of Legacy Clarus’ assets.

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 was amortized to interest expense over the life of the notes. For the years ended December 31, 2021 and 2020, we recorded $2.2 million and $2.1 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 December 31, 2021.

During the years ended December 31, 2021 and 2020, we recorded $8.9 million and $6.8 million, respectively in interest expense on the senior secured notes, of which $2.7 million and $2.2 million, respectively, was non-cash interest expense associated with the amortization of the debt discount and debt issue costs. We did not make any cash interest payments during the years ended December 31, 2021 and 2020.

Pursuant to the indenture governing the senior secured notes, Legacy Clarus was required 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, Legacy 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 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 $42.3 million related to the senior secured notes as a current liability within the December 31, 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. See Note 2 to our audited consolidated financial statements included elsewhere in this prospectus for further disclosure related to our assessment of the ability to operate as a going concern as of December 31, 2021.

**Forbearance Agreement**

On March 17, 2021, Legacy Clarus entered into a forbearance agreement with noteholders in relation to the senior secured notes. It was unable to and did not pay interest of $3.1 million due on March 1, 2021. As of March 31, 2021, Legacy 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, Clarus Therapeutics, Inc. 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 it, amongst other things, executed the Merger Agreement and provided financial reporting requirements by April 27, 2021.
Forbearance Extension

In August 2021, Legacy 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.

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, Legacy 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 it 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, Legacy 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 Common Stock upon the closing of the merger.

Second Indenture Note

In July 2021, Legacy 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 Common Stock upon the closing of the merger.

PPP Loan

In March of 2020, 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, Legacy Clarus received an unsecured loan of $0.5 million from the SBA. After considering further guidance issued by the SBA, it 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 years ended December 31, 2021 and 2020 (in thousands):
Net cash used in operating activities was $43.8 million for the year ended December 31, 2021, reflecting net loss of $40.6 million and cash used in net operating assets and liabilities of $7.2 million, offset by non-cash charges of $4.0 million. The non-cash charges consist of non-cash interest expense on debt financings and the royalty obligation of $13.1 million, settlement of interest with payment-in-kind note of $3.1 million, gain on extinguishment of senior note of $0.3 million, change in fair value of warrant liability of $12.5 million, stock-based compensation expense of $668 thousand and depreciation expense of $25 thousand. The change in net operating assets and liabilities was primarily due to an increase in inventory of $8.4 million, an increase in accounts receivable of $1.9 million, an increase in prepaid expenses and other current assets of $2.8 million, a decrease in deferred revenue of $0.4 million, partially offset by an increase in accrued expenses of $3.6 million and an increase in accounts payable of $1.8 million.

Net cash used in operating activities was $41.6 million for the year ended December 31, 2020, reflecting net income of $4.3 million, offset by a net change of $7.6 million in net operating assets and non-cash charges of $53.6 million. The non-cash charges primarily consist of the change in fair value of the warrant and derivative liabilities, 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 accounts payable of $7.7 million, an increase in accrued expenses of $2.9 million, an increase in deferred revenue of $1.2 million, partially offset by a decrease in accounts receivable of $4.4 million, and a decrease in prepaid expenses of $0.8 million.

Investing Activities

During the years ended December 31, 2021 and 2020, net cash used in investing activities was approximately $25 thousand and $63 thousand, respectively, and was used for the purchases of property and equipment.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $63.0 million, related to $23.6 million of proceeds from the issuance of convertible notes payable, $17.0 million in net proceeds from the Business Combination, $13.8 million of proceeds from issuance in a private placement of shares and accompanying purchase warrants, net of issuance costs, and $8.6 million of proceeds from the issuance of senior notes payable.

During the year ended December 31, 2020, net cash provided by financing activities was $47.2 million, primarily related to $49.1 million of gross 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, but not limited to, potential worsening global economic conditions and our stock price, and the recent disruptions to, and volatility in, the credit and financial markets in the United States.
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 expect our expenses to increase substantially in connection with its ongoing activities, particularly as we advance the commercialization of our product JATENZO. 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 audited consolidated financial statements are issued.

Since inception, Legacy Clarus has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Legacy Clarus, and since the merger, we, have incurred significant losses from operations since inception and has an accumulated deficit of $321.7 million as of December 31, 2021. Further, as of December 31, 2021, we had a working capital deficit of $14.4 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 8, Debt, in the Notes to the audited consolidated financial statements in this prospectus 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 our future operations, as of the issuance date of the audited consolidated financial statements for the year ended December 31, 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 consolidated financial statements are available to be issued and that there is substantial doubt about our ability to continue as a going concern. Management believes that our existing cash and cash equivalents of $26.4 million as of December 31, 2021 and revenue generated from sales of JATENZO will fund our operations into April 2022.

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:

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- 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.

Material Cash Requirements from Contractual and Other Obligations

Purchase Obligations

We have an agreement with Catalent under which we must make minimum annual purchases of JATENZO softgel capsules, through March 2025. Any shortfall between the minimum annual purchase quantities and actual purchases will be multiplied by a unit price, as defined in such 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. Purchases under the manufacturing agreement with Catalent (the “Catalent Agreement”) for the years ended December 31, 2021 and 2020 were $6.2 million and $3.2 million, respectively. The aggregate amount of future purchase obligations under the Catalent Agreement total $10.0 million as of December 31, 2021, of which $3.6 million is to be paid within one year.

We have an agreement with Pfizer, under which we must make minimum annual purchases of TU equal to approximately $1.8 million per year through January 2024. If there is a shortfall between the minimum annual purchase amount 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 supply agreement with Pfizer (the “Pfizer Agreement”) during the year ended December 31, 2021. The aggregate amount of future purchase obligations under the Pfizer Agreement total $4.7 million as of December 31, 2021, of which $1.8 million is to be paid within one year.

Lease Commitments

We have entered operating leases for rental space in Northbrook, Illinois and Murfreesboro, Tennessee that extend to December 31, 2022 and September 30, 2022, respectively. Total minimum rental payments owed under the leases as of December 31, 2021 totaled $90 thousand and are all due within one year.

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.

Long-Term Debt Commitments

As discussed above and in Note 8 to our audited consolidated financial statements included elsewhere in this prospectus, we have outstanding senior secured notes.
License Agreement Commitments

Under the terms of our licensing agreement with HavaH, 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.

Under the terms of our licensing agreement with McGill, 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

Our management’s discussion and analysis of financial condition and results of operations is based on its financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in its financial statements. We base its estimates on historical experience, known trends and events and various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate its estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in greater detail in Note 2 to our audited consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of its financial statements.

Revenue Recognition

In accordance with ASC 606, Revenue from Contracts with Customers (“ASC 606”), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled to in exchange for those goods or services. We perform the following five steps to recognize revenue under ASC 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only recognize revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations. We then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. We have determined that the delivery of its product to its customer constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered fulfillment activities and are not considered to be a separate performance obligation. We have assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore, no amount of consideration has been allocated as a financing component. Taxes collected related to product sales are remitted to governmental authorities and are excluded from revenue.
Net Product Sales

We began selling JATENZO in February 2020, in the United States through a 3PL which takes title and control of the goods. The 3PL distributes the product to wholesale distributors (collectively the “Distributors”), with whom we have entered into formal agreements for delivery to retail pharmacies. We have also entered into arrangements with payors that provide government mandated and/or privately negotiated rebates, chargebacks and discounts for the purchase of our products.

We recognize revenue on sales of JATENZO when the customer obtains control of the product, which occurs at a point in time, typically upon delivery. Product revenues are recorded at the product’s wholesale acquisition costs, net of applicable reserves for variable consideration that are offered within contracts between us and our customers, wholesale distributors, payors, and other indirect customers relating to the sale of JATENZO. Components of variable consideration include government and commercial contract rebates, product returns, chargebacks, commercial co-payment assistance program transactions and distribution services fees. These deductions are based on the amounts earned or to be claimed on the related sales and are classified as a current liability or reduction of receivables, based on expected value method and a range of outcomes and are probability weighted in accordance with ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognition under contracts will not occur in a future period. Our analyses contemplate the application of the constraint in accordance with ASC 606. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from its estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Transaction Price and Variable Consideration

We utilize the expected value method when estimating the amount of variable consideration to include in the transaction price with respect to each of the foregoing variable components. Variable consideration is included in the transaction price only to the extent it is probable that a significant revenue reversal will not occur when the uncertainty associated with the variable consideration is resolved. The variable component of the transaction price is estimated based on factors such as our direct and indirect customers’ buying patterns and the estimated resulting contractual deduction rates, historical experience, specific known market events and estimated future trends, current contractual and statutory requirements, industry data, estimated customer inventory levels, current contract sales terms with our direct and indirect customers and other competitive factors. We subsequently review its estimates for sales deductions based on new or revised information that becomes available to us and make revisions to our estimates if and when appropriate, which would affect product revenue and earnings in the period such variances become known.

Co-payment Assistance

We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-payment assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Rebates

We establish contracts with wholesalers, chain stores and indirect customers that provide for rebates, sales incentives, DSA fees and other allowances. Some customers receive rebates upon attaining established sales volumes. Direct rebates are generally rebates paid to direct purchasing customers based on a percentage applied to a direct customer’s purchases from us, including fees paid to wholesalers under distribution service agreements. Indirect rebates are rebates paid to indirect customers that have purchased our products from a wholesaler under a contract with us.

We are subject to discount obligations under state Medicaid programs and Medicare. For example, we are required to provide a discount to patients who fall within the Medicare Part D coverage gap, also referred to as the donut hole. We also pay Medicaid rebates owed based upon contractual agreements or legal requirements with public sector (Medicaid) benefit providers after the final dispensing of the product by a pharmacy to a benefit plan participant. Medicaid reserves are based on expected payments, which are driven by patient usage, contract
performance and field inventory that will be subject to a Medicaid rebate. Medicaid rebates are typically billed up to 180 days after the product is shipped, but can be as much as 270 days after the quarter in which the product is dispensed to the Medicaid participant. Periodically, we adjust the Medicaid rebate provision based on actual claims paid. Due to the delay in billing, adjustments to actual claims paid may incorporate revisions of this provision for several periods. Because Medicaid pricing programs involve particularly difficult interpretations of complex statutes and regulatory guidance, our estimates could differ from actual experience.

We also enter into contracts with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of our product.

Rebate reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the balance sheets. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

In determining our estimates for rebates, it considers the terms of its contracts and relevant statutes, together with information about sales mix (to determine which sales are subject to rebates and the amount of such rebates), historical relationships of rebates to revenues, past payment experience, estimated inventory levels of our customers and estimated future trends. Changes in the level of utilization of our product through private or public benefit plans and group purchasing organizations ("GPOs") will affect the amount of rebates that we owe.

Product Returns

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, a product may be returned for a period beginning six months prior to its expiration date and up to one year after its expiration date. The right of return expires on the earlier of one year after the product expiration date or the time that the product is dispensed to a patient. Returns are settled through the issuance of a credit to the customer. We calculate sales returns using the expected value method. Sales returns are recorded in accrued expenses and as a reduction of revenue.

In determining our estimates for returns, we are required to make certain assumptions regarding the timing of the introduction of new products and the potential of these products to capture market share. In addition, we make certain assumptions with respect to the extent and pattern of decline associated with generic competition. To make these assessments, we utilize market data for similar products as analogs for its estimations. We use its best judgment to formulate these assumptions based on past experience and information available to us at the time. We continually reassesses and make appropriate changes to its estimates and assumptions as new information becomes available to us.

Our estimate for returns and allowances may be impacted by a number of factors, but the principal factor relates to the level of inventory in the distribution channel. Where available, we utilize information received from its wholesaler customers about the quantities of inventory held, including the information received from Distributors, which we have not independently verified. As of December 31, 2021, we believe that its estimates of the level of inventory held by its customers is within a reasonable range as compared to both historical amounts and expected demand for each respective product.

Chargebacks

We market and sell products to both: (i) direct customers including its 3PL and (ii) indirect customers including independent pharmacies, other wholesalers, non-warehousing chains, managed care organizations, GPOs and government entities. We enter into agreements with certain of its indirect customers to establish contract pricing for its product. These indirect customers then independently select a wholesaler from which to purchase the product at these contracted prices. Chargebacks represent the estimated obligations resulting from contractual commitments to sell our product at prices lower than the list prices charged to our Distributors. These Distributors charge us for the difference between what they pay for the product and the contracted selling price. These reserves are established in the same period that the related revenue is recognized,
resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that we expect to pay for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but which have not yet been settled.

**Other Sales Deductions**

We offer prompt-pay cash discounts to certain of its customers. Provisions for such discounts are estimated and recorded at the time of sale. We estimates provisions for cash discounts based on contractual sales terms with customers, an analysis of unpaid invoices and historical payment experience. Estimated cash discounts have historically been predictable and less subjective due to the limited number of assumptions involved, the consistency of historical experience and the fact that we generally settles these amounts within 30 to 60 days.

Shelf-stock adjustments are credits issued to customers to reflect decreases in the selling prices of our products. These credits are customary in the industry and are intended to reduce a customer’s inventory cost to better reflect current market prices. The primary factors we considers when deciding whether to record a reserve for a shelf-stock adjustment include:

- the estimated number of competing products being launched as well as the expected launch date, which we determine based on market intelligence;
- the estimated decline in the market price of product, which we determine based on historical experience and customer input; and
- the estimated levels of inventory held by customers at the time of the anticipated decrease in market price, which we determine based upon historical experience and customer input.

**Inventory**

Inventory is stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method. Inventories are written down for product that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. Write-downs of inventory establish a new cost basis which is not increased for future increases in the net realizable value of inventories or changes in estimated obsolescence.

**Research and Development Expenses**

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Examples of estimated accrued research and development expenses include fees paid to vendors in connection with preclinical development activities, vendors related to development, and manufacturing and distribution of product candidate materials.

Our research and development expenses include salaries and benefits, clinical trials costs, contract services and manufacturing development costs, all of which are recorded as incurred. If, however, any of the goods are not to be delivered or services are no longer expected to be performed, then we would expense the advance payments previously recorded. We had no capitalized nonrefundable advance payments and no refundable advance payments as of December 31, 2021 or 2020.

We base its expenses related to clinical studies on its estimates of the services received and efforts expended pursuant to contracts with multiple vendors that conduct and manage preclinical studies on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, We estimate the time period over which services will be performed and the level of effort to be expended in each period and adjust accordingly.
Valuation of Private Placement Warrants

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.

Stock-Based Compensation

We account for all stock-based compensation awards granted as stock-based compensation expense at fair value. Stock-based payments include stock options and grants of common stock, restricted for vesting conditions. The measurement date for awards is the date of grant, and stock-based compensation costs are recognized as expense over the requisite service period, which is generally the vesting period, on a straight-line basis. Stock-based compensation expense is classified in the accompanying statements of operations based on the function to which the related services are provided. We recognize stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur.

Prior to the Merger, Legacy Clarus estimated the fair value of each stock option grant and restricted common stock award. It considered the fair value of its common stock, an input to the option pricing models, a critical accounting estimate.

Valuation of Common Stock

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the common stock and assumptions for the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option and our expected dividend yield.

The expected term of options granted to employees was determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, dividends on the Common Stock; therefore, the expected dividend yield is assumed to be zero. We determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. We expect to continue to do so until we have adequate historical data regarding the volatility of the trading price of the Common Stock on Nasdaq.

As there was no public market for Legacy Clarus’ common stock, the estimated fair value of its common stock was determined by its most recently available third-party valuations of common stock. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using an operating profit margin (“OPM”). The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes.

Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.
In addition to considering the results of these third-party valuations, Legacy Clarus’ board of directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, including:

- the prices at which it sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to common stock at the time of each grant;
- the progress of research and development programs, including the status and results of preclinical studies for product candidates;
- stage of development and commercialization and its business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- Legacy Clarus’ financial position, including cash on hand, and historical and forecasted performance and operating results;
- the lack of an active public market for common stock and preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management’s best estimate, which involved inherent uncertainties and the application of management’s judgment. As a result, if Legacy Clarus had used different assumptions or estimates, the fair value of its common stock and its stock-based compensation expense could have been materially different.

Recently Issued Accounting Pronouncements

See Note 2 to our audited consolidated financial statements for the year ended December 31, 2021 included elsewhere in this prospectus.

Qualitative and Quantitative 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 December 31, 2021 and 2020, we had cash and cash equivalents of $26.4 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 December 31, 2021 and, 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 percent of our total debt, on an amortized cost basis. As of December 31, 2021 and 2020, our outstanding debt obligations at fixed interest rates were comprised of convertible promissory notes and senior notes.
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 we are 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 elected 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 we choose to early adopt a new or revised accounting standard.
BUSINESS

Overview

We are a pharmaceutical company focused on the commercialization of JATENZO, the first and only oral T-replacement or TRT of its kind that has received final approval by the 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 to become a pharmaceutical company initially focused on the development and commercialization of JATENZO and other metabolic therapies for men and women.

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 produg 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, 2021, JATENZO was available under health plans, representing approximately 70% of all insured lives. Of these patients, 77% of patients with commercial insurance had access to JATENZO. In the year ended December 31, 2021, JATENZO generated net revenues of approximately $14.0 million, demonstrating consistent month over month prescription growth since beginning commercialization despite the commercial challenges presented by the ongoing COVID-19 pandemic. 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 for the protected conditions of use of JATENZO until March 27, 2022.

Initial Business Combination

We were a blank check company incorporated in Delaware on May 22, 2020 and 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. On September 9, 2021, we consummated the previously announced business combination pursuant to the terms of the Merger Agreement by and among the Company, our wholly-owned merger subsidiary, and Legacy Clarus, in which our merger subsidiary merged with and into Legacy Clarus, with Legacy Clarus surviving as the post-merger company and as a wholly owned subsidiary of the Company. On the Merger Closing Date, we changed our name from Blue Water Acquisition Corp. to Clarus Therapeutics Holdings, Inc. At the Effective Time, Legacy Clarus security holders received an aggregate of 17,886,348 shares of Common Stock (which included 135,000 shares that were transferred from the Sponsor pursuant to a share allocation agreement), assumed some Legacy Clarus warrants that are now exercisable for 9,246 shares of Common Stock, and the remaining shares of Legacy Clarus capital stock and all outstanding options, warrants or rights to purchase or subscribe for any Legacy Clarus capital stock, securities convertible into or exchangeable for, or that otherwise conferred on the holder any right to acquire any capital stock of Legacy Clarus were cancelled, retired and terminated without any consideration or any liability to Legacy Clarus with respect thereto. In addition, all shares of our Class B common stock, par value $0.00001 per share, were converted into Class A common stock and then redesignated as Common Stock.

Capital Raising and Restructuring Plan

In light of our current liquidity, we need to raise additional capital to support our operations and debt obligations and concurrently, we are exploring strategic alternatives for the purpose of maximizing stockholder value. We have been and expect to continue to devote significant efforts to raise capital, restructure our indebtedness and identify and evaluate potential strategic alternatives but there can be no assurance that these efforts will be successful, that we will be able to raise necessary capital on acceptable terms, reach agreement with our lenders, or that the strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Board has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders. Any failure in these efforts could force us to delay, limit or terminate our operations, make reductions in our workforce, discontinue our commercialization efforts for JATENZO as well as other development programs, liquidate all or a portion of our assets or pursue other strategic alternatives, fall into forbearance on our debt obligations, and/or seek protection under the provisions of the U.S. Bankruptcy Code.
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**TRT Overview**

T-deficiency is diagnosed in men by a simple blood test that identifies a T concentration below 300 nanograms per deciliter. Common symptoms identified in the Endocrine Society’s clinical guidelines that suggest testing for T deficiency include reduced sexual activity and desire, decreased energy, increased body fat and reduced muscle mass, depressed mood and other emotional and physiological issues. T-deficiency affects approximately 20 million men over the age of 45, according to a study published in the International Journal of Clinical Practice in 2006. Of this population, about 8 million are diagnosed with hypogonadism, and even fewer, approximately 2.2 million, actually receive TRT, the standard treatment for hypogonadism. Even with this low treatment rate, the overall market for TRT grew 7% in 2020 over 2019, despite the ongoing COVID-19 pandemic, which followed a 6.6% growth in prescriptions in the United States in 2019 as compared to 2018. The overall T-replacement therapy market was nearly 8 million prescriptions in 2020 and has been growing at a 5% compound annual growth rate, according to Symphony Health (Payer/Plan TRx Volume).

Existing therapeutic options for hypogonadal men, including T-injections (intramuscular and subcutaneous), T-gels, T-patches, T-buccal T-patches and implanted subcutaneous T-pellets, all suffer from limitations due to their routes of administration and ease of use. Consequently, these TRT options have low rates of adherence to prescribed dosing regimens. For example, only 31% and 14% of men continued taking T-gel six and 12 months after commencing therapy, respectively, according to a peer-reviewed study that reviewed enrollment and medical records of more than 15,000 men with hypogonadism. In addition, according to a survey we commissioned in 2020, 76% of the surveyed men reported that their needs are not being met by existing T-replacement therapies. This same poll found that 82% of TRT users were interested in learning about an oral TRT option. We believe that many hypogonadal patients are not satisfied with non-oral therapies due to administration and other challenges. Thus, they often discontinue their TRT or switch from one option to another in a cyclical search of a TRT that is acceptable. We believe JATENZO not only provides patients with the convenience of an oral route of administration but also the efficacy and safety necessary to treat hypogonadism. Although T-injections and T-gels collectively represent 95% of the TRT market, these products have significant challenges. Injections are painful, yield considerable inter-day T level variability and carry the risk of pulmonary micro-embolisms ("POMEs"). Gels are messy, pose a significant risk of T transference to the patient’s partner or children and result in substantial amounts of T entering the environment when patients shower, bathe or swim. Overall, we believe that JATENZO is more convenient than currently approved T therapies, thus making it more likely that men will adhere to their treatment.

We own patents and pending applications in the United States and several other countries worldwide having claims covering the formulation and use of JATENZO, and have been involved in a U.S. district court patent infringement action, and USPTO interference proceedings with Lipocine involving Lipocine patents and Clarus patent application having claims covering the use of JATENZO and/or Lipocine’s TLANDO product. See *Business—Legal Proceedings:* We have established a contract sales force of approximately 60 sales representatives as of December 17, 2021 to promote JATENZO in the United States. Assuming we are able to raise additional capital, we intend to invest additional resources to expand our national footprint to approximately 100 targeted sales representatives and to bring this sales force in-house by the end of 2022. Our sales force currently targets high volume prescribing health care providers ("HCPs") comprised of endocrinologists, urologists and primary care physicians. We continue to evaluate marketing or co-promotion arrangements to leverage our existing sales force and provide even broader JATENZO penetration in the U.S. market. We continue to explore potential strategic partnerships to assist in obtaining marketing approval for and commercialization of JATENZO outside of the United States (particularly in Europe, Asia and the Middle East). Success in achieving sales of JATENZO outside the United States could be a source of non-dilutive funding. We are also actively exploring potential business development transactions to expand our portfolio and leverage our existing sales force.

Since the beginning of our operations in 2004 through our wholly-owned subsidiary, Clarus Therapeutics, Inc., we have assembled a seasoned management team with significant commercial TRT and large pharmaceutical experience. President and Chief Executive Officer, Dr. Robert Dudley, and founder of Clarus Therapeutics, Inc., has over 30 years of experience in the T-replacement field and led the discovery, development, regulatory approval and launch of AndroGel, the first T-gel product. He also co-invented JATENZO and oversaw its development through approval by the FDA. Our senior management team includes industry veterans who have collectively more than 60 years of experience in the TRT market.
Our Strategy

Assuming we are able to raise additional capital, our goal is to build a pharmaceutical company that commercializes products complementary to our lead product, JATENZO. Key elements of our strategy to achieve this goal include:

- **Establish JATENZO as the preferred choice among appropriate hypogonadal men for T-replacement.** We will continue to drive awareness of JATENZO by leveraging the convenience of JATENZO’s oral administration and will seek to establish JATENZO as the preferred TRT treatment for HCPs and their hypogonadal patients.

- **Accelerate the build of our commercial infrastructure to successfully grow the market for JATENZO and launch any additional products we develop or acquire.** We will grow our commercial infrastructure and sales force that targets endocrinologists, urologists and PCPs who are high prescribers of TRT.

- **Explore additional indications for JATENZO and consider business development opportunities to grow our pipeline and product portfolio.** We plan to use exploratory trials to guide the development of JATENZO for additional potential indications, including, for example, treatment of hypogonadism associated female-to-male transgender T therapy and chronic kidney disease. We will also seek to leverage the commercial launch of JATENZO with our sales organization and commercial infrastructure to develop or acquire the rights to additional complementary products or product candidates.

### Hypogonadism and the T-Replacement Therapy Market

#### Hypogonadism or T-Deficiency

T is a key male sex hormone and is essential to the development of male growth. It is responsible for promoting growth of muscle mass, increasing bone density and strength, and stimulating linear growth and bone maturation. In addition, researchers increasingly have identified T as an important factor in metabolic function and other physiological processes, including the observation that normal levels help maintain energy levels and an overall sense of well-being in men.

Approximately 20 million men in the United States between the ages of 45 and 75 years old may have deficient levels of T, defined as circulating T levels below 300 nanograms per deciliter, based upon age-based prevalence rates published in the International Journal of Clinical Practice in 2006 and the U.S. Census Bureau’s 2012 population estimates.

The Endocrine Society, a professional medical organization comprised of HCPs with medical expertise in the area of hormones and related medical disorders, has published clinical guidelines identifying signs and symptoms of hypogonadism, including the following:
There are two types of hypogonadism: primary, or classical, hypogonadism and secondary hypogonadism.

Primary hypogonadism is caused by the failure (inability) of the testes to synthesize and secrete T. Causes of primary hypogonadism include Klinefelter’s syndrome, a condition in which males have an extra X chromosome, testicular tumors, testicular damage, varicocele, which is an abnormal enlargement of the vein in the scrotum that drains blood from the testicles, disease-associated testicular damage, including that from mumps, certain systemic diseases, such as renal insufficiency, and exposure to alcohol in chronic excess.

Secondary hypogonadism is caused by a fault in the hypothalamic-pituitary axis that results in an inadequate gonadotropin signal to the testes to produce T. Secondary hypogonadism is relatively common among men with diseases such as type-2 diabetes and its common precursor, metabolic syndrome. For example, approximately 33% and 12% of men with type-2 diabetes and metabolic syndrome, respectively, are hypogonadal, according to research published in Diabetes Care in 2007 and the Journal of Andrology in 2009. Secondary hypogonadism is also associated with obesity, chronic heart disease, chronic kidney disease, asthma and chronic obstructive pulmonary disease.

**U.S. TRT Market Dynamics %**

U.S. sales of T-replacement therapies, currently the standard treatment for T deficiency, exceeded $1.3 billion in 2020, according to Symphony Health, and almost 8 million prescriptions for T-replacement therapies are written per year. U.S. sales represent the vast majority of global TRT sales, with injections representing 36% and gels representing 58% of the U.S. sales dollars in 2020. Injections represent 75% and gels represent 24%, respectively, of all U.S. prescriptions written in 2020.

The following graph demonstrates year-over-year prescription growth in the U.S. TRT market over the last 5 years.
We believe there is potential for continued TRT market expansion. According to a study published in the *Archives of Internal Medicine* in 2008, only 12% of hypogonadal men, representing less than half of all men diagnosed with hypogonadism, actually receive TRT. Additionally, the overall TRT market in 2020 grew 7% over 2019, to approximately 8 million prescriptions per year, despite the COVID-19 pandemic. This followed a 6.6% growth in prescriptions in 2019 as compared to 2018. Our expectation of continued growth and penetration in the TRT market in the United States is based on a number of factors, including:

- a growing awareness among physicians to diagnose and treat hypogonadism and willingness by patients to discuss signs and symptoms of their medical condition than in the past;
- recognition and association by HCPs of the association of hypogonadism with other increasingly prevalent diseases, such as metabolic syndrome, type 2 diabetes, chronic renal disease and chronic heart disease;
- the ability to easily identify low serum T levels through a simple blood test; and
- continuing guidance from medical societies (including the Endocrine Society, American Association of Clinical Endocrinologists and American Urological Association), that clinicians measure serum T levels of patients if they present with symptoms or signs typically associated with hypogonadism.

**Limitations of Existing Treatments for Hypogonadism**

The U.S. TRT market is comprised primarily of non-oral T treatments, including injections, gels, topical and buccal patches, and implanted subcutaneous pellets. Each of these products is associated with different T pharmacokinetic profiles which, in turn, can lead to significant intra- and inter-patient variabilities in circulating T response and associated symptom relief. Furthermore, each TRT delivery route has been associated with user challenges. For example, the pain of weekly deep muscle injections, skin irritation associated with the T-patch or T-gels, risk of T transference to women and children by T-gel users, potential anaphylactic reactions observed with a long-acting depot form of TU, thrice-daily administration of a nasal T preparation, and a surgical procedure for placement of T-pellets. Consequently, there has been relatively poor patient adherence and significant ‘switching’ from one TRT to another. Missing from the available armamentarium of TRT therapies was an oral T product that was effective in meeting current T-replacement regulatory standards and one not associated with potentially serious liver toxicity. Prior to JATENZO’s approval, the only oral T-replacement product approved by FDA (over 60 years ago) was methyltestosterone — a chemical cousin of T that has been associated with serious liver toxicity and thus has been rarely prescribed. Therefore, when viewed in the historical context of TRT, we believe JATENZO offers appropriate hypogonadal patients an easy-to-use, safe and effective TRT option that was not previously available.
Prior to 2000, with the introduction of a T-gel, T was primarily available through either scrotal or non-scrotal patches, pellets, or injections. T-injections, which became the dominant mode of administration and remain so today. However, besides having pain at the injection site, intramuscular T products carry significant risk of POME and polycythemia (i.e., increase in red blood cell count) which requires monitoring by the healthcare provider.

With the introduction of a T-gel formulation in 2000, topical T administration became desirable because of its ease of use. However, over time common side effects including itching, irritation and discomfort at the application site became increasingly problematic for patients. Additionally, topical T-gels place partners and children at risk of T transference (secondary exposure to T when transferred from user to non-user (e.g., women and children)). This prompted the FDA to add boxed warnings to the labeling for T-gels relating to T transference. Despite these limitations, gels have continued to demonstrate significant market penetration.

The other approved TRT therapies have their own limitations, including gum, nasal and skin irritation and difficulty of administration (e.g., office procedure). As a result, non-oral TRT products are associated with low rates of patient compliance and adherence. More than 95,000 men change T-replacement therapies more than once per year. According to a peer-reviewed study published in the Journal of Sexual Medicine in 2013, only 31% and 14% of patients were still on gel therapy six months and 12 months, respectively, after first dosing, and only about half of those who discontinued therapy later resumed treatment.

Our Solution — JATENZO

Our first commercial product, JATENZO, was approved in March 2019 by the FDA for oral TRT use in adult males for conditions associated with a deficiency or absence of endogenous, or naturally produced, T, including congenital or acquired primary and secondary hypogonadism, with a boxed warning. JATENZO was the first oral T-medicine approved by the FDA in more than 60 years, the first oral T-prodrug, and the first and only oral softgel TRT.

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 Oral Dosing.** JATENZO as either one or two easy-to-swallow softgels is taken twice daily with a regular meal. We believe oral dosing is preferred by most patients, is easier to use than other TRTs currently on the market and will ultimately improve the low TRT adherence rates.

- **Normalized T Levels.** After dose adjustment (if necessary), 87% of men treated with JATENZO in our clinical trials achieved average serum T levels in the normal range. In addition, JATENZO improved the classic signs and symptoms associated with hypogonadism, including psychosexual symptoms, body mass index, fat mass and bone mineral density.

- **Avoids Administration Challenges.** Unlike other TRT products, JATENZO is an oral product and as such avoids the challenges, risks and safety issues seen with non-oral products. JATENZO avoids the risk of T transfer to partners and children that exists with gel treatment; injection site pain, risk of POME and polycythemia seen with injections, and the gum, nasal and skin irritation and difficulty of administration seen with other TRT products.

- **Safety Profile.** JATENZO’s overall safety profile is generally consistent with that observed in clinical trials of other FDA approved TRTs. The modest increase in systolic blood pressure observed in men treated with JATENZO is not unique and has been observed with injectable T and other oral TU products under development in the United States or marketed outside the United States. Importantly, JATENZO has not been associated with liver toxicity in Phase 3 clinical testing that included patients treated with JATENZO for up to two years.
We commercially launched JATENZO in the United States in February 2020. In the year ended December 31, 2020, JATENZO generated net revenue of approximately $6.4 million and in the year ended December 31, 2021, JATENZO generated net revenue of approximately $14.0 million. Despite the ongoing COVID-19 pandemic which had a profound effect on our ability to market JATENZO to HCPs, we achieved prescription growth month-over-month during the first two years of our launch as a result of our increasing educational efforts and increasing commercial payor coverage.

As of December 31, 2021, JATENZO was available and covered for approximately 70% of all insured lives. Of these patients, 77% of patients with commercial insurance had access to JATENZO. This level coverage is consistent within the class of approved T-replacement products. We anticipate being able to secure additional payor coverage for JATENZO but there is no guarantee this will occur.

JATENZO is available in three capsule strengths yielding five available dosing levels, for twice daily administration with food. In our pivotal Phase 3 trial of JATENZO, an open-label study designed to evaluate the efficacy and safety of JATENZO in adult hypogonadal male subjects referred to as the ‘inTUne trial’, JATENZO was evaluated for safety against Axiron, a then commonly prescribed topical T formulation. A total of 222 hypogonadal men were randomized, with 166 in the JATENZO group and 56 in the Axiron group. JATENZO achieved the primary endpoint, with 87% of patients treated with JATENZO achieving an average T level in the normal male range by the end of the trial period and in some cases in as little as seven days. Notably, a robust dose-titration paradigm was tested and validated such that T responses to JATENZO could be tailored to individual patient requirements if a dose adjustment was necessary. As shown in the following graphic, JATENZO also improved classic signs and symptoms associated with hypogonadism in the inTUne trial, including free (i.e., bioactive) T, psychosexual symptoms, body composition, and bone mineral density, each as illustrated in the figures below.

The safety profile of JATENZO was consistent with data generated in two earlier Phase 3 trials and the general safety profiles for TRT products as a therapeutic class. No liver toxicity was observed. The most common adverse events of JATENZO were headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%). Each of the treatment-emergent adverse events of an increased hematocrit was considered by the investigator as mild in intensity. Compared to baseline, mean serum sex hormone binding globulin concentrations declined significantly in response to JATENZO but remained within the normal range after approximately three to four months of JATENZO. In parallel, concentrations of free T increased such that by the end of treatment, mean levels were significantly higher than baseline but still within the normal range. JATENZO was associated with a modest increase in average systolic blood pressure of about 3-5 mmHg — an increase consistent in magnitude with a currently marketed form of injectable testosterone. Because any increase in systolic blood pressure increases the theoretical risk of an adverse cardiovascular event (e.g., heart attack or stroke), FDA required that JATENZO (as well as an injectable T product approved in 2018 XYOSTED) to carry a boxed warning.
about potential increased blood pressure. Due to this risk, the boxed warning also states that use of JATENZO is only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies. We are also required by the FDA to conduct certain post-marketing studies to assess patient understanding of key risks relating to JATENZO, evaluate adrenal function with chronic JATENZO therapy, and conduct a pediatric study of JATENZO in adolescent hypogonadal patients.

In recent years, the FDA has mandated changes to all TRT product labeling to define the indicated uses of TRT products more explicitly and to strengthen precautions and warnings about their use. For example, language about potential cardiovascular risks, including deep vein thrombosis, now appears in TRT labeling as does a caution against TRT use in men with “age-related hypogonadism.”

Assuming we have sufficient capital, we plan to explore additional potential indications for JATENZO including, for example, treatment of hypogonadal men with chronic kidney disease and as T replacement in female-to-male transgender patients. We plan to conduct small exploratory Phase 4 studies to confirm our hypotheses that JATENZO therapy in these patient populations will restore T levels to the normal male range and improve other biomarkers and symptoms associated with T deficiency. We then expect to conduct Phase 3 studies based on FDA guidance that would potentially result in expanded labeling indications for JATENZO. The following table summarizes our current pipeline of product candidates.

We will also continue to explore commercial partnerships with outside organizations to maximize the sales and marketing potential for JATENZO. Of particular interest are establishing marketing partnerships for JATENZO in Europe, Asia and the Middle East.

**Additional Product Candidates**

Assuming we have sufficient capital, we will seek to leverage the commercial launch of JATENZO with our sales team and commercial infrastructure to develop or acquire rights to additional complementary products or product candidates. Our business strategy is to identify complementary development and commercialization opportunities that apply our management expertise, commercial infrastructure and sales force to approved products or product candidates. Our strategy is to pursue these opportunities both on our own and with industry leading partners. We believe this strategy offers a distinct value to patients, healthcare providers, pharmaceutical partners and our stockholders.

In May 2021, we entered into a licensing agreement to acquire the exclusive worldwide (excluding Australia) development and commercialization rights for HAVAH T+Ai™ (CLAR-121). CLAR-121 is a proprietary combination of T (natural ligand for the androgen receptor; (“AR”)) and anastrozole (an aromatase inhibitor that blocks T conversion to estradiol) delivered by a subcutaneous implant for treatment of AR-mediated breast disease.
that predominantly affects women. Our initial therapeutic target will be inflammatory periductal mastitis ("PDM") — a painful, often debilitating inflammation of breast tissue. We estimate that the annual total U.S. patient population of women with PDM is approximately 150,000. We are not aware of any effective pharmaceutical intervention for PDM and intend to seek FDA Orphan Drug designation for CLAR-121 for use in the treatment of PDM. However, there can be no guarantee that FDA will grant such designation. In addition to PDM, CLAR-121 may have potential use to treat estrogen receptor-positive ("ER+") breast cancer as AR is a tumor suppressor in ER+ breast cancer. Of the approximately 280,000 annual cases of breast cancer in the United States, 80% of these are ER+ and 90% of ER+ breast cancers are also AR+. We will need to undertake significant development to demonstrate clinical efficacy and safety and to secure FDA approval for both of these potential uses for CLAR-121. There is no guarantee such development will be successful and result in FDA approval of CLAR-121 for either condition.

In September 2021, we entered into a licensing agreement with McGill, Canada’s top ranked medical doctoral university, whereby we will develop and commercialize McGill’s proprietary technology to develop potential treatments for rare, endocrine, metabolic, and neurological conditions associated with primary and secondary CoQ10 (ubiquinone) deficiencies that belong to the wider class of mitochondrial diseases.

CoQ10 is synthesized in the inner membrane of mitochondria, a cellular organelle whose primary function is to produce the body’s chemical energy. Deficiencies of CoQ10 can lead to severe multiple organ dysfunctions that involve the brain, nerves, kidneys, heart, gastrointestinal tract and muscle. Oral CoQ10 is largely ineffective because it does not result in intracellular uptake of CoQ10. McGill has identified a method to substantially increase such uptake, thereby forming the basis for a new, and potentially profound, method of addressing deficiencies of CoQ10. There is no guarantee that such method will be successful.

Mitochondrial diseases are chronic, genetic diseases that occur when the mitochondria, structures in our body cells that produce energy from oxygen and food, fail to function properly. Mitochondrial diseases can affect almost any area of the body and can occur at any age, making them often misdiagnosed.

**Sales, Marketing and Distribution**

We have built a robust internal commercial organization in the United States to market and sell JATENZO and any additional products we may develop or acquire. We have also established with a commercial outsource partner a sales force at the time of launch (February 2020) of approximately 55 representatives dedicated solely to promoting JATENZO in the United States. On December 17, 2021, we increased that number to 60 representatives. Assuming we have sufficient capital, we intend to invest additional resources to bring our sales force in-house while expanding our national footprint. Our sales force targets high prescribing endocrinologists, urologists and primary care physicians. We believe that this approach allows us to achieve broad geographic coverage while connecting with the most valuable targets. In addition, we conduct direct outreach to hypogonadal men through paid search, social media and programmatic advertising. In April 2020, in connection with the COVID-19 pandemic, we incorporated digital assets and virtual marketing into our sales force approach, including virtual sales calls, and we expect to proceed with a hybrid virtual and in-person approach moving forward. We also intend to explore additional strategies to engage both the patient and the consumer through various direct-to-consumer modalities. The launch of any future products may require further expansion of our existing sales force.

In addition to developing our own commercial organization, we continue to evaluate distribution or co-promotion arrangements with established pharmaceutical companies that have either complimentary product offerings or with established pharmaceutical companies to expand the footprint for JATENZO.

We are considering strategic partners with demonstrated commercial capabilities to assist in obtaining marketing approval for and commercialization of JATENZO outside of the United States. We intend to seek approval and launch commercial sales of JATENZO in territories outside of the United States by establishing additional collaborations with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs and our available resources. In May 2014, we entered into an agreement with CBC SPVI, Ltd. ("C-Bridge"), pursuant to which we and C-Bridge agreed to make commercially reasonable efforts to jointly develop a plan for the commercial manufacture, marketing, promotion, sale, distribution, and commercial importation and exportation of JATENZO and any related products in China. As part of this agreement, C-Bridge also purchased convertible promissory notes and became an investor in our company.
We have contracted with numerous wholesale distributors, including Cardinal, McKesson Corporation and Amerisource Bergen Corporation, to distribute JATENZO to retail pharmacies. In addition to shipping our product, these distributors provide inventory and sales reports as well as other services. In exchange for these services, we pay fees to certain distributors based on a percentage of wholesale acquisition cost. We also plan to explore using alternative, non-retail channels to distribute JATENZO.

Manufacturing

We have established a comprehensive supply chain for commercial manufacture of JATENZO capsules. We rely on contract manufacturers to produce the drug substance and drug product required for our commercial supply and clinical studies. We have qualified two sources of bulk TU, entered into an exclusive manufacturing relationship for the manufacture of the softgel capsules and engaged with a commercial packager for the production of finished JATENZO capsules. All lots of drug substance and drug product used for our commercial supply and clinical studies are manufactured, packaged and labeled under cGMP. The FDA inspects manufacturing facilities periodically, with the frequency based on its assessment of risk. We have established an internal quality control and quality assurance program, including a set of standard operating procedures and specifications that we believe is cGMP-compliant.

We expect to continue to rely on third parties for our manufacturing processes and for the production of all drug substance and drug product used for our commercial supply and clinical studies of JATENZO and any other product or product candidate we may develop or acquire. We plan to continue to rely upon contract manufacturers and, potentially, collaboration partners, to manufacture commercial quantities of JATENZO and any other product we may develop or acquire, if such product is approved in Europe or in territories outside of the United States and Europe.

For the commercialization of JATENZO, we have:

- qualified two sources of bulk TU, Pfizer and Xianju, both of which are subject to continuing FDA review and periodic inspection, and entered into a commercial supply agreement with each;
- entered into an exclusive manufacturing agreement with Catalent for the manufacture of JATENZO softgel capsules; and
- entered into an agreement with a commercial packager for finished JATENZO capsules.

In March 2021, we entered into the Pfizer Agreement, for the bulk supply of TU. We provide Pfizer estimates of our projected supply requirements. These supply forecasts are binding for an initial period, can be altered by a certain percentage over a subsequent period and then are used only to assist with Pfizer’s production planning over the final period. We have an obligation to purchase a minimum amount of TU from Pfizer, subject to an annual maximum, for the first three years of the Pfizer agreement. The price per kilogram of bulk TU under the Pfizer Agreement is fixed based on the total volume purchased during a calendar year. If Pfizer is unable to satisfy our delivery requirements, we may purchase more supply needs from an alternative supplier. The term of the Pfizer Agreement expires in January 2024. The Pfizer Agreement may be terminated by either party without cause upon 18 months’ prior written notice or upon the other party’s uncured breach of any material obligation. The Pfizer Agreement also contains customary representations and warranties, indemnification, limitation on liability, assignment, confidentiality and other provisions.

Our January 2014 agreement with Xianju (the “Xianju Agreement”) similarly requires us to project our bulk TU supply needs for the United States. Our purchase orders are then bound by each such supply forecast for an initial period, can be altered by a certain percentage over a subsequent period and then are used only to assist with Xianju’s production planning over such projection’s final period. The price per kilogram of bulk TU under the Xianju Agreement is fixed based on the total volume purchased in a year; however, Xianju may increase the price if there are sudden changes in economic circumstances that increase the cost of production or raw materials. In addition, Xianju may request each year that the parties renegotiate the agreed upon prices from the previous year. The Xianju Agreement had an initial term of seven years and automatically renewed for two consecutive three-year terms unless either party gives notice of non-renewal no later than six months prior to the expiration of any initial or renewal term. The Xianju Agreement is also terminable by either party upon the other party’s bankruptcy, uncured material breach or for any changes in law or regulations that would render it impossible for a party to perform its
In the event of either non-renewal or termination, however, Xianju will continue to supply us with bulk TU on the terms of the Xianju Agreement for up to 18 months. The Xianju Agreement also contains customary representations and warranties, indemnification, limitation on liability, assignment and confidentiality provisions, as well as provisions with respect to quality control and manufacturing procedures.

The JATENZO formulation is encapsulated in a softgel form. We have chosen Catalent, a third-party manufacturer, to produce clinical trial supplies and commercial quantities of JATENZO softgel capsules. JATENZO softgel capsules come in 158 mg TU, 198 mg TU, and 237 mg TU forms. We have entered into the Catalent Agreement, which remains in effect until March 2025, six years following the date on which the FDA approved Catalent as a manufacturer of JATENZO, and automatically renews for successive two-year periods, if not terminated one year prior to the expiration of the initial term or any then-current renewal term. Either we or Catalent may terminate the Catalent Agreement upon the other party’s bankruptcy, uncured material breach or upon 24 months’ prior written notice for convenience. In addition, Catalent may terminate the Catalent Agreement or cease performing its obligations if we fail to pay amounts within ten days of being due. We are required to purchase a minimum quantity of JATENZO softgel capsules, and we are required to pay to Catalent an annual commercial occupancy fee and an annual product maintenance fee. The unit price of capsules under the Catalent Agreement is determined based on batch size and the total volume shipped in a year. The price may be increased annually based on a market price index. The Catalent Agreement contains customary representations and warranties, indemnification, limitation on liability, assignment and confidentiality provisions.

We, along with our contract manufacturers, are subject to extensive governmental regulations, including requirements that our products be manufactured, packaged and labeled in conformity with current cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. The FDA typically inspects manufacturing facilities every two years. We have established an internal quality control and quality assurance program, including a set of standard operating procedures and specifications that we believe is cGMP-compliant.

### Third Party Reimbursement and Pricing

In the United States and elsewhere, sales of pharmaceutical products to consumers depend to a significant degree on the availability of coverage and reimbursement by third-party payors, such as government and private insurance plans. Third-party payors increasingly are challenging the prices charged for medical products and services and implementing other cost containment mechanisms. This is especially true in markets where generic options exist. It is, and will be, time consuming and expensive for us to go through the process of maintaining or seeking reimbursement for our products from Medicaid, Medicare and commercial payors. Our products and those of our partners may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis, potentially resulting in contract changes with these major payors.

Third-party payors often utilize a tiered reimbursement system, which may adversely affect demand for our products by placing them in a more expensive patient co-payment tier. Additionally, third party payors may require step edits or prior authorizations. We cannot be certain that our products will successfully be placed on the list of drugs covered by particular health plan formularies or in a more preferential position on their formularies. Third-party payors are currently demanding, and will most likely continue to demand, more aggressive pricing and rebates for favorable formulary placement. Some U.S. states have also created Medicaid preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our products are not included on these preferred drug lists, they may be subject to prior authorization. Physicians may not be inclined to prescribe JATENZO to their Medicaid patients, and even if they do prescribe it, Medicaid may not authorize payment, thereby diminishing the potential market for our products in this market segment.

Currently, most of our prescriptions are open access, and we have negotiated agreements with several pharmacy benefits managers, including Express Scripts. We offer a co-pay assistance program to patients for JATENZO under which patients covered by commercial pharmacy benefit plans receive discounts on their prescriptions. Our JATENZO GO Co-pay Assistance Program provides financial support to most commercially insured patients to assist with out-of-pocket costs of JATENZO, such that most commercial covered patients will pay $0 for their prescription.
Similarly, in order to ensure coverage by Medicare Part D and commercial pharmacy benefit plans, we participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program. We also provide discounts to authorized users of the Federal Supply Schedule (“FSS”) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs, including discounts mandated by the Veterans Health Care Act, discounted prescriptions to DoD’s Tricare retail pharmacy program, and discounts to federal grantees and safety net providers referred to as covered entities pursuant to our pharmaceutical pricing agreement with the U.S. Department of Health and Human Services (“HHS”) and the 340B drug discount program, which is required as a condition of Medicaid coverage. Government agencies ordering under the FSS and covered entities purchase products from the wholesale distributors at the discounted price, and the wholesale distributors then charge back the difference between the current wholesale acquisition cost and the price the entity paid for the product.

**Patents and Proprietary Rights**

Our success will depend, in part, on our ability to obtain and protect our proprietary rights in the United States and in other countries. To do so, we will continue to rely on patents, trademarks, trade secrets, and confidentiality and other agreements to protect our proprietary rights. We intend to seek patent protection whenever appropriate for any product candidates, including methods for their manufacture and use, and related technology we develop or acquire in the future.

We have been building and continue to expand our intellectual property portfolio relating to JATENZO. We strive to protect and enhance the proprietary technologies that we believe are important to our business and seek patent protection, where appropriate, in the United States and internationally for compositions related to JATENZO, its methods of use and any other inventions that are important to the development of our business. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad, including Europe and other major countries when appropriate, relating to proprietary technologies that are important to the development of our business.

However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology. There is also the risk that third parties have patents or may obtain patents having claims that also cover JATENZO. For example, Lipocine asserted the use of JATENZO infringed its patents, and attacked patents and applications in our portfolio by provoking patent interferences, see Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for the technologies, inventions, know-how and products we consider important to our business, defend our patents, preserve the confidentiality of our trade secrets and operate our business without infringing the patents and proprietary rights of third parties.

Our U.S. patent portfolio on JATENZO currently includes seven issued patents: U.S. Patent No. 11,179,402, which expires in April 2026, U.S. Patent No. 8,241,664, which expires in March 2029; U.S. Patent No. 8,492,369, which expires in December 2030, as well as U.S. Patent Nos. 8,778,916, 10,543,219, 10,617,696, and 11,179,403 each of which expires in April 2030. 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.
Our portfolio also contains pending applications around the world, including in the United States, Brazil, Canada and Europe. These patent applications, if they were to issue, have the potential to extend the patent coverage beyond 2030.

We solely own all the issued patents and the pending patent applications in our JATENZO patent portfolio. However there is risk that the USPTO could declare other interference proceedings involving patent claims that cover JATENZO as discussed in more detail in Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus.

TU, the active pharmaceutical ingredient in JATENZO, as well as its use for treating hypogonadism, are well known in this field. Accordingly, The TU active ingredient, standing alone, is not protected by any valid and unexpired third-party patents, although there are third party patents with claims that are alleged to cover use of TU in treating hypogonadism and the use of JATENZO as discussed in more detail in Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus.

**Competition**

There are several approved T-replacement therapies on the market, as well as several therapies under review by the FDA. The TRT market is highly competitive, and our future success will depend on our ability to capture market share from currently approved therapies most notably injections and gels, the continued expansion of the TRT market, and our ability to operate freely with regard to or to preclude from competing against us several competitors who have also develop oral TU products, including Lipocine which has received tentative approval from the FDA and has alleged that JATENZO infringes certain Lipocine patents, as described in Note 13 – Commitments and Contingents, to the consolidated financial statements included elsewhere in this prospectus.

**Injectables**

Injectable T-esters (e.g., T-enanthate; T-cypionate) continue to represent the majority of the prescriptions in the TRT market. Over 5.9 million prescriptions were written for T injectables (75% of all TRT prescriptions and 36% of U.S. sales) in 2020. T-injectables are predominantly given as T-cypionate (95% of all injections) and T-enanthate (1% of all injections). Injectables have experienced significant prescription growth in the U.S. market due to overall market demand for TRT and due to their generic availability and low cost. These men receive an injection every two to three weeks, most often intramuscularly, instead of applying a daily administration of other products. We believe physicians and their hypogonadal patients perceive the primary downsides of injections to be pain at injection site and risk for POME and polycythemia (excess concentration of red blood cells). Additionally, injecting T weekly or bi-weekly is associated with wide fluctuations in serum T levels between treatment cycles. For example, in many men limit of normal on day one of the injection, which may lead to undesirable side effects. Conversely, T levels often fall into the hypogonadal range before it is time for the next injection which leads to a return of undesirable symptoms.

**Gels**

Gels represent the second largest segment within the TRT market. Over 1.9 million prescriptions were written for gels in 2020 and represented 58% of U.S. sales in 2020. The gel-based T replacement products that are currently available include AbbVie’s AndroGel®, and Endo’s Testim® and Fortesta® along with their respective authorized generics as well as generic equivalents of each version.

The FDA has granted a therapeutic equivalence (“TE”) rating of AB to “generic” versions of approved products that have been approved via a 505(b)(2) NDA. In July 2014, the FDA granted the AB rating to Perrigo’s 1% T-gel drug product (NDA 203098) approved in January 2013, and a BX rating to Teva’s 1% gel drug product (NDA 202763) approved in February 2012. Each are versions of AbbVie’s AndroGel 1.0% and employed 505(b)(2) submissions citing AndroGel as their reference listed drugs (“RLD”). Teva’s version was found not to be bioequivalent to AndroGel, hence the BX rating. Upsher-Smith Laboratories also received approval for a version of Endo’s Testim (Vogelxo; NDA 204399) in June 2014 using the same pathway. In January of 2015, the FDA determined that Vogelxo is therapeutically equivalent to Testim and received an AB rating. In August 2015, the FDA granted AB rating to Perrigo’s 1.62% T-gel drug product (NDA 204268) which also received FDA approval in August 2015. Eli Lilly and Acrux’s Axiron had patent expiry in February 2017. On July 6, 2017, Acrux confirmed
that a generic version of Axiron Topical Solution, 30 mg/1.5 mL (T-Topical Solution, 30 mg/1.5 mL) has been launched in the United States by Perrigo Company plc. AcruX also confirmed the availability of an authorized generic version of Axiron in the United States, through a marketing and distribution agreement between Lilly and a leading authorized generics company.

**Other Current T-Delivery Methods**

JATENZO also competes with other TRT products such as a nasal T-gel, auto-injectable subcutaneous T, buccal T and topical T-patches, and implantable subcutaneous T-pellets.

Transdermal T-patches include Allergan’s Androderm. An intramuscular depot form of TU also exists in branded form as Aveed by Endo. Additionally, Endo markets the buccal TRT Striant and the Testopel implantable T-pellets, which it acquired from Auxilium in 2015. Antares Pharma, Inc. markets a sub-cutaneous weekly auto-injector T therapy, Xyosted. Aytu BioScience Inc. markets an intranasal T therapy, Natesto, which it licensed from Acerus Pharmaceuticals in 2016.

**Other T-Products in Development**

We are aware of a number of products in clinical development that, if approved by the FDA, would compete with JATENZO.

Lipocine has developed an oral TU formulation, TLANDO. The FDA has granted tentative market approval to TLANDO for use as a TRT in adult males for conditions associated with a deficiency or absence of endogenous T, specifically congenital or acquired primary and secondary hypogonadism. In granting tentative approval, the FDA has concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval, but TLANDO has not received final approval and is not eligible for final approval and marketing in the United States until the expiration of JATENZO’s exclusivity period which expires on March 27, 2022. Like JATENZO and XYOSTED, we expect TLANDO to also carry a boxed warning about the potential for increased blood pressure because this was observed in clinical trials conducted by Lipocine. The FDA has also required Lipocine to conduct certain post-marketing studies to assess patient understanding of key risks relating to TLANDO and evaluate adrenal function with chronic TLANDO therapy, and conduct a pediatric study. In October 2021, Lipocine licensed the exclusive U.S. rights for TLANDO to Antares Pharma. In February 2022, Antares Pharma announced that the FDA accepted its NDA resubmission for TLANDO. The FDA designated the NDA as a Class 1 resubmission with a two-month review goal period and set a PDUFA date of March 28, 2022.

Marius Pharmaceuticals has developed an oral T-undecanoate under the name of KYZATREX as a TRT for the treatment of primary and secondary hypogonadism in adult men. The product was submitted to the FDA on January 5, 2021 with an expected PDUFA action date on October 31, 2021. Should KYZATREX meet all of the required quality, safety, and efficacy standards necessary for approval, we believe it will not receive a final approval or be eligible to receive final approval or marketing in the United States until the expiration, on March 27, 2022, of our Hatch-Waxman 3-year exclusivity period with respect to JATENZO. We expect KYZATREX labeling to carry boxed warning regarding the potential for increased blood pressure. We also believe that the FDA will require Marius Pharmaceuticals to assess patient understanding of key risks relating to KYZATREX, evaluate adrenal function with chronic KYZATREX therapy and conduct a pediatric study.

Mereo BioPharma Group Ltd. is currently developing BGS649, a once weekly aromatase inhibitor, for first-line therapy for the treatment of obese men with hypogonadotropic hypogonadism. BGS649 has completed Phase 2b testing. Based on published guidance from the FDA regarding treatment of hypogonadism with non-T approaches Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders: Guidance for Industry U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) May 2018, Clinical we expect that development of BGS649 will be challenging. Moreover, we believe that any approval of BGS649 will result in highly restricted product labeling that will preclude its use to treat the vast majority of men with classic hypogonadism.

TesoRx Pharma LLC is developing an oral ‘bio-identical’ testosterone, TSX-002, for the treatment of Constitutional Delay of Growth and Puberty. Phase 2 clinical studies have been completed. TesoRx is also developing a potential once-daily oral TU product candidate, TSX-049, as TRT for hypogonadal in men.
Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, packaging, recordkeeping, tracking, approval, import, export, distribution, advertising and promotion of our products.

U.S. Government Regulation of Drug Products

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the “FDCA”) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- nonclinical laboratory and animal tests that must be conducted in accordance with Good Laboratory Practices;
- submission to the FDA of an Investigational New Drug ("IND"), which must become effective before clinical trials may begin;
- approval by an independent institutional review board ("IRB") for each clinical site or centrally before each trial may be initiated;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed product candidate for its intended use, performed in accordance with good clinical practices ("GCPs");
- submission to the FDA of an NDA and payment of user fees;
- satisfactory completion of an FDA advisory committee review, if applicable;
- pre-approval inspection of manufacturing facilities and selected clinical investigators for their compliance with cGMP and GCP;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- FDA review and approval of an NDA to permit commercial marketing for particular indications for use.

Preclinical Studies

Preclinical studies include laboratory evaluation of drug substance chemistry, pharmacology, toxicity and drug product formulation, as well as animal studies to assess potential safety and efficacy. Prior to commencing the first clinical trial with a product candidate, a sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data and any available clinical data or literature, among other required information, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the conduct of the clinical trial and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.
Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development, as well as amendments to previously submitted clinical trials. Further, an independent IRB for each institution participating in the clinical trial must review and approve the plan for any clinical trial, its informed consent form and other communications to study subjects before the clinical trial commences at that site. The IRB must continue to oversee the clinical trial while it is being conducted, including any changes to the study plans.

Regulatory authorities, an IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA’s or the IRB’s requirements or if the drug has been associated with unexpected serious harm to subjects. Some studies also include a data safety monitoring board, which receives special access to unblinded data during the clinical trial and may advise the sponsor to halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Human clinical trials are typically conducted in three sequential phases that may be combined or overlap.

- **Phase 1** — Studies are initially conducted to test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution and excretion in healthy volunteers or subjects with the target disease or condition. If possible, Phase 1 clinical trials may also be used to gain an initial indication of product effectiveness.

- **Phase 2** — Controlled studies are conducted with groups of subjects with a specified disease or condition to provide enough data to evaluate the preliminary efficacy, optimal dosages and dosing schedule and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expansive Phase 3 clinical trials.

- **Phase 3** — These clinical trials are generally undertaken in larger subject populations to provide statistically significant evidence of clinical efficacy and to further test for safety in an expanded subject population at multiple clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. These clinical trials may be done at trial sites outside the United States as long as the global sites are also representative of the U.S. population and the conduct of the study at global sites comports with FDA regulations and guidance, such as compliance with GCPs. In most cases, FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single trial may be sufficient in rare instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase 4 trials may be made a condition to be satisfied after approval. The results of Phase 4 trials can confirm the effectiveness of a product candidate and can provide important safety information.

Clinical trials must be conducted under the supervision of qualified investigators in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent in writing for their participation in any clinical trial and the review and approval of the study by an IRB. Investigators must also provide information to the clinical trial sponsors to allow the sponsors to make specified financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated and a statistical
analysis plan. Information about some clinical trials, including a description of the trial and trial results, must be submitted within specific timeframes to the U.S. National Institutes of Health for public dissemination on its ClinicalTrials.gov website. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur.

The manufacture of investigational drugs for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and active pharmaceutical ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational drug products outside of the United States is subject to regulatory requirements of the receiving country, as well as U.S. export requirements under the FDCA. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if serious adverse events occur.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

**Orphan Drug Designation**

Under the Orphan Drug Act, the FDA may designate a drug product as an “orphan drug” if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will be receiving orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in limited circumstances. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

**Special FDA Expedited Review and Approval Programs**

The FDA has various programs, including fast track designation, breakthrough therapy designation, orphan drug designation, accelerated approval and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast-track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the drug candidate. To be eligible for a fast-track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to
address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides additional opportunities for interaction with the FDA’s review team and may allow for rolling review of NDA components before the completed application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the NDA. However, the FDA’s time period goal for reviewing an application does not begin until the last section of the NDA is submitted. The FDA may decide to rescind the fast-track designation if it determines that the qualifying criteria no longer apply.

In addition, a sponsor can request breakthrough therapy designation for a drug if it is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are eligible for intensive guidance from the FDA on an efficient drug development program, organizational commitment to the development and review of the product, including involvement of senior managers, and, like fast-track products, are also eligible for rolling review of the NDA. Both fast track and breakthrough therapy products may be eligible for accelerated approval and/or priority review, if relevant criteria are met.

Under the FDA’s accelerated approval regulations, the FDA may approve a drug for a serious or life threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. A drug candidate approved on this basis is subject to rigorous post marketing compliance requirements, including the completion of Phase 4 or post approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post approval studies or confirm a clinical benefit during post marketing studies will allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated approval regulations are subject to prior review by the FDA.

Once an NDA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (“PDUFA”) goals. Under the current PDUFA performance goals, these six-and ten-month review periods are measured from the 60-day filing date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review from the date of submission.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

NDA Submission and Review by the FDA

Assuming successful completion of the required clinical and preclinical testing, among other items, the results of product development, including chemistry, manufacture and controls, nonclinical studies and clinical trials are submitted to the FDA, along with proposed labeling, as part of an NDA. The submission of an NDA requires payment of a substantial user fee to the FDA. This user fee must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in some circumstances.
In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA for a new active ingredient, indication, dosage form, dosage regimen or route of administration must contain data that are adequate to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers from the pediatric data requirements.

Once the FDA receives an application, it has 60 days to review the NDA to determine if it is substantially complete to permit a substantive review, before it files the application. Once the submission is filed by the FDA, the FDA begins an in-depth review of the NDA. Under the goals agreed to by the FDA under PDUFA, the FDA has set the review goal of 10 months from the 60-day filing date to complete its initial review of a standard NDA for a new molecular entity, or NME, and make a decision on the application. For priority review applications, the FDA has set the review goal of reviewing NME NDAs within six months of the 60-day filing date. Such deadlines are referred to as the PDUFA date. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date may also be extended if the FDA requests or the NDA sponsor otherwise provides certain additional information or clarification regarding the submission during the review period that amends the original application.

The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product’s identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontracts, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs.

The FDA must refer applications for drugs that contain active ingredients, including any ester or salt of the active ingredients, that have not previously been approved by the FDA to an advisory committee or provide in an action letter a summary of the reasons for not referring it to an advisory committee. The FDA may also refer drugs which present difficult questions of safety, purity or potency to an advisory committee. An advisory committee is typically a panel that includes clinicians and other experts who review, evaluate and make a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Once the FDA's review of the application is complete, the FDA will issue either a Complete Response Letter ("CRL") or approval letter. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL generally contains a statement of specific deficiencies and provides recommendations for securing approval of the NDA. These recommendations may include additional clinical or preclinical testing or other information or analyses in order for the FDA to reconsider the application in the future. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If, or when the deficiencies have been met to the FDA's satisfaction, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information, require post-marketing testing and surveillance to monitor safety or efficacy of a product and/or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a REMS as a condition of approval or following approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The FDA may prevent or limit further marketing of a product or impose additional post-marketing requirements, based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements, FDA notification and FDA review and approval. Further, should new safety information arise, additional testing, product labeling or FDA notification may be required.
If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed or may include contraindications, warnings or precautions in the product labeling. The FDA may require certain contraindications and serious warnings to be placed in a box at the beginning of the labeling to highlight the information for prescribers, particularly those contraindications and warnings that may lead to death or serious injury. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require Phase 4 post-marketing studies to monitor the effect of approved products and may limit further marketing of the product based on the results of these post-marketing studies.

U.S. Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including periodic reporting, product sampling and distribution, advertising, promotion, drug shortage reporting, compliance with any post-approval requirements imposed as a conditional of approval such as Phase 4 clinical trials, REMS and surveillance, recordkeeping and reporting requirements, including adverse experiences.

After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for approved products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and to list their drug products and are subject to periodic announced and unannounced inspections by the FDA and these state agencies for compliance with cGMPs and other requirements, which impose procedural and documentation requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval or notification before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and specifications and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in withdrawal of marketing approval, mandatory revisions to the approved labeling to add new safety information or other limitations, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMS program, among other consequences.

The FDA closely regulates the marketing and promotion of drugs. A company can make only those claims relating to safety and efficacy that are consistent with the FDA approved labeling. Physicians, in their independent professional medical judgment, may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested in clinical trials and approved by the FDA. However, manufacturers and third parties acting on their behalf are prohibited from marketing or promoting drugs in a manner inconsistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Failure to comply with any of the FDA’s requirements could result in significant adverse enforcement actions. These include a variety of administrative or judicial sanctions, such as refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, debarment, injunctions, fines, consent decrees, corporate integrity agreements, refusals of government contracts and new orders under existing contracts, exclusion from participation in federal and state programs.
healthcare programs, restitution, disgorgement or civil or criminal penalties, including fines and imprisonment. It is also possible that failure to comply with the FDA’s requirements relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws. Any of these sanctions could result in adverse publicity, among other adverse consequences.

U.S. Marketing Exclusivity

The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the pharmaceutical innovation represented by its approved drug for a period of three or five years following the FDA’s approval of the NDA. Five years of exclusivity are available to new chemical entities (“NCES”). An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds or other noncovalent bonds not involving the sharing of electron pairs between atoms, derivatives, such as a complex (i.e., formed by the chemical interaction of two compounds), chelate (i.e., a chemical compound) or clathrate (i.e., a polymer framework that traps molecules) of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application (“ANDA”) or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed.

Three years of exclusivity are available for an application for a drug product containing a previously approved active moiety. To qualify for such exclusivity the NDA applicant must conduct or sponsor a new clinical investigation that FDA determines is essential to the approval of the application. Three-year exclusivity prevents the approval of an ANDA or a 505(b)(2) NDA for a drug product containing the same active moiety for the protected conditions of approval. The scope of any three-year exclusivity granted by the FDA is determined on a case-by-case basis and depends on several factors, including the FDA’s analysis of the scope of the new clinical investigations essential to approval conducted or sponsored by the applicant. JATENZO was awarded 3-year new product marketing exclusivity by the FDA. This exclusivity expires on March 27, 2022.

A drug can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study. We may be able to provide data supporting the use of JATENZO in a pediatric population if invited to do so by the FDA. If we do so, and this data is deemed acceptable by the FDA, we may receive an additional six-month extension of any unexpired exclusivity and an additional six-month regulatory exclusivity that the FDA recognizes at the end of a patent term.

Controlled Substances

The CSA and its implementing regulations establish a “closed system” of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence.
Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances.

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Regulation outside the United States

We will be subject to similar foreign laws and regulations concerning the development of our product candidates outside of the United States.

Other Healthcare Laws

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward or in return for, either the referral of an individual for, or the purchase order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. On November December 20, 2020, the HHS Office of Inspector General ("OIG") finalized published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rules (with exceptions) became effective January 19, 2021.

- Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the current administration and may be amended or repealed;
The federal civil and criminal false claims laws, including the civil False Claims Act ("FCA"), which prohibit individuals or entities from, among other things, knowingly presenting or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using or causing to be made or used a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery.

The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

HIPAA, which imposes criminal and civil liability for knowingly and willfully executing a scheme or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;

The Physician Payments Sunshine Act, enacted as part of ACA, which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, for certain payments and “transfers of value” provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted and may have a more prohibitive effect than the Physician Payments Sunshine Act, thus further complicating compliance efforts. Effective January 1, 2022, these reporting obligations extend to include transfers of value made and investment and ownership interested held in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

The ACA, which became law in the United States in March 2010, increases minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs and biologic products, and creates a new Medicare
Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%, effective January 1, 2019, by the Bipartisan Budget Act of 2018) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;

• The MMA expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates;

• Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and

• Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party-payers, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to drug pricing and payments and other transfers of value to physicians and other healthcare providers and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws that govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

In addition, pharmaceutical manufacturers may also be subject to federal and state consumer protection and unfair competition laws and regulations, which broadly regulate marketplace activities and that potentially harm consumers.

The distribution of drugs and biological products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

In the United States, to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the U.S. Centers for Medicare & Medicaid Services (“CMS”) issued guidance to the issuers of qualified health plans sold through the ACA’s marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.
Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor’s product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to prevent our involvement in government claims or investigations.

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time-consuming and resource-consuming and can divert a company’s attention from its business.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.
In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company’s revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare. For example, in March 2010, the U.S. Congress ("Congress") enacted the ACA, which, among other things, included changes to the coverage and payment for products under government health care programs. The ACA included provisions of importance to our potential product candidate that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- expanded manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of “average manufacturer price,” (“AMP”) for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers’ outpatient drugs to be covered under Medicare Part D; and
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.
Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. For example, an October 2017 executive order terminated the cost-sharing subsidies that reimburse insurers under the ACA based on a conclusion that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA had not received necessary appropriations from Congress and accordingly, decided to discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit’s decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

Congress has also enacted laws that modify certain provisions of the ACA, including decreasing the tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the “individual mandate,” to $0 effective January 1, 2019 as part of the Tax Cuts and Jobs Act. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was effectively nullified, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit held the individual mandate is unconstitutional, but remanded the case to the lower court to reconsider its earlier invalidation of the full law. In March 2020, the U.S. Supreme Court agreed to hear this case and oral arguments were held on November 10, 2020. The Supreme Court’s decision in this case is forthcoming. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the ACA long term.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The Consolidated Appropriations Act of 2021, extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021, has extended the suspension period to December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2019, the Further Consolidated Appropriations Act (H.R. 1865) was signed into law, which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives and there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to
product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the previous administration’s budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the previous administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the previous administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change, which was effective as of January 1, 2019. Additionally, On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the Fiscal Years 2019 and 2018 reimbursement formula on specified covered outpatient drugs. The court ruled this change was not an “adjustment” that was within the Secretary’s discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court’s decision and found that the changes were within the Secretary’s authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. Plaintiffs-appellees filed a petition for a writ of certiorari at the Supreme Court on February 10, 2021. On Friday July 2, 2021, the Supreme Court granted the petition. The 340B drug pricing program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities.

Although a number of these and other measures may require additional authorization to become effective, Congress and the current administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. A July 2021 executive order affirmed the administration’s policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the executive order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA’s implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for “best price” or Average Manufacturer Price purposes. Because these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation Model under which Medicare Part B reimbursement rates would have been be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021 CMS rescinded the Most Favored Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Further, on December 31, 2020, CMS published a new rule,
effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 21, 2021, PhRMA sued the HHS in the U.S. District Court for the District of Columbia, to stop the implementation of the rule claiming that the rule contradicts federal law surrounding Medicaid rebates. It is unclear how the outcome of this litigation will affect the rule. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current or future administrations may reverse or otherwise change these measures, both the current administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the ongoing COVID-19 pandemic.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

The Hatch-Waxman Amendments to the FDCA

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA information on each patent whose claims cover the applicant’s drug product, drug substance, or an approved method of using the drug. Upon approval of a drug, information on each of the patents listed in the application for the drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patent information listed in the Orange Book for the approved product. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; (iv) the listed patent is invalid or will not be infringed by the proposed ANDA product or (v) that there are no relevant patents. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding a patented method-of-use rather than certify to a listed method-of-use patent. If the ANDA applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired.
A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid or unenforceable, is called a Paragraph IV certification. If the ANDA applicant has submitted a Paragraph IV certification to the FDA, the applicant must also send notice (“Notice Letter”) of the Paragraph IV certification to the NDA and patent holders no later than 20 days after the FDA issues a Paragraph IV acknowledgement letter. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of the Notice Letter by the NDA and patent holders automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be finally approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. Drugs listed in the Orange Book can also be cited by Section 505(b)(2) NDA applicants who must make relevant patent certifications as described above for ANDA applicants.

To date, no Paragraph IV certification has been filed relative to JATENZO.

**Non-Patent Exclusivities**

JATENZO was awarded 3-year new product marketing exclusivity by the FDA. This exclusivity expires on March 27, 2022.

In the United States, FDA-approved products also may be eligible for 6-month pediatric exclusivity which could extend not only any unexpired non-patent exclusivities, but also the effective term of an Orange Book-listed patent, provided the FDA decides to award pediatric exclusivity on a date that is not less than nine months prior to the expiration of any patent or non-patent exclusivity. We may be able to provide data supporting the use of JATENZO in a pediatric population if invited to do so by the FDA. If we do so, and this data is deemed acceptable by the FDA, we may receive an additional six-month extension of any unexpired exclusivity and an additional six-month regulatory exclusivity that the FDA recognizes at the end of a patent term.

**Human Capital Resources**

As of December 31, 2021, we had 16 full-time employees. Two of our employees have Ph.D. degrees and one is an M.D. Three of our employees hold M.B.A.s. None of our employees is represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

**Facilities**

We lease our office spaces, which consist of 4,612 square feet located at 555 Skokie Boulevard, Suite 340, Northbrook, Illinois and 1,130 square feet located at 745 South Church Street, Suite 407, Murfreesboro, Tennessee. In December 2021, we amended our Northbrook, Illinois lease which resulted in an extension of the lease term through December 31, 2022. Our Murfreesboro, Tennessee lease expires September 2022. We believe our current office space is sufficient to meet our needs until the expiration of our lease and we expect to have additional space reserved sufficient to meet our needs prior to this expiration.

**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.
On April 2, 2019, an action for patent infringement was filed against Legacy 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 Legacy Clarus’ intent to market and sell JATENZO, based on the FDA’s approval of JATENZO in March 2019. Lipocine ultimately alleged that Legacy 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-judging interest, post-judging interest, and attorneys’ fees, costs and disbursements, and injunctive relief.

Legacy 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. Legacy Clarus’ 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, Legacy Clarus requested the Court to schedule a bench trial on Legacy 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, Legacy Clarus and Lipocine entered into a settlement agreement that settled all claims between the parties, including a pending interference matter (No. 106,128) and the pending Legacy Clarus counterclaims against Lipocine, and provided for a payment by Lipocine to Legacy 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 USPTO’s Patent Trial and Appeal Board (PTAB) on July 26, 2021. The Company believes that its U.S. Patent Application No. 16/656,178 involved in the interference may proceed to issuance due to entry of the decision adverse to Lipocine by the PTAB, but the ‘178 application has not issued to date.
Executive Officers, Key Employees and Board of Directors

Our directors and executive officers and their ages as of April 1, 2022 are listed below:

Executive Officers

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert E. Dudley, Ph.D.</td>
<td>67</td>
<td>Chief Executive Officer, President and Chairman of the Board</td>
</tr>
<tr>
<td>Richard Peterson</td>
<td>54</td>
<td>Chief Financial Officer</td>
</tr>
<tr>
<td>Steven A. Bourne</td>
<td>60</td>
<td>Chief Administrative Officer, Secretary and Treasurer</td>
</tr>
<tr>
<td>Frank Jaeger</td>
<td>51</td>
<td>Chief Commercial Officer</td>
</tr>
</tbody>
</table>

Non-Management Directors

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<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Amory</td>
<td>54</td>
<td>Director</td>
</tr>
<tr>
<td>Elizabeth A. Cermak</td>
<td>64</td>
<td>Director</td>
</tr>
<tr>
<td>Joseph Hernandez</td>
<td>49</td>
<td>Director</td>
</tr>
<tr>
<td>Kimberly Murphy</td>
<td>59</td>
<td>Chairman of the Board</td>
</tr>
<tr>
<td>Mark A. Prygocki, Sr</td>
<td>55</td>
<td>Director</td>
</tr>
<tr>
<td>Alex Zisson</td>
<td>52</td>
<td>Director</td>
</tr>
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</table>

Executive Officers

Robert E. Dudley, Ph.D., has served as our President, Chief Executive Officer and Director since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’s Chief Executive Officer, President and Chairman of the board of directors from February 2004 through the Merger Closing Date. Prior to that, from 2001 to 2003, he served as President and Chief Executive Officer and a member of the board of directors of Anagen Therapeutics, Inc., a private biopharmaceutical company. From 1994 to 1999, he held several senior level executive positions at Unimed Pharmaceuticals, Inc. (“Unimed”), a public company acquired by Solvay Pharmaceuticals in 1999, and from 1999 to 2001 he served as Unimed’s President and Chief Executive Officer and was a member of its board of directors, during which time Unimed received FDA approval for and launched AndroGel. Dr. Dudley received a B.S. in Biology from Pepperdine University, Seaver College, an M.S. in Biology from University of New Mexico, and a Ph.D., with honors, in Pharmacology and Toxicology from the University of Kansas School of Medicine. Dr. Dudley is also a board-certified toxicologist. We believe Dr. Dudley’s experience as a scientist with a leading role in commercializing the market leading T-replacement therapy, coupled with an insider’s perspective his role as our Chief Executive Officer brings to board discussions, provide him with the qualifications and skills to serve on the Board.

Richard Peterson has served as our Chief Financial Officer since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’s Chief Financial Officer from February 2021 through the Merger Closing Date. Prior to joining Legacy Clarus, Mr. Peterson served as Chief Financial Officer for several clinical stage biopharmaceutical companies, most recently at Botanix Pharmaceutical, Ltd. (ASX:BOT) (from August 2019 to May 2020). Prior to this role, Mr. Peterson served as Chief Financial Officer at Dermavant Sciences Inc. (from March 2018 to February 2019), Sienna Biopharmaceuticals, a biopharmaceutical company (Nasdaq:SNNA) (“Sienna”) (from March 2017 to March 2018), and Novan, Inc. (Nasdaq:NOVN) (“Novan”) (from September 2015 to March 2017). Mr. Peterson also served as Chief Financial Officer of Medicis Pharmaceutical Corporation (“Medicis”), a commercial pharmaceutical company from June 1995 to December 2012. Under Mr. Peterson’s leadership, Novan and Sienna completed successful initial public offerings. While at Medicis, he played an integral role in guiding the company’s tremendous growth, which resulted in its acquisition for $2.6 billion by Valeant Pharmaceuticals International. Since 2014, Mr. Peterson has served on the board of directors of Universal Insurance Holdings, Inc. (NYSE:UVE), and is currently the audit committee chair and a member of the compensation committee. Mr. Peterson began his career with PricewaterhouseCoopers, after receiving a degree in accountancy from Arizona State University.
Steven A. Bourne has served as our Chief Administrative Officer and Secretary since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’s Chief Administrative Officer beginning February 2021 and as its Secretary and Treasurer from February 2004, in each case through the Merger Closing Date. He previously served as Legacy Clarus’s Chief Financial Officer from February 2004 to February 2021. Prior to that, from 2002 to 2003, he served as Chief Financial Officer, Secretary and Treasurer at Anagen Therapeutics, Inc., a private biopharmaceutical company. Further, Mr. Bourne served as Controller, Secretary and Treasurer of Aksys, Ltd., a public medical device company, from 1996 to 2001. Mr. Bourne received a B.S. in Accounting from Miami University and is a Certified Public Accountant.

Frank Jaeger has served as our Chief Commercial Officer since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’ Chief Commercial Officer from September 2019 through the Merger Closing Date. Mr. Jaeger is responsible for all commercial matters of sales, marketing, commercial operations and market access for JATENZO. Prior to his joining Legacy Clarus, Mr. Jaeger served as the Regional Sales Director at AbbVie Inc. (NYSE: ABBV) from January 2014 to August 2019, where he was responsible for sales of AndroGel and Synthroid for the West Region in the Metabolics division. Mr. Jaeger received a B.A. in Psychology and an M.A. in Clinical Psychology from the University of Illinois at Chicago and he received a M.B.A. from the Lake Forest Graduate School of Management.

Key Employees

Jay Newmark, M.D. has served as our Chief Medical Officer since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’s Chief Medical Officer from December 2019 through the Merger Closing Date. Prior to joining Legacy Clarus, Dr. Newmark was an independent urologist in private practice for 16 years, establishing himself as a leading voice in men’s health. Dr. Newmark served as Senior Director of Medical Affairs (Medical Diagnostics) at Genomic health from April 2018 to August 2019 and Senior Director of Medical Affairs (Medical Diagnostics) at OPKO Health (Nasdaq: OPK) from to August 2014 to April 2018, and has worked closely with both commercial development organizations and academic researchers to design clinical trial protocols and co-author publications in oncology and urology. Dr. Newmark received his M.D. from the University of Michigan Medical School and completed his residency in urology at The Johns Hopkins Hospital. Dr. Newmark also holds an M.B.A. from the University of Chicago.

James Holloway has served as our Senior Vice President of Manufacturing and Supply since the Merger Closing Date. Prior thereto, he served as Legacy Clarus’s Vice President of Manufacturing and Supply from October 2019 through the Merger Closing Date. Mr. Holloway has extensive experience in pharmaceutical manufacturing operations. Prior to joining Clarus, Mr. Holloway served at CareFusion (now BD Medical) (NYSE: BDX) (March 2011 to May 2018), and previously also held roles at Boehringer Ingelheim, Pfizer, Catalent, Cardinal Health and DSM Pharmaceuticals. Mr. Holloway received a B.S. and M.Sc. in organic chemistry from Fisk University.

Non-Management Directors

John Amory, M.D., M.P.H, M.Sc. joined the Board in connection with the Merger Closing. Since July 2011, Dr. Amory has served as a Professor of Medicine at the University of Washington in Seattle. Prior to this role, he served as a member of the faculty of the University of Washington since 1997. Dr. Amory has published more than 154 peer-reviewed papers in the field of male reproduction and his areas of research include male infertility, testosterone deficiency and the development of novel male contraceptives. Dr. Amory earned his M.D. from the University of California—San Francisco and both his M.P.H. and M.Sc. (pharmaceutics) from the University of Washington. We believe Dr. Amory’s knowledge and expertise in the industry provide him with the qualifications and skills to serve on the Board.

Elizabeth A. Cermak joined the Board in connection with the Merger Closing, and served as a member of Legacy Clarus’s board of directors from July 2014 through the Merger Closing. Ms. Cermak also serves on the board of directors of Moleculin Biotech, Inc. (Nasdaq: MBRX) and the board of directors of QUE Oncology, a private company, and Neurana Pharmaceuticals, a private company. She has also served on the board of directors of SteadyMed Therapeutics (Nasdaq: STDY) from 2015 to 2018, a public company acquired by United Therapeutics. From 2009 to 2013, Ms. Cermak was the Chief Commercial Officer and Executive Vice President at POZEN, now Aralez Pharmaceuticals. As Chief Commercial Officer at POZEN, Ms. Cermak developed the commercial strategy and launch plans for the Company’s first self-marketed product, and signed licensing deals with Johnson & Johnson,
Joseph Hernandez has served on the Board since founding Blue Water, and prior to the Merger Closing, served as Blue Water’s Chairman and Chief Executive Officer. Mr. Hernandez is an entrepreneurial leader with over 25 years of experience in the healthcare field. He has a background in company creation, early-stage technology development, as well as private and public market financing. He brings leadership to the team, backed by a strong educational foundation in biology, medicine, molecular genetics, microbiology, epidemiology, marketing, and finance. Over the course of his career, he has founded or led eight entrepreneurial companies in cutting edge areas of healthcare and pharmaceuticals. After years of building his career at Merck & Co. (NYSE:MRK) from to December 1998 to January 2001 and Digene (acquired by Qiagen (NYSE:QGEN)) from 2005 to 2009, Mr. Hernandez founded and became the President and CEO of Innovative Biosensors from 2004 to 2009. Later, Mr. Hernandez served as the Founder and Chairman of Microlin Bio Inc. from August 2013 to January 2017 and as Chairman of the Board of Ember Therapeutics (OTCMKTS:EMBT) from April 2014 to January 2019. He was also the Chairman of Sydys Corporation from May 2016 to January 2019. In 2018, Mr. Hernandez founded Blue Water Vaccines, Inc. (Nasdaq:BWV), a biotechnology company focused on manufacturing a universal influenza vaccine in partnership with the University of Oxford in England. He has served as Chairman of Blue Water Vaccines, Inc. since January 2019 and currently serves as its Chief Executive Officer and director. Most recently, in January 2020, he founded and in May 2020 sold Noachis Terra, Inc. (acquired by Oragenics (NYSE:OGEN)) a company developing a vaccine for COVID-19. Mr. Hernandez brings experience in managing and interacting with diverse cultures, high level executives, and elected officials, to the team. Mr. Hernandez received a B.S. in Neuroscience, M.S. in Molecular Genetics and Microbiology from the University of Florida and a MBA from the University of Florida, and is currently pursuing a MSc in Chronic Disease Epidemiology and Biostatistics from Yale University. We believe he is well qualified to serve on the Board due to his extensive biotech entrepreneurship and early-stage technology development experience in the healthcare industry.

Kimberly Murphy joined the Board in connection with the Blue Water IPO and was appointed Chairman upon the Merger Closing. Ms. Murphy has more than 25 years of experience at leading pharmaceutical companies including Novartis (NYSE:NVS) and Merck & Co (NYSE:MRK). In her distinguished career at Merck, she rose through various public affairs and business roles to leadership positions as Region Marketer for U.S. Commercial Operations, U.S. Marketing Leader for Adult Vaccines and Director of the HPV/Gardasil Franchise. Most recently, Ms. Murphy served as the Vice President and Global vaccines Commercialization Leader, Influenza Franchise, at GlaxoSmithKline (NYSE:GSK). Ms. Murphy was with GSK from 2011 through 2019, serving as VP of US Vaccines Customer Strategy from October 2012 to June 2014, then VP of the North America Vaccines Integration Planning from June 2014 to May 2015, followed by VP and Global Marketing Head for the Shingles Vaccines from May 2015 to February 2016, before transitioning to the Global Vaccines Commercialization Leader for the Influenza Franchise. Kim has Board and Advisory experience that includes serving on the boards of Oragenics, Inc. (NYSE:OGEN) and Blue Water Vaccines, Inc. (Nasdaq:BWV), as well as the GSK Representative to the Biotechnology Industry Organization’s Biodefense Advisory Council, and on the St. Joseph’s University Pharmaceutical & Healthcare Marketing MBA Program’s Advisory Board. Ms. Murphy received a B.A. in English from Old Dominion University, a M.B.A. in Marketing from St. Joseph’s University, and the Marketing Excellence Program from the Wharton School of University of Pennsylvania. We believe Ms. Murphy is well qualified to serve on the Board due to her extensive experience in the healthcare industry.

Mark A. Prygocki, Sr. joined the Board in connection with the Merger Closing, and served as a member of Legacy Clarus’s board of directors from July 2014 through the Merger Closing and as executive director from July 2020 through May 2021. From January 2017 until January 2020, he served as President, Chief Executive Officer and a member of the board of directors of Illustris Pharmaceuticals, Inc., (“Illustris”) a privately held bio-development company. Prior to joining Illustris, Mr. Prygocki worked at Medicis for more than 20 years and served most recently at Medicis as President from 2010 to 2012. Prior to that, Mr. Prygocki held several senior-level positions at Medicis, including Chief Operating Officer, Executive Vice President, and Chief Financial Officer and Treasurer. Since 2012, Mr. Prygocki has served as a consultant to the pharmaceutical and retail industries through his consulting company. Mr. Prygocki’s previous experience includes work at Citigroup, an investment banking
firm, in the regulatory reporting division and several years in the audit department of Ernst & Young, LLP. Mr. Prygocki currently serves on the board of directors of Verrica Pharmaceuticals, Inc. (Nasdaq: VRCA), since 2018 and is Chairman of its audit committee. Mr. Prygocki also served on the board of directors of Revance Therapeutics, Inc. (Nasdaq: RVNC) within the last five years. He is certified by the American Institute of Certified Public Accountants. Mr. Prygocki serves on the board of Whispering Hope Ranch Foundation, a non-profit organization that assists children with special needs. Mr. Prygocki holds a B.A. in accounting from Pace University. We believe Mr. Prygocki’s operating experience and financial expertise in the life science companies provides him with the qualifications and skills to serve on the Board.

Alex Zisson joined the Board in connection with the Merger Closing, and served as a member of Legacy Clarus’s board of directors from February 2004 through the Merger Closing. Since January 2016, Mr. Zisson has been a Managing Director at H.I.G. BioHealth Partners, focusing on pharmaceuticals, genetics, drug delivery and specialty pharma and biotechnology. Prior to this role, from 2002 to 2016, he served as a Venture Investor and Partner at Thomas, McNerney, where he focused on investment opportunities in the life sciences sector. Prior to that, Mr. Zisson spent 11 years in the research department at Hambrecht & Quist, an investment bank (and its successor firms Chase H&Q and JPMorgan H&Q), from 1991 to 2002, including serving as Managing Director from 1997 to 2002 and as the firm’s Health Care Strategist following the merger of Chase H&Q and JPMorgan. Mr. Zisson also serves on the board of directors of a number of private companies, including Leiters Pharmacy, Neurana Pharmaceuticals, Taconic Biosciences and BioVectra Inc. Mr. Zisson received an A.B. in History from Brown University. We believe Mr. Zisson’s experience as a healthcare strategist combined with his experience in investing in life science companies provides him with the qualifications and skills to serve on the Board.

Composition of the Board

The Board consists of seven members, including our President and Chief Executive Officer. In accordance with the Certificate of Incorporation, the Board is divided into three classes, Classes I, II and III, each to serve a three year term, except for the initial term after the Merger Closing, for which the Class I directors will be up for reelection at the first annual meeting of stockholders occurring after the Merger Closing, and for which the Class II directors will be up for reelection at the second annual meeting of stockholders occurring after the Merger Closing. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following the election. Directors will not be able to be removed during their term except for cause, and then only by the affirmative vote of the holders of not less than two thirds (2/3) of the outstanding shares of capital stock then entitled to vote at an election of directors. The directors are divided among the three classes as follows:

- the Class I directors are Alex Zisson and John Amory, and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors are Mark Prygocki and Elizabeth Cermak, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors are Robert Dudley, Kimberly Murphy and Joseph Hernandez, and their terms will expire at the annual meeting of stockholders to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of the Board into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Director Independence

Each of the directors on the Board, other than Dr. Dudley, qualify as independent directors, as defined under the listing rules of The Nasdaq Stock Market LLC (the “Nasdaq listing rules”), and the Board consists of a majority of “independent directors,” as defined under the rules of the SEC and Nasdaq listing rules relating to director independence requirements. In addition, we are subject to the rules of the SEC and Nasdaq relating to the membership, qualifications and operations of the audit committee, as discussed below.
Family Relationships

There are no family relationships among any of the directors and executive officers.

Committees of the Board

Effective upon the consummation of the Merger, the Board reconstituted the membership of its standing committees, which are governed by the Certificate of Incorporation that complies with the applicable requirements of current Nasdaq listing rules. We intend to comply with future requirements to the extent they are applicable to us. Copies of the amended and restated charters for each committee are available on the investor relations portion of our website, at www.clarustherapeutics.com. The Board may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

The audit committee of the Board consists of Elizabeth Cermak, Joseph Hernandez and Mark Prygocki. The Board has determined each member is independent under the Nasdaq listing rules and Rule 10A-3(b)(1) under the Exchange Act. The chairperson of the audit committee is Mr. Prygocki. Mr. Prygocki also qualifies as an “audit committee financial expert” as such term is defined in Item 407(d)(5) of Regulation S-K and possesses financial sophistication, as defined under the Nasdaq listing rules.

The primary purpose of the audit committee is to discharge the responsibilities of the Board with respect to our accounting, financial, and other reporting and internal control practices and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

• selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
• helping to ensure the independence and performance of the independent registered public accounting firm;
• discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
• developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
• reviewing policies on risk assessment and risk management;
• reviewing related party transactions;
• obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality-control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
• approving (or, as permitted, pre-approving) all audit and all permissible non-audit service to be performed by the independent registered public accounting firm.

Compensation Committee

The compensation committee of the Board consists of Joseph Hernandez, Kimberly Murphy and Alex Zisson. The Board has determined each member is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act. The chairperson of the compensation committee is Mr. Zisson. The primary purpose of the compensation committee is to discharge the responsibilities of the Board to oversee its compensation policies, plans and programs and to review and determine the compensation to be paid to its executive officers, directors and other senior management, as appropriate.
Specific responsibilities of the compensation committee include:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to the Chief Executive Officer’s compensation, evaluating the Chief Executive Officer’s performance in light of such goals and objectives and determining and approving the remuneration (if any) of the Chief Executive Officer based on such evaluation;
- reviewing and approving the compensation of the other executive officers;
- reviewing and recommending to the Board the compensation of the directors;
- reviewing our executive compensation policies and plans;
- reviewing and approving, or recommending that the Board approve, incentive compensation and equity plans, severance agreements, change-of-control protections and any other compensatory arrangements for the executive officers and other senior management, as appropriate;
- administering our incentive compensation equity-based incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committee’s compensation advisors;
- assisting management in complying with this prospectus statement and annual report disclosure requirements;
- if required, producing a report on executive compensation to be included in the annual proxy statement;
- reviewing and establishing general policies relating to compensation and benefits of our employees; and
- reviewing our overall compensation philosophy.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee of the Board consists of John Amory, Elizabeth Cermak and Kimberly Murphy. The Board determined each member is independent under the Nasdaq listing rules. The chairperson of the nominating and corporate governance committee is Ms. Cermak.

Specific responsibilities of the nominating and corporate governance committee include:

- identifying, evaluating and selecting, or recommending that the Board approve, nominees for election to the Board;
- evaluating the performance of the Board and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans; and
- developing and making recommendations to the Board regarding corporate governance guidelines and matters.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The Code of Business Conduct and Ethics is available on our website at https://clarustherapeutics.com/. Information contained on or accessible through such website is not a part of this prospectus, and the inclusion of the website address in this prospectus is an inactive textual reference only. We intend to disclose any amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements.
Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has ever been an officer or employee of either company. None of our executive officers serve, or have served during the last year, as a member of the board of directors, compensation committee, or other board committee performing equivalent functions of any other entity that has one or more executive officers serving as one of our directors or on either company’s compensation committee.

Role of the Board in Risk Oversight

One of the key functions of the Board is informed oversight of our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through its various standing committees that address risks inherent in their respective areas of oversight. In particular, the Board is responsible for monitoring and assessing strategic risk exposure and its audit committee is responsible for considering and discussing our major financial risk exposures and the steps our management will take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our compensation committee assesses and monitors whether our compensation plans, policies and programs comply with applicable legal and regulatory requirements.
DIRECTOR COMPENSATION

In December 2021, we adopted a non-employee director compensation policy (the “NED Policy”), which sets forth the terms upon which non-employee directors will be compensated for their service on the Board. Under the terms of the NED Policy, each non-employee director will receive an annual cash retainer of $45,000 and the non-executive chairperson of the Board will receive an additional annual cash retainer of $30,000. Members of our audit committee, compensation committee and nominating and corporate governance committee will each receive additional annual cash retainers of $10,000, $7,500 and $5,000, respectively, while the chairs of the audit committee, compensation committee and nominating and corporate governance committee will receive additional annual cash retainers of $20,000, $15,000 and $10,000, respectively.

Under the terms of the NED Policy, each newly elected non-employee member of the Board will automatically receive a one-time grant of an option to purchase 9,610 shares of Common Stock and an award of restricted stock units (“RSUs”) representing 3,844 shares of Common Stock. These initial awards vest in equal annual installments over three years from the date of grant, provided that the non-employee director is, as of such vesting date, in a service relationship with us. In addition, on each date of our annual general meeting of stockholders, each non-employee director will be automatically granted an option to purchase 4,805 shares of Common Stock and an RSU award representing 1,922 shares of Common Stock. These annual awards will vest in full upon the earlier of (i) our next annual meeting of stockholders or (ii) the one year anniversary of the grant date; provided that the applicable non-employee director is, as of such vesting date, in a service relationship with us.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director in a calendar year will not exceed $1,000,000 in the first calendar year such individual becomes a non-employee director and $650,000 in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the Board and committees thereof. Employee directors will receive no additional compensation for their service as a director.

2021 Director Compensation Table

The following table presents the total compensation for the year ended December 31, 2021 for each person who served as a non-employee director of Legacy Clarus and became a member of the Board in connection with the completion of the Business Combination. Other than as set forth in the table below, we did not pay any compensation or make any equity awards to our non-employee directors during 2021, and Blue Water did not pay any compensation to its non-employee directors prior to completion of the Business Combination. Dr. Dudley, our President and Chief Executive Officer, did not receive any additional compensation for his services on the Board. The compensation received by Dr. Dudley is set forth in “Executive Compensation – 2021 Summary Compensation Table.” Mr. Zisson, a director and the chairperson of our compensation committee, waived all compensation under the NED Policy and did not receive compensation from Legacy Clarus prior to completion of the Business Combination.

<table>
<thead>
<tr>
<th>Name</th>
<th>Fees Earned or Paid in Cash ($)</th>
<th>Stock Awards ($)</th>
<th>Option Awards ($)</th>
<th>All Other Compensation ($)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Amory (4)</td>
<td>15,489</td>
<td>18,374</td>
<td>31,329</td>
<td></td>
<td>65,192</td>
</tr>
<tr>
<td>Elizabeth Cermak (5)</td>
<td>20,136</td>
<td>18,374</td>
<td>31,329</td>
<td></td>
<td>69,839</td>
</tr>
<tr>
<td>Joseph Hernandez (6)</td>
<td>19,361</td>
<td>18,374</td>
<td>31,329</td>
<td></td>
<td>69,064</td>
</tr>
<tr>
<td>Kimberly Murphy (7)</td>
<td>27,106</td>
<td>18,374</td>
<td>31,329</td>
<td></td>
<td>76,809</td>
</tr>
<tr>
<td>Mark A. Prygocki (8)</td>
<td>20,136</td>
<td>18,374</td>
<td>31,329</td>
<td>115,310(9)</td>
<td>223,149</td>
</tr>
<tr>
<td>Alex Zisson</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) The amounts reported represent the annual cash retainer and committee fees paid to or earned by each of our non-employee directors pursuant to our NED Policy.
(2) The amounts reported represent the aggregate grant date fair value of the RSUs granted to our non-employee directors during the year ended December 31, 2021, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the RSUs reported in this column are set forth in Note 10 of our consolidated financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these grants, and do not correspond to the actual economic value that may be received by our non-employee directors from the vesting and settlement of the RSUs or any sale of the underlying shares of Common Stock.

(3) The amounts reported represent the aggregate grant date fair value of the stock option awards granted to our non-employee directors during the year ended December 31, 2021, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option awards reported in this column are set forth in Note 10 of our consolidated financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these grants, and do not correspond to the actual economic value that may be received by our non-employee directors from the exercise of the stock option awards or any sale of the underlying shares of Common Stock.

(4) As of December 31, 2021, Mr. Amory held 9,610 outstanding stock options and 3,844 outstanding RSUs.

(5) As of December 31, 2021, Ms. Cermak held 9,610 outstanding stock options and 3,844 outstanding RSUs.

(6) As of December 31, 2021, Mr. Hernandez held 9,610 outstanding stock options and 3,844 outstanding RSUs.

(7) As of December 31, 2021, Ms. Murphy held 9,610 outstanding stock options and 3,844 outstanding RSUs.

(8) As of December 31, 2021, Mr. Prygocki held 9,610 outstanding stock options and 3,844 outstanding RSUs.

(9) Represents amounts paid to Mr. Prygocki for service as an Executive Director for the period January 1, 2021 through May 15, 2021, consisting of $92,250 in cash compensation and $15,185 for medical insurance premiums. Mr. Prygocki also received consulting fees in the amount of $7,875 for assistance with business development activities after the conclusion of his duties as Executive Director. In connection with Mr. Prygocki’s appointment as an Executive Director in July 2020, the Board approved the following compensation to Mr. Prygocki: (i) a cash payment in an amount equal to 70% of our Chief Executive Officer’s salary, payable on a monthly basis, if Mr. Prygocki is not eligible for and has not elected coverage under our healthcare plans, (ii) a cash payment amount equal to 60% of our Chief Executive Officer’s salary, payable on a monthly basis, if Mr. Prygocki is eligible for and has elected coverage under our healthcare plans, and (iii) eligibility to receive an annual bonus in an amount of up to 60% of our Chief Executive Officer’s bonus, contingent upon achievement of certain performance measures as determined by the Board in its sole discretion. Accordingly, Mr. Prygocki earned a bonus in the amount of $110,656 for his 2020 performance, which amount is not included in the table above.
EXECUTIVE COMPENSATION

This section discusses the material components of the executive compensation program offered to our Chief Executive Officer and our two most highly compensated executive officers (other than our Chief Executive Officer) who earned more than $100,000 during the fiscal year ended December 31, 2021 and were serving as executive officers as of such date. Such executive officers consist of the following persons, referred to herein as our named executive officers:

- Robert E. Dudley, Ph.D., President and Chief Executive Officer
- Richard Peterson, Chief Financial Officer
- Frank A. Jaeger, Chief Commercial Officer

2021 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to our named executive officers in the fiscal years ended December 31, 2021 and 2020, for services rendered to us in all capacities.

<table>
<thead>
<tr>
<th>Name and Principal Position</th>
<th>Year</th>
<th>Salary ($)(1)</th>
<th>Bonus ($)(2)</th>
<th>Stock Awards ($)(3)</th>
<th>Option Awards ($)(4)</th>
<th>Nonequity Incentive Plan Compensation ($)(5)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert E. Dudley</td>
<td>2021</td>
<td>471,811</td>
<td>—</td>
<td>645,300</td>
<td>1,100,250</td>
<td>328,860</td>
<td>2,546,221</td>
</tr>
<tr>
<td></td>
<td>2020</td>
<td>410,000</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>147,600</td>
<td>557,600</td>
</tr>
<tr>
<td>Richard Peterson</td>
<td>2021</td>
<td>406,767</td>
<td>30,000</td>
<td>266,724</td>
<td>454,770</td>
<td>177,221</td>
<td>1,335,482</td>
</tr>
<tr>
<td>Chief Financial Officer(6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frank A. Jaeger</td>
<td>2021</td>
<td>348,296</td>
<td>—</td>
<td>138,620</td>
<td>236,350</td>
<td>162,000</td>
<td>885,266</td>
</tr>
<tr>
<td>Chief Commercial Officer</td>
<td>2020</td>
<td>325,000</td>
<td>—</td>
<td>—</td>
<td>24,000-</td>
<td>89,234</td>
<td>438,734</td>
</tr>
</tbody>
</table>

(1) Amounts reported reflect salary increases that took effect September 9, 2021. In addition, Mr. Peterson joined Legacy Clarus in February 2021, and his salary has been prorated to reflect such start date.

(2) Reflects a sign-on bonus paid to Mr. Peterson in February 2021.

(3) The amounts reported represent the aggregate grant date fair value of the RSUs granted to our named executive officers during 2021 calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the RSUs reported in this column are set forth in Note 10 of our consolidated financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these grants, and do not correspond to the actual economic value that may be received by our named executive officers from the vesting and settlement of the RSUs or the sale of the underlying shares of Common Stock.
(4) The amounts reported represent the aggregate grant date fair value of the stock option awards granted to our named executive officers during the applicable fiscal year, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock option awards reported in this column are set forth in Note 10 of our consolidated financial statements included for Fiscal Year 2021 which are included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these grants, and do not correspond to the actual economic value that may be received by our named executive officers upon the exercise of the stock option awards or any sale of the underlying shares of Common Stock.

(5) The amounts reported reflect bonuses earned based on the achievement of pre-defined performance objectives. Bonuses are reported in the year earned, even though paid the following year.

(6) Mr. Peterson commenced employment with us in February 2021. His base salary and bonus were pro-rated accordingly.

**Narrative Disclosure to the Summary Compensation Table**

The Board and compensation committee review compensation annually for all employees, including our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, the compensation committee and the Board consider compensation for comparable positions in the market, the historical compensation levels of our executive officers, individual performance as compared to our expectations and objectives, internal equity, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to us. We target a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus and long-term incentives.

Our compensation committee is primarily responsible for determining the compensation for our executive officers. Our compensation committee typically reviews and discusses management’s proposed compensation with our Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the compensation committee then sets the compensation for each executive officer other than the Chief Executive Officer and recommends the compensation for the Chief Executive Officer to the Board for approval. The Board discusses the compensation committee’s recommendation and ultimately approves the compensation of our Chief Executive Officer without members of management present. Our compensation committee has the authority to engage the services of a consulting firm or other outside advisor to assist it in designing our executive compensation programs and in making compensation decisions. During 2021, the compensation committee retained the services of FW Cook as its external compensation consultant to advise on executive compensation matters including our overall compensation program design and collection of market data to inform our compensation programs for our executive officers and members of the Board. FW Cook reports directly to our compensation committee. Prior to engaging FW Cook, our compensation committee assessed its independence consistent with Nasdaq listing standards and concluded that the engagement of such consultant did not raise any conflict of interest.

**Base Salaries**

The annual base salaries of our named executive officers are generally determined, approved and reviewed periodically by our compensation committee in order to compensate our named executive officers for their satisfactory performance of duties to our company. Annual base salaries are intended to provide a fixed component of compensation to our named executive officers, reflecting their skill sets, experience, roles and responsibilities. Base salaries for our named executive officers have generally been set at levels deemed necessary to attract and retain individuals with superior talent.

<table>
<thead>
<tr>
<th>Name</th>
<th>2020 Base Salary ($)</th>
<th>2021 Base Salary ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert E. Dudley</td>
<td>410,000</td>
<td>609,000</td>
</tr>
<tr>
<td>Richard Peterson</td>
<td>0</td>
<td>445,000</td>
</tr>
<tr>
<td>Frank A. Jaeger</td>
<td>325,000</td>
<td>400,000</td>
</tr>
</tbody>
</table>

(1) 2021 salary increases from 2020 amounts (or from 348,000 as of February 2021 for Mr. Peterson) were effective as of September 9, 2021.
Annual Cash Bonuses

During the year ended December 31, 2021, each named executive officer was eligible to earn an annual bonus based on the achievement of corporate and individual objectives. For the year ended December 31, 2021, the earned annual bonuses for Dr. Dudley and Messrs. Peterson and Jaeger were $328,860, $177,221 and $162,000, respectively. Mr. Peterson also received a guaranteed sign-on bonus of $30,000 upon commencement of his employment in February 2021.

Equity Incentive Plan

We grant our employees, including our named executive officers, a mix of stock options and RSUs. In December 2021, Dr. Dudley and Messrs. Peterson and Jaeger were granted options to purchase 337,500, 139,500 and 72,500 shares of Common Stock, respectively, and 135,000, 55,800, and 29,000 RSUs respectively. As a general practice, our stock options and RSUs vest 25% on the first anniversary of the vesting commencement date, with the remaining 75% vesting in 36 equal monthly installments thereafter. These awards have a vesting commencement date of September 9, 2021 and are described in more detail in the “Outstanding Equity Awards at 2021 Fiscal Year-End” table.

Other Compensation and Benefits

We provide benefits to our named executive officers on the same basis as provided to all of our employees, including health, dental and vision insurance; and disability insurance. We do not maintain any executive-specific benefit or executive perquisite programs.

Agreements with Our Named Executive Officers

We entered into employment agreements with our named executive officers effective as of September 9, 2021: Robert E. Dudley, Ph.D. (Chief Executive Officer and President), Richard Peterson (Chief Financial Officer), and Frank A. Jaeger (Chief Commercial Officer). Each employment agreement provides for an indefinite employment term that may be terminated in accordance with the terms and conditions of the employment agreement, and sets forth the executive officer’s annual base salary and annual cash performance-based bonus with a target of a certain percentage of base salary based on the achievement of certain performance objectives as determined by the compensation committee of the Board. Each employment agreement provides for severance benefits upon a termination of employment due to death or “disability” (as defined in the employment agreements), including (i) any unpaid annual bonus for the fiscal year ended prior to the date of termination, paid at the same time as annual bonuses are paid to the senior executives, (ii) pro-rata annual bonus for the year of termination, paid within 30 days of the executive’s termination date, and (iii) payment of the employer-portion of COBRA premiums for 18 months for Dr. Dudley and 12 months for each of Messrs. Peterson and Jaeger. Each employment agreement also provides for severance benefits upon a termination of employment without “cause” or by the executive officer for “good reason” (each as defined in the employment agreements), subject to the execution of a release, including (i) any unpaid annual bonus for the fiscal year ended prior to the date of termination, paid at the same time as annual bonuses are paid to the senior executives, (ii) a pro-rata annual bonus for the year of termination (based on actual performance), paid at the same time as annual bonuses are paid to the senior executives, (iii) a certain number of months of base salary (18 months for Dr. Dudley and 12 months for each of Messrs. Peterson and Jaeger), payable in installments over the applicable severance period (or in the event such termination occurs on or following a “change in control” (as defined in the employment agreements), payable in a lump sum following such termination), (iv) payment of the employer-portion of COBRA premiums during the applicable severance period (or until the executive officer becomes eligible to receive health benefits as a result of subsequent employment or service during the severance period, if earlier), and (v) outplacement services up to a maximum cost of $25,000. Each employment agreement provides a Section 280G partial clawback, in which each executive is entitled to receive the greater of (a) the best net after-tax amount of any payments that are “parachute payments” under Section 280G of the Code of and (b) the amount of parachute payments the executive would be entitled to receive if they were reduced to an amount equal to 2.99 times the executive’s “base amount” (as defined in the employment agreement). Each employment agreement also contains certain restrictive covenants, including a 12-month (18-month for Dr. Dudley) non-competition, a 12-month (18-month for Dr. Dudley) non-solicitation, and confidentiality covenants.
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**Outstanding Equity Awards at 2021 Fiscal Year-End**

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2021.

<table>
<thead>
<tr>
<th>Name</th>
<th>Grant date</th>
<th>Vesting commencement date</th>
<th>Number of securities underlying unexercised options (#) exercisable</th>
<th>Option awards (1)</th>
<th>Number of securities underlying unexercised options (#) unexercisable</th>
<th>Stock Awards (2)</th>
<th>Market Value of Shares or Units of Stock That Have Not Vested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert E. Dudley</td>
<td>12/12/2021</td>
<td>9/9/2021</td>
<td>337,500(3)</td>
<td>4.78</td>
<td>12/12/2031</td>
<td>135,000 (4)</td>
<td>328,050</td>
</tr>
<tr>
<td></td>
<td>12/12/2021</td>
<td>9/9/2021</td>
<td>139,500(3)</td>
<td>4.78</td>
<td>12/11/2031</td>
<td>55,800 (4)</td>
<td>135,594</td>
</tr>
<tr>
<td>Richard Peterson</td>
<td>12/11/2021</td>
<td>9/9/2021</td>
<td>72,500(3)</td>
<td>4.78</td>
<td>12/11/2031</td>
<td>29,000 (4)</td>
<td>70,470</td>
</tr>
<tr>
<td>Frank A. Jaeger</td>
<td>12/11/2021</td>
<td>9/9/2021</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>12/11/2021(4)</td>
<td>9/9/2021</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) Each option grant is subject to the terms of our 2021 Stock Option and Incentive Plan (the “2021 Plan”).

(2) Each RSU grant is subject to the terms of our 2021 Plan.

(3) 25% of the shares subject to this stock option vest on the one year anniversary of the vesting commencement date, and 75% of the shares subject to the stock option vest in 36 equal monthly installments thereafter, in each case, subject to the named executive officer’s continued service relationship through each applicable vesting date.

(4) 25% of the shares subject to this RSU vest on the one year anniversary of the vesting commencement date, and 75% of the shares subject to the RSU vest in 36 equal monthly installments thereafter, in each case, subject to the named executive officer’s continued service relationship through each applicable vesting date.

(5) Calculated in accordance with SEC rules as the number of unvested shares or units multiplied by the closing market price of a share of Common Stock on December 31, 2021, which was $2.43.

### Employee Benefits and Stock Plans

#### 2004 Stock Incentive Plan

All awards previously granted under the 2004 Plan were cancelled and extinguished at the Merger Closing.

#### 2021 Stock Option and Incentive Plan

The Board unanimously adopted the Clarus Therapeutics Holdings, Inc. 2021 Plan and the stockholders approved its adoption on August 27, 2021 (the “2021 Plan Effective Date”).

The 2021 Plan allows us to make equity and equity-based incentive awards to officers, employees, directors and consultants. The Board anticipates that providing such persons with a direct stake in our company will assure a closer alignment of the interests of such individuals with us and our stockholders, thereby stimulating their efforts on our behalf and strengthening their desire to remain with the Company.
The Board initially reserved 3.475 million shares of Common Stock for the issuance of awards under the 2021 Plan (the “Initial Limit”). The 2021 Plan provides that the number of 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”). This limit is subject to adjustment in the event of a reorganization, recapitalization, reclassification, stock split, stock dividend, reverse stock split or other similar change in our capitalization. The maximum aggregate number of shares of Common Stock that may be issued upon exercise of incentive stock options under the 2021 Plan shall not exceed the Initial Limit cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase or 3.475 million shares of Common Stock. Shares underlying any awards under the 2021 Plan that are forfeited, cancelled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, satisfied without the issuance of stock or otherwise terminated (other than by exercise) will be added back to the shares available for issuance under the 2021 Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, the shares that may be issued as incentive stock options.

The 2021 Plan contains a limitation whereby the value of all awards under the 2021 Plan and all other cash compensation paid by us to any non-employee director may not exceed $1,000,000 for the first calendar year a non-employee director is initially appointed to the Board, and $650,000 in any other calendar year.

The 2021 Plan is administered by the compensation committee of the Board, the Board or such other similar committee pursuant to the terms of the 2021 Plan. The plan administrator, which initially is the compensation committee of the Board, has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Plan. The plan administrator may delegate to a committee consisting of one or more of our officers, including our Chief Executive Officer, the authority to award to individuals who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not members of the delegated committee, subject to certain limitations and guidelines.

Persons eligible to participate in the 2021 Plan are our officers, employees, non-employee directors and consultants as selected from time to time by the plan administrator in its discretion.

The 2021 Plan permits the granting of both options to purchase Common Stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. Options granted under the 2021 Plan will be non-qualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive awards under the 2021 Plan. The option exercise price of each option will be determined by the plan administrator but generally may not be less than 100% of the fair market value of the Common Stock on the date of grant or, in the case of an incentive stock option granted to a ten percent stockholder, 110% of such share’s fair market value. The term of each option will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each option may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the plan administrator or by delivery (or attestation to the ownership) of shares of Common Stock that are beneficially owned by the optionee free of restrictions or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the plan administrator may permit non-qualified options to be exercised using a “net exercise” arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with fair market value that does not exceed the aggregate exercise price.

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of Common Stock, or cash, equal to the value of the appreciation in the Company’s stock price over the exercise price. The exercise price generally may not be less than 100% of the fair market value of Common Stock on the date of grant. The term of each stock appreciation right will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each stock appreciation right may be exercised, including the ability to accelerate the vesting of such stock appreciation rights.
The plan administrator may award restricted shares of Common Stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. The plan administrator may also grant shares of Common Stock that are free from any restrictions under the 2021 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant. The plan administrator may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of Common Stock.

The plan administrator may grant cash-based awards under the 2021 Plan to participants, subject to the achievement of certain performance goals, including continued employment with us.

The 2021 Plan requires the plan administrator to make appropriate adjustments to the number of shares of common stock that are subject to the 2021 Plan, to certain limits in the 2021 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

The 2021 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2021 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2021 Plan. To the extent that awards granted under the 2021 Plan are not assumed or continued or substituted by the successor entity, all awards granted under the 2021 Plan shall terminate and in such case except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting conditions or restrictions shall become fully vested and exercisable or nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and exercisable or nonforfeitable in connection with a sale event in the plan administrator’s discretion or to the extent specified in the relevant award certificate. In the event of such termination, individuals holding options and stock appreciation rights will, for each such award, either (a) receive a payment in cash or in kind for each share subject to such award that is exercisable in an amount equal to the per share cash consideration payable to stockholders in the sale event less the applicable per share exercise price (provided that, in the case of an option or stock appreciation right with an exercise price equal to or greater than the per share cash consideration payable to stockholders in the sale event, such option or stock appreciation right shall be cancelled for no consideration) or (b) be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. The plan administrator shall also have the option (in its sole discretion) to make or provide for a payment, in cash or in kind, to the grantees holding other awards in an amount equal to the per share cash consideration payable to stockholders in the sale event multiplied by the number of vested shares under such awards.

Participants in the 2021 Plan are responsible for the payment of any federal, state or local taxes that we or our subsidiaries are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any tax withholding obligation of the Company or its subsidiaries to be satisfied, in whole or in part, by the applicable entity withholding from shares of Common Stock to be issued pursuant to an award a number of shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any tax withholding obligation of us or our subsidiaries to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to us or our subsidiaries in an amount that would satisfy the withholding amount due.

The 2021 Plan generally does not allow for the transfer or assignment of awards, other than by will or by the laws of descent and distribution or pursuant to a domestic relations order; however, the plan administrator may permit the transfer of non-qualified stock options by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners.

The plan administrator may amend or discontinue the 2021 Plan and the plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder’s consent. Certain amendments to the 2021 Plan will require the approval of our stockholders. The plan administrator is specifically authorized to exercise its discretion to reduce the exercise price of outstanding options or stock appreciation rights, effect the repricing of such awards through cancellation and re-grants or cancel such awards in exchange for cash or other awards.
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No awards may be granted under the 2021 Plan after the date that is ten years from the 2021 Plan Effective Date.

Employee Stock Purchase Plan

The Board unanimously adopted the Clarus Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (the “ESPP”) and the stockholders approved its adoption on August 27, 2021. We believe that the ESPP benefits us by providing employees with an opportunity to acquire shares of Common Stock and will enable us to attract, retain and motivate valued employees.

An aggregate of 347,500 shares was initially reserved and available for issuance under the ESPP. The 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 Common Stock, 1.0% of the outstanding number of shares of the Common Stock on the immediately preceding December 31, or such lesser amount as determined by the plan administrator. If our capital structure changes because of a stock dividend, subdivision of outstanding shares or similar event, the number of shares that can be issued under the ESPP will be appropriately adjusted.

The ESPP will be administered by the person or persons appointed by the Board. Initially, the compensation committee of the Board will administer the plan and has full authority to make, administer and interpret such rules and regulations regarding the ESPP as it deems advisable.

Any of our employees or of our subsidiaries that has been designated to participate in the ESPP is eligible to participate in the ESPP so long as the employee is customarily employed for more than 20 hours a week. No person who owns or holds, or as a result of participation in the ESPP would own or hold, Common Stock or options to purchase Common Stock, that together equal to 5% or more of total combined voting power or value of all of our classes of stock or any parent or subsidiary is entitled to participate in the ESPP. No employee may exercise an option granted under the ESPP that permits the employee to purchase Common Stock having a value of more than $25,000 (determined using the fair market value of the stock at the time such option is granted) in any calendar year.

Participation in the ESPP is limited to eligible employees who authorize payroll deductions equal to a whole percentage of base pay to the ESPP. Employees may authorize payroll deductions, with a minimum of 1% of base pay and a maximum of 15% of base pay. Once an employee becomes a participant in the ESPP, that employee will automatically participate in successive offering periods, as described below, until such time as that employee withdraws from the ESPP, becomes ineligible to participate in the ESPP, or his or her employment ceases.

Unless otherwise determined by the compensation committee, each offering of Common Stock under the ESPP will be for a period of six months, which we refer to as an “offering period.” The first offering period under the ESPP will begin and end on such date or dates as determined by the administrator. Offerings under the ESPP will generally begin on the first business day occurring on or after each November 1 and May 1 and will end on the last business day occurring on or before the following December 31 and June 30, respectively. Shares are purchased on the last business day of each offering period, with that day being referred to as an “exercise date.” The plan administrator may establish different offering periods or exercise dates under the ESPP.

On the exercise date of each offering period, the employee is deemed to have exercised the option, at the exercise price for the lowest of (i) a number of shares of Common Stock determined by dividing such employee’s accumulated payroll deductions or contributions on such exercise date by the exercise price; (ii) a number of shares of Common Stock determined by dividing $25,000 by the fair market value of the Common Stock on the first day of the offering; or (iii) such lesser number as established by the plan administrator in advance of the offering. The exercise price is equal to the lesser of (i) 85% the fair market value per share of Common Stock on the first day of the offering period or (ii) 85% of the fair market value per share of Common Stock on the exercise date.

In general, if an employee is no longer a participant on an exercise date, the employee’s option will be automatically terminated, and the amount of the employee’s accumulated payroll deductions will be refunded.
Except as may be permitted by the plan administrator in advance of an offering, a participant may not increase or decrease the amount of his or her payroll deductions during any offering period but may increase or decrease his or her payroll deduction with respect to the next offering period by filing a new enrollment form within the period beginning 15 business days before the first day of such offering period and ending on the day prior to the first day of such offering period. A participant may withdraw from an offering period at any time without affecting his or her eligibility to participate in future offering periods. If a participant withdraws from an offering period, that participant may not again participate in the same offering period, but may enroll in subsequent offering periods. An employee’s withdrawal will be effective as of the beginning of the next payroll period immediately following the date that the plan administrator receives the employee’s written notice of withdrawal under the ESPP.

In the case of and subject to the consummation of a “sale event,” the plan administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions under the ESPP or with respect to any right under the ESPP or to facilitate such transactions or events: (a) to provide for either (i) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (ii) the replacement of such outstanding option with other options or property selected by the plan administrator in its sole discretion; (b) to provide that the outstanding options under the ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (c) to make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding options under the ESPP and/or in the terms and conditions of outstanding options and options that may be granted in the future; (d) to provide that the offering with respect to which an option relates will be shortened by setting a new exercise date on which such offering will end; and (e) to provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

The ESPP will automatically terminate on the 10-year anniversary of the ESPP effective date. The Board may, in its discretion, at any time, terminate or amend the ESPP.
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2019 to which we have been a party in which the amount involved exceeded or will exceed the lesser of (x) $120,000 or (y) 1% of our average total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Director Compensation — 2021 Director Compensation Table” and “Executive Compensation — Summary Compensation Table.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Amended and Restated Registration Rights Agreement

In connection with the Merger Closing, we entered into the Registration Rights Agreement (the "A&R Registration Rights Agreement") with certain persons and entities holding securities of Clarus and certain persons and entities receiving Common Stock pursuant to the Merger Agreement. Pursuant to the A&R Registration Rights Agreement, we had an obligation to file a registration statement under the Securities Act covering the resale of (i) shares of Common Stock held by the Sponsor or issuable to the Sponsor upon conversion or exercise of other Company securities held by it, and (ii) shares of Common Stock issuable to the Legacy Clarus securityholders party thereto in the Merger. Accordingly, we filed a registration statement on Form S-1 on September 30, 2021, which was declared effective on October 7, 2021 (the "Resale Registration Statement"). Either the Sponsor or a majority of the Legacy Clarus securityholders party to the A&R Registration Rights Agreement holding registrable securities are entitled to make a written demand for registration under the Securities Act of all or part of their registrable securities. Subject to certain exceptions, if at any time we propose to file a registration statement under the Securities Act with respect to our securities, under the A&R Registration Rights Agreement we are required to give notice to the other parties thereto as to the proposed filing and offer them the opportunity to register the sale of such number of registrable securities as they may request in writing. The A&R Registration Rights Agreement will terminate upon the earlier of (i) the fifth anniversary of the date of the A&R Registration Rights Agreement or (ii) the date as of which (A) all of the Registrable Securities (as defined therein) have been sold pursuant to a registration statement (but in no event prior to the applicable period referred to in Section 4(a)(3) of the Securities Act and Rule 174 thereunder (or any successor rule promulgated thereafter by the SEC)) or (B) the holders of all Registrable Securities are permitted to sell the Registrable Securities under Rule 144 (or any similar provision) under the Securities Act without limitation on the amount of securities sold or the manner of sale (the “Effectiveness Period”).

Stockholder Lock-Up Agreements

In connection with the Merger Closing, we entered into Lock-Up Agreements with certain significant Legacy Clarus stockholders (each, a "Stockholder Lock-Up Agreement"). Pursuant to the Stockholder Lock-Up Agreements, each Legacy Clarus stockholder party thereto agreed not to, during the period commencing from the Merger Closing and ending 180 days after the date of the Merger Closing (subject to early release if we consummate a liquidation, merger, capital stock, reorganization exchange or other similar transaction with an unaffiliated third party that results in all of our stockholders having the right to exchange their equity holdings for cash, securities or other property): (x) lend, offer, pledge, hypothecate, encumber, donate, assign, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any restricted securities, (y) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the restricted securities, or (z) publicly disclose the intention to do any of the foregoing, whether any such transaction described in clauses (x), (y) or (z) above is to be settled by delivery of restricted securities or other securities, in cash or otherwise (in each case, subject to certain limited permitted transfers where the recipient takes the shares subject to the restrictions in the Stockholder Lock-Up Agreement).
Lender Lock-Up Agreements

In connection with the Merger Closing, we entered into Lock-Up Agreements with certain Legacy Clarus noteholders (the “Lenders”) (each, a “Lender”). Pursuant to the Lender Lock-Up Agreements, each Lender party thereto agreed not to, during the period commencing from the Merger Closing and ending 180 days after the date of the Merger Closing (subject to early release if we consummate a liquidation, merger, capital stock, reorganization exchange or other similar transaction with an unaffiliated third party that results in all of the stockholders having the right to exchange their equity holdings for cash, securities or other property): (x) lend, offer, pledge, hypothecate, encumber, donate, assign, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any restricted securities, (y) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the restricted securities, or (z) publicly disclose the intention to do any of the foregoing, whether any such transaction described in clauses (x), (y) or (z) above is to be settled by delivery of restricted securities or other securities, in cash or otherwise (in each case, subject to certain limited permitted transfers where the recipient agrees to be bound by the restrictions in the Lender Lock-Up Agreement). However, during the second half of the lock-up period (the “Lock-Out Period”), each Lender is able to engage in limited transfers of restricted securities that would otherwise be prohibited by the lock-up, up to a daily maximum volume based on the number of restricted securities held by such Lender at the commencement of the Lock-Out Period prorated to the number of trading days in the Lock-Out Period, with the ability to cumulate unused daily volume limits over a maximum period of five trading days.

Indebtedness

At the Effective Time, certain of Legacy Clarus’ senior secured noteholders were given Common Stock (which included 405,000 shares of Common Stock that were allocated to the senior secured noteholders pursuant to a share allocation agreement, of which 270,000 shares were reallocated from Legacy Clarus equity holders and 135,000 shares were transferred from the Sponsor) in exchange for $10.0 million of principal on the senior secured notes and certain royalty rights. For additional information, see Note 8 and Note 15 to our consolidated financial statements included elsewhere in this prospectus.

Legacy Clarus Support Agreements

Simultaneously with the execution of the Merger Agreement, Blue Water and Legacy Clarus entered into support agreements (the “Clarus Support Agreements”) with certain significant stockholders of Legacy Clarus holding in the aggregate approximately 70.0% of Legacy Clarus’s outstanding capital stock. Pursuant to the Clarus Support Agreement, each such stockholder agreed, among other things, to vote all of its shares of Legacy Clarus stock in favor of the Merger Agreement and related transactions and to otherwise take certain actions in support of the Merger Agreement and related transactions and the other matters submitted to Legacy Clarus stockholders for their approval, and provide a proxy to Blue Water to vote such Legacy Clarus stock accordingly. The Clarus Support Agreement prevents transfers of the Clarus stock held by such stockholder between the date of the Clarus Support Agreement and the date of the Merger Closing, except for certain permitted transfers where the recipient also agrees to comply with the Clarus Support Agreement.

Sponsor Support Agreement

Simultaneously with the execution of the Merger Agreement, Blue Water and Legacy Clarus entered into a support agreement (the “Sponsor Support Agreement”) with the Sponsor. Under the Sponsor Support Agreement, the Sponsor agreed that it would abide by its undertakings in that certain letter agreement dated December 15, 2020, by and among Blue Water and its officers, its directors and the Sponsor filed as Exhibit 10.1 to Blue Water’s Current Report on Form 8-K filed with the SEC on December 21, 2020 (the “Insider Letter”), including voting its Blue Water shares in favor of the Merger Agreement and the Business Combination and not redeeming such shares in connection with the Merger, and that in the event of a transfer of its shares permitted under the Insider Letter, the Sponsor ensures that the transferee agrees to be bound by the restrictions in the Sponsor Support Agreement. The Sponsor also agreed in connection with the Merger to enforce the Sponsor’s obligations under the Insider Letter.

Blue Water Related Person Transactions

Founder Shares

On June 30, 2020, Blue Water issued an aggregate of 1,437,500 Founder Shares to the Sponsor for an aggregate purchase price of $25,000 in cash, or approximately $0.017 per share. The number of Founder Shares issued was determined based on the expectation that such Founder Shares would represent 20% of the outstanding shares upon completion of the Blue Water IPO. The Founder Shares (including the Class A common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder.
Placement Warrants

On December 17, 2020, the Sponsor purchased an aggregate of 3,445,000 Placement Warrants for a purchase price of $1.00 per warrant, for an aggregate purchase price of $3,445,000, in a placement that occurred simultaneously with the closing of the Blue Water IPO. Each Placement Warrant entitles the holder thereof to purchase one share of Common Stock at a price of $11.50 per share. The Placement Warrants (including the common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder.

Administrative Support Services

Commencing December 2020, we paid the Sponsor a total of $10,000 per month for office space, utilities and secretarial and administrative support. Upon completion of the Merger, Blue Water ceased paying these monthly fees.

Related Party Loans

Prior to the consummation of the Blue Water IPO, the Sponsor loaned us approximately $157,000 under an unsecured promissory note, which were used for a portion of the expenses of the IPO. The loan was non-interest bearing and unsecured and was repaid in full on December 17, 2020 out of the offering proceeds that were allocated to the payment of offering expenses (other than underwriting commissions).

Legacy Clarus Related Person Transactions

Sales and Purchases of Securities

2018 Note Financings

On February 13, 2018, Legacy Clarus entered into a note purchase agreement (the “February Notes”) pursuant to which its existing investors committed to purchase convertible promissory notes.

On August 16, 2018, Legacy Clarus entered into a note purchase agreement (the “August Notes”, and together with the February Notes, the “Notes”), pursuant to which its existing investors committed to purchase convertible promissory notes. The August Notes were amended on June 7, 2019, March 17, 2021 and April 26, 2021 to allow for subsequent closings and certain mandatory conversion rights.

The Notes are subject to certain mandatory conversion rights such that if the conditions are met, the Notes shall convert to Mandatory Conversion Stock (as defined in the August Notes). Further, in the event of a SPAC Transaction (as defined in the August Notes), if the August Notes have not been previously converted, the note holder will receive the number of shares of common stock of the SPAC Acquirer (as defined in the August Notes) equal to the quotient obtained by dividing (A) the outstanding principal balance of the August Note and any interest accrued and unpaid as of immediately prior to the SPAC Transaction by (B) (i) if the August Notes was issued prior to April 2021, $10.20, or (ii) if the August Notes were issued in or after April 2021, $10.00.

The following table summarizes the aggregate participation in the Notes beginning January 1, 2018 by any of Clarus’s directors, executive officers, holders of more than 5% of Clarus’s voting securities, or any member of the immediate family of the foregoing persons.

<table>
<thead>
<tr>
<th>Name and Date of Issuance</th>
<th>Aggregate Principal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>February Notes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>February 13, 2018</strong></td>
<td></td>
</tr>
<tr>
<td>Entities affiliated with Thomas, McNerney &amp; Partners(1)</td>
<td>$1,654,756.18</td>
</tr>
<tr>
<td>Entities affiliated with H.I.G. BioVentures(2)</td>
<td>$ 783,554.49</td>
</tr>
<tr>
<td>CBC SPVI Ltd(3)</td>
<td>$ 876,618.82</td>
</tr>
</tbody>
</table>
## August Notes

<table>
<thead>
<tr>
<th>Table</th>
<th>Initial 2018 Closing</th>
<th>First Subsequent 2019 Closing</th>
<th>Second Subsequent 2019 Closing</th>
<th>Third Subsequent 2019 Closing</th>
<th>First Subsequent 2021 Closing</th>
<th>Second Subsequent 2021 Closing</th>
<th>Third Subsequent 2021 Closing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entities affiliated with Thomas, McNerney &amp; Partners</td>
<td>$1,946,771.98</td>
<td>$3,893,543.96</td>
<td>$1,946,774.98</td>
<td>$1,160,295.79</td>
<td>$2,920,157.98</td>
<td>$2,133,681.77</td>
<td>$1,609,295.79</td>
</tr>
<tr>
<td>Entities affiliated with H.I.G. BioVentures</td>
<td>$1,727,269.09</td>
<td>$3,454,538.18</td>
<td>$1,727,269.09</td>
<td>$549,419.29</td>
<td>$2,590,903.63</td>
<td>$1,413,053.83</td>
<td>$549,419.29</td>
</tr>
<tr>
<td>CBC SPVI Ltd</td>
<td>$1,031,316.26</td>
<td>$2,062,632.52</td>
<td>$1,031,316.52</td>
<td>$614,674.90</td>
<td>$1,546,974.38</td>
<td>$1,130,333.05</td>
<td>$614,674.90</td>
</tr>
</tbody>
</table>

(1) James E. Thomas is a partner at Thomas, McNerney & Partners and was a member of Legacy Clarus’s board of directors.
(2) Bruce C. Robertson, Ph.D. and Alex Zisson are managing directors at H.I.G. BioHealth Partners and were members of Legacy Clarus’s board of directors. Alex Zisson is a member of the Board.
(3) Mengjiao Jiang is a managing partner at C-Bridge Capital Partners and was a member of Legacy Clarus’s board of directors.

### Indemnification Agreements

Legacy Clarus entered into indemnification agreements with each of its directors. These agreements, among other things, required Legacy Clarus to indemnify each director to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of Legacy Clarus, arising out of the person’s services as a director. In connection with the Business Combination, we entered into new agreements to indemnify our directors and executive officers. These agreements require us to indemnify these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on our behalf or that person’s status as a member of the Board to the maximum extent allowed under Delaware law.
Policies for Approval of Related Person Transactions

We have adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A “Related Person Transaction” is any transaction involving over $120,000 in which the Company is a participant and a Related Person has a direct or indirect material interest; provided, however, that if the Company is a “smaller reporting company” such threshold shall be the lesser of (x) $120,000 or (y) 1% of the average of the Company’s total assets at year-end for the last two completed fiscal years. A “Related Person” means:

- any director or executive officer of the Company;
- any director nominee;
- security holders known to the Company to beneficially own more than 5% of any class of the Company’s voting securities, and
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than 5% of its voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than 5% of its voting stock.

We have designed these policies and procedures to minimize potential conflicts of interest arising from any dealings it may have with its affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, pursuant to its charter, the audit committee of the Board will have the responsibility to review related party transactions.

Employment Arrangements

We have entered into employment arrangements with each of our executive officers. In 2020, Legacy Clarus’s board of directors requested an expansion of board duties in turn for compensation with one of its current directors. For more information regarding these agreements with Clarus’s executive officers and directors, please see “Executive Compensation – Employment Agreements with Our Executive Officers” of this prospectus.
PRINCIPAL SECURITYHOLDERS

The following table sets forth information known to us regarding the beneficial ownership of the Common Stock as of March 24, 2022, by:

- each person who is known by us to be the beneficial owner of more than 5% of the outstanding shares of the Common Stock;
- each current named executive officer and director of the Company; and
- all current executive officers and directors of the Company, as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provides that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security, including options and Warrants that are currently exercisable or exercisable within 60 days.

The beneficial ownership percentages set forth in the table below are based on 24,750,011 shares of Common Stock issued and outstanding as of March 24, 2022 and do not take into account the issuance of any shares of Common Stock upon the exercise of Warrants that remain outstanding.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons and entities named in the table have sole voting and investment power with respect to their beneficially owned Common Stock. The business address of each of the persons and entities listed below is c/o Clarus Therapeutics Holdings, Inc., 555 Skokie Boulevard, Suite 340, Northbrook, Illinois 60062, unless otherwise indicated.

<table>
<thead>
<tr>
<th>Name of Beneficial Owner</th>
<th>Number of Shares</th>
<th>Percentage of Outstanding Shares</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Directors and Named Executive Officers</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kimberly Murphy</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>John Amory</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Elizabeth A. Cermak</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Joseph Hernandez(1)</td>
<td>1,302,500</td>
<td>5.3%</td>
</tr>
<tr>
<td>Mark A. Prygocki, Sr</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Alex Zisson(2)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Robert E. Dudley</td>
<td>4,566</td>
<td>*</td>
</tr>
<tr>
<td>Richard Peterson</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Frank Jaeger</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td><strong>All directors and executive officers as a group (9 individuals)</strong></td>
<td>1,307,066</td>
<td>5.3%</td>
</tr>
<tr>
<td><strong>Five Percent Holders:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Entities affiliated with H.I.G. BioVentures(2)</td>
<td>5,692,381</td>
<td>23.0%</td>
</tr>
<tr>
<td>Entities affiliated with Thomas, McNerney &amp; Partners(3)</td>
<td>5,498,571</td>
<td>22.2%</td>
</tr>
<tr>
<td>CBC SPVI Ltd.(4)</td>
<td>3,602,287</td>
<td>14.6%</td>
</tr>
<tr>
<td>Armistice Capital Master Fund Ltd.(5)</td>
<td>2,452,376</td>
<td>9.9%</td>
</tr>
<tr>
<td>Entities affiliated with Bracebridge Capital, LLC(6)</td>
<td>2,002,495</td>
<td>8.1%</td>
</tr>
<tr>
<td>Blue Water Sponsor LLC(1)</td>
<td>1,302,500</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

* Less than 1%.

(1) Joseph Hernandez, a member of the Board, is the managing member of Blue Water Sponsor LLC, and as such may be deemed to have sole voting and investment discretion with respect to the securities held by Blue Water Sponsor LLC.
Information herein is based on the Schedule 13D filed with the SEC on September 21, 2021 by H.I.G. Bio – Clarus I, L.P. (“H.I.G. I LP”), H.I.G. Bio – Clarus II, L.P. (“H.I.G. II LP”), H.I.G. Ventures – Clarus, LLC (“H.I.G. LLC”), H.I.G.-GPII, Inc. (“H.I.G. GP” and together with H.I.G. I LP, H.I.G. II LP and H.I.G. LLC, the “H.I.G. Entities”), Anthony Tamer and Sami Mnaymneh. Consists of (i) 490,531 shares of Common Stock directly held by H.I.G. I LP, (ii) 2,470,756 shares of Common Stock directly held by H.I.G. II LP and (iii) 2,731,094 shares of Common Stock directly held by H.I.G. LLC. H.I.G. GP is the general partner of H.I.G. I LP, H.I.G. II LP and H.I.G. LLC, and Mr. Tamer and Mr. Mnaymneh serve as executive officers of H.I.G. GP. The H.I.G. Entities are owned by private funds advised by H.I.G. Capital, LLC, an SEC registered investment advisor, and its affiliates. Alex Zisson, a member of the Board, is a managing director of H.I.G. Capital LLC, but does not share voting and investment power with respect to the shares directly held by any of the H.I.G. Entities, and disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address for the H.I.G. Entities, Mr. Tamer and Mr. Mnaymneh is 1450 Brickell Ave., 31st Floor, Miami, FL 33131.

Information herein is based on the Schedule 13D filed with the SEC on December 10, 2021 by James E. Thomas, Thomas, McNerney & Partners, LLC (“TMP LLC”), Thomas, McNerney & Partners II, LLC (“TMP II LLC”), Thomas, McNerney & Partners, L.P. (“TMP Partners”), Thomas, McNerney & Partners II, L.P. (“TMP Partners II”), TMP Nominee, LLC (“TMP Nominee”), TMP Nominee II, LLC (“TMP Nominee II”), TMP Associates, L.P. (“TMP Associates”) and TMP Associates II, L.P. (“TMP Associates II” and together with TMP LLC, TMP II LLC, TMP Partners, TMP Partners II, TMP Nominee, TMP Nominee II and TMP Associates, the “TMP Entities”). Consists of (i) 2,436,725 shares of Common Stock directly held by TMP Partners, (ii) 3,020,674 shares of Common Stock directly held by TMP Partners II, (iii) 8,383 shares of Common Stock directly held by TMP Nominee (iv) 19,970 shares of Common Stock directly held by TMP Nominee II, (v) 1,706 shares of Common Stock directly held by TMP Associates and (vi) 11,113 shares of Common Stock directly held by TMP Associates II. TMP LLC, the general partner of TMP Partners, TMP Partners II, TMP Associates and TMP Associates II, has voting and dispositive power over the shares held by TMP Partners, TMP Partners II, TMP Associates and TMP Associates II. In addition, each of TMP Nominee and TMP Nominee II has entered into an agreement that it shall vote and dispose of securities in the same manner as directed by TMP Partners, TMP Partners II, TMP Nominee and TMP Nominee II. James Thomas is manager of TMP LLC and TMP II LLC, and of TMP Nominee and TMP Nominee II. He disclaims beneficial ownership of the shares owned by TMP Partners, TMP Partners II, TMP Nominee, TMP Nominee II, TMP Associates and TMP Associates II. The address for Mr. Thomas and the TMP Entities is 12527 Central Avenue NE, #297, Minneapolis, MN 55434.

Information herein is based on the Schedule 13G filed with the SEC on February 15, 2022 by Armistice Capital, LLC (“Armistice Capital”) and Steven Boyd. Consists of 2,452,376 shares of Common Stock directly held by Armistice Capital Master Fund Ltd, a Cayman Islands exempted company (the “Master Fund”), and may be deemed to be indirectly beneficially owned by (i) Armistice Capital, as the investment manager of the Master Fund and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice Capital and Steven Boyd disclaim beneficial ownership of the securities except to the extent of their respective pecuniary interests therein. The address of Master Fund is c/o Armistice Capital, LLC, 510 Madison Ave, 7th Floor, New York, NY 10022.
Information herein is based on the Schedule 13G/A filed with the SEC on February 14, 2022 by FFI Fund Ltd., FYI Ltd., Olifant Fund, Ltd. (collectively, the “Bracebridge Funds”) and Bracebridge Capital, LLC. Consists of (i) 1,461,822 shares of Common Stock held by FFI Fund Ltd., (ii) 280,349 shares of Common Stock held by FYI Ltd. and (iii) 260,324 shares of Common Stock held by Olifant Fund, Ltd. Bracebridge Capital, LLC is the investment manager of each of the Bracebridge Funds, and has the authority to vote and dispose of all of the shares reflected herein. The business address of the Bracebridge Funds and Bracebridge Capital, LLC is 888 Boylston St., 15th Floor, Boston, MA 02199.
SELLING SECURITYHOLDERS

Certain of the Selling Securityholders acquired the Placement Warrants and shares of Common Stock from us in private offerings pursuant to exemptions from registration under Section 4(a)(2) of the Securities Act in connection with a private placement concurrent with Blue Water’s IPO. Pursuant to the Registration Rights Agreement and the Warrant Agreement, we agreed to file a registration statement with the SEC for the purposes of registering for resale (i) the Placement Warrants (and the shares of Common Stock that may be issued upon exercise of the Placement Warrants), and (ii) the shares of Common Stock issued to the Selling Securityholders pursuant to the Merger Agreement.

Except as set forth in the footnotes below, the following table sets forth, based on written representations from the Selling Securityholders, certain information as of September 9, 2021 regarding the beneficial ownership of Common Stock and Warrants by the Selling Securityholders and the shares of Common Stock and Warrants being offered by the Selling Securityholders. The applicable percentage ownership of Common Stock is based on 24,750,011 shares of Common Stock outstanding as of March 24, 2022. Information with respect to shares of Common Stock and Placement Warrants owned beneficially after the offering assumes the sale of all of the shares of Common Stock and Placement Warrants offered and no other purchases or sales of Common Stock or Placement Warrants. The Selling Securityholders may offer and sell some, all or none of their shares of Common Stock or Placement Warrants, as applicable.

We have determined beneficial ownership in accordance with the rules of the SEC. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the Selling Securityholders have sole voting and investment power with respect to all shares of Common Stock and Warrants that they beneficially own, subject to applicable community property laws. Except as otherwise described below, based on the information provided to us by the Selling Securityholders, no Selling Securityholder is a broker-dealer or an affiliate of a broker-dealer.

Up to 5,750,000 shares of Common Stock issuable upon exercise of the Public Warrants are not included in the table below, unless specifically indicated in the footnotes therein.

<table>
<thead>
<tr>
<th>Name of Selling Securityholder</th>
<th>Number of Shares of Common Stock Beneficially Owned</th>
<th>Warrants Beneficially Owned Prior to Offering</th>
<th>Number of Shares of Common Stock Being Offered</th>
<th>Number of Warrants Being Offered</th>
<th>Shares of Common Stock Beneficially Owned After the Offered Shares of Common Stock are Sold</th>
<th>Warrants Beneficially Owned After the Offered Warrants are Sold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas, McNerney &amp; Partners, L.P (1)</td>
<td>2,436,725</td>
<td>—</td>
<td>2,436,725</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>TMP Associates, L.P. (1)</td>
<td>1,706</td>
<td>—</td>
<td>1,706</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>TMP Nominee, LLC (1)</td>
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<td>8,383</td>
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<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Thomas, McNerney &amp; Partners II, L.P (1)</td>
<td>3,020,674</td>
<td>—</td>
<td>3,020,674</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>TMP Associates II, L.P. (1)</td>
<td>11,113</td>
<td>—</td>
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<tr>
<td>TMP Nominee II, LLC (1)</td>
<td>19,970</td>
<td>—</td>
<td>19,970</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>H.I.G. Ventures—Clarus, LLC (2)</td>
<td>2,731,094</td>
<td>—</td>
<td>2,731,094</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>H.I.G. Bio—Clarus I, L.P. (2)</td>
<td>490,531</td>
<td>—</td>
<td>490,531</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>
Table of Contents

<table>
<thead>
<tr>
<th>Name</th>
<th>Shares</th>
<th>Options</th>
<th>Shares</th>
<th>Options</th>
<th>Shares</th>
<th>Options</th>
<th>Shares</th>
<th>Options</th>
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<th>Shares</th>
<th>Options</th>
<th>Shares</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC SPVI Ltd (3)</td>
<td>3,602,287</td>
<td>—</td>
<td>3,602,287</td>
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<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Robert E. Dudley, Ph.D. (4)</td>
<td>4,566</td>
<td>—</td>
<td>4,566</td>
<td>—</td>
<td>—</td>
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</tr>
<tr>
<td>Steven A. Bourne (5)</td>
<td>1,305</td>
<td>—</td>
<td>1,305</td>
<td>—</td>
<td>—</td>
<td>—</td>
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</tr>
<tr>
<td>Blue Water Sponsor LLC (6)</td>
<td>1,302,500</td>
<td>3,445,000</td>
<td>1,302,500</td>
<td>3,445,000</td>
<td>—</td>
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</tr>
<tr>
<td>FFI Fund Ltd (7)</td>
<td>1,627,795</td>
<td>—</td>
<td>78,840</td>
<td>—</td>
<td>1,548,955</td>
<td>6.3%</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>FYI Ltd. (7)</td>
<td>312,179</td>
<td>—</td>
<td>15,120</td>
<td>—</td>
<td>297,059</td>
<td>1.2%</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<td>—</td>
<td>—</td>
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</tr>
<tr>
<td>Olifant Fund, Ltd. (7)</td>
<td>289,881</td>
<td>—</td>
<td>14,040</td>
<td>—</td>
<td>275,841</td>
<td>1.1%</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Nineteen77 Capital Solutions A L.P (8)</td>
<td>507,292</td>
<td>—</td>
<td>24,570</td>
<td>—</td>
<td>482,722</td>
<td>2.0%</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Bermudez Mutuari Ltd. (9)</td>
<td>50,171</td>
<td>—</td>
<td>2,430</td>
<td>—</td>
<td>47,741</td>
<td>*</td>
<td>—</td>
<td>—</td>
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<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

* Less than one percent.

(1) Consists of (i) 2,436,725 shares of Common Stock directly held, and registered for sale, by Thomas, McNerney & Partners, L.P., or TMP, (ii) 3,020,674 shares of Common Stock directly held by Thomas, McNerney & Partners II, L.P., or TMP II, (iii) 8,383 shares of Common Stock directly held, and registered for sale, by TMP Nominee, LLC, or TMP Nominee, (iv) 19,970 shares of Common Stock held and registered for sale, by TMP Nominee II, LLC or TMP Nominee II, (v) 1,706 shares of Common Stock directly held, and registered for sale, by TMP Associates, L.P., or TMP Associates, and (vi) 11,113 shares of Common Stock directly held, and registered for sale, by TMP Associates II, L.P. or TMP Associates II. TMP GP, the general partner of TMP, TMP II, TMP Associates and TMP Associates II, has voting and dispositive power over the shares held by TMP, TMP II, TMP Associates and TMP Associates II. In addition, each of TMP Nominee and TMP Nominee II has entered into an agreement that it shall vote and dispose of securities in the same manner as directed by TMP GP with respect to the shares held by TMP and TMP Associates and as directed by TMP GP II with respect to shares held by TMP II and TMP Associates II. James Thomas is manager of TMP GP and TMP GP II, and of TMP Nominee and TMP Nominee II and has the power to vote or dispose of the securities owned by TMP, TMP II, TMP Nominee, TMP Nominee II, TMP Associates and TMP Associates II. Mr. Thomas was a member of Legacy Clarus’s board of directors.

(2) Consists of (i) 2,731,094 shares of Common Stock directly held by H.I.G. Ventures—Clarus, LLC, (ii) 2,470,756 shares of Common Stock directly held by H.I.G. Bio—Clarus II, L.P., and (iii) 490,531 shares of Common Stock directly held by H.I.G. Bio—Clarus I, L.P. H.I.G.—GPII, Inc. (“H.I.G. GP”) is the general partner of each of H.I.G. Bio—Clarus II, L.P., and H.I.G. Bio—Clarus I, L.P. and is the manager of H.I.G. Ventures—Clarus, LLC (together with H.I.G. Bio—Clarus II, L.P., and H.I.G. Bio—Clarus I, L.P., the “H.I.G. Entities”) and has sole voting and investment control over the shares owned by the H.I.G. Entities. Anthony Tamer and Sami Mnaouneh are the sole shareholders of H.I.G. GP and may be deemed to share beneficial ownership of the shares held by the H.I.G. Entities. Alex Zisson, a member of the Board, is a managing director of H.I.G. Capital LLC and Bruce Robertson, a managing director of H.I.G. Capital LLC was a member of Legacy Clarus’s board of directors.

(3) Wei Fu has the power to vote or dispose of the securities held by CBC SPV I Ltd. Mengjiao Jiang, a managing director of CBC group, which controls CBC SPV I Ltd. was a member of Legacy Clarus’s board of directors.

(4) Dr. Dudley is our Chief Executive Officer and a member of the Board.

(5) Mr. Bourne is our Chief Administrative Officer.
The securities are held directly by Blue Water Sponsor LLC. Joseph Hernandez, a member of the Board, is the managing member of Blue Water Sponsor LLC, and as such may be deemed to have sole voting and investment discretion with respect to the securities held by Blue Water Sponsor LLC. Mr. Hernandez served as the chief executive officer and chairman of the board of directors of Blue Water Acquisition Corp., the Company’s predecessor.

Bracebridge Capital, LLC (the “Bracebridge Investment Manager”) is the investment manager of each of FFI Fund Ltd., FYI Ltd. and Olifant Fund, Ltd. (collectively, the “Bracebridge Funds”) and has the authority to vote and dispose of all of the shares reflected herein.

The securities reported are held by Nineteen77 Capital Solutions A LP (the “O’Connor Client”). Kevin Russell, the chief investment officer of UBS O’Connor LLC, the investment manager of the O’Connor Client, has voting and/or investment control over the shares of common stock held by the O’Connor Client. Kevin Russell disclaims beneficial ownership of the securities reported herein for purposes of Section 16 of the Securities and Exchange Act of 1934, as amended, except as to such extent of his pecuniary interest in the securities.

The securities reported are held by Bermudez Mutuari Ltd. (the “O’Connor Client”). Kevin Russell, the chief investment officer of UBS O’Connor LLC, the investment manager of the O’Connor Client, has voting and/or investment control over the shares of common stock held by the O’Connor Client. Kevin Russell disclaims beneficial ownership of the securities reported herein for purposes of Section 16 of the Securities and Exchange Act of 1934, as amended, except as to such extent of his pecuniary interest in the securities.
DESCRIPTION OF SECURITIES

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities, and is qualified by reference to the Certificate of Incorporation, the Bylaws and the Warrant-related documents described herein, which are exhibits to the registration statement of which this prospectus is a part. We urge you to read each of the Certificate of Incorporation, the Bylaws and the Warrant-related documents described herein in their entirety for a complete description of the rights and preferences of our securities.

Authorized and Outstanding Stock

The Certificate of Incorporation authorizes the issuance of 135,000,000 shares, consisting of 125,000,000 shares of common stock, $0.0001 par value per share and 10,000,000 shares of preferred stock, $0.0001 par value per share.

As of March 24, 2022, there were 24,750,011 shares of Common Stock outstanding and no shares of preferred stock outstanding.

Common Stock

Holders of common stock are entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders are generally entitled to vote; provided, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding series of preferred stock if the holders of such affected series of preferred stock are entitled, either separately or together with the holders of one or more other such series of preferred stock, to vote thereon pursuant to the Certificate of Incorporation or the DGCL. There is no cumulative voting. Our stockholders are entitled to receive ratable dividends when, as and if declared by the Board out of funds legally available therefor.

Holders of Common Stock have no preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to the Common Stock. If we liquidate, dissolve or wind up, our stockholders are entitled to share ratably in all assets remaining available for distribution to them after payment of liabilities and after provision is made for each class of stock, if any, having preference over Common Stock.

Preferred Stock

The Certificate of Incorporation provides that shares of preferred stock may be issued from time to time in one or more series. The Board is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions, applicable to the shares of each series.

Warrants

Public Warrants

There are 5,750,000 Public Warrants issued and outstanding as of March 24, 2022. Each Public Warrant entitles the registered holder to purchase one share of Common Stock at a price of $11.50 per share, subject to adjustment as discussed below, at any time commencing 30 days after the Merger Closing. The Public Warrants will expire five years after the Merger Closing, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any shares of Common Stock pursuant to the exercise of a Public Warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the shares of Common Stock underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration. No warrant will be exercisable and we will not be obligated to issue shares of Common Stock upon exercise of a warrant unless the Common Stock issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a Public Warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any warrant.
We have agreed that as soon as practicable, but in no event later than 15 business days after the Merger Closing, we will use our best efforts to file with the SEC a registration statement covering the shares of Common Stock issuable upon exercise of the warrants, to cause such registration statement to become effective and to maintain a current prospectus relating to those shares of Common Stock until the warrants expire or are redeemed, as specified in the warrant agreement. If a registration statement covering the shares of Common Stock issuable upon exercise of the warrants is not effective by the 60th business day after the Merger Closing, warrant holders may, until such time as there is an effective registration statement and during any period when we will have failed to maintain an effective registration statement, exercise warrants on a “cashless basis” in accordance with Section 3(a)(9) of the Securities Act or another exemption. Notwithstanding the foregoing, if a registration statement covering Common Stock issuable upon exercise of the warrants is not effective within a specified period following the Merger Closing, warrant holders may, until such time as there is an effective registration statement and during any period when we shall have failed to maintain an effective registration statement, exercise warrants on a cashless basis pursuant to the exemption provided by Section 3(a)(9) of the Securities Act of 1933, as amended, or the Securities Act, provided that such exemption is available. If that exemption, or another exemption, is not available, holders will not be able to exercise their warrants on a cashless basis.

Once the Public Warrants become exercisable, we may call the warrants for redemption:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days’ prior written notice of redemption to each warrant holder; and
- if, and only if, the reported last sale price of the Common Stock equals or exceeds $18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending three business days before we send the notice of redemption to the warrant holders.

If and when the Public Warrants become redeemable by us, we may not exercise our redemption right if the issuance of shares of common stock upon exercise of the warrants is not exempt from registration or qualification under applicable state blue sky laws or we are unable to effect such registration or qualification.

We have established the last of the redemption criteria discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the Public Warrants, each warrant holder will be entitled to exercise its warrant prior to the scheduled redemption date. However, the price of the Common Stock may fall below the $18.00 redemption trigger price (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) as well as the $11.50 warrant exercise price after the redemption notice is issued.

If we call the Public Warrants for redemption as described above, our management will have the option to require any holder that wishes to exercise its warrant to do so on a “cashless basis.” In determining whether to require all holders to exercise their warrants on a “cashless basis,” our management will consider, among other factors, our cash position, the number of warrants that are outstanding and the dilutive effect on our stockholders of issuing the maximum number of shares of Common Stock issuable upon the exercise of our warrants. If our management takes advantage of this option, all holders of Public Warrants would pay the exercise price by surrendering their warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the “fair market value” (defined below) by (y) the fair market value. The “fair market value” shall mean the average reported last sale price of the Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of redemption is sent to the holders of warrants. If our management takes advantage of this option, the notice of redemption will contain the information necessary to calculate the number of shares of Common Stock to be received upon exercise of the Public Warrants, including the
“fair market value” in such case. Requiring a cashless exercise in this manner will reduce the number of shares to be issued and thereby lessen the
dilutive effect of a warrant redemption. We believe this feature is an attractive option to us if we do not need the cash from the exercise of the warrants
after the Merger Closing. If we call our Public Warrants for redemption and our management does not take advantage of this option, the Sponsor and its
permitted transferees would still be entitled to exercise their Placement Warrants for cash or on a cashless basis using the same formula described above
that other warrantholders would have been required to use had all warrantholders been required to exercise their warrants on a cashless basis, as
described in more detail below.

A holder of a Public Warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to
exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person’s affiliates), to the warrant agent’s
actual knowledge, would beneficially own in excess of 4.9% or 9.8% (or such other amount as a holder may specify) of the shares of Common Stock
outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of Common Stock is increased by a stock dividend payable in shares of Common Stock, or by a split-up of
shares of Common Stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of
Common Stock issuable on exercise of each Public Warrant will be increased in proportion to such increase in the outstanding shares of Common Stock.
A rights offering to holders of Common Stock entitling holders to purchase shares of Common Stock at a price less than the fair market value will be
deemed a stock dividend of a number of shares of Common Stock equal to the product of (i) the number of shares of Common Stock actually sold in
such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Common Stock)
and (ii) one (1) minus the quotient of (x) the price per share of Common Stock paid in such rights offering divided by (y) the fair market value. For these
purposes (i) if the rights offering is for securities convertible into or exercisable for Common Stock, in determining the price payable for Common
Stock, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion
and (ii) fair market value means the volume weighted average price of Common Stock as reported during the ten (10) trading day period ending on the
trading day prior to the first date on which the shares of Common Stock trade on the applicable exchange or in the applicable market, regular way,
without the right to receive such rights.

In addition, if we, at any time while the Public Warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or
other assets to the holders of New Blue Water common stock on account of such shares of Common Stock (or other shares of our capital stock into
which the warrants are convertible), other than (a) as described above, (b) certain ordinary cash dividends, (c) to satisfy the redemption rights of the
holders of Common Stock in connection with the Merger Closing, (d) to satisfy the redemption rights of the holders of New Blue Water common stock
in connection with an Extension Rea stockholder vote to amend the Blue Water Charter (i) for an Extension or (ii) with respect to any other provision
relating to stockholders’ rights or pre-initial business combination activity, or (e) in connection with the redemption of our public shares upon our failure
to complete our initial business combination, then the warrant exercise price will be decreased, effective immediately after the effective date of such
event, by the amount of cash and/or the fair market value of any securities or other assets paid on each share of Common Stock in respect of such event.

If the number of outstanding shares of Common Stock is decreased by a consolidation, combination, reverse stock split or reclassification of
shares of Common Stock other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or
similar event, the number of shares of Common Stock issuable on exercise of each Public Warrant will be decreased in proportion to such decrease in
outstanding shares of Common Stock.

Whenever the number of shares of Common Stock purchasable upon the exercise of the Public Warrants is adjusted, as described above, the
warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of
which will be the number of shares of Common Stock purchasable upon the exercise of the warrants immediately prior to such adjustment, and (y) the
denominator of which will be the number of shares of Common Stock so purchasable immediately thereafter.
In case of any reclassification or reorganization of the outstanding shares of Common Stock (other than those described above or that solely affects the par value of such shares of Common Stock), or in the case of any merger or consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding shares of Common Stock), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the Public Warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the warrants and in lieu of the shares of Common Stock immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of shares of stock or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the warrants would have received if such holder had exercised their warrants immediately prior to such event. If less than 70% of the consideration receivable by the holders of Common Stock in such a transaction is payable in the form of Common Stock in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the warrant properly exercises the warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the warrant agreement based on the Black-Scholes value (as defined in the warrant agreement) of the warrant. The purpose of such exercise price reduction is to provide additional value to holders of the warrants when an extraordinary transaction occurs during the exercise period of the warrants pursuant to which the holders of the warrants otherwise do not receive the full potential value of the warrants in order to determine and realize the option value component of the warrant. This formula is to compensate the warrant holder for the loss of the option value portion of the warrant due to the requirement that the warrant holder exercise the warrant within 30 days of the event. The Black-Scholes model is an accepted pricing model for estimating fair market value where no quoted market price for an instrument is available.

The Public Warrants and the Placement Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and Blue Water. A copy of the warrant agreement has been publicly filed with the SEC. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 65% of the then outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants.

The Public Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of Common Stock and any voting rights until they exercise their warrants and receive shares of Common Stock. After the issuance of shares of Common Stock upon exercise of the warrants, each holder will be entitled to one (1) vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the Public Warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number of shares of Common Stock to be issued to the warrantholder.

Placement Warrants

There are 3,445,000 Placement Warrants issued and outstanding as of March 24, 2022. Except as described below, the Placement Warrants have terms and provisions that are identical to those of the Public Warrants, including as to exercise price, exercisability and exercise period. The Placement Warrants (including the Common Stock issuable upon exercise of the Placement Warrants) are not transferable, assignable or salable until 30 days after the Merger Closing (except, among certain other limited exceptions to our officers and directors and other persons or entities affiliated with the Sponsor) and they will not be redeemable by us so long as they are held by the Sponsor or its permitted transferees. The Sponsor, or its permitted transferees, has the option to exercise the Placement Warrants on a cashless basis. If the Placement Warrants are held by holders other than the Sponsor or its permitted transferees, the Placement Warrants will be subject to the same terms and conditions as the Public Warrants, and among other matters, be redeemable by us and exercisable by the holders on the same basis as the Public Warrants.
If holders of the Placement Warrants elect to exercise them on a cashless basis, they would pay the exercise price by surrendering their warrants for that number of shares of Common Stock equal to the quotient obtained by dividing (x) the product of the number of shares of Common Stock underlying the warrants, multiplied by the difference between the exercise price of the warrants and the “fair market value” (defined below) by (y) the fair market value. The “fair market value” shall mean the average reported last sale price of the Common Stock for the 10 trading days ending on the third trading day prior to the date on which the notice of warrant exercise is sent to the warrant agent.

Pre-Funded Warrants

Each Pre-Funded Warrant entitles the registered holder to purchase one share of Common Stock at a price of $0.00001 per share, subject to adjustment as discussed below, at any time after the PIPE Closing. The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants have customary provisions for cashless exercise and anti-dilution adjustments for transactions affecting our capital stock.

We have agreed that as soon as practicable, but in no event later than 30 days after the PIPE Closing, we will use our commercially reasonable efforts to file a registration statement with the SEC covering the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants, to cause such registration statement to become effective and to maintain a current prospectus relating to those shares of Common Stock until the Pre-Funded Warrants expire, as specified in the Pre-Funded Warrants.

Common Warrants

Except as described below, the Common Warrants have terms and provisions that are identical to those of the Pre-Funded Warrants. The Common Warrants have an exercise price of $5.25 per share, are exercisable beginning six months following the PIPE Closing and expire five years after the PIPE Closing, subject to customary adjustments. If at the time of exercise of the Common Warrants there is no effective registration statement registering, or the prospectus contained therein is not available for the resale of the shares of Common Stock underlying such Common Warrant for a period of 15 successive days, then the Common Warrants may be exercised, in whole or in part, by means of a “cashless exercise.”

In the event of a Fundamental Transaction (as defined in the Common Warrant), the Company or any Successor Entity (as defined in the Common Warrant) shall, at the holder’s option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase the Common Warrants from the holder by paying to the holder an amount of cash equal to the Black Scholes Value (as defined in the Common Warrant) of the remaining unexercised portion of the Common Warrants on the date of the consummation of such Fundamental Transaction; provided, however, that if the Fundamental Transaction is not within the Company’s control, including not approved by the Board, the holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the Common Warrants, that is being offered and paid to the holders of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction. However, if holders of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Stock will be deemed to have received common stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction.

Dividends

We have not paid any cash dividends on the Common Stock to date and do not intend to pay cash dividends. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial conditions and will be within the discretion of the Board at such time. Further, our ability to declare dividends may be limited by restrictive covenants we may agree to in connection with our indebtedness.
Rule 144

Pursuant to Rule 144, a person who has beneficially owned restricted shares of Common Stock or warrants for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as we were required to file reports) preceding the sale.

Persons who have beneficially owned restricted shares of Common Stock or warrants for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- 1% of the total number of shares of common stock then outstanding; or
- the average weekly reported trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by our affiliates under Rule 144 are also limited by manner of sale provisions and notice requirements and to the availability of current public information about us.

Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Among other things, the Certificate of Incorporation the By-laws:

- permit the Board to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change of control;
- provide that the authorized number of directors may be changed only by resolution of the Board;
- provide that, subject to the rights of any series of preferred stock to elect directors, directors may be removed only with cause by the holders of not less than two thirds (2/3) of all of our then-outstanding shares of the capital stock entitled to vote generally at an election of directors;
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- provide that, subject to the rights of any series of preferred stock to fill director vacancies, all director vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder’s notice;
- provide that Special Meetings of our stockholders may be called by the Board pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that the Board will be divided into three classes of directors, with the classes to be as nearly equal as possible, and with the directors serving three-year terms, therefore making it more difficult for stockholders to change the composition of the Board; and
- not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose.

The combination of these provisions will make it more difficult for the existing stockholders to replace the Board as well as for another party to obtain control of the Company by replacing the Board. Because the Board has the power to retain and discharge its officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Board to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control. These provisions are intended to enhance the likelihood of continued stability in the composition of the Board and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock.

Delaware Anti-Takeover Law

We have opted out of Section 203 of the DGCL. Section 203 of the DGCL prohibits a Delaware corporation from engaging in a “business combination” with an “interested stockholder” (i.e., a stockholder owning 15% or more of company’s voting stock) for three years following the time that the “interested stockholder” becomes such, subject to certain exceptions.

Limitations on Liability and Indemnification of Officers and Directors

The Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by the DGCL, and the Bylaws provide that we will indemnify them to the fullest extent permitted by such law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the Board. Under the terms of such indemnification agreements, we are required to indemnify each of our directors and officers, to the fullest extent permitted by the laws of the state of Delaware, if the basis of the indemnitee’s involvement was by reason of the fact that the indemnitee is or was a director or officer of the Company or any of its subsidiaries or was serving at our request in an official capacity for another entity. We must indemnify our officers and directors against all reasonable fees, expenses, charges and other costs of any type or nature whatsoever, including any and all expenses and obligations paid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal), or preparing to defend, be a witness or participate in any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative, or establishing or enforcing a right to indemnification under the indemnification agreement. The indemnification agreements also require us, if so requested, to advance within 30 days of such request all reasonable fees, expenses, charges and other costs that such director or officer incurred, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.
Exclusive Jurisdiction of Certain Actions

The Bylaws require, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty, actions asserting a claim arising pursuant to any provision of the DGCL or the Certificate of Incorporation or the Bylaws, actions to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Bylaws and actions asserting a claim against us governed by the internal affairs doctrine may be brought only in the Court of Chancery in the State of Delaware and, if brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder’s counsel. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

In addition, the Bylaws require that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for resolving any action asserting a claim arising under the Securities Act.

Listing of Securities

The Common Stock and Public Warrants are listed on the Nasdaq Global Market under the symbols “CRXT” and “CRXTW”, respectively.

Transfer Agent and Warrant Agent

The transfer agent for the Common Stock and warrant agent for the Warrants is Continental Stock Transfer & Trust Company.
The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock, which we refer to as our securities. This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the Code), including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own five percent or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the securities;
- persons holding the securities as part of a “straddle,” hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the IRS as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of our securities, the U.S. federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your tax advisor.
U.S. Holders

This section applies to you if you are a “U.S. holder.” A U.S. holder is a beneficial owner of our shares of common stock who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) organized in or under the laws of the United States, any state thereof or the District of Columbia; or
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a U.S. person.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of Common Stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder’s adjusted tax basis in Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under “U.S. Holders – Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock” below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute “qualified dividends” that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock. Upon a sale or other taxable disposition of Common Stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder’s adjusted tax basis in the common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder’s holding period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.
Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder’s adjusted tax basis in its common stock so disposed of. A U.S. holder’s adjusted tax basis in its common stock generally will equal the U.S. holder’s acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder’s U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Non-U.S. Holders

This section applies to you if you are a “Non-U.S. holder.” As used herein, the term “Non-U.S. holder” means a beneficial owner of Common Stock who or that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the U.S. subject to U.S. tax as expatriates);
- a foreign corporation or
- an estate or trust that is not a U.S. holder;

but generally does not include an individual who is present in the U.S. for 183 days or more in the taxable year of disposition. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of our securities.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder’s conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder’s adjusted tax basis in its shares of Common Stock and, to the extent such distribution exceeds the Non-U.S. holder’s adjusted tax basis, as gain realized from the sale or other disposition of the common stock, which will be treated as described under “Non-U.S. Holders – Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock” below.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. holder’s conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional “branch profits tax” imposed at a rate of 30% (or a lower treaty rate).
Gain on Sale, Taxable Exchange or Other Taxable Disposition of common stock. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of Common Stock, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder); or
- we are or have been a “U.S. real property holding corporation” for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held Common Stock, and, in the case where shares of Common Stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of Common Stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder’s holding period for the shares of Common Stock. There can be no assurance that Common Stock will be treated as regularly traded on an established securities market for this purpose.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional “branch profits tax” at a 30% rate (or lower treaty rate).

If the second bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of Common Stock will be subject to tax at generally applicable U.S. federal income tax rates.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our shares of common stock. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder’s U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes. Provisions commonly referred to as “FATCA” impose withholding of 30% on payments of dividends (including constructive dividends) on Common Stock to “foreign financial institutions” (which is broadly defined for this purpose and in general includes investment vehicles) and certain other Non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied by, or an exemption applies to, the payee (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). Pursuant to proposed Treasury Regulations, the U.S. Treasury Department has indicated its intent to eliminate the requirement under FATCA of withholding on gross proceeds from the sale or other disposition of property of a type which can produce U.S. source dividends or interest. The U.S. Treasury Department has indicated that taxpayers may rely on these proposed Treasury Regulations pending their finalization. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a Non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a Non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits. Prospective investors should consult their tax advisers regarding the effects of FATCA on their investment in our securities.
PLAN OF DISTRIBUTION

We are registering the issuance by us of (i) up to 3,445,000 shares of Common Stock that are issuable upon the exercise of the Placement Warrants by the holders thereof and (ii) up to 5,750,000 shares of Common Stock that are issuable upon the exercise of the Public Warrants by the holders thereof. We are also registering the resale by the Selling Securityholders or their permitted transferees from time to time of (i) up to 19,816,610 shares of Common Stock and (ii) up to 3,445,000 Placement Warrants.

We are required to pay all fees and expenses incident to the registration of the securities to be offered and sold pursuant to this prospectus. The Selling Securityholders will bear all commissions and discounts, if any, attributable to their sale of securities.

We will not receive any of the proceeds from the sale of the securities by the Selling Securityholders. We will receive proceeds from Warrants exercised in the event that such Warrants are exercised for cash. The aggregate proceeds to the Selling Securityholders will be the purchase price of the securities less any discounts and commissions borne by the Selling Securityholders.

The shares of Common Stock beneficially owned by the Selling Securityholders covered by this prospectus may be offered and sold from time to time by the Selling Securityholders. The term “Selling Securityholders” includes donees, pledgees, transferees or other successors in interest selling securities received after the date of this prospectus from a Selling Securityholder as a gift, pledge, partnership distribution or other transfer. The Selling Securityholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The Selling Securityholders may sell their securities by one or more of, or a combination of, the following methods:

• purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
• ordinary brokerage transactions and transactions in which the broker solicits purchasers;
• block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
• an over-the-counter distribution in accordance with the rules of Nasdaq;
• through trading plans entered into by a Selling Securityholder pursuant to Rule 10b5-1 under the Exchange Act, that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
• short sales;
• distribution to employees, members, limited partners or stockholders of the Selling Securityholders; through the writing or settlement of options or other hedging transaction, whether through an options exchange or otherwise;
• by pledge to secured debts and other obligations;
• delayed delivery arrangements;
• to or through underwriters or broker-dealers;
• in “at the market” offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
• in privately negotiated transactions;
• in options transactions;
• through a combination of any of the above methods of sale; or
• any other method permitted pursuant to applicable law.

In addition, any securities that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the securities or otherwise, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the securities in the course of hedging the positions they assume with Selling Securityholders. The Selling Securityholders may also sell the securities short and deliver the securities to close out such short positions. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Securityholders may also pledge securities to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged securities pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In effecting sales, broker-dealers or agents engaged by the Selling Securityholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Selling Securityholders in amounts to be negotiated immediately prior to the sale.

In offering the securities covered by this prospectus, the Selling Securityholders and any broker-dealers who execute sales for the Selling Securityholders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any profits realized by the Selling Securityholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the securities must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the Selling Securityholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of securities in the market and to the activities of the Selling Securityholders and their affiliates. In addition, we will make copies of this prospectus available to the Selling Securityholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Securityholders may indemnify any broker-dealer that participates in transactions involving the sale of the securities against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of securities is made, if required, a prospectus supplement will be distributed that will set forth the number of securities being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallocated to any dealer, and the proposed selling price to the public.

A holder of Warrants may exercise its Warrants in accordance with the Warrant Agreement on or before the expiration date set forth therein by surrendering, at the office of the Warrant Agent, Continental Stock Transfer & Trust Company, the certificate evidencing such Warrant, with the form of election to purchase set forth thereon, properly completed and duly executed, accompanied by full payment of the exercise price and any and all applicable taxes due in connection with the exercise of the Warrant, subject to any applicable provisions relating to cashless exercises in accordance with the Warrant Agreement.
A Selling Securityholder that is an entity may elect to make an in-kind distribution of Common Stock or Warrants to its members, partners or stockholders pursuant to the registration statement of which this prospectus is a part by delivering a prospectus. To the extent that such members, partners or stockholders are not affiliates of ours, such members, partners or stockholders would thereby receive freely tradable Common Stock or Warrants pursuant to the distribution through a registration statement.
LEGAL MATTERS

The validity of any securities offered by this prospectus will be passed upon for us by Goodwin Procter LLP.

EXPERTS

The consolidated financial statements of Clarus Therapeutics Holdings, Inc. as of December 31, 2021 and 2020 and for each of the years in the two-year period ended December 31, 2021 included in this prospectus have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon which report expresses an unqualified opinion and includes an explanatory paragraph relating to going concern, and included in this prospectus and registration statement in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

CHANGE IN AUDITOR

On September 10, 2021, the audit committee of the Board approved a resolution appointing RSM US LLP (“RSM”) as the Company’s independent registered public accounting firm to audit the Company’s financial statements for the fiscal year ended December 31, 2021, and Marcum LLP (“Marcum”) was dismissed from its role as the Company’s independent registered public accounting firm.

Marcum’s report on the Company’s financial statements for the fiscal year ended December 31, 2020 and the period from May 22, 2020 (inception) to December 31, 2020 did not contain an adverse opinion or a disclaimer of opinion, nor was either report qualified or modified as to uncertainty, audit scope or accounting principles except for an explanatory paragraph in such report regarding substantial doubt about the registrant’s ability to continue as a going concern.

At no point during the fiscal year ended December 31, 2020 and the subsequent interim period through September 10, 2021 were there any (i) disagreements with Marcum on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Marcum, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report, or (ii) “reportable events” as that term is defined in Item 304(a)(1)(v) of Regulation S-K, other than as noted above regarding the registrant’s ability to continue as a going concern.

We provided Marcum with a copy of the foregoing disclosure and requested that Marcum furnish the Company with a letter addressed to the SEC stating whether or not it agrees with the statements made herein, each as required by applicable SEC rules. A copy of Marcum’s letter to the SEC is filed as Exhibit 16.1 to the Company’s Current Report on Form 8-K filed on September 15, 2021.

During the fiscal year ended December 31, 2020 and the subsequent interim period through date of this prospectus, the Company did not consult with RSM regarding any of the matters or events set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC as required by the Exchange Act. We have also filed a registration statement on Form S-1, including exhibits, under the Securities Act, with respect to the common stock offered by this prospectus. This prospectus is part of the registration statement, but does not contain all of the information included in the registration statement or the exhibits. You can read our SEC filings, including this prospectus, over the Internet at the SEC’s website at http://www.sec.gov.
Our website address is www.clarustherapeutics.com. Through our website, we make available, free of charge, the following documents as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC, including our annual reports on Form 10-K; our proxy statements for our annual and special stockholder meetings; our quarterly reports on Form 10-Q; our current reports on Form 8-K and reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not a part of, and is not incorporated into, this prospectus.
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Report of Independent Registered Public Accounting Firm

Stockholders and the Board of Directors of Clarus Therapeutics Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Clarus Therapeutics Holdings, Inc. and its subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders’ deficit and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a net capital deficiency and requires additional capital to finance operations that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company’s auditor since 2006.

Chicago, Illinois
March 31, 2022
### Consolidated Balance Sheets

**CLARUS THERAPEUTICS HOLDINGS, INC.**

**(in thousands, except share and per share data)**

<table>
<thead>
<tr>
<th></th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current assets:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
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<td>$7,233</td>
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<tr>
<td>Accounts receivable, net</td>
<td>6,341</td>
<td>4,400</td>
</tr>
<tr>
<td>Inventory, net</td>
<td>14,214</td>
<td>5,857</td>
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<tr>
<td>Prepaid expenses</td>
<td>4,673</td>
<td>1,846</td>
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<tr>
<td><strong>Total current assets</strong></td>
<td>$51,643</td>
<td>$19,336</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>65</td>
<td>64</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>$51,708</td>
<td>$19,400</td>
</tr>
</tbody>
</table>

| **Liabilities, and stockholders’ equity (deficit)** |                   |                   |
| Current liabilities:                                  |                   |                   |
| Senior notes payable                                 | $42,269 | $41,902 |
| Accounts payable                                     | 13,945 | 12,107 |
| Accrued expenses                                     | 8,261 | 4,631 |
| Deferred revenue                                     | 1,585 | 1,172 |
| **Total current liabilities**                        | $66,060 | $59,812 |
| Convertible notes payable to related parties         | — | 77,911 |
| Royalty obligation                                   | — | 9,262 |
| Derivative warrant liability                         | 1,567 | — |
| **Total liabilities**                                | $67,627 | $146,985 |

Commitments and contingencies (See Note 12)

Redeemable convertible preferred stock, $0.001 par value, 0 and 53,340,636 shares authorized at December 31, 2021 and December 31, 2020, respectively; 0 and 36,756,498 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | — | 198,195 |

Stockholders’ equity (deficit):

Preferred stock, $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | — | — |

Common stock $0.0001 par value; 125,000,000 shares authorized; 24,025,817 and 0 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively | 2 | — |

Additional paid-in capital | 305,734 | — |

Accumulated deficit | $(321,655) | $(325,780) |

**Total stockholders’ equity (deficit)** | $(15,919) | $(325,780) |

**Total liabilities, redeemable convertible preferred stock, and stockholders’ deficit** | $51,708 | $19,400 |

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

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<thead>
<tr>
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<th>Years Ended December 31,</th>
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<td></td>
<td>2021</td>
</tr>
<tr>
<td>Net product revenue</td>
<td>$13,957</td>
</tr>
<tr>
<td>Cost of product sales</td>
<td>2,720</td>
</tr>
<tr>
<td>Gross profit (loss)</td>
<td>11,237</td>
</tr>
<tr>
<td>Operating expenses:</td>
<td></td>
</tr>
<tr>
<td>Sales and marketing</td>
<td>30,677</td>
</tr>
<tr>
<td>General and administrative</td>
<td>16,662</td>
</tr>
<tr>
<td>Research and development</td>
<td>3,630</td>
</tr>
<tr>
<td>Total operating expenses</td>
<td>50,969</td>
</tr>
<tr>
<td>Loss from operations</td>
<td>(39,732)</td>
</tr>
<tr>
<td>Other (expense) income, net:</td>
<td></td>
</tr>
<tr>
<td>Change in fair value of warrant liability and derivative, net</td>
<td>12,508</td>
</tr>
<tr>
<td>Interest income</td>
<td>2</td>
</tr>
<tr>
<td>Interest expense</td>
<td>(15,895)</td>
</tr>
<tr>
<td>Litigation settlement</td>
<td>2,500</td>
</tr>
<tr>
<td>Total other (expense) income, net</td>
<td>(885)</td>
</tr>
<tr>
<td>Net (loss) income before income taxes</td>
<td>(40,617)</td>
</tr>
<tr>
<td>Provision for income taxes</td>
<td>—</td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$ (40,617)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders, basic (Note 14)</td>
<td>$ (40,205)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders, diluted (Note 14)</td>
<td>$ (40,205)</td>
</tr>
<tr>
<td>Net loss per common share, basic</td>
<td>$(5.72)</td>
</tr>
<tr>
<td>Net loss per common share, diluted</td>
<td>$(5.72)</td>
</tr>
<tr>
<td>Weighted-average common shares used in net loss, basic (Note 14)</td>
<td>7,027,860</td>
</tr>
<tr>
<td>Weighted-average common shares used in net loss, diluted (Note 14)</td>
<td>7,027,860</td>
</tr>
</tbody>
</table>

*The accompanying notes are an integral part of these consolidated financial statements.*
## CLARUS THERAPEUTICS HOLDINGS, INC.

### Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders’ Deficit

(in thousands, except share and per share data)

<table>
<thead>
<tr>
<th>Shares</th>
<th>Amount</th>
<th>Shares</th>
<th>Amount</th>
<th>Additional Paid-in Capital</th>
<th>Accumulated Deficit</th>
<th>Total Stockholders’ Deficit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeemable Convertible Preferred Stock</td>
<td>36,756,498</td>
<td>$ 183,513</td>
<td>870,263</td>
<td>$ 1</td>
<td>$(316,269)</td>
<td>$(316,268)</td>
</tr>
<tr>
<td>Common Stock</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retroactive application of the recapitalization due to the Business Combination (Note 3)</td>
<td>—</td>
<td>—</td>
<td>(870,263)</td>
<td>(1)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Adjusted balance at December 31, 2019</td>
<td>36,756,498</td>
<td>183,513</td>
<td>—</td>
<td>—</td>
<td>$ (316,268)</td>
<td>(316,268)</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value</td>
<td>—</td>
<td>14,682</td>
<td>—</td>
<td>—</td>
<td>(825)</td>
<td>(14,682)</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>825</td>
<td>825</td>
</tr>
<tr>
<td>Net income (loss)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>4,345</td>
</tr>
<tr>
<td>Balance at December 31, 2020</td>
<td>36,756,498</td>
<td>198,195</td>
<td>—</td>
<td>—</td>
<td>$ (325,780)</td>
<td>(325,780)</td>
</tr>
<tr>
<td>Conversion of Legacy Clarus convertible notes payable into Legacy Clarus Series D redeemable convertible preferred stock (1)</td>
<td>747,451</td>
<td>3,360</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Accretion of Legacy Clarus Series D redeemable convertible preferred stock to redemption value (1)</td>
<td>—</td>
<td>7,737</td>
<td>—</td>
<td>—</td>
<td>(7,737)</td>
<td>(7,737)</td>
</tr>
<tr>
<td>Recapitalization on September 9, 2021</td>
<td>(37,503,949)</td>
<td>(209,292)</td>
<td>17,886,348</td>
<td>1</td>
<td>281,993</td>
<td>44,742</td>
</tr>
<tr>
<td>Proceeds from Blue Water Acquisition Corp. in Business Combination</td>
<td>—</td>
<td>—</td>
<td>3,839,469</td>
<td>1</td>
<td>17,008</td>
<td>17,009</td>
</tr>
<tr>
<td>Issuance of shares in connection with the Private Placement Equity Offering</td>
<td>—</td>
<td>—</td>
<td>2,300,000</td>
<td>—</td>
<td>13,801</td>
<td>13,801</td>
</tr>
<tr>
<td>Stock-based compensation</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>668</td>
<td>668</td>
</tr>
<tr>
<td>Net loss</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>(40,617)</td>
</tr>
<tr>
<td>Balance at December 31, 2021</td>
<td>—</td>
<td>—</td>
<td>24,025,817</td>
<td>2</td>
<td>$305,734</td>
<td>(321,655)</td>
</tr>
</tbody>
</table>

(1) Relates to activity associated with the Redeemable Convertible Preferred Stock prior to the reverse recapitalization on September 9, 2021.

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

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### CLARUS THERAPEUTICS HOLDINGS, INC.

#### Consolidated Statements of Cash Flows

*in thousands, except share and per share data*

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>$(40,617)</td>
<td>$4,345</td>
</tr>
<tr>
<td>Adjustments to reconcile net loss (income) to net cash used in operating activities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-cash interest expense related to debt financing and royalty obligation</td>
<td>13,065</td>
<td>12,459</td>
</tr>
<tr>
<td>Settlement of interest with payment-in-kind note</td>
<td>3,125</td>
<td>—</td>
</tr>
<tr>
<td>Non-cash gain on partial extinguishment of senior notes</td>
<td>296</td>
<td>—</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(12,508)</td>
<td>(66,340)</td>
</tr>
<tr>
<td>Stock-based compensation expense</td>
<td>668</td>
<td>825</td>
</tr>
<tr>
<td>Depreciation</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>Changes in operating assets and liabilities:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts receivable</td>
<td>(1,941)</td>
<td>(4,400)</td>
</tr>
<tr>
<td>Inventory</td>
<td>(8,357)</td>
<td>1,104</td>
</tr>
<tr>
<td>Prepaid expenses and other current assets</td>
<td>(2,830)</td>
<td>(804)</td>
</tr>
<tr>
<td>Accounts payable</td>
<td>1,838</td>
<td>7,728</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>3,629</td>
<td>2,864</td>
</tr>
<tr>
<td>Deferred revenue</td>
<td>413</td>
<td>1,172</td>
</tr>
<tr>
<td>Net cash used in operating activities</td>
<td>$(43,786)</td>
<td>$(41,580)</td>
</tr>
<tr>
<td><strong>Investing activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchases of property and equipment</td>
<td>(25)</td>
<td>(63)</td>
</tr>
<tr>
<td>Net cash used in investing activities</td>
<td>(25)</td>
<td>(63)</td>
</tr>
<tr>
<td><strong>Financing activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeds from business combination, net</td>
<td>17,009</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from issuance of convertible notes payable</td>
<td>23,591</td>
<td>1,611</td>
</tr>
<tr>
<td>Proceeds from issuance of senior notes payable</td>
<td>8,592</td>
<td>49,125</td>
</tr>
<tr>
<td>Proceeds from issuance of common stock and warrants, net of issuance costs</td>
<td>13,801</td>
<td>—</td>
</tr>
<tr>
<td>Proceeds from PPP loan</td>
<td>—</td>
<td>488</td>
</tr>
<tr>
<td>Repayment of PPP loan</td>
<td>—</td>
<td>(488)</td>
</tr>
<tr>
<td>Debt issuance costs</td>
<td>—</td>
<td>(3,516)</td>
</tr>
<tr>
<td>Net cash provided by financing activities</td>
<td>62,993</td>
<td>47,220</td>
</tr>
<tr>
<td>Net increase in cash and cash equivalents</td>
<td>19,182</td>
<td>5,577</td>
</tr>
<tr>
<td>Cash and cash equivalents—beginning of period</td>
<td>7,233</td>
<td>1,656</td>
</tr>
<tr>
<td>Cash and cash equivalents—end of period</td>
<td><strong>$ 26,415</strong></td>
<td><strong>$ 7,233</strong></td>
</tr>
<tr>
<td><strong>Supplemental disclosure of cash flow information:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash paid for interest</td>
<td>$ —</td>
<td>$3,125</td>
</tr>
<tr>
<td>Conversion of convertible notes payable into Series D redeemable convertible preferred stock</td>
<td>$3,360</td>
<td>—</td>
</tr>
<tr>
<td>Accretion of redeemable convertible preferred stock to redemption value, including dividends on preferred stock</td>
<td>7,737</td>
<td>14,682</td>
</tr>
<tr>
<td>Senior secured note principal and royalty obligation balance conversion to shares of common stock upon merger (Note 3)</td>
<td>$ 28,254</td>
<td>—</td>
</tr>
<tr>
<td>Convertible notes principal and accrued interest balance conversion to shares of common stock upon merger (Note 3)</td>
<td>$103,267</td>
<td>—</td>
</tr>
<tr>
<td>Conversion of Series D redeemable convertible preferred stock into share of common stock</td>
<td>$209,290</td>
<td>—</td>
</tr>
<tr>
<td>Value of warrants assumed upon merger (Note 3)</td>
<td>$14,075</td>
<td>—</td>
</tr>
</tbody>
</table>

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

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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 (each unit representing a share of common stock and a warrant to purchase a share of common stock (“IPO warrants”)), including 750,000 additional Units to cover over-allotments, 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. The resale of the common stock by the purchaser in the private placement.

In December 2021, the Company issued and sold 3,024,194 units in a private placement at a purchase price of $4.96 per unit, resulting in net proceeds of $13.8 million, after deducting offering expenses. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), and a five-year warrant to purchase one share of common stock at an exercise price of $5.25 per share. In connection with the private placement, the Company filed a resale registration statement with the Securities and Exchange Commission (the “SEC”) in December 2021 to register the resale of the common stock by the purchaser in the private placement.

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 (“Legacy Clarus”), pursuant to which, subject to the terms and conditions set forth in the Merger Agreement, Merger Sub merged with and into Legacy Clarus, with Legacy Clarus surviving as a wholly-owned subsidiary of the Company, and with Legacy 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, Legacy Clarus’s convertible noteholders and senior secured noteholders provided $25.0 million in additional capital to Legacy 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 Legacy Clarus prior to the Closing Date. The additional capital was used to fund the remaining working capital requirements of the business combination.

At the effective time of the Merger (the “Effective Time”), shares of Legacy Clarus’s Series D redeemable convertible preferred stock (“Series D Preferred Stock”) issued and outstanding and all principal and accrued interest under Legacy Clarus’s convertible notes in excess of 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 Legacy Clarus’s 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 Legacy 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 note holders as further described in Note 3, which included 270,000 shares reallocated to the senior secured note holders from Legacy 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 Legacy 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 Legacy Clarus preferred stock, common stock and stock options were cancelled and extinguished upon completion of the Merger. In addition, Legacy Clarus’s existing equity incentive plans were terminated.

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

Since its inception, Legacy Clarus has devoted substantially all its efforts to business planning, clinical development, commercial planning and raising capital. Legacy Clarus, and since the Merger, the Company has incurred significant losses from operations since inception and has an accumulated deficit of $321.6 million as of December 31, 2021. Further, as of December 31, 2021, the Company had a working capital deficit of $14.4 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 8, 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 consolidated financial statements for the year ended December 31, 2021, the Company has concluded that its cash and cash equivalents at December 31, 2021 will not be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least 12 months from the date that these 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. Management believes that the Company’s existing cash and cash equivalents of $26.4 million as of December 31, 2021 and revenue generated from sales of JATENZO will fund its operations into April 2022.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated 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 ongoing COVID-19 pandemic had a significant negative impact on the Company’s consolidated financial statements for the year ended December 31, 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 the COVID-19 pandemic worsens, such as by the omicron variant or other variants that may surface, 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 8, Debt). The extent to which
the ongoing 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, vaccine rates and mandates, 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

Basis of Presentation

The accompanying consolidated financial statements are presented in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”). The consolidated financial statements include the accounts and operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated upon consolidation.

As a result of the Merger, the shares and corresponding capital amounts and loss per share related to Legacy 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 because of the conversion terms in the Merger Agreement. For additional information on the Business Combination, please refer to Note 3, Business Combination, to these consolidated financial statements.

Reclassification

Certain prior period amounts may have been reclassified to conform to the current year presentation. Such reclassifications did not affect reported net income.

Segment Information

The Company’s chief operating decision maker manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. All of the Company’s long-lived assets are held in the United States.

Use of Estimates

Preparation of the 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 financial statements and the reported amounts of revenues and expenses during the reporting period covered by the financial statements and accompanying notes. The most significant estimates relate to determination of sales discounts and allowances, 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.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The three levels of inputs that may be used to measure fair value are defined below:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3: Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management’s own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Cash and Cash Equivalents

Cash and cash equivalents represent cash and highly liquid investments with an original contractual maturity at the date of purchase of three months or less. As of December 31, 2021 and 2020, cash and cash equivalents included government-backed money market funds.
Concentrations of Risk

Substantially all of the Company’s cash and money market funds are held with a single financial institution. Due to its size, the Company believes this financial institution represents minimal credit risk. Deposits in this institution may exceed the amount of insurance provided on such deposits by the Federal Deposit Insurance Corporation for U.S. institutions. The Company has not experienced any losses on its deposits of cash and cash equivalents. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

The Company’s accounts receivable balance and revenue recognized is compromised solely from transactions with the Company’s single third-party logistics provider, or 3PL. The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection.

The Company depends on two third-party suppliers for its supply of TU, the active pharmaceutical ingredient of JATENZO.

Accounts Receivable, Net

Accounts receivables are stated at net realizable value. On a periodic basis, management evaluates its accounts receivable and determines whether to provide an allowance or if any accounts should be written off based on a past history of write-offs, collections and current credit conditions. A receivable is considered past due if the Company has not received payments based on agreed-upon terms. The Company generally does not require any security or collateral to support its receivables. The Company performs ongoing evaluations of its customers. The Company has recorded an allowance against its receivables of $0.5 million and $0.2 million as of December 31, 2021, and 2020, respectively.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined using the first-in, first-out (“FIFO”) method. Inventories are written down for product that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. Write-downs of inventory establish a new cost basis which is not increased for future increases in the net realizable value of inventories or changes in estimated obsolescence.

Property and Equipment, net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets, as follows:

<table>
<thead>
<tr>
<th>Asset Class</th>
<th>Estimated Useful Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer and office equipment</td>
<td>3 years</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>7 years</td>
</tr>
</tbody>
</table>

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Repair and maintenance costs are charged to expense as incurred.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset group may not be recoverable. There were no charges as a result of impairment losses for the years ended December 31, 2021 or 2020.

Deferred Financing Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings or debt financings as deferred financing costs until such financings are consummated. After consummation of a financing, these costs are presented in the balance sheets as a direct reduction from the carrying amount of the respective equity or debt instrument issued. Should an in-process financing be abandoned, the deferred financing costs will be expensed immediately as a charge to operating expenses in the statements of operations and loss.

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 IPO warrants 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 warrant.

Revenue Recognition

In accordance with ASC 606, Revenue from Contracts with Customers (“ASC 606”), an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to be entitled to in exchange for those goods or services. The Company performs the following five steps to recognize revenue under ASC 606: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. The Company has determined that the delivery of its product to its customer constitutes a single performance obligation as there are no other promises to deliver goods or services. Shipping and handling activities are considered fulfillment activities and are not considered to be a separate performance obligation. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with its customers do not exceed one year and therefore, no amount of consideration has been allocated as a financing component. Taxes collected related to product sales are remitted to governmental authorities and are excluded from revenue.

Net Product Sales

The Company began selling JATENZO in February 2020, in the United States through a 3PL which takes title and control of the goods. The 3PL distributes the product to wholesale distributors (collectively the “Distributors”), with whom the Company has entered into formal agreements for delivery to retail pharmacies. The Company has also entered into arrangements with payors that provide government mandated and/or privately negotiated rebates, chargebacks and discounts for the purchase of the Company’s products.

The Company recognizes revenue on sales of JATENZO when the customer obtains control of the product, which occurs at a point in time, typically upon delivery. Product revenues are recorded at the product’s wholesale acquisition costs, net of applicable reserves for variable consideration that are offered within contracts between the Company and its customers, wholesale distributors, payors, and other indirect customers relating to the sale of JATENZO. Components of variable consideration include government and commercial contract rebates, product returns, chargebacks, commercial co-payment assistance program transactions and distribution services fees. These deductions are based on the amounts earned or to be claimed on the related sales and are classified as a current liability or reduction of receivables, based on expected value method and a range of outcomes and are probability weighted in accordance with ASC 606.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognition under contracts will not occur in a future period. The Company’s analyses contemplate the application of the constraint in accordance with ASC 606. Actual amounts of consideration ultimately received may differ from its estimates. If actual results in the future vary from its estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

The below table includes a rollforward of the deferred revenue contract liability balance for the year ended December 31, 2021.

<table>
<thead>
<tr>
<th>Description</th>
<th>Deferred Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance at December 31, 2020</td>
<td>$ 1,172</td>
</tr>
<tr>
<td>Amounts deferred</td>
<td>14,370</td>
</tr>
<tr>
<td>Revenue recognized</td>
<td>(13,957)</td>
</tr>
<tr>
<td>Balance at December 31, 2021</td>
<td>$ 1,585</td>
</tr>
</tbody>
</table>

Cost of Product Sales

Cost of product sales include manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on net product sales, freight, shipping, handling, storage costs, salaries of employees involved with production, and a reserve for short-dated, obsolete inventory. The Company began capitalizing inventory upon FDA approval of JANTENZO®.

Research and Development Expenses

Research and development expenses include salaries and benefits, clinical trials costs, contract services and manufacturing development costs. Research and development expenses are charged to operations as they are incurred. The Company follows the provisions of the Research and Development Topic of the Codification which requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered or the services are no longer expected to be performed, the Company would be required to expense the related capitalized advance payments. The Company had no capitalized nonrefundable advance payments and no refundable advance payments as of December 31, 2021 or 2020.

The Company is required to estimate its accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of the Company’s service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company make estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Examples of estimated accrued research and
development expenses include fees paid to vendors in connection with preclinical development activities and vendors related to development, manufacturing and distribution of product candidate materials.
The Company bases its expenses related to clinical studies on its estimates of the services received and efforts expended pursuant to contracts with multiple vendors that conduct and manage preclinical studies on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period and adjust accordingly.

**Leases**

The Company leases office space and recognizes related rent expense on a straight-line basis over the term of the lease.

**Stock-Based Compensation**

The Company accounts for all stock-based compensation awards granted as stock-based compensation expense at fair value. The Company’s stock-based payments include stock options and grants of common stock, restricted for vesting conditions. The measurement date for awards is the date of grant, and stock-based compensation costs are recognized as expense over the requisite service period, which is generally the vesting period, on a straight-line basis. Stock-based compensation expense is classified in the accompanying statements of operations based on the function to which the related services are provided. The Company recognizes stock-based compensation expense for the portion of awards that have vested. Forfeitures are recorded as they occur. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model.

**Patents and Trademarks**

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty of the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statement of operations.

**Basic and Diluted 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. Net income (loss) attributable to common stockholders is allocated first based on dividend rights and then to common and preferred stockholders based on ownership interests. 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, 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. See Note 14, Net Loss per Share, for further detail.

**Comprehensive Loss**

The Company’s comprehensive loss was the same as its reported net loss for all periods presented.

**Income Taxes**

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determines deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, it would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.
The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) the Company determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying statement of operations. As of December 31, 2021 and 2020, no accrued interest or penalties are included on the related tax liability line in the balance sheet.

**Emerging Growth Company Status**

The Company is an “emerging growth company” (“EGC”), as defined in the Jumpstart Our Business Startups Act (“JOBS Act”) and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company expects to elect to avail itself of the extended transition period and, therefore, while the Company is an EGC it will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not EGCs, unless it chooses to early adopt a new or revised accounting standard.

**Recently Issued Accounting Pronouncements Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”). Under ASU 2016-02, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. For leases with a term of twelve months or less, the lessee is permitted to make an accounting policy election not to recognize lease assets and lease liabilities by class of underlying assets. The new lease standard is effective for the Company beginning January 1, 2022. The Company will adopt the new standard using a modified retrospective basis, which requires the Company to reflect its leases on its balance sheet for the earliest comparative period presented. The Company expects to elect the package of practical expedients, which allows entities to not reassess (i) whether an arrangement is or contains a lease, (ii) the classification of its leases, and (iii) the accounting for initial direct costs. Further, the Company anticipates electing, by class of underlying asset, the short-term lease exception for leases with terms of twelve months or less. In doing so, the Company will not recognize a lease liability or right-of-use asset on its consolidated balance sheets for such short-term leases. Finally, the Company expects to elect, by class of underlying asset, the practical expedient to not separate lease and non-lease components. The adoption of this standard is not expected to have a material impact on the Company’s financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the impact that the adoption for ASU 2016-13 will have on its financial statements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740) (“ASU 2019-12”): Simplifying the Accounting for Income Taxes, which adds or clarifies guidance on accounting for income taxes. The new guidance will become effective for the Company on January 1, 2022, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company’s financial statements and related disclosures.

In March 2020, the FASB issued ASU 2020-04, Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting (“ASU 2020-4”), which applies to entities that have contracts, such as debt agreements, lease agreements or derivative instruments, which reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. Entities can elect not to apply certain modification accounting requirements for contract modifications that replace a reference rate affected by reference rate reform. If elected, such contracts are accounted for as a continuation of the existing contract and no reassessments or remeasurements are required. ASU 2020-04 is effective for all entities from March 12, 2020 through December 31, 2022 and does not apply to contract modifications made after December 31, 2022. The Company is currently evaluating the impact that the adoption for ASU 2020-04 will have on its financial statements.

In June 2020, the FASB issued ASU 2020-06, Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity (“ASU 2020-06”). ASU 2020-06 simplifies the accounting for certain convertible instruments, amends guidance on derivative scope exceptions for contracts in an entity’s own equity and modifies the guidance on diluted earnings per share calculations as a result of these changes. The new guidance will become effective for the Company on January 1, 2021, with early adoption permitted. The Company is currently evaluating the impact that the adoption for ASU 2020-06 will have on its financial statements.
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3. Business Combination

On September 9, 2021, the business combination between Blue Water Merger Sub and Legacy 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 Legacy Clarus, with Legacy 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 Legacy Clarus is treated as the acquirer for financial statement reporting and accounting purposes. As a result, the historical operations of Legacy Clarus are deemed to be those of the Company. Therefore, the financial statements included in this report reflect (i) the historical operating results of Legacy Clarus prior to the Business Combination; (ii) the combined results of the Blue Water and Legacy Clarus following the Business Combination on September 9, 2021; (iii) the assets and liabilities of Legacy 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 Legacy Clarus.

The aggregate consideration issued or reserved for issuance to Legacy Clarus securityholders upon the closing of the Merger was 17,886,348 shares of Company common stock. The 17,886,348 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 8, of which 270,000 shares reallocated to the senior secured note holders from Legacy 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 Legacy 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 Legacy Clarus securityholders is also 2,549,939 shares of common stock at $10.00 per share, that were issued to Legacy 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 Legacy 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 consolidated balance sheet as of December 31, 2021.

Summary of Net Proceeds

The following table summarizes the elements of the net proceeds from the Business Combination as of December 31, 2021 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash – Blue Water Trust Account and cash (net of redemptions)</td>
<td>$25,394</td>
</tr>
<tr>
<td>Less: Equity issuance costs and other costs paid</td>
<td>(8,385)</td>
</tr>
<tr>
<td>Net Proceeds from the Business Combination</td>
<td>$17,009</td>
</tr>
</tbody>
</table>

Summary of Shares Issued

Previously authorized, issued and outstanding shares common stock of Legacy Clarus were cancelled and extinguished upon completion of the Business Combination. The following table summarizes the number of shares of Common Stock outstanding immediately following the consummation of the Business Combination:

<table>
<thead>
<tr>
<th>Description</th>
<th>Shares</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blue Water shares outstanding prior to the Business Combination</td>
<td>3,839,469</td>
</tr>
<tr>
<td>Conversion of Legacy Clarus Series D Preferred Stock</td>
<td>4,901,564</td>
</tr>
<tr>
<td>Conversion of Legacy Clarus convertible notes</td>
<td>8,529,846</td>
</tr>
<tr>
<td>Conversion of additional capital provided by Legacy Clarus convertible note and senior note holders</td>
<td>2,549,938</td>
</tr>
<tr>
<td>Conversion of Senior Secured Note principal and royalty rights</td>
<td>1,905,000</td>
</tr>
<tr>
<td>Total shares of the Company’s common stock outstanding immediately following the Business Combination</td>
<td>21,725,817</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion of senior notes and royalty obligation carrying value</td>
<td>$28,254</td>
</tr>
<tr>
<td>Conversion of Legacy Clarus convertible notes carrying value</td>
<td>103,267</td>
</tr>
<tr>
<td>Conversion of Series D redeemable convertible preferred stock carrying value</td>
<td>209,290</td>
</tr>
<tr>
<td>Assumption of warrant liabilities</td>
<td>(14,075)</td>
</tr>
<tr>
<td>Total reverse recapitalization impact on statement of equity</td>
<td>$326,736</td>
</tr>
</tbody>
</table>
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:

### December 31, 2021

<table>
<thead>
<tr>
<th>Assets</th>
<th>Total</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash equivalents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$13,002</td>
<td>$13,002</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Total assets</td>
<td>$13,002</td>
<td>$13,002</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private placement warrant liability</td>
<td>$1,567</td>
<td>$—</td>
<td>$—</td>
<td>$1,567</td>
</tr>
<tr>
<td>Total Liabilities</td>
<td>$1,567</td>
<td>$—</td>
<td>$—</td>
<td>$1,567</td>
</tr>
</tbody>
</table>

### December 31, 2020

<table>
<thead>
<tr>
<th>Assets</th>
<th>Total</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash equivalents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Money market funds</td>
<td>$7,205</td>
<td>$7,205</td>
<td>$—</td>
<td>$—</td>
</tr>
<tr>
<td>Total assets</td>
<td>$7,205</td>
<td>$7,205</td>
<td>$—</td>
<td>$—</td>
</tr>
</tbody>
</table>

During the years ended December 31, 2021 and 2020, there were no transfers between levels.

As of December 31, 2021 and 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 years ended December 31, 2021 and 2020.

As of December 31, 2021 and 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 December 31, 2021 the Warrant Liabilities were valued at $1.6 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 Legacy 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 Legacy Clarus’s stock. At December 31, 2020 the Warrant Liability was valued at zero. During the year ended December 31, 2020, the Company recorded a gain of $0.6 million associated with the change in the fair value of the warrant liability. 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 IPO 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 IPO 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 the assumptions used to estimate the fair value of the Private Placement Warrant Liability at December 31, 2021:

<table>
<thead>
<tr>
<th>Assumption</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair value of underlying instrument</td>
<td>$2.43</td>
</tr>
<tr>
<td>Risk-free interest rate</td>
<td>1.22%</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>4.7</td>
</tr>
<tr>
<td>Expected volatility</td>
<td>65.0%</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>—%</td>
</tr>
</tbody>
</table>
The following table sets forth a summary of changes in the fair value of the Company’s warrant liability for the year ended December 31, 2021 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning warrant liability balance</td>
<td>$ —</td>
</tr>
<tr>
<td>Private placement warrant liability assumed</td>
<td>14,075</td>
</tr>
<tr>
<td>Change in fair value of warrant liability</td>
<td>(12,508)</td>
</tr>
<tr>
<td>Balance at December 31, 2021</td>
<td>$ 1,567</td>
</tr>
</tbody>
</table>

**Derivative Liability**

From 2016 through 2020, Legacy Clarus entered into convertible notes purchase agreements with related parties for a total aggregate borrowing amount of $81.3 million (see Note 8, 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. During the year ended December 31, 2020, the Company recorded a gain of $66.3 million within other income and expense associated with the change in the fair value of the derivative liability. All of Legacy 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 December 31, 2021 and 2020 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material</td>
<td>$ 6,850</td>
<td>$ 4,225</td>
</tr>
<tr>
<td>Work-in-process</td>
<td>1,452</td>
<td>—</td>
</tr>
<tr>
<td>Finished goods</td>
<td>14,500</td>
<td>9,475</td>
</tr>
<tr>
<td>Total inventory</td>
<td>22,802</td>
<td>13,700</td>
</tr>
<tr>
<td>Inventory reserve</td>
<td>(8,588)</td>
<td>(7,843)</td>
</tr>
<tr>
<td>Total inventory, net of reserve</td>
<td>$ 14,214</td>
<td>$ 5,857</td>
</tr>
</tbody>
</table>

**6. Property and Equipment.**

Property and equipment consisted of the following as of December 31, 2021 and 2020 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office equipment and computer hardware</td>
<td>$ 124</td>
<td>$ 99</td>
</tr>
<tr>
<td>Furniture and fixtures</td>
<td>109</td>
<td>109</td>
</tr>
<tr>
<td>Total property and equipment</td>
<td>233</td>
<td>208</td>
</tr>
<tr>
<td>Less accumulated depreciation</td>
<td>(168)</td>
<td>(144)</td>
</tr>
<tr>
<td>Property and equipment, net</td>
<td>65</td>
<td>64</td>
</tr>
</tbody>
</table>

Depreciation expense for the years ended December 31, 2021 and 2020 was approximately $25 thousand and $18 thousand, respectively.

**7. Accrued Expenses**

Accrued expenses consisted of the following as of December 31, 2021 and 2020 (in thousands):

<table>
<thead>
<tr>
<th>Description</th>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selling and marketing costs</td>
<td>$ 6,031</td>
<td>$ 3,468</td>
</tr>
<tr>
<td>Employee compensation and related benefits</td>
<td>2,005</td>
<td>1,090</td>
</tr>
<tr>
<td>Professional fees</td>
<td>225</td>
<td>73</td>
</tr>
<tr>
<td>Total</td>
<td>$ 8,261</td>
<td>$ 4,631</td>
</tr>
</tbody>
</table>
8. Debt

Convertible Notes

From 2016 to 2021, Legacy Clarus issued several convertible notes (the “Convertible Notes”) pursuant to which Legacy 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 Legacy Clarus’ convertible notes 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 December 31, 2021.

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

<table>
<thead>
<tr>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal amount</td>
</tr>
<tr>
<td>Accrued and unpaid interest</td>
</tr>
<tr>
<td>Unamortized debt discount</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

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 Legacy 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 $5.0 million and $6.1 million related to the Convertible Notes during the years ended December 31, 2021 and 2020, respectively.

Senior Secured Notes

The carrying value of the Company’s senior secured notes consisted of the following as of December 31, 2021 and 2020 (in thousands):

<table>
<thead>
<tr>
<th>December 31, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal amount</td>
<td>$43,125</td>
</tr>
<tr>
<td>Accrued and unpaid interest</td>
<td>4,354</td>
</tr>
<tr>
<td>Unamortized debt discount</td>
<td>(5,210)</td>
</tr>
<tr>
<td>Total</td>
<td>$42,269</td>
</tr>
</tbody>
</table>

On March 12, 2020, Legacy 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 Legacy Clarus received $43.6 million in net proceeds after deducting transaction expenses of $3.5 million and prepaid interest of $2.9 million.

In the second quarter of 2021, Legacy 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 3), $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 Legacy 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 Legacy Clarus’s equity holders and 135,000 shares that were transferred from the Sponsor pursuant to the share allocation agreement). 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 December 31, 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.
Future principal payments of the senior secured notes are as follows (in thousands):

<table>
<thead>
<tr>
<th>Years ended December 31</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2022</td>
<td>$ 6,000</td>
</tr>
<tr>
<td>2023</td>
<td>15,125</td>
</tr>
<tr>
<td>2024</td>
<td>14,000</td>
</tr>
<tr>
<td>2025</td>
<td>8,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$43,125</strong></td>
</tr>
</tbody>
</table>

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 was amortized to interest expense over the life of the notes. For the years ended December 31, 2021 and 2020 the Company recorded $2.2 million and $2.1 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 December 31, 2021.

During the years ended December 31, 2021 and 2020, the Company recorded $8.9 million and $6.8 million, respectively, in interest expense on the senior secured notes, of which $2.7 million and $2.2 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 years ended December 31, 2021 and 2020.

Pursuant to the indenture governing the senior secured notes, there are various covenants that limit the Company’s ability to engage in specified types of transactions including selling, transferring, leasing, or disposing certain assets, encumbering or permitting liens on certain assets, making certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to common stock, and entering into certain transaction with affiliates. Also, pursuant to the indenture governing the senior secured notes, Legacy 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, Legacy 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 $42.3 million related to the senior secured notes as a current liability within the December 31, 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 December 31, 2021.

PIK Note

In May 2021, Legacy Clarus entered into a payment-in-kind, or PIK, note (the “PIK Note”), in relation to its missed interest payment (which was due in January 2021) on its senior secured notes, pursuant to which Legacy 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. The principal amount due on the PIK note is included within the total principal balance of the senior secured notes of $43.1 million.

Indenture Note

In June 2021, Legacy 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. As such, there is no balance outstanding associated with the Indenture Note at December 31, 2021.

Second Indenture Note

In July 2021, Legacy 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. As such, there is no balance outstanding associated with the Second Indenture Note at December 31, 2021.
9. Stockholders' Equity (Deficit)

The consolidated financial statements have 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 shares 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 December 31, 2021.

As of December 31, 2020, Legacy Clarus redeemable convertible preferred stock consisted of the following (in thousands, except for share data):

<table>
<thead>
<tr>
<th>Preferred Stock</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized</td>
<td>Issued and Outstanding</td>
</tr>
<tr>
<td>A Preferred Stock</td>
<td>2,500,000</td>
</tr>
<tr>
<td>B Preferred Stock</td>
<td>5,066,637</td>
</tr>
<tr>
<td>C Preferred Stock</td>
<td>9,438,744</td>
</tr>
<tr>
<td>D Preferred Stock</td>
<td>36,756,498</td>
</tr>
</tbody>
</table>

Each share of redeemable convertible preferred stock had voting rights, conversion rights into common stock, redemption rights, liquidation preferences and provided for an 8% cumulative dividend. As of December 31, 2020, the convertible redeemable preferred stock was classified separately from equity in the accompanying balance sheet. In connection with the closing of the Business Combination, all previously issued and outstanding shares of Series A Redeemable Convertible Preferred Stock, Series B Redeemable Convertible Preferred Stock, and Series C Redeemable Convertible 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 December 31, 2021, there were 21,725,817 shares of common stock issued and outstanding.

Previously authorized, issued and outstanding shares common stock of Legacy Clarus were cancelled and extinguished upon completion of the Business Combination. For purposes of earnings per share, the Company has retroactively adjusted the common shares issued and outstanding prior to September 9, 2021 to zero to give effect to the cancellation of Legacy Clarus common stock 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.

Warrants

On December 17, 2020, the Company consummated its IPO of 5,750,000 units (each unit representing a share of common stock and a warrant to purchase a share of common stock (“IPO warrants”)), at $10.00 per unit. 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 IPO Warrants and Private Placement Warrants became exercisable on the Closing Date of the Merger. The warrants have an exercise price of $11.50 per share, subject to adjustments, and will expire five years from the Closing Date. The Private Placement Warrants are identical to the Public Warrants, except that the Private Placement Warrants and the shares of Class A common stock issuable upon exercise of the Private Placement Warrants will not be transferable, assignable or salable until the completion of a Business Combination, subject to certain limited exceptions. Additionally, the

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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, Legacy Clarus received an unsecured loan of $0.5 million from the SBA. After considering further guidance issued by the SBA, Legacy Clarus elected to repay the loan in full in May of 2020 with no interest due under safe harbor provisions of the CARES Act.
Private Placement Warrants will be non-redeemable so long as they are held by the Sponsor or their permitted transferees. As of December 31, 2021, there were 5,750,000 of the IPO Warrants and 3,445,000 of the Private Placement Warrants remain outstanding.

In December 2021, the Company issued and sold 3,024,194 units, in a private placement, at a purchase price of $4.96 per unit, resulting in net proceeds of $13.8 million, after deducting offering expenses. Each unit consisted of one share of common stock (or one pre-funded warrant in lieu thereof), and a five-year warrant to purchase one share of common stock at an exercise price of $5.25 per share. The exercise price and the number of shares of common stock issuable upon exercise of each warrant is subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events.
affecting the Company’s common stock. In connection with the private placement, the Company filed a resale registration statement with the Securities and Exchange Commission (the “SEC”) in December 2021 to register the resale of the common stock by the purchaser (including the shares of common stock underlying the pre-funded warrants and warrants) in the private placement. Upon issuance, the Company classified the warrants within equity in the consolidated balance sheet. As of December 31, 2021, there were 2,300,000 warrants outstanding with an exercise price of $5.25 per share and 724,194 pre-funded warrants outstanding, which were purchased for $4.96 per share.

10. Stock-Based Compensation

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 December 31, 2021, there were 1,083,550 options and 433,420 restricted stock units granted under the 2021 Plan. There are 1,958,030 shares remaining available for grant under the 2021 Plan at December 31, 2021.

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 December 31, 2021 the Company had not issued any shares under the ESPP.

Stock Options

Stock options typically vest over three years and have a maximum term of 10 years. The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The Company utilized the Black-Scholes option-pricing model to estimate the fair value of stock options awarded to employees. The Black-Scholes option-pricing model requires several key assumptions. The key assumptions used to apply this pricing model were as follows:

<table>
<thead>
<tr>
<th></th>
<th>Year Ended December 31, 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk free interest rate</td>
<td>1.34%</td>
</tr>
<tr>
<td>Expected term (in years)</td>
<td>5.95</td>
</tr>
<tr>
<td>Expected dividend yield</td>
<td>0%</td>
</tr>
<tr>
<td>Expected volatility of underlying common stock</td>
<td>79.76%</td>
</tr>
</tbody>
</table>

The following table summarizes the stock option activity under the 2021 Plan:

<table>
<thead>
<tr>
<th>Stock Options</th>
<th>Weighted Average Exercise Price</th>
<th>Weighted Average Remaining Contractual Life (in Years)</th>
<th>Intrinsic Value (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outstanding January 1, 2021</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granted</td>
<td>1,083,550</td>
<td>4.78</td>
<td>9.95</td>
</tr>
<tr>
<td>Exercised</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canceled</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding December 31, 2021</td>
<td>1,083,550</td>
<td>$ 4.78</td>
<td>9.95</td>
</tr>
<tr>
<td>Options vested or expected to vest as of December 31, 2021</td>
<td>$ —</td>
<td>$ —</td>
<td>$ —</td>
</tr>
<tr>
<td>Stock options unvested as of December 31, 2021</td>
<td>1,083,550</td>
<td>$ 4.78</td>
<td>9.95</td>
</tr>
</tbody>
</table>

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the reporting period. The weighted average grant-date fair value of stock options granted in 2021 was $3.26 per share. The total fair value of stock options vested during the year ended December 31, 2021 was zero.

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Restricted Common Stock

The Company has granted restricted common stock with service based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder, except for transfers for estate planning purposes in which the transferee agrees to remain bound by all restrictions set forth in the original common stock purchase agreement. They are legally issued and outstanding but only accounted for as outstanding when vested. These restrictions lapse over the three-year vesting term of each award. The purchase price of each share of restricted common stock was $0.0001 per share. A summary of the activity for the year ended December 31, 2021 is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Number of Shares</th>
<th>Weighted Average Grant Date Fair Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvested restricted stock as of January 1, 2021</td>
<td>—</td>
<td>$ —</td>
</tr>
<tr>
<td>Granted</td>
<td>433,420</td>
<td>$ 4.78</td>
</tr>
<tr>
<td>Unvested restricted stock as of December 31, 2021</td>
<td>433,420</td>
<td>$ 4.78</td>
</tr>
</tbody>
</table>

The aggregate fair value of restricted stock awards that vested during the year ended December 31, 2021 was zero.

Legacy Clarus Stock Option and Incentive Plan

Legacy Clarus previously maintained various stock option and incentive plans and awarded options under such plans. Upon completion of the Business Combination, all such plans 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 plans during the period ended December 31, 2021.

Stock-Based Compensation Expense

Stock-based compensation expense, including expense associated with the Legacy Clarus incentive plans up until the date of the business combination ($559 in 2021 and $825 in 2020), is as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Years Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2021</td>
</tr>
<tr>
<td>Selling and marketing</td>
<td>$ 43</td>
</tr>
<tr>
<td>Research and development</td>
<td>60</td>
</tr>
<tr>
<td>General and administrative</td>
<td>565</td>
</tr>
<tr>
<td>Total stock-based compensation expense</td>
<td>$ 668</td>
</tr>
</tbody>
</table>

As of December 31, 2021, there was $5.5 million of unrecognized stock-based compensation expense related to unvested stock options and restricted common stock, which is estimated to be recognized over a period of 3.70 years.

11. Income Taxes

No provision for federal or state income taxes was recorded during the years ended December 31, 2021 and 2020, as the Company incurred operating losses and maintains a full valuation allowance against its net deferred tax assets. The reported amount of income tax benefit for the years ended December 31, 2021 and 2020 differs from the amount that would result from applying the domestic federal statutory rates to pretax losses primarily because of changes in the valuation allowance, state taxes, and the generation of research and development credits.

A reconciliation of the Company’s statutory income tax rate to the Company’s effective income tax rate is as follows (in thousands):

<table>
<thead>
<tr>
<th></th>
<th>Year Ended December 31,</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2021</td>
</tr>
<tr>
<td>Income at U.S. statutory rate</td>
<td>$ (8,530)</td>
</tr>
<tr>
<td>State taxes, net of federal benefit</td>
<td>(2,578)</td>
</tr>
<tr>
<td>Change in fair value</td>
<td>(2,627)</td>
</tr>
<tr>
<td>Interest Expense</td>
<td>1,077</td>
</tr>
<tr>
<td>Stock compensation</td>
<td>70</td>
</tr>
<tr>
<td>Transaction costs</td>
<td>(664)</td>
</tr>
<tr>
<td>Permanent differences and other</td>
<td>1</td>
</tr>
<tr>
<td>Valuation allowance</td>
<td>13,251</td>
</tr>
<tr>
<td>—</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

F-21
The net deferred income tax asset balance related to the following:

<table>
<thead>
<tr>
<th>Deferred tax assets</th>
<th>Years Ended December 31,</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2021</td>
<td>2020</td>
<td></td>
</tr>
<tr>
<td>Stock compensation</td>
<td>$10</td>
<td>$64</td>
<td></td>
</tr>
<tr>
<td>Accruals and other</td>
<td>6,507</td>
<td>4,151</td>
<td></td>
</tr>
<tr>
<td>Debt discount</td>
<td>597</td>
<td>483</td>
<td></td>
</tr>
<tr>
<td>Royalty liability</td>
<td>2,272</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net operating loss carryforwards</td>
<td>62,606</td>
<td>51,981</td>
<td></td>
</tr>
<tr>
<td>Tax credits</td>
<td>6,731</td>
<td>6,774</td>
<td></td>
</tr>
<tr>
<td>Total deferred tax assets</td>
<td>76,451</td>
<td>65,662</td>
<td></td>
</tr>
<tr>
<td>Less: valuation allowance</td>
<td>(76,451)</td>
<td>(65,662)</td>
<td></td>
</tr>
<tr>
<td>Deferred tax assets, net</td>
<td>$—</td>
<td>$—</td>
<td></td>
</tr>
</tbody>
</table>

At December 31, 2021, the Company had approximately $231.7 million and $202.7 million of federal and state net operating loss ("NOL") carryforwards, respectively. Approximately $134.9 million of the federal NOL and $120.0 million of the state NOL was generated prior to the 2018 tax year. As a result, these net operating loss carryforwards will expire, if not utilized, between 2022 and 2037 for federal and state income tax purposes. As a result of the Tax Cuts and Jobs Act, federal NOLs generated in tax years ending after December 31, 2017 are limited to a deduction of 80% of the taxpayer’s taxable income. Furthermore, the post 2017 NOLs are subject to an indefinite carryforward period; therefore, $96.8 million of federal NOL generated after 2017 may be carried forward indefinitely. As it pertains to the approximately $82.7 million of state NOLs generated after 2017, not all states have conformed to the Act; therefore, the NOL expiration will vary based on the state. The Company also has federal tax credits of $6.7 million, which begin to expire in 2024 and state tax credits of $0.1 million which begin to expire in 2022.

Future realization of the tax benefits of existing temporary differences and net operating loss carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2021 and 2020, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2021 and 2020.

The Company’s valuation allowance for the year ended December 31, 2021 and 2020 is as follows:

<table>
<thead>
<tr>
<th>Valuation allowance at beginning of year</th>
<th>$65,662</th>
<th>$52,487</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increases recorded due to income tax provisions</td>
<td>13,251</td>
<td>13,175</td>
</tr>
<tr>
<td>Decreases recorded to equity</td>
<td>(2,462)</td>
<td>—</td>
</tr>
<tr>
<td>Valuation allowance at end of year</td>
<td>$76,451</td>
<td>$65,662</td>
</tr>
</tbody>
</table>

Under Internal Revenue Code Section 382, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. The Company has not completed a study to assess whether an “ownership change” has occurred or whether there have been multiple ownership changes since it became a “loss corporation” as defined in Section 382. Future changes in the Company’s stock ownership, which may be outside of its 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 the Company.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which we operate or do business in. ASC 740 states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records uncertain tax positions as liabilities in accordance with ASC 740 and adjust these liabilities when its judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company’s current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2020 and 2021 the Company has not recorded any uncertain tax positions in its financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2021 and 2020, no accrued interest or penalties are included on the related tax liability line in the consolidated balance sheet.
The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. The earliest tax years that remain subject to examination by jurisdiction is 2018 for both federal and state. However, to the extent the Company utilizes net operating losses from years prior to 2018, the statute remains open to the extent of the net operating losses or other credits are utilized. The resolution of tax matters is not expected to have a material effect on the Company’s financial statements.

12. License Agreements

Agreement with HavaH

In May 2021, Legacy 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.

13. 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, 2022 and September 30, 2022, respectively. Total rent expense under the lease agreements was $0.2 million for the years ended December 31, 2021 and 2020, respectively. The future minimum lease payments required under the lease agreements through the remaining terms total $90 thousand.

Purchase Obligation

In July of 2009, Legacy 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 years ended December 31, 2021 and 2020 were $6.2 million and $3.2 million, respectively.

The Company 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 $1.8 million of purchases under the Pfizer Agreement during the year ended December 31, 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 Legacy 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 Legacy Clarus’ intent to market and sell JATENZO, based on the FDA’s approval of JATENZO in March 2019. Lipocine ultimately alleged that Legacy 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.

Legacy 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. Legacy 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, Legacy Clarus requested the Court to schedule a bench trial on Legacy 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, Legacy Clarus and Lipocine entered into a settlement agreement that settled all claims between the parties, including a pending interference matter (No. 106,128) and the pending Legacy Clarus counterclaims against Lipocine, and provided for a payment by Lipocine to Legacy 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 USPTO’s Patent Trial and Appeal Board (PTAB) on July 26, 2021. The Company believes that its U.S. Patent Application No. 16/656,178 involved in the interference may proceed to issuance due to entry of the decision adverse to Lipocine by the PTAB, but the ‘178 application has not issued to date.

14. Net Income (Loss) Per Share

As a result of the Business Combination, all common stock of Legacy Clarus was cancelled and terminated and shares of Series D Preferred Stock were converted to common stock of the Company. For purposes of presenting earnings per share, the shares and income (loss) per share related to Legacy Clarus’s outstanding common stock prior to the Business Combination have been retroactively restated to zero, as all the Legacy Clarus common stock was cancelled. Basic and diluted earnings (loss) per share attributable to common stockholders are calculated as follows:

<table>
<thead>
<tr>
<th>Years Ended December 31</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net (loss) income</td>
<td>(40,617)</td>
<td>4,345</td>
</tr>
<tr>
<td>Accretion of preferred stock (3)</td>
<td>—</td>
<td>(14,682)</td>
</tr>
<tr>
<td>Gain on extinguishment of convertible notes (1)</td>
<td>412</td>
<td>—</td>
</tr>
<tr>
<td>Net (loss) income attributable to common stockholders, basic</td>
<td>(40,205)</td>
<td>(10,337)</td>
</tr>
<tr>
<td>Effect of convertible notes (2)</td>
<td>—</td>
<td>(59,626)</td>
</tr>
<tr>
<td>Net loss attributable to common stockholders, diluted</td>
<td>(40,205)</td>
<td>(69,963)</td>
</tr>
<tr>
<td>Denominator:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighted-average common shares attributable to common stockholders, basic</td>
<td>7,027,860</td>
<td>—</td>
</tr>
<tr>
<td>Effect of convertible notes (2)</td>
<td>—</td>
<td>8,529,846</td>
</tr>
<tr>
<td>Weighted average number of common shares—diluted</td>
<td>7,027,860</td>
<td>8,529,846</td>
</tr>
<tr>
<td>Net loss per common share attributable to common stockholders, basic</td>
<td>(5.72)</td>
<td>—</td>
</tr>
<tr>
<td>Effect of convertible notes</td>
<td>—</td>
<td>(8.20)</td>
</tr>
<tr>
<td>Net loss per common share attributable to common stockholders, diluted</td>
<td>(5.72)</td>
<td>(8.20)</td>
</tr>
</tbody>
</table>

(1) 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.
(2) The effect of the convertible notes on the numerator for the year ended December 31, 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. The effect of the convertible notes on the shares in the denominator for the year ended December 31, 2020 was calculated based on the carrying value of the convertible notes balance at December 31, 2020, converted at the series D price of $4.50 per share and further retroactively adjusted for the effect of the Business Combination and are added back to the denominator when calculating diluted EPS using the if-converted method. These are excluded from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2021 because including them would have had an anti-dilutive effect.
(3) The effect of accretion of preferred stock is $0 in 2021 because of the effect of the reversal of previous accretion forgone by the preferred shareholders upon completion of the Business Combination provided no benefit to the holders of the canceled Legacy Clarus common stock.
The Company excluded the following shares from the computation of diluted net loss per share attributable to common stockholders as of December 31, 2021 and 2020 because including them would have had an anti-dilutive effect:

<table>
<thead>
<tr>
<th>Shares</th>
<th>2021</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redeemable convertible preferred stock</td>
<td>—</td>
<td>36,756,498</td>
</tr>
<tr>
<td>Legacy Clarus warrants</td>
<td>9,246</td>
<td>183,438</td>
</tr>
<tr>
<td>IPO warrants</td>
<td>5,750,000</td>
<td>—</td>
</tr>
<tr>
<td>Private Placement warrants</td>
<td>3,445,000</td>
<td>—</td>
</tr>
<tr>
<td>PIPE warrants</td>
<td>3,748,338</td>
<td>—</td>
</tr>
<tr>
<td>Stock options and unvested stock</td>
<td>1,516,970</td>
<td>—</td>
</tr>
</tbody>
</table>

15. Related Party Transactions

In July of 2020, a member of Legacy 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 $0.3 million and $0.1 million in consulting fees during the year ended December 31, 2021 and 2020, respectively.

Upon completion of the Business Combination on September 9, 2021, the Company’s senior secured note holders were given common stock in exchange for $10.0 million of principal on the senior secured notes and certain royalty rights, making certain senior secured note holders significant beneficial owners of the Company. As of December 31, 2021 the Company owed $28.1 million in principal and interest to the related party senior secured note holders and incurred $2.8 million in interest expense during the year ended December 31, 2021.

16. Subsequent Events

On March 10, 2022, 724,194 pre-funded warrants issued as part of the December 2021 private placement were exercised for a price of $0.00001 per share and were converted into shares of common stock.
Up to 19,816,610 Shares of Common Stock

Up to 9,195,000 Shares of Common Stock Issuable Upon Exercise of Warrants

Up to 3,445,000 Warrants

PROSPECTUS

, 2022
PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following is an estimate of the expenses (all of which are to be paid by the registrant) that we may incur in connection with the securities being registered hereby.

<table>
<thead>
<tr>
<th>Expense</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEC registration fee</td>
<td>$16,066.47</td>
</tr>
<tr>
<td>Legal fees and expenses</td>
<td>*</td>
</tr>
<tr>
<td>Accounting fees and expenses</td>
<td>$50,000</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>*</td>
</tr>
<tr>
<td>Total</td>
<td>$*</td>
</tr>
</tbody>
</table>

* These fees are calculated based on securities offered and the number of issuances and accordingly cannot be defined at this time.


Section 145(a) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the DGCL provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the DGCL.
Additionally, the Certificate of Incorporation, which became effective upon completion of the Business Combination, provides that no director of ours shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (1) for any breach of the director’s duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) in respect of unlawful dividend payments or stock redemptions or repurchases, or (4) for any transaction from which the director derived an improper personal benefit. In addition, the Certificate of Incorporation provides that if the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of ours shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

The Certificate of Incorporation further provides that any repeal or modification of such article by its stockholders or amendment to the DGCL will not adversely affect any right or protection existing at the time of such repeal or modification with respect to any acts or omissions occurring before such repeal or modification of a director serving at the time of such repeal or modification.

The Bylaws provide that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of the Company) by reason of the fact that he or she is or was, or has agreed to become, the Company’s director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys’ fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. The Bylaws also provide that we will advance expenses to Indemnitees in connection with a legal proceeding, subject to limited exceptions.

In connection with the Business Combination, we entered into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors and such officers to the fullest extent permitted by law and the Certificate of Incorporation and the Bylaws.

We will also maintain a general liability insurance policy, which will cover certain liabilities of directors and officers of ours arising out of claims based on acts or omissions in their capacities as directors or officers.

**Item 15. Recent Sales of Unregistered Securities.**

On June 30, 2020, Blue Water issued an aggregate of 1,437,500 Founder Shares to the Sponsor for an aggregate purchase price of $25,000 in cash, or approximately $0.017 per share. The number of Founder Shares issued was determined based on the expectation that such Founder Shares would represent 20% of the outstanding shares upon completion of the Blue Water IPO. The Founder Shares (including the Class A common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder. The Founder Shares were issued pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act.

On December 17, 2020, the Sponsor purchased an aggregate of 3,445,000 Placement Warrants for a purchase price of $1.00 per warrant, for an aggregate purchase price of $3,445,000, in a placement that occurred simultaneously with the closing of the Blue Water IPO. Each Placement Warrant entitles the holder thereof to purchase one share of Common Stock at a price of $11.50 per share. The Placement Warrants (including the common stock issuable upon exercise thereof) may not, subject to certain limited exceptions, be transferred, assigned or sold by the holder. The Placement Warrants were issued pursuant to an exemption from registration contained in Section 4(a)(2) of the Securities Act.

On December 3, 2021, Clarus entered into a Securities Purchase Agreement with the Selling Securityholder, pursuant to which Clarus issued and sold, in a private placement, an aggregate of (i) 2,300,000 shares of Common Stock, together with Common Warrants to purchase up to 2,300,000 shares of Common Stock, and (ii) 724,194 Pre-Funded Warrants with each Pre-funded Warrant exercisable for one share of Common Stock, together with Common Warrants to purchase up to 724,194 shares of Common Stock. Each share of Common Stock and accompanying Common Warrant was sold together at a combined offering price of $4.96, and each Pre-funded Warrant and accompanying Common Warrant was sold together at a combined offering price of $4.95999. The Shares, Pre-Funded Warrants and Warrants were issued pursuant to exemptions from registration contained in Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.
## Table of Contents

### Item 16. Exhibits.

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>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).</td>
</tr>
<tr>
<td>3.2</td>
<td>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).</td>
</tr>
<tr>
<td>4.1</td>
<td>Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1/A1, filed by Blue Water Acquisition Corp. on November 30, 2020).</td>
</tr>
<tr>
<td>4.2</td>
<td>Specimen Warrant Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A1, filed by Blue Water Acquisition Corp. on November 30, 2020).</td>
</tr>
<tr>
<td>5.1</td>
<td>Opinion of Goodwin Procter LLP (incorporated by reference to Exhibit 5.1 to the initial filing of this Registration Statement on December 17, 2021).</td>
</tr>
<tr>
<td>10.2</td>
<td>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).</td>
</tr>
<tr>
<td>10.3</td>
<td>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).</td>
</tr>
<tr>
<td>10.5</td>
<td>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).</td>
</tr>
<tr>
<td>10.6</td>
<td>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).</td>
</tr>
<tr>
<td>10.7</td>
<td>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).</td>
</tr>
<tr>
<td>10.8</td>
<td>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 Company on September 30, 2021).</td>
</tr>
<tr>
<td>10.9</td>
<td>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).</td>
</tr>
<tr>
<td>10.10</td>
<td>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 Company on September 30, 2021).</td>
</tr>
<tr>
<td>10.11</td>
<td>Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 to the initial filing of this Registration Statement on December 17, 2021).</td>
</tr>
<tr>
<td>10.12</td>
<td>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/A filed by Blue Water Acquisition Corp. on June 25, 2021).</td>
</tr>
<tr>
<td>10.13</td>
<td>Ninth Amendment to Office Lease dated as of December 17, 2021, by and between Clarus Therapeutics, Inc. and MJH Northbrook LLC (incorporated by reference to Exhibit 10.13 to the initial filing of this Registration Statement on December 17, 2021).</td>
</tr>
<tr>
<td>10.14</td>
<td>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).</td>
</tr>
<tr>
<td>10.15†</td>
<td>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 Blue Water Acquisition Corp. on June 25, 2021).</td>
</tr>
<tr>
<td>10.16</td>
<td>Supplemental Indenture No. 1, dated May 27, 2021 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 Blue Water Acquisition Corp. on July 19, 2021).</td>
</tr>
<tr>
<td>10.19</td>
<td>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).</td>
</tr>
<tr>
<td>10.20</td>
<td>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).</td>
</tr>
<tr>
<td>10.21</td>
<td>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).</td>
</tr>
<tr>
<td>10.22</td>
<td>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).</td>
</tr>
<tr>
<td>10.23</td>
<td>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).</td>
</tr>
<tr>
<td>10.24</td>
<td>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).</td>
</tr>
<tr>
<td>10.25</td>
<td>Registration Rights Agreement, dated September 9, 2021, by and among the Company, Blue Water Sponsor LLC and Legacy 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).</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>10.26</td>
<td>Form of Stockholder Lock-Up Agreement by and between the Company and the stockholder of Legacy 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 the Proxy Statement/Prospectus).</td>
</tr>
<tr>
<td>10.27</td>
<td>Form of Lender Lock-Up Agreement by and between the Company and the noteholder of Legacy 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).</td>
</tr>
<tr>
<td>10.28</td>
<td>Warrant Agreement, dated December 15, 2020, by and between Blue Water Acquisition Corp. and Continental Stock Transfer &amp; 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).</td>
</tr>
<tr>
<td>10.29</td>
<td>Promissory Note, dated June 30, 2020, issued to Blue Water Sponsor LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed by Blue Water Acquisition Corp. on September 3, 2020).</td>
</tr>
<tr>
<td>10.30</td>
<td>Letter Agreement, dated December 15, 2020, by and among Blue Water Acquisition Corp., its officers, directors and Blue Water Sponsor LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed by Blue Water Acquisition Corp. on December 21, 2020).</td>
</tr>
<tr>
<td>10.31</td>
<td>Securities Subscription Agreement, dated June 30, 2020, between Blue Water Acquisition Corp. and Blue Water Sponsor LLC (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed by Blue Water Acquisition Corp. on September 3, 2020).</td>
</tr>
<tr>
<td>10.32</td>
<td>Private Placement Warrant Purchase Agreement, dated December 15, 2020, between Blue Water Acquisition Corp. and Blue Water Sponsor LLC (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K, filed by Blue Water Acquisition Corp. on December 21, 2020).</td>
</tr>
<tr>
<td>10.33</td>
<td>Securities Purchase Agreement, dated December 3, 2021, among the Company and each purchaser party thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed by the Company on December 7, 2021).</td>
</tr>
<tr>
<td>10.34</td>
<td>Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed by the Company on December 7, 2021).</td>
</tr>
<tr>
<td>10.35</td>
<td>Form of Common Stock Warrant (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K, filed by the Company on December 7, 2021).</td>
</tr>
<tr>
<td>10.36</td>
<td>Registration Rights Agreement, dated December 7, 2021, among the Company and each purchaser party thereto (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K, filed by the Company on December 7, 2021).</td>
</tr>
<tr>
<td>21.1</td>
<td>List of Subsidiaries of Clarus Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 21.1 to the initial filing of this Registration Statement on December 17, 2021).</td>
</tr>
<tr>
<td>23.1*</td>
<td>Consent of RSM US LLP, independent registered public accounting firm of Clarus Therapeutics Holdings, Inc.</td>
</tr>
<tr>
<td>23.2</td>
<td>Consent of Goodwin Procter LLP (included as part of Exhibit 5.1).</td>
</tr>
<tr>
<td>24.1</td>
<td>Power of Attorney (incorporated by reference to the signature page of the initial filing of this Registration Statement on December 17, 2021).</td>
</tr>
<tr>
<td>101.INS*</td>
<td>XBRL Instance Document</td>
</tr>
<tr>
<td>101.SCH*</td>
<td>XBRL Taxonomy Extension Schema Document</td>
</tr>
<tr>
<td>101.CAL*</td>
<td>XBRL Taxonomy Extension Calculation Linkbase Document</td>
</tr>
</tbody>
</table>
Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that: Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act, that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Post-Effective Amendment No. 1 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Northbrook, State of Illinois on April 1, 2022.

CLARUS THERAPEUTICS HOLDINGS, INC.

/s/ Robert E. Dudley
Name: Robert E. Dudley, Ph.D.
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the date indicated.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Title</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>/s/ Robert E. Dudley</td>
<td>President, Chief Executive Officer, and Director</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td></td>
<td>(Principal Executive Officer)</td>
<td></td>
</tr>
<tr>
<td>/s/ Richard Peterson</td>
<td>Chief Financial Officer</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td></td>
<td>(Principal Financial Officer and Principal Accounting Officer)</td>
<td></td>
</tr>
<tr>
<td>*</td>
<td>Chairman of the Board</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>Kimberly Murphy</td>
<td>Director</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>*</td>
<td>John Amory</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>*</td>
<td>Elizabeth Cermak</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>*</td>
<td>Joseph Hernandez</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>*</td>
<td>Mark Prygocki</td>
<td>April 1, 2022</td>
</tr>
<tr>
<td>*</td>
<td>Alex Zisson</td>
<td>April 1, 2022</td>
</tr>
</tbody>
</table>

* By: /s/ Robert E. Dudley
   Robert E. Dudley, Ph.D.
   As Attorney-in-Fact
Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the use in this Post-Effective Amendment No. 1 to the Registration Statement (No. 333-259915) on Form S-1 of Clarus Therapeutics Holdings, Inc. of our report dated March 31, 2022, relating to the consolidated financial statements of Clarus Therapeutics Holdings, Inc., appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to our firm under the heading "Experts" in such Prospectus.

/s/ RSM US LLP

Chicago, Illinois
April 1, 2022