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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission File Number 001-38890

Quince Therapeutics, Inc.

(Exact name of registrant as specified in its Charter)

Delaware	**90-1024039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
601 Gateway Boulevard, Suite 1250 South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 910-5717

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	QNCX	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7265(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $70 million, based on the closing price of the registrant's common stock, as reported by the Nasdaq Global Select Market on June 30, 2022 of $2.22 per share.

The number of shares of the registrant's common stock outstanding as of March 10, 2023 was 36,276,945.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement (the "Proxy Statement") relating to its 2023 Annual Meeting of Stockholders. The Proxy Statement will be filed with the United States Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, forward-looking statements may be identified by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "expect," "objective," "plan," "potential," "seek," "grow," "target," "if," and similar expressions intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, including risks described in the section titled “Risk Factors” set forth in Part I, Item 1A of this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission (the "SEC"). It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur, and actual results may differ materially and adversely from those anticipated or implied in the forward-looking statements. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our ability to successfully execute on our current strategic direction;
- our ability to successfully identify and acquire or in-license one or more clinical-stage assets targeting debilitating and rare diseases;
- the success of our pursuit of business development opportunities for our suspended programs;
- future research and development activities, including the scope, success, cost and timing of any future development activities, preclinical studies and clinical trials, including clinical trials of in-licensed, or acquired compounds or other pipeline compounds we advance through the drug development process;
- the timing and focus of any potential future clinical trials, and the reporting of data from those trials;
- our ability and timing of seeking and obtaining FDA and any other regulatory approval for our potential drug candidates;
- the willingness of the FDA or other regulatory authorities to accept any future completed or planned clinical and preclinical studies and other work, as the basis for review and approval of our potential drug candidates for their respective indications;
- success of our clinical development and business strategy, including our ability to realize expected cost saving from our recent reduction in force;
- the ability of any future clinical trials to demonstrate safety and efficacy of our potential drug candidates, and other positive results;
- our financial performance;
- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements, including the acquisition of potential drug candidates;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our potential drug candidates;
- our plans relating to commercializing our potential drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any potential drug candidates for which we obtain approval;
- our ability to attract and retain key scientific and clinical personnel, in light of recent management changes and reduction in force;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;

- our reliance on third parties to conduct clinical trials of our drug candidates, and for the manufacture of our drug candidates for preclinical studies and clinical trials;
- the potential effects of the shut down of our lab facility;
- our ability to expand our potential drug candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety and efficacy of our potential drug candidates;
- governmental or regulatory delays, information requests, clinical holds, and regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our potential drug candidates, and any related restrictions, limitations and/or warnings in the label of any approved drug candidate;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our potential drug candidates and technology; and
- potential claims relating to our intellectual property.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

You should not rely upon forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, we do not intend to update any of these forward-looking statements after the date of this Annual Report on Form 10-K or to conform these statements to actual results or revised expectations.

You should read this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

This Annual Report on Form 10-K contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. We obtained the industry, market and similar data set forth in this report from our own internal estimates and research and from academic and industry research, publications, surveys and studies conducted by third parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe that the data we use from third parties are reliable, we have not separately verified these data. Further, while we believe our internal research is reliable, such research has not been verified by any third party. You are cautioned not to give undue weight to any such information, projections and estimates.

Summary of Risk Factors

We may be unable for many reasons, including those that are beyond our control, to implement our business strategy successfully. The occurrence of any single risk or any combination of risks could materially and adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. Some of these risks are:

- The impact and results of our previously announced strategic direction are uncertain and may not be successful.
- We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.
- We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.
- There can be no assurance that we will be successful in our pursuit of business development opportunities for our suspended preclinical programs.

- We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the Acquisition, or any potential acquisition of new assets that we may pursue.
- If we are unable to successfully out-license our bone targeting assets, our business could materially suffer.
- Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.
- Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.
- We are a preclinical stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.
- We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.
- We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.
- Clinical failure can occur at any stage of clinical development and we have never conducted a Phase 3 trial or submitted an NDA before.
- If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.
- We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.
- The shut down of our lab facilities may result in impairment loss on our lease as well as the sale of our fixed assets.
- If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.
- The COVID-19 pandemic, as well as other public health crises, catastrophic events or other events outside of our control, may adversely affect our capabilities or the capabilities of third parties on which we depend.

PART I

Item 1. Business.

We are a preclinical stage biopharmaceutical company focused on advancing innovative precision therapeutics for debilitating and rare diseases.

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. Our predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis, or P. gingivalis, and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. Following the Acquisition, we changed our corporate name to Quince Therapeutics, Inc.

On January 27, 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc.

On January 30, 2023, we provided an update on our development pipeline and business outlook for 2023. We intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. We plan to partner or out-license to support further development of our bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

2022 and 2023 Key Events

- In January 2022, we received a letter from the U.S. Food and Drug Administration (FDA) placing a full clinical hold on atuzaginstat's (COR388). In response, we implemented a cost reduction program to rationalize operations and to allow continued support for the continuing business operations.
- In January 2022, Casey Lynch resigned as chairperson of the board and as president and Chief Executive Officer and Steve Dominy resigned as a director on the Board and as the Chief Scientific Officer.
- In May 2022, we completed the acquisition of Novosteo, Inc. ("Novosteo"), a privately-held biotech company focused on targeted therapeutics to treat rare skeletal diseases, bone cancer and injury.
- In conjunction with the acquisition of Novosteo, we appointed Dirk Thye, M.D. as Chief Executive Officer, Dr. Karen Smith, M.D., Ph.D. as Chief Medical Officer and Brendan Hannah as Chief Business Officer.
- In January 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., an entity co-founded by Casey Lynch, former Chief Executive Officer of our predecessor company, Cortexyme, Inc.

Drug Candidate Portfolio

NOV004

NOV004 was discovered using our broad drug-targeting platform designed to precisely deliver small molecules, peptides, or large molecules directly to the site of bone fracture and disease to promote more rapid healing. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. By improving fracture site accumulation and retention, NOV004 stimulates a robust healing response in preclinical studies. Notable preclinical observations include:

- In a fracture induction study in healthy mice, at 3 weeks post femur fracture, NOV004 treated mice could withstand greater than 1.5 times the force in a four-point bend test compared to both the vehicle controls and the non-targeted bone anabolic peptide at the same point in time.
- Similar improvements in fracture repair have been observed in mouse bone fracture models with comorbidities such as osteoporosis, diabetes, or osteogenesis imperfecta – a rare genetic bone disease that manifests in skeletal deformities and high fracture rates.

- Other improvements in fracture repair were observed by tracking animal's voluntary movements. As early as 12 days post fracture, mice treated with NOV004 moved significantly faster, as measured by cm/s travelled, than either the mice treated with vehicle or ibuprofen (8.1 cm/s vs 6.0 cm/s and 5.5cm/s respectively). In addition, by day 28, both distances traveled (cm) and time spent (seconds) were also significantly higher in NOV004 treated mice compared to vehicle or ibuprofen controls.

Our discovery pipeline is potentially applicable across multiple skeletal therapeutic indications to address underserved therapeutic areas with major, unmet medical needs, including osteogenesis imperfecta, fractures, spinal fusion, and other severe bone diseases. We are currently exploring partnership and out-licensing opportunities to support the future development of NOV004.

Legacy Small Molecule Protease Inhibitor Portfolio

Atuzaginstat (COR388)

Atuzaginstat (COR388) is a novel, orally-administered, small molecule, bacterial protease inhibitor targeting gingipains produced by the periodontal pathogen Porphyromonas gingivalis (P gingivalis). This pathogen has been associated with several diseases in humans including Alzheimer's disease, periodontal disease and certain head and neck cancers. On October 26, 2021, we announced top-line results from our global Phase 2/3 clinical trial of atuzaginstat (COR388), called the GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) trial, in mild to moderate Alzheimer's patients. The 643-participant study did not meet statistical significance on its co-primary cognitive and functional endpoints as measured by ADAS-Cog11 and ADCS- ADL at end of the treatment period in the overall cohort.

On January 25, 2022, we received a letter from the Food and Drug Administration ("FDA") Division of Neurology 1 placing a full clinical hold on the IND application for atuzaginstat (COR388). We sold this compound to Lighthouse Pharmaceutical, Inc., see "Sale of legacy portfolio" section below.

COR588

COR588 is a second-generation brain penetrant lysine gingipain inhibitor which has completed IND-enabling studies. We began a Phase 1 SAD/MAD trial of COR588 in a cohort of healthy participants in Australia in August 2021. In March 2022, we announced results from the SAD portion of the Phase 1 trial and in July 2022 we announced results from the MAD portion of the Phase 1 trial. Preliminary results indicate COR588 was well-tolerated across all cohorts in the dose range from 25 mg to 200 mg with no serious adverse events. No clinically significant findings were observed on other safety measures, including vital signs, laboratory findings, telemetry, or ECGs. We sold this compound to Lighthouse Pharmaceutical, Inc., see "Sale of legacy portfolio" section below.

COR803

COR803 for coronavirus is a novel patent-pending small molecule 3CL pro inhibitor discovered and developed by us based on our expertise in cysteine protease inhibition. We sold this compound to Lighthouse Pharmaceutical, Inc., see "Sale of legacy portfolio" section below.

Business Acquisition

On May 19, 2022, we acquired all of the equity voting interests and completed the acquisition of Novosteo (the "Acquisition") pursuant to a certain Agreement and Plan of Merger and Reorganization dated as of May 9, 2022 (the "Merger Agreement"). To effect this transaction, a combination of transactions was executed with the intention of being treated as integrated steps in a single transaction resulting in Novosteo being a wholly owned subsidiary of the Company.

In conjunction with the Acquisition, we appointed Novosteo executives Dirk Thye, M.D. as Chief Executive Officer, Dr. Karen Smith, M.D., Ph.D. as Chief Medical Officer and Brendan Hannah as Chief Business Officer. We also appointed Dr. Thye and Philip S. Low, Ph.D. to our Board of Directors as Class II and Class I directors, respectively.

Effective August 1, 2022, we changed our corporate name from Cortexyme, Inc. to Quince Therapeutics, Inc. and our ticker symbol from "CRTX" to "QNCX".

Sale of Legacy Portfolio

On January 27, 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803 (the "Transaction"), pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc. (the "Purchaser").

Upon the consummation of the Transaction, we received shares of common stock of Purchaser ("Common Stock") equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by us and Purchaser on January 27, 2023 (the "Stock Agreement"). The Stock Agreement contains certain anti-dilution rights and certain transfer restrictions on the Common Stock, including a right of first offer in favor of Purchaser and certain restrictions with respect to non-U.S. persons.

Pursuant to the terms of the Purchase Agreement, we are eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, we are eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

We and the Purchaser have made certain covenants in the Purchase Agreement with respect to the transfer of the assets, including requisite filings to be made with regulatory authorities, and the milestone, royalty and sublicense payments and have agreed to indemnify each other for any breaches of such party's covenants, assumed liabilities (in the case of Purchaser) and retained liabilities, subject to certain customary survival periods and mitigation requirements. In addition, Purchaser granted to us an exclusive option until June 30, 2023 to obtain worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license under the transferred intellectual property related to COR388 to research, develop, manufacture, use, commercialize and otherwise exploit COR388 in any animal health indication.

Corporate Restructuring

In January 2023, we made the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities. As a result, we approved the cost reduction program (the "Plan") to align operations with the changes in corporate strategy. Under the Plan, we are reducing headcount by approximately 47% through a reduction in our workforce. The reduction in force began in February 2023 and is expected to be completed by April 2023. As a result, we expect to realize estimated annualized operating expense savings of approximately $10 million in the year ending December 31, 2023 (excluding share-based compensation and any one-time costs related to strategic actions).

In connection with the Plan, we estimate that we will incur expenses of approximately $0.6 million to $0.8 million, substantially all of which will be cash expenditures and other costs relating to the Plan through August 2023. We may incur other charges, including contract termination costs, retirement of fixed assets and facility-related costs and will record these expenses in the appropriate period as they are determined. These estimates are subject to a number of assumptions, and actual results may differ. we may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Plan.

Business Update Regarding COVID-19

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting the world economy and financial markets. 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, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

At this time the impact of the COVID-19 pandemic has not resulted in changes to our previously stated analysis timelines and milestones. We have not experienced significant hinderances to our operations or material negative financial impacts as compared to prior periods. We continue to assess the risks of the COVID-19 pandemic, which take into account applicable public health authority and local government guidelines and are designed to ensure community and employee safety.

The effects of the COVID-19 pandemic continue to evolve and we may have to resume a more restrictive remote work model or close again certain of our offices, whether as a result of spikes or surges in COVID-19 infection or hospitalization rates or public authority mandates. Also, as long as the pandemic continues, our employees may be exposed to health risks. We will continue to monitor the COVID-19 situation and its impact on our business and operations.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in this report.

Manufacturing

We do not currently own or operate facilities for manufacturing, storing, distributing or testing our drug candidates. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture and supply our preclinical and clinical materials to be used during the development of our drug candidate.

We are in the process of halting the manufacturing of the production of NOV004 and terminating our contracts with the manufacturing vendor. We are currently obligated to our vendors for certain drug substance and drug product development work. We do not expect to incur significant additional costs to terminate the manufacturing activities above our current contractual obligations.

Commercialization Plan

We do not currently have any approved drugs. Therefore, we have no sales, marketing or commercial product distribution capabilities and have no experience as a company in marketing drugs.

When and if any of our drug candidates are approaching commercialization, we intend to develop a commercialization infrastructure for those drug candidates in the United States and potentially in certain other key markets. We may also rely on partnerships to provide commercialization infrastructure, including sales and marketing and commercial distribution.

Competition

We face competition from a number of different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. We believe that the key competitive factors affecting the success of any drug candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

There are many bone building and osteoporosis drugs currently in development and available in the United States include anti-resorptive agents, anabolic agents, and an agent that has both anabolic and anti-resorptive characteristics. Anti-resorptive agents including bisphosphonates, hormone therapy, selective estrogen receptor modulators (SERMs), and Amgen's Prolia (denosumab), are the most common treatments for osteoporosis. Teriparatide, marketed by Lilly under the name Forteo/Forsteo (outside the U.S.) and abaloparatide, marketed by Radius Health under the name Tymlos are both anabolic drugs targeting the PTH receptor approved in the United States for the treatment of osteoporosis. We are aware of companies pursuing development in the United States of teriparatide through various regulatory pathways, including Teva Pharmaceutical Industries, Ltd., and APOTEX. We believe other companies may be in earlier stages of development of a generic version of teriparatide. Romosozumab, an anti-sclerostin monoclonal antibody for the treatment of osteoporosis, is marketed by Amgen and UCB under the name Evenity, following regulatory approval in the US, Europe and Japan.

There are several therapies in development for osteogenesis imperfecta including setrusumab, an anti-sclerostin monoclonal antibody, in development by Ultragenyx and Mereo BioPharma; SAR439459, and fresolimumab, both anti-TGF-beta monoclonal antibodies, in development by Sanofi; and romosozumab, in development by Amgen.

These competitors may influence our ability to successfully out-license NOV004 and the terms thereof.

Intellectual Property

The divesture of the legacy protease inhibitor compounds to Lighthouse Pharmaceuticals, Inc. included the associated patents. However, we maintain certain rights, including;

- Potential for Quince to receive up to $150 million in regulatory and commercial milestones payments on a product-by-product basis, subject to the terms and conditions set forth in the Purchase Agreement,
- Potential tiered royalty rates on a product-by-product basis ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, subject to the terms and conditions in the Purchase Agreement.

We actively protect our commercially important proprietary technology by, among other methods, obtaining, maintaining, and defending our patent rights. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is

called patent term extension. The period of patent term extension in the United States cannot be longer than five years and the total patent term, including the extension period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Some countries also provide mechanisms to recapture a portion of the patent term lost during regulatory review, similar to patent term extension in the United States. The amount of patent term that can be recaptured depends on the laws of the relevant jurisdictions.

We have filed or licensed numerous patent applications covering NOV004 in the United States and in jurisdictions outside of the United States. We pursue patent protection for all inventions and improvements throughout development, including, when possible, compositions of matter, methods of use, dosage regimens, formulations, and manufacturing processes.

We have licensed exclusive rights in numerous patents and patent applications relating to NOV004. Issued patents covering the compound NOV004 as a composition of matter and therapeutic methods of using NOV004 have been obtained in the United States and Russia and are estimated to expire 2037, not including any available patent term adjustments or extensions. We have also exclusively licensed additional patent applications relating to NOV004 and its method of use, which when issued, are estimated to expire between 2037 and 2041, not including any available patent term adjustments or extensions. Novosteo LLC, a wholly owned subsidiary, owns an additional patent application relating to therapeutic methods of using NOV004, which, when issued, is estimated to expire in 2042, not including any available patent term adjustments or extensions.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our drug candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We cannot guarantee that our owned pending patent application, or any patent applications that we may in the future file or license from third parties, will result in the issuance of patents. We also cannot predict the scope of claims that may be allowed or enforced in our patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our programs and drug candidates. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. For example, we cannot be certain of the priority rights of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States or other jurisdictions that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings, post-grant review, reissue, or reexamination in the USPTO and equivalent foreign courts, which could result in substantial costs to us even if the eventual outcome, which is highly unpredictable, is favorable to us. In addition, because of the extensive time required for clinical development and regulatory review of a drug candidate we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting any protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Relating to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application in the United States. In the United States, the patent term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our drug candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those drug candidates. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Relating to Our Intellectual Property."

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets and we cannot guarantee, however, that these agreements will afford us adequate

protection of our intellectual property and proprietary information rights. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached, and we may not have adequate remedies for any such breach. Additionally, some of our trade secrets and know-how for which we decide to not pursue additional patent protection may, over time, be disseminated within the industry through independent development and public presentations describing the methodology. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Relating to Our Intellectual Property."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future drug candidates may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Risk Factors—Risks Relating to Our Intellectual Property."

Regulatory Matters

Government authorities in the United States at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, sampling and export and import of pharmaceutical products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Drug Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate 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 post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each proposed indication;
- preparation and submission to the FDA of a New Drug Application, or NDA, requesting marketing for one or more proposed indications;
- review by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before an applicant begins testing a compound with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as *in vitro* and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

The IND and IRB Processes

The authorization for an IND must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects will be exposed to unreasonable health risks. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval. Specifically, the FDA has promulgated regulations governing the acceptance of foreign clinical studies not conducted under an IND, establishing that such studies will be accepted as support for an IND or application for marketing approval if the study was conducted in accordance with GCP including review and approval by an independent ethics committee, or IEC, and informed consent from subjects, and the FDA is able to validate the data from the study through an on-site inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies. If a marketing application is based solely on foreign clinical data, the FDA requires that the foreign data be applicable to the U.S. population and U.S. medical practice; the studies must have been performed by clinical investigators of recognized competence; and the FDA must be able to validate the data through an on-site inspection or other appropriate means, if the FDA deems such an inspection to be necessary.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of

development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1:* The drug is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- *Phase 2:* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3:* The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.
- *Phase 4:* Post-approval studies, which are conducted following initial approval, are typically conducted to gain additional experience and data from treatment of patients in the intended therapeutic indication.

The clinical drug development phases described above are general guidelines. The phases are not clearly delineated from each other in every regard, and it is common practice to separate (e.g., Phase 1a and 1b trials) or combine (e.g., a Phase 2/3 trial) phases, which is accepted by the FDA and other global regulatory agencies.

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. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, and the sponsor of an approved NDA is also subject to annual program fees.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the filing date, and most applications for "priority review" products are meant to be reviewed within six months of the filing date. The review process and the Prescription Drug User Fee Act goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving a NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities 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 sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. A REMS uses risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. A REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides 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.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. 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 user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP 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.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. 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 revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warning or other safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. 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.

Pharmaceutical Coverage, Pricing 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. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Even if our drug candidates are approved, sales of our products 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, such products. The process for determining whether a payor will provide coverage for a product is separate from the process for setting the price or reimbursement rate that the payor will pay for the product if 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 marketing approvals. Nonetheless, drug candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover our drug candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a 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 drug 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. Third-party reimbursement and coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Within the United States, if we obtain appropriate approval in the future to market any of our drug product candidates, those products could potentially be covered by various government health benefit programs as well as purchased by government agencies. The participation in such programs or the sale of products to such agencies is subject to regulation.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. 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 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 marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the generation of revenue, attainment of profitability, or commercialization of products. In addition, it is possible that there will be further legislation or regulation that could harm the business, financial condition and results of operations.

Outside the United States, ensuring adequate coverage and payment for our drug candidates will face challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians, certain other healthcare providers and teaching hospitals and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services (HHS), information related to payments and other transfers of value made by that entity to physicians (defined to include to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Failure to comply with the aforementioned laws can result in the imposition of significant civil, criminal and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, and integrity oversight and reporting obligations.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for drug products under government healthcare programs.

Since its enactment, there have been executive, legal and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures will impact the ACA and our business. Other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our drug candidates, if approved.

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, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid

drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures.

In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. For example, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent presidential executive orders, Congressional inquiries, and proposed federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA will, among other things (i) allow HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the "negotiated fair price" under the law and (ii) impose rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether these or similar policy initiatives will be implemented in the future. 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. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the generation of revenue, attainment of profitability, or commercialization of products. In addition, it is possible that there will be further legislation or regulation that could harm the business, financial condition and results of operations.

Employees

As of December 31, 2022, we had 21 total employees, of which 11 are in research and development and 10 are in general and administrative. Our employees are located in South San Francisco, California and West Layfette, Indiana and others work remotely from their residences located across the United States. To align operations with the changes in corporate strategy, we are reducing headcount by approximately 47% through a reduction in our workforce. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that we have good relations with our employees.

Corporate Information

We were incorporated in Delaware on June 20, 2012. Our principal executive offices are located at 601 Gateway Blvd Suite 1250, South San Francisco, CA 94080. Our telephone number at that location is (415) 910-5717. Our corporate website address is www.quincetx.com. Information contained on, or that may be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

Quince is a registered trademark of Quince Therapeutics, Inc. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. You should carefully consider the following risks, together with all of the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K

Risks Relating to Our Evaluation of Strategic Alternatives and Our Business

The impact and results of our previously announced strategic direction are uncertain and may not be successful.

As announced in January 2023, we intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Since that time, our management has been actively engaged in identifying and evaluating numerous biopharmaceutical assets for their potential fit with our corporate objectives.

Our Board remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the company and its shareholders. There can be no assurance, however, that our current strategic direction, or the Board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will enhance shareholder value.

We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.

We have no drug candidates approved for sale and none in development, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the years ended December 31, 2022 and 2021, our net losses were $51.7 million and $89.9 million, respectively. We had an accumulated deficit of $288.3 million as of December 31, 2022.

Before we are able to generate any revenue, we will need to commit substantial funds to in-license or acquire new drug candidates, then continue development of any drug candidates, and we may not be able to obtain sufficient funds on acceptable terms, if at all. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us and/or result in dilution to our stockholders.

We expect that it will be several years, if ever, before we may have a potential drug candidate ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we pursue our current strategic direction, and seek regulatory approvals for any potential drug candidates, prepare for and begin the commercialization of any approved drug candidates, and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses have fluctuated significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize a drug with significant revenue.

We may never succeed in developing a commercial drug. On January 25, 2022, the FDA placed a full clinical hold on the IND for atuzaginstat (COR388), one of our assets that has since been out-licensed. The FDA may place additional clinical holds on our current or currently contemplated clinical programs or otherwise limit our ability to proceed with other clinical programs in our pipeline, which will harm our business, financial condition, results of operations and may force us to cease our operations.

We expect to explore partnership and licensing opportunities to support the future development of NOV004, our bone targeting molecule designed to accelerate fracture repair, but we may not be able to find a suitable partner. See also the risk factor titled "Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully identify potential patients to out-license this asset." We may also encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown challenges as we pursue our current strategic direction.

There are numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional drug candidates.

We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.

The pursuit of our strategy to acquire one or more clinical-stage assets targeting debilitating and rare diseases involves significant management time, effort and associated expense, and if such assets are identified, will require us to incur significant additional expenses to consummate. Moreover, we expect to require substantial additional funding to finance such acquisitions and to advance the development and optimize the commercialization of such assets, and there can be no assurance that such additional funding will be available on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may not be able to effectively implement our strategic plan.

We may seek to raise any necessary funds through public or private equity offerings, debt financings or strategic alliances and licensing arrangements. We currently have an effective universal shelf registration statement pursuant to which we may offer and sell any combination of the securities described in the registration statement from time to time. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets.

Our acquisition strategy involves numerous risks and uncertainties, including intense competition for suitable acquisition targets, which could increase valuations or adversely affect our ability to consummate deals on favorable or acceptable terms, the potential unavailability of financial resources necessary to consummate acquisitions in the future, the risk that we improperly value and price a target, the inability to identify all of the risks and liabilities inherent in a target company notwithstanding our due diligence efforts, the diversion of management's attention from the operations of our business and strain on our existing personnel, increased leverage due to additional debt financing that may be required to complete an acquisition, dilution of our stockholder's net current book value per share if we issue additional equity securities to finance an acquisition, difficulties in identifying suitable acquisition targets or in completing any transactions identified on sufficiently favorable terms and the need to obtain regulatory or other governmental approvals that may be necessary to complete acquisitions.

There can be no assurance that we will be successful in our pursuit of business development opportunities for our suspended clinical and preclinical programs.

We are actively exploring partnership and licensing opportunities, including out-licenses, for our now suspended development program related to NOV004. We face significant competition in our pursuit of these opportunities, and any arrangements will likely be complex and time-consuming to negotiate and document. We may not be able to negotiate any such arrangements on acceptable terms, or at all.

We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the Acquisition, or any potential acquisition of new assets that we may pursue.

On May 19, 2022, we completed our previously announced Acquisition, and our new business strategy anticipated additional acquisition of one or more clinical-stage assets targeting debilitating and rare diseases. The anticipated benefits we expect from the Acquisition or any future acquisitions will depend in part on our ability to realize the expected operational efficiencies and associated cost synergies and anticipated business opportunities and growth prospects from combining new businesses in an efficient and effective manner. We may not be able to fully realize the operational efficiencies and associated cost synergies or leverage the potential business opportunities and growth prospects to the extent anticipated or at all.

Challenges associated with the integration may include those related to retaining and motivating executives and other key employees, blending corporate cultures, eliminating duplicative operations, and making necessary modifications to internal control over financial reporting and other policies and procedures in accordance with applicable laws.

Our management may face significant challenges in consolidating the operations of potential new businesses, integrating the technologies, procedures, and policies. Some of these factors are outside our control, and any of them could delay or increase the cost of our integration or out-licensing efforts.

The integration process could take longer than anticipated and could result in the loss of key employees, the disruption of each company's ongoing businesses, increased tax costs, inefficiencies, and inconsistencies in standards, controls, information technology systems, policies and procedures, any of which could adversely affect our ability to maintain relationships with employees or third parties, or our ability to achieve the anticipated benefits of the transaction, and could harm our financial performance. If we are unable to successfully integrate certain aspects of the new operations or experience delays, we may incur unanticipated liabilities and be unable to fully realize the potential benefit of future revenue and other anticipated benefits resulting from the arrangement, and our business, results of operations and financial condition could be adversely affected.

Our stockholders may realize little or no value from the divestiture of our legacy assets or potential out-license of NOV004, and as a result our stock price may decline, we could be subject to litigation, and our business may be adversely affected.

We have recently sold our legacy small molecule protease inhibitor portfolio to Lighthouse Pharmaceuticals, which is a newly organized, private development stage company in the start-up phase, and has only recently commenced its operations. There is currently no existing public market for the shares of Lighthouse Pharmaceuticals' common stock, and there can be no assurance that an active public market will ever develop. The absence of an active public market for these securities would make it difficult for us to sell the shares of Lighthouse Pharmaceuticals' common stock and realize any value from them. To date, Lighthouse's operations have

been primarily limited to organizing and staffing its company and completing the acquisition of our legacy assets. Accordingly, it is difficult if not impossible to predict Lighthouse's future performance or to evaluate its business and prospects, or ability to develop our legacy assets. For these and other reasons, our stockholders may realize little or no value from the divestiture of our legacy assets.

The divestiture of our legacy assets or recently announced change in our corporate strategy, including potential partnership or licensing of NOV004, could result in litigation against us, including litigation arising from or related to the value, received in the sale of our legacy assets to Lighthouse. For example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our small molecule protease inhibitor portfolio, others because they were interested in our bone-targeting drug platform. Thus, certain stockholders may attribute substantial financial value to our legacy assets or NOV004. If our stockholders believe that the financial value which is or may be received by us or them from the divestiture of our assets is inadequate, our stock price may decline and litigation may occur. As a result of these and other factors, we may be exposed to a number of risks, including declines or fluctuations in our stock price, additional legal fees, and distractions to our management caused by activities undertaken in connection with resolving any disputes related to these transactions. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition.

Our future results could suffer if we do not effectively manage our operations.

In connection with our new strategic pursuits, we may expand our size and operations through acquisitions or other strategic transactions. Our future success depends, in part, upon our ability to manage such expanded business, which may pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. There can be no assurances that we will be successful or that we will realize the expected synergies and other benefits anticipated from any future acquisitions or strategic transactions that we may undertake in the future.

The Novosteo Acquisition may result in impairment charges from the recording of goodwill and intangible assets that could adversely affect our financial results.

Our financial results may be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with the Novosteo Acquisition. For example the company incurred a $0.8 million goodwill impairment charge in the quarter ended September 30, 2022. Due to the announced changes in corporate strategy on January 30, 2023, we will perform an impairment analysis of our IPR&D intangible asset. The amount and timing of further possible charges are not yet known. If such assets are found to be impaired, they will be written down to their estimated fair value, with a charge against earnings. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we are assuming as a result of the Novosteo Acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates. Our acquisition and in-licensing efforts focus on identifying assets in development by third parties across a diverse range of therapeutic areas that, in our view, are underserved or undervalued. We may decide to proceed with the development of a product candidate and later determine that the more costly and time intensive trials do not support the initial value the product candidate was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction, we might incur costs in excess of what we anticipate, and management resources and attention might be diverted from other necessary or valuable activities. For instance, in May 2022, we completed our acquisition of Novosteo, Inc. In connection with the acquisition and our integration of Novosteo’s historical operations into our business, the attention of certain members of each company’s management and each company’s resources were diverted from day-to-day business operations. Additionally, the interests of our stockholders were diluted as a result of our issuance of shares of our common stock to Novosteo’s

stockholders and our assumption of certain equity awards of Novosteo's in connection with the transaction. We may engage in similar discussions in the future with respect to other potential transactions that may divert our time and resources from our ongoing operations.

Risks Related to Our Business and the Development of Our Drug Candidates

If we are unable to successfully out-license our bone targeting assets, our business could materially suffer.

We have developed our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. Currently, we intend to explore partnership and licensing opportunities to support the future development of NOV004. However, we may not be able to identify suitable partners. If we are unable to identify suitable partners for our indications or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer. Additionally, while we have sold our legacy assets, we may not realize the benefits of that sale.

Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.

NOV004 is a precision bone growth molecule for rare disease. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with NOV004, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, or patient foundations, and may prove to be incorrect or contain errors. New studies have in the past and may continue to change the estimated incidence or prevalence of these diseases. We cannot accurately predict the number of patients for whom treatment might be possible. Additionally, since the potentially addressable patient population for this product candidates is limited, even if we successfully license these assets, and our partners obtain commercial approval, they may not be able to achieve significant market share for NOV004. Because the potential target populations are very small, we may not realize any significant return from the potential sale of this asset.

Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs is extremely risky. Only a small percentage of drug candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidate may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier preclinical studies or clinical trials. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete preclinical studies or clinical trials of any future drug candidates, due to safety or efficacy concerns, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for our current and any future drug candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those drug candidates. Moreover, if we are not able to differentiate our drug candidate against other approved drug candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.

Our strategy is to identify and pursue clinical development of drug candidates. Identifying, developing, obtaining regulatory approval and commercializing drug candidates will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire drug candidates, advance any drug candidates through the development process, successfully commercialize any such drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize drug candidates. If we are unable to successfully identify, acquire, develop and commercialize drug candidates, we may not be able to continue our operations.

We will incur additional costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our potential drug candidates, including:

- regulatory authorities, institutional review boards or ethics committees, or IRBs or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or we may fail to reach a consensus with regulatory authorities on trial design;
- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may differ from each other on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may not be able to generate sufficient preclinical data to support clinical development for potential drug candidates;
- we may require preclinical studies or manufacturing of drug supplies for our potential drug candidates, which may delay our timeline for the clinical development for our potential drug candidates;
- we may experience delays in reaching a consensus with regulatory agencies on preclinical and clinical study design;
- we may not be able to obtain appropriate or sufficient test agents or preclinical animal models in connection with the indications out potential drug candidates are meant to address;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations, or CROs, and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- changes to clinical trial protocols;
- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate, and we may lack adequate funding to continue one or more clinical trials;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities or institutional review boards to suspend or terminate the trials;

- occurrence of serious adverse events in trials of the same class of agents conducted by other companies; and
- the occurrence of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States, Australia or Europe.

Preclinical studies and clinical trials are expensive and time consuming, additional or unsuccessful clinical trials could cause our clinical development activities to be delayed or otherwise adversely affected.

The risk of failure is high for any potential drug candidates we may acquire that are in clinical and preclinical development. The clinical trials and manufacturing of our potential drug candidates are, and the manufacturing and marketing of our potential drug candidates, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our drug candidates. Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate thorough lengthy, complex and expensive preclinical testing and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. We may not be able to develop a trial design that the FDA and other foreign regulatory authorities can accept. Each potential drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if any future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our potential product candidates for their targeted indications or support continued clinical development of such product candidates. Our ongoing and any future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our potential drug candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our potential drug candidates.

If we are required to conduct preclinical studies, clinical trials or other testing of our potential drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our potential drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our potential drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications, dosages or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the medicine removed from the market after obtaining marketing approval.

Drug development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be amended or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our potential drug candidates, if approved, any of which may harm our business and results of operations. In addition, many of the factors that cause, or lead to a delay in the commencement or completion of, clinical trials may also ultimately lead to termination or suspension of a clinical trial. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our potential drug candidates will harm our commercial prospects and our ability to generate revenues.

Risks Relating Our Financial Position

We are a preclinical stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. After the Acquisition in 2022, we shifted our operational focus on the development of our bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. In January 2023, we made a strategic decision to out-license our bone-targeting drug platform and prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of other clinical-stage assets targeting debilitating and rare diseases. We have a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have only initiated one late stage clinical trial, and have not obtained marketing approval for any drug candidate, manufactured a commercial scale drug candidate, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful drug candidate commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we evaluate potential drug candidates. In addition, if we obtain marketing approval for any future drug candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution.

Accordingly, we will need to obtain substantial additional funding in order to fully execute on our corporate strategy. As of December 31, 2022, we had $93.8 million in cash, cash equivalents and investments. Our balance sheet includes publicly-traded corporate debt securities. We may be required to recognize impairments in the value of these investments if the relevant companies are materially adversely effected, become unable to repay debt securities when due, or experience credit rating downgrades, or if the public trading price of these securities decreases.

We believe that our existing capital resources will be sufficient to fund our projected operations through at least 2026, but does not include any costs or cash expenditures associated with in-licensing activities. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- our ability to successfully identify partnership and licensing opportunities to support the future development of NOV004;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our potential drug candidates;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and drug candidates and other market developments;

- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. Additionally, while the potential global economic impact and the duration of the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant long-term disruption of global financial markets, which could in the future reduce our ability to access capital and negatively affect our liquidity. In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity. Furthermore, a recession or decline in market value resulting from the spread of COVID-19 could materially affect our operations, overall yields from our investment portfolio, including through impairment and loss of investment, and the value of our common stock.

Risks Relating to Regulatory Review and Approval of Our Drug Candidates and Other Legal Compliance Matters

We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.

We currently have no drug candidates approved for sale and we cannot guarantee that we will ever have marketable drug candidates. Our ability to generate revenue related to sales, if ever, will depend on the successful development and regulatory approval of our potential product candidates.

The development of a drug candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market any potential drug candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA. We have not submitted any marketing applications for a drug candidate.

NDAs must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding our drug candidates or other drug candidates. Also, regulatory approval for any of our drug candidates may be withdrawn.

Clinical failure can occur at any stage of clinical development and we have never conducted a Phase 3 trial or submitted an NDA before.

The FDA or other foreign regulatory authorities may limit our ability to proceed with potential clinical programs, which could have a materially adverse impact on us. The submission of a successful NDA is a complicated process. As an organization, we have never conducted a registrational clinical trial and have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in seeking approval for, and if approved, commercializing our drug candidates, and failure to successfully complete any of these activities in a timely manner for any of our drug candidates could have a material adverse impact on our business and financial performance. The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our drug candidates;
- inability to obtain approval from IRBs to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients, which have resulted and may result in a full or partial clinical hold by the FDA or non-U.S. regulators;
- inability to timely manufacture sufficient quantities of the drug candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates;
- inability to retain enrolled patients after a clinical trial is underway; and
- enrollment may be delayed or interrupted or patients may drop out of clinical trials due to or the fear of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States or Europe. For example, the coronavirus outbreak may delay or impede enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to release clinical results and could impact our product candidates testing, development and timelines.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, if we are required to conduct additional clinical trials or other preclinical studies of our drug candidates beyond those contemplated, our ability to obtain regulatory approval of these drug candidates and generate revenue from their sales would be similarly harmed.

If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. Each drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our potential drug candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our potential drug candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial

protocols and the rate of dropout among clinical trial participants. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in degenerative diseases, where failure rates historically have been higher than in many other disease areas. Most drug candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our drug candidates for approval. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of any of our drug candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our drug candidates. Even if regulatory approval is secured for any of our drug candidates, the terms of such approval may limit the scope and use of our drug candidate, which may also limit its commercial potential.

We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.

We rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical trials. We also rely on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our future drug development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with current good clinical practice regulations, or GCP, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register any future clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Reliance on third-party manufacturers entails additional risks, such as the possible breach of the manufacturing agreement by the third party, the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us and reliance on the third party for regulatory compliance, quality assurance, safety and related reporting. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any drug candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our future clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any drug candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential drug revenue.

The shutdown of our lab facility may result in impairment loss on our lease as well as the sale of our fixed assets.

We presently develop our product candidates at our lab facilities in West Lafayette, Indiana. Due to the announced changes in corporate strategy on January 30, 2023, we anticipate impairment of our financing and operating lease right of use asset, as well as a loss on the sale of our fixed assets in the first quarter of 2023. The successful closure of our West Lafayette lab facility will require certain personnel to remain employed with the Company through the closure. If these employees do not remain with the Company, it could adversely impact our closure timelines and our related expenses with closing the facility.

If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our potential drug candidates are highly regulated and subject to multiple risks. As drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our potential drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In order to conduct clinical trials of our potential drug candidates, or supply future commercial drug candidates, if approved, we will need to manufacture them in small and large quantities. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our drug candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our potential drug candidates in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any potential drug candidates that we may develop is subject to FDA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including complying with current good manufacturing practices, or cGMPs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce drug candidates in accordance with the requirements of the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such future drug candidates. Even if we obtain regulatory approval for any of our potential drug candidates, there is no assurance that either we or our third party contract manufacturers will be able to manufacture the approved drug in accordance with the requirements of the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the drug, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical drug candidates. To achieve commercial success for any approved potential drug candidate for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with collaborators for, some of our potential drug candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, factors that may inhibit our efforts to commercialize any potential drug candidates, if and when approved, whether alone or in collaboration with others:

- our inability to recruit and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs, and other support personnel;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved drug candidates;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our drug candidates at a sufficient price point to ensure an adequate and attractive level of profitability;
- the pricing of our products, particularly as compared to alternative treatments;
- availability of alternative effective treatments for indications our therapeutic candidates are intended to treat and the relative risks, benefits and costs of those treatments;
- restricted or closed distribution channels that make it difficult to distribute our drug candidates to segments of the patient population;
- the lack of complementary drug candidates to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug candidate lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If the commercial launch of a future drug candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our sales revenue or the profitability of sales revenue may be lower than if we were to market and sell any drug candidates we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our potential drug candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our potential drug candidates if approved in the future.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk when and if we commercialize any drug candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our drug candidates. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our drug candidates;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- drug recalls, withdrawals or labeling, marketing or promotional restrictions;
- termination of clinical trial sites or entire trial programs;

- injury to our reputation and significant negative media attention;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drug candidates we develop, alone or with potential collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be exposed to a variety of international risks that could materially adversely affect our business.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States. In particular, we are conducting clinical trial operations in Australia. We may enter into agreements with third parties for the development and commercialization of drug candidates in international markets. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called "parallel importing," which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- the potential for so-called "parallel exporting," which is what occurs when a local seller buys goods meant for the locals and sells the goods for a higher price in another country, potentially causing or aggravating supply problems;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries;
- taxes in other countries;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism, public health crises, such as pandemics and epidemics, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

The COVID-19 pandemic, as well as other public health crises, catastrophic events or other events outside of our control, may adversely affect our capabilities or the capabilities of third parties on which we depend.

Our headquarters are located in California near major geologic faults that have experienced earthquakes in the past. An earthquake or other natural disaster or power shortages or outages could disrupt operations, impair critical systems or result in loss of clinical samples. Any of these disruptions or other events outside of our control could have a material adverse impact on our business, harming our operating results. In addition, if any of our suppliers or third-party service providers, such as our manufacturing partners or CROs, are affected by natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control, our business and operating results could suffer. Disasters, public health crises and political crises occurring at third-party facilities also could negatively impact our clinical development and regulatory approval timelines, our reputation and the perception of our company. For example, as a result of the COVID-19 pandemic, we and our third-party service providers temporarily limited our operations or implemented limitations, including work-from-home policies. All employees have now returned to their pre-pandemic work locations and activities. However, as long as the pandemic continues, our employees may be exposed to health risks and government directives may require us to close again certain of our offices or our laboratory facility. In addition, as a result of "shelter-in-place" orders or other mandated travel restrictions, our on-site staff conducting research and development activities may not be able to access our laboratories, and these core activities may be significantly limited or curtailed, possibly for an extended period of time. Further, due to travel restrictions and “shelter-in-place” orders, we may experience limitations on the ability to recruit and hire key personnel due to the inability to meet with candidates and reduced ability to engage with the medical and investor communities due to the cancelation of conferences scheduled throughout the year. We also may experience operational challenges caused by sickness of our employees or their families, the desire of employees to avoid contact with large groups of people, and an increased reliance on working from home or mass transit disruptions. Furthermore, new quarantines for COVID-19 or other viruses could impact personnel at contract manufacturing facilities in the United States and Europe or elsewhere to deliver key materials or the availability or cost of starting materials. Any disruption of our contract manufacturing vendors in the United States and Europe or elsewhere to deliver key materials on a timely basis could have a material adverse effect on the initiation of new trials, the duration of open label extension studies and overall product development.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants, and the loss of such persons could negatively impact the operations of the company.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses or any other circumstances that would cause them no longer to provide their professional services to us in the near future. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. In addition, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses.

In addition, we recently announced a reduction in force, impacting a number of employees. Any further reduction in force may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees, reduced employee morale and could adversely affect our reputation as an employer, which could make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the cost reduction program.

Our industry has experienced a high rate of turnover of management personnel in recent years. Potential changes in management could be disruptive to our business and may also result in our loss of unique skills and loss of knowledge about our business. Such turnover may also result in the departure of other existing employees or partners.

Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize drug candidates successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain or replace key personnel or consultants could materially harm our business. Additionally, the members of our management team have limited experience managing a public company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that specifically govern public companies, which could cause our management to have to expend time and resources helping them become familiar with such requirements. We may lose our ability to implement our business strategy successfully and could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Non-compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing drug candidates or technologies that may compete with ours.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, which could include civil or criminal penalties, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any of our potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and

security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we violate HIPAA.

Several foreign jurisdictions, including the European Union, or the EU, its member states, the United Kingdom and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. These laws and regulations are complex and change frequently, at times due to changes in political climate, and existing laws and regulations are subject to different and conflicting interpretations, which adds to the complexity of processing personal data from these jurisdictions. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

The General Data Protection Regulation, or GDPR, imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulatory authorities and affected individuals of personal data breaches, extensive new internal privacy governance obligations, and obligations to honor expanded rights of individuals in relation to their personal information (for example, the right to access, correct and delete their data). In addition, the GDPR generally maintains restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional potential mechanisms to ensure compliance.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the European Union, or EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures will impact the ACA and our business. Other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our drug candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is unclear how these or similar policy initiatives will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent

laws, which began in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. New laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our drug candidates and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed drug candidates, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA will, among other things (i) allow HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the "negotiated fair price" under the law and (ii) impose rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved drug candidate. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates, once marketing approval is obtained.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, each individually decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs, or VA, hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our product candidates, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage or reimbursement will be available for any drug candidate that we commercialize and, if coverage or reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. In order to get coverage and reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. It is possible that a third-party payor may consider our product candidates, once approved, and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, once approved, compared to existing products, pricing of existing products may limit the amount we will be able to charge for our product candidates. once approved. Third-party payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because NOV004 is in the early stages of development, we are unable at this time to determine the likely level or method of coverage and reimbursement from third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage decisions and

reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but make their determinations independently and may impose additional restrictions. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug candidates, and our overall financial condition. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the EU, coverage and reimbursement status of any drug candidates for which we obtain regulatory approval are provided for by the national laws of EU member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

We are presently engaging in a strategy to acquire businesses, technologies or drug candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology or drug candidate into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

Interim, top-line and preliminary data from our future clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our future clinical studies, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies.

In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from future clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise

appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in funding for the FDA and other government agencies or other disruptions at these agencies could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other agencies to review and approve new drugs can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for a potential drug candidate, it will remain subject to extensive ongoing regulatory review and requirements.

If any of our future drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMPs regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our potential drug candidates will be subject to limitations on the approved indicated uses for which the drug candidate may be marketed and promoted or to the conditions of approval (including the potential for a requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in drug development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drug candidates to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our potential drug candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug candidate's approved label. As such, we may not promote our potential drug candidates for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved drug candidate labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our potential drug candidates in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our drug candidates. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug candidate is manufactured, or disagrees with the promotion, marketing or labeling of a drug candidate, such regulatory agency may impose restrictions on that drug candidate or us, including requiring withdrawal of the drug candidate from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning or untitled letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain drug candidates; or
- require a drug candidate recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our drug candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our potential drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any future marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Our operations are subject to various federal and state fraud and abuse and other healthcare laws. The laws that may impact our operations include:

- federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government.

Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require the registration of sales representatives; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including compensating physicians with stock or stock options, could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement 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 any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, drug development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our drug candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize potential future drug candidates.

We may consider collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of drug candidates depending on the merits of retaining or divesting some or all commercialization rights. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;

- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drug candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drug candidates that compete directly or indirectly with our drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more drug candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future drug candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;
- collaborators may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Relating to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.

Our commercial success will depend in part on obtaining and maintaining a combination of patent protection, trade secret protection and confidentiality agreements to protect the intellectual property related to our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the issued patents that we currently own, or in patents that may issue from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others may have filed, and in the future are likely to file, patent applications covering drug candidates that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party

will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our current or future drug candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We have applied, and we intend to continue applying, for patents covering aspects of our current drug candidates, any future drug candidates, or other proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future drug candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of December 31, 2022, we were the owner of record of 10 issued U.S. patents, 39 non-U.S. patents, and 35 pending U.S. and non-U.S. patent applications and Novosteo LLC, a wholly owned subsidiary, is the owner of record of 1 additional pending PCT patent application (all issued U.S. patents, non-U.S. patents, and pending U.S. and non-U.S. patent applications mentioned above, collectively, "the Quince patent portfolio").

As of December 31, 2022, we had seven issued U.S. patents and 36 issued non-U.S. patents in the Quince patent portfolio related to atuzaginstat (COR388), with claims directed to atuzaginstat (COR388) and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and use of these compounds in the treatment of various indications. Pending U.S. and non-U.S. patent applications in the Quince patent portfolio relate to atuzaginstat (COR388) and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, methods of using these compounds in the treatment of various indications, and methods of making these compounds.

In addition, four issued U.S. patents and four non-U.S. patents in the Quince patent portfolio relate to pharmaceutical compounds that do not encompass atuzaginstat (COR388), with claims directed to pharmaceutical compounds, pharmaceutical compositions containing these compounds, and use of these compounds in the treatment of various indications. Pending U.S. and non-U.S. patent applications relate to additional compounds in these areas, as well as to diagnostic methods and assay methods. We assigned these patents to Lighthouse Pharmaceuticals, Inc. effective January 27, 2023.

One issued U.S. patent in the Quince patent portfolio relates to NOV004, with claims directed to NOV004 and related pharmaceutical compounds and use of these compounds in the treatment of bone fractures. Pending U.S. and non-U.S. patent applications in the Quince patent portfolio relate to NOV004 and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and methods of using these compounds in the treatment of various indications.

Without patent protection on the composition of matter of our current or future drug candidates, our ability to assert our patents to stop others from using or selling our current or future drug candidates may be limited. Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our current or future drug candidates or methods involving the use of these candidates in a particular patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries, where applicable, to obtain claim coverage for inventions which were disclosed but not claimed in a particular parent patent application.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our current drug candidates, any future drug candidate, and other proprietary technologies and their uses by obtaining, defending, and enforcing patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential drug candidates;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same compounds, compositions of matter, or methods, or formulations, or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary to prevent others from practicing our technologies or to successfully commercialize any drug candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our current drug candidates, any future drug candidates, and other proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of applications we may in-license which have an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing drug candidates in those countries.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensor's operations. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time

consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We depend on a license agreement with Purdue and termination of this license could result in the loss of significant rights, which would harm our business.

On June 3, 2020, Novosteo entered into a License Agreement with Purdue Research Foundation, as amended on March 21, 2022 and July 22, 2022 (the "Purdue Agreement"). Under the Purdue Agreement, we obtained an exclusive worldwide license under certain bone fracture repair and oncology therapeutics related patents and technology developed by the Purdue University and owned by Purdue Research Foundation to make or have made, use, sell or have sold, and import, and otherwise exploit products that are covered by such patents and technology, including the right to grant and authorize sublicenses, subject to Purdue Research Foundation's consent. Such exclusive license is subject to certain rights retained by the U.S. government and Purdue Research Foundation.

In addition, we are required to pay Purdue Research Foundation annual license maintenance fee, development milestones (up to $4.25 million for each licensed product), low single digit running royalty on the gross receipts of the licensed products (subject to minimum annual royalty), and a share of certain payments that we may receive from our sublicensees. As a result, it may not be possible for us to develop and manufacture any drug candidates at a cost or in quantities sufficient to make these drugs commercially viable or to maintain current operating margins. The Purdue Agreement also requires us to bear the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the Purdue Agreement, we are required to use commercially reasonable efforts to develop, manufacture and commercialize the licensed product in accordance with a mutually agreed development timelines and commercialization plan.

If we fail to pay any sum due, miss any milestone timelines or otherwise materially breach the agreement or fail to cure such breach within specified cure period), Purdue has the right to terminate our license, and upon the effective date of such termination, we must cease all activities licensed all rights, data, information, know-how, and material licensed or transferred to us under this license agreement will revert to Purdue and all rights, data, information, know-how, material, records and registrations developed or made by us that relate in whole or in part to the activities contemplated by our amended and restated license agreement with Purdue will be transferred to Purdue. Any uncured, material breach under the license agreement could result in loss in our rights to develop and market NOV004 and experience significant delays in the development or commercialization of NOV004, which could have a material adverse impact on our operations and financial condition and results.

Further, Purdue Research Foundation or any future licensors may not always act in our best interest. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. Under the Bayh-Dole Act, the federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit in invention produced with its financial assistance. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties, including competitors, may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may

not protect those rights as fully as in the United States. If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in non-U.S. patent offices and may result in the revocation, cancellation, or amendment of any non-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents, or those of our licensor's, invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensor's. 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 does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. 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. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our current and any future drug candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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 have a material adverse effect on the price of our common stock.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their drug candidates. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's drug candidate. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents, including those of our licensor's, could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our drug candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our drug candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates.

Our success will depend in part on our ability to operate without infringing the intellectual property rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third-party patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant drug candidate. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, our collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of drug candidates or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from out-licensing our legacy assets or commercializing NOV004, or our other drug candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our drug candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult.

For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates.

We do not routinely conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our drug candidates or the use of our drug candidates;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our drug candidates. Further, we may incorrectly determine that our technologies, or drug candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our drug candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our drug candidates and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing drug candidates. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial

investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant

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, renewal fees, annuity fees and various other governmental fees on any issued patents and/or pending applications are due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. If we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. However, 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and drug candidate could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. We may also be subject to claims that former employees, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and invention assignment agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets could over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions.

Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our drug candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed.

In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technology from third parties to further develop or commercialize our drug candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our drug candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our drug candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of

our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license.

Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any exclusive licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, drug candidates identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations, we would be required to pay on sales of future drug candidates, if any, the amounts may be significant. The amount of our future royalty obligations will likely depend on the technology and intellectual property we use in drug candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize drug candidates, we may be unable to achieve or maintain profitability.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make drug candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drug candidates for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our drug candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable drug candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or drug candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our drug candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.
- Should any of these events occur, they would significantly harm our business, results of operations and prospects.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our drug candidates 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. As such, 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 drug candidates made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit, and in those countries, we and our licensors and licensees may have limited remedies if patents are infringed or if we or our licensors or licensees are compelled to grant a license to a third party, which could diminish the value of those patents. This could limit our potential revenue opportunities. Further, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories where we have patent protection but where enforcement is not as strong as that in the United States. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. 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.

European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Our patent rights may be affected by developments or uncertainty in U.S. or non-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of non-U.S. patent offices.

Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, Congress may pass patent reform legislation that is unfavorable to us.

The U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances and weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our drug candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, we may be unsuccessful in executing agreements assigning such intellectual property to us with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time, and if we do not obtain patent term extension for our drug candidates, our business may be materially harmed.

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. In addition, although upon issuance a U.S. patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such drug candidates are commercialized. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from generic

products. A patent term extension of up to five years based on regulatory delay may be available in the United States under the Hatch-Waxman Act. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single drug candidate. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the drug candidate as approved. Further, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug candidate approval and only those claims covering such approved drug candidate, a method for using it or a method for manufacturing it may be extended. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug candidate will be shortened and our competitors may obtain approval of competing drug candidates following our patent expiration, and our revenue could be reduced.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we have proposed to use with our drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed drug candidate names, including an evaluation of potential for confusion with other drug candidate names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug candidate names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks Relating to Owning Our Common Stock

The market price of our common stock is likely to be volatile and could fluctuate or decline, resulting in a substantial loss of your investment.

The market price of our common stock has been and may continue to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the outcome of our review and evaluation of strategic alternatives;
- changes in our business strategy;
- results of clinical trials;

- our ability to identify partnership and licensing opportunities to support the future development of NOV004;
- our ability to in-license or acquire clinical stage therapeutics
- any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for potential drug candidates;
- regulatory actions with respect to our potential drug candidates or our competitors' drug candidates;
- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcement of actual or anticipated reduction in force, including our recent reduction in force;
- announcements of technological innovations by us or our competitors;
- overall conditions in our industry and the markets in which we operate;
- addition or loss of significant customers, or other developments with respect to significant customers;
- changes in laws or regulations applicable to our drug candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- competition from existing drug candidates or new drug candidates that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for pharmaceutical stocks in general;
- the expiration of contractual lock-up agreements with our executive officers, directors and stockholders;
- general economic and market conditions, including developments relating to the COVID-19 pandemic and the associated economic downturn; and
- ineffectiveness of our disclosure controls or internal controls.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We may be subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business and adversely impact our business, results of operations and financial condition.

We may become the target of securities class actions or stockholder derivative claims. Securities-related class action litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs. Any preclinical or clinical trial

results that the investors may deem as unfavorable, volatility in our stock price and other matters affecting our business and operations may subject us to actual and threatened securities class actions or stockholder derivative claims. In addition, we may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of Novosteo's business and ours following the Acquisition, out-licensing of our legacy assets or any potential strategic transactions. These types of proceedings may result in substantial costs, divert management's attention from other business concerns and adversely impact our business, results of operations and financial condition.

Future sales of our common stock in the public market could cause our share price to fall.

On December 23, 2021, we entered into an Open Market Sales Agreement with Jefferies, whereby we may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market. Moreover, we have also registered under the Securities Act shares of common stock that we may issue under our equity compensation plans.

In addition, the issuance of shares under awards granted under existing or future employee equity benefit plans may cause immediate and substantial dilution to our existing stockholders. In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

The price of our common stock currently does not meet the requirements for continued listing on Nasdaq. If we fail to maintain or regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The Nasdaq Stock Market LLC has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock. The bid price of our common stock has recently closed below the minimum $1.00 per share requirement and on December 13, 2022 we received a notification of noncompliance from Nasdaq. In accordance with Nasdaq's listing rules, we will be afforded 180 calendar days to regain compliance with the bid price requirement. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

If we fail to regain compliance with the minimum bid price requirement, or if we fail to meet other continued listing requirements in the future, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to consummate a strategic transaction and raise additional financing through the public or private sale of equity securities, and would significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees and the loss of institutional investor interest.

We may be treated as a "public shell" company, which could have negative consequences, including potential Nasdaq delisting of our common stock.

We may be treated as a "public shell" company under the Nasdaq rules and the Securities Act. Although the evaluation of whether a listed company is a public shell company is based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell. Listed companies determined to be public shells by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

If Nasdaq should delist our common stock from trading, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of our common stock; the number of institutional and general investors that will consider investing in our common stock; the number of investors in general that will consider investing in our common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of our common stock; and the number of broker-dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public

shell, including the unavailability of Rule 144 thereunder for the resale of restricted securities, the inability to utilize Form S-8 for the registration of employee benefit plan securities; and the inability to utilize Form S-3 under the "baby shelf" rules applicable to companies with a non-affiliate market capitalization of less than $75 million. In addition, the potential determination that we are a public shell company or the prospective loss of our listing on Nasdaq could make us less attractive as a partner in any potential strategic transaction.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

General Risk Factors

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine;

provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions.

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.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not 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, ongoing 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 rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, 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 systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of taxable income for tax years beginning January 1, 2018.

Under Sections 382 and 383 of the Internal Revenue Code, limitations on a corporation's ability to use its NOLs and tax credit carryforwards apply if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing NOL carryforwards and other tax attributes to offset taxable income or tax liability. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we earn net taxable income in the future, our ability to use our pre-change NOL carryforwards and other tax attributes to offset such taxable income or tax liability may be subject to limitations, which could potentially result in increased future income tax liability to us.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

Our corporate headquarters are currently located in South San Francisco, California, where we lease 4,280 square feet of office, research and development, and laboratory space pursuant to a lease agreement that expires in November 2023, with the option to extend the lease until December 2023. We also lease 3,168 square feet of office space in San Diego, California that will expire in July 2023. We also lease 4,982 square feet of office and lab space for our non-clinical department in West Lafayette, Indiana that will expire in December 2023. In response to the reprioritization of our pipeline we entered into a sublease agreement for the West Lafayette property on February 27, 2023. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of business. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "QNCQ".

Our common stock has been traded under the ticker symbol "CRTX" on The Nasdaq Global Select Market since May 9, 2019, and since August 1, 2022 under the ticker symbol "QNCX". As of March 3, 2023, there were 62 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Sales of Unregistered Securities

None

Issuer Purchases of Equity Securities

None

Item 6. [Reserved.]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions, that are based on the beliefs of our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report on Form 10-K

Overview

We are a preclinical stage biopharmaceutical company focused on advancing innovative precision therapeutics for debilitating and rare diseases.

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. Our predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis, or P. gingivalis, and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. At that time we changed our corporate name to Quince Therapeutics, Inc.

Business Acquisition

On May 19, 2022, we acquired all of the equity voting interests and completed the acquisition of Novosteo, Inc. ("Novosteo"), a Delaware corporation, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of May 9, 2022, by and among the Company, Quince Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Quince Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Company, Novosteo, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the securityholders' representative. To effect this transaction a combination of transactions was executed with the intention of being treated as integrated steps in a single transaction resulting in Novosteo being a wholly owned subsidiary of the Company.

Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition (the "Effective Time"), each share of capital stock of Novosteo that was issued and outstanding immediately prior to the Effective Time was automatically cancelled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share. We issued 5,520,000 shares of common stock representing approximately 15.5% of outstanding stock on the completion of the Acquisition. We also assumed 507,108 options to purchase shares of our common stock upon conversion of the outstanding Novosteo options with awards retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition.

In conjunction with the Acquisition, we appointed Novosteo executives Dirk Thye, M.D. as Chief Executive Officer, Dr. Karen Smith, M.D., Ph.D. as Chief Medical Officer and Brendan Hannah as Chief Business Officer. We also appointed Dr. Thye and Philip S. Low, Ph.D. to our Board of Directors as Class II and Class I directors, respectively.

Effective August 1, 2022, we changed our corporate name to Quince Therapeutics, Inc. and our ticker symbol to "QNCX".

Sale of legacy portfolio

On January 27, 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., an entity co-founded by Casey Lynch, former chief executive officer of Quince's predecessor company Cortexyme, Inc. The Transaction was also consummated on January 27, 2023.

Upon the consummation of the Transaction, we received shares of common stock of Purchaser ("Common Stock") equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by us and Purchaser on January 27, 2023 (the "Stock Agreement"). The Stock Agreement contains certain anti-dilution rights and certain transfer restrictions on the Common Stock, including a right of first offer in favor of Purchaser and certain restrictions with respect to non-U.S. persons.

Pursuant to the terms of the Purchase Agreement, we are eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, we are eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

We and the Purchaser have made certain covenants in the Purchase Agreement with respect to the transfer of the assets, including requisite filings to be made with regulatory authorities, and the milestone, royalty and sublicense payments and have agreed to indemnify each other for any breaches of such party's covenants, assumed liabilities (in the case of Purchaser) and retained liabilities, subject to certain customary survival periods and mitigation requirements. In addition, Purchaser granted to us an exclusive option until June 30, 2023 to obtain worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license under the transferred intellectual property related to COR388 to research, develop, manufacture, use, commercialize and otherwise exploit COR388 in any animal health indication.

We do not expect a material gain or loss on the sale of this portfolio after deal expenses to be recognized in the first quarter of 2023.

Out-licensing of NOV004

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. Our predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis, or P. gingivalis, and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. Following the Acquisition, we changed our corporate name to Quince Therapeutics, Inc.

On January 30, 2023, we provided an update on its development pipeline and business outlook for 2023. We intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. We plan to out-license our bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

We discovered a broad bone-targeting drug platform designed to precisely deliver small molecules, peptides, or large molecules directly to the site of bone fracture and disease to promote more rapid healing with fewer off-target safety concerns compared to non-targeted therapeutics. Our discovery pipeline is positioned for rapid expansion across multiple skeletal therapeutic indications to address underserved therapeutic areas with major, unmet medical needs, including osteogenesis imperfecta, fractures, spinal fusion, and other severe bone diseases.

Corporate Restructuring

We approved the cost reduction program (the "Plan") to align operations with the changes in corporate strategy. Under the Plan, we are reducing headcount by approximately 47% through a reduction in its workforce. The reduction in force began in February 2023 and will be completed by April 2023. As a result, we expect to realize estimated annualized operating expense savings of approximately $10 million in the year ending December 31, 2023 (excluding share-based compensation and any one-time costs related to strategic actions).

In connection with the Plan, we estimate that we will incur expenses of approximately $0.6 million to $0.8 million, substantially all of which will be cash expenditures and other costs relating to the Plan through August 2023. We may incur other charges, including contract termination costs, retirement of fixed assets and facility-related costs and will record these expenses in the appropriate period as they are determined. These estimates are subject to a number of assumptions, and actual results may differ. we may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the Plan.

Financial Overview

Since commencing material operations in 2014, we have devoted substantially all of our efforts and financial resources to building our research and development capabilities, establishing our corporate infrastructure and most recently, executing our Phase

1a, Phase 1b and Phase 2/3 clinical trials of atuzaginstat (COR388), our Phase I SAD/MAD clinical trial of COR588 and to a lesser extent readying NOV004 for Phase 1 clinical trials.

To date, we have not generated any revenue and we have never been profitable. We have incurred net losses since the commencement of our operations. As of December 31, 2022, we had an accumulated deficit of $288.3 million. We incurred a net loss of $51.7 million in the year ended December 31, 2022. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and redeemable convertible preferred stock and common stock. From inception through December 31, 2022, we received net proceeds of approximately $303.7 million from the issuance of redeemable convertible preferred stock, convertible promissory notes and common stock.

On December 23, 2021, we entered into an Open Market Sales Agreement, with Jefferies, whereby we may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. During the year ended December 31, 2022, we sold 51,769 shares of common stock, resulting in net proceeds of approximately $0.6 million, after commissions and other offering costs.

As of December 31, 2022 and 2021, we had cash, cash equivalents and short-term investments of $90.2 million and $106.8 million, respectively. The balances exclude long-term investments of $3.6 million and $19.9 million as of those same periods. Our cash equivalents, short-term and long-term investments are held in money market funds, certificate of deposits, repurchase agreements, investments in corporate debt securities, municipal debt obligations and government agency obligations.

Based on our current business plans including an analysis of our contractual obligations and commitments as of December 31, 2022 we believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations through at least 2026, but does not include any costs or cash expenditures associated with in-licensing activities. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

In response to the reprioritization of our pipeline on January 30, 2023, the Board of Directors approved a cost reduction program to align operations with the change in corporate strategy to prioritize capital resources toward the expansion of its development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Under the Plan, we plan to reduce headcount by approximately 47% through a reduction in our workforce. The reduction in force began in February 2023 be completed by April 2023. In connection with the cost reduction program, we estimate that we will incur expenses of up to approximately $0.8 million, substantially all of which will be cash expenditures relating to severance through the second quarter of 2023. These estimates are subject to a number of assumptions, and actual results may differ.

We will need substantial additional funding to support our continuing operations and pursue our development strategy once we successfully in-license and acquire a clinical-stage asset targeting debilitating and rare diseases. We expect to finance our operations through the sale of equity, debt financings or other capital sources. Adequate funding may not be available to us on acceptable 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 development and commercialization of any drug candidates or delay our efforts to expand our product pipeline.

Critical Accounting Policies, Significant Judgments and Use of Estimates

For a description of our significant accounting policies, see Note 2 to our consolidated financial statements.

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions in certain circumstances that affect the amounts reported in the accompanying consolidated financial statements and related footnotes. Actual results may differ from these estimates. We base our judgments on our experience and on various assumptions that we believe to be reasonable under the circumstances.

Of our policies, the following are considered critical to an understanding of our consolidated financial statements as they require the application of subjective and complex judgment, involving critical accounting estimates and assumptions impacting our consolidated financial statements.

The critical accounting estimates relate to the following:

- Research and Development Expenses
- Stock-based Compensation Expenses
- Income Taxes
- Business Combination
- Goodwill
- Indentifiable Intangible Assets

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of clinical trial and contract manufacturing expenses related to development of our drug candidates. Also included are personnel costs for our research and product development employees, non-personnel costs such as professional fees payable to third parties for preclinical studies and research services, laboratory supplies and equipment maintenance, product licenses, and other consulting costs.

We estimate preclinical and clinical study and research expenses based on the services performed, pursuant to arrangements with contract research organizations, or CROs that conduct and manage preclinical and clinical studies and research services on our behalf. Research and development contracts vary significantly in length, and may be for a fixed amount, based on milestones or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. We estimate these expenses based on regular reviews with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. Based upon the combined inputs of internal and external resources, if the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. Our accrual is dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party vendors. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered.

To date, there have been no material differences from our accrued estimated expenses to the actual clinical trial expenses; and our methodology and assumptions used in developing these estimates have not changed materially during the periods presented. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates, which could materially affect our results of operations. Adjustments to our accruals are recorded as changes in estimates become evident. Furthermore, based on amounts invoiced to us by our service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as services are rendered. Due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our research and development activities.

Stock-Based Compensation Expense

We measure and record compensation expense using the applicable accounting guidance for share-based payments related to stock options and performance-based awards granted to our directors and employees. The fair value of stock options is determined by using the Black-Scholes option-pricing model. The fair value of performance stock option awards is estimated at the date of grant, using the Monte Carlo Simulation model. The Black-Scholes and Monte Carlo Simulation valuation models incorporate assumptions as to stock price volatility, the expected life of options or awards, a risk-free interest rate and dividend yield. In valuing our stock options and market-based stock awards, significant judgment is required in determining the expected volatility of our common stock and the expected life that individuals will hold their stock options prior to exercising. Expected volatility for stock options is based on the historical volatility of our own stock and the stock of companies within our defined peer group. Further, our expected volatility may change in the future, which could substantially change the grant-date fair value of future awards and, ultimately, the expense we record.

We expense stock-based compensation for stock options and performance awards over the requisite service period. For awards with only a service condition, we expense stock-based compensation using the straight-line method over the requisite service period for the entire award. For awards with a market condition, we expense over the vesting period regardless of the value that the award recipients ultimately receive.

We estimate the fair value of stock-based compensation utilizing the Black-Scholes and Monte Carlo Simulation option-pricing models, which are impacted by the following variables:

Expected Term—We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected Volatility—Due to our limited operating history and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of our own stock and the stock of companies within our defined peer group. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options.

Expected Dividend—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

Income Taxes

We prepare and file income tax returns based on our interpretation of each jurisdiction's tax laws and regulations. In preparing our consolidated financial statements, we estimate our income tax liability in each of the jurisdictions in which we operate by estimating our actual current tax expense together with assessing temporary differences resulting from differing treatment of items for tax and financial reporting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets.

Significant management judgment is required in assessing the realizability of our deferred tax assets. In performing this assessment, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. In making this determination, under the applicable financial accounting standards, we are allowed to consider the scheduled reversal of deferred tax liabilities, projected future taxable income and the effects of tax planning strategies. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to increase or decrease our valuation allowance, when management determines it is more likely than not that some or all of the tax benefits will not be realized. This could materially impact our consolidated financial position and results of operations.

We account for uncertain tax positions using a "more likely than not" threshold for recognizing and resolving uncertain tax positions. We evaluate uncertain tax positions on a quarterly basis and consider various factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in process audit activities and changes in facts or circumstances related to a tax position. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished, through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the "more likely than not" threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews, we have no plans to appeal or litigate any aspect of the tax position and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Business Combination

We make certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. We evaluate the inputs, processes, and outputs associated with the acquired set of activities. If the assets in a transaction include an input and a substantive process that

together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business. We account for business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed generally be recorded at their fair values as of the acquisition date.

The Company accounts for business combinations using the acquisition method pursuant to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 805. This method requires, among other things, that results of operations of acquired companies are included in the Company's financial results beginning on the respective acquisition dates, and that identifiable assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Intangible assets acquired in a business combination are recorded at fair value using a discounted cash flow model. The discounted cash flow model requires assumptions about the timing and amount of future net cash flows, the cost of capital and terminal values from the perspective of a market participant. Any excess of the fair value of consideration transferred (the "Purchase Price") over the fair values of the net assets acquired is recognized as goodwill. The fair value of identifiable assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other acquisition-related costs are expensed when incurred.

Goodwill

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We test goodwill for impairment annually and when events or changes in circumstances indicate that the carrying value may not be recoverable. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. In performing the annual impairment test, the fair value of the reporting unit is compared to its corresponding carrying value, including goodwill. If the carrying value exceeds the fair value of the reporting unit an impairment loss will be recognized for the amount by which the reporting unit's carrying amount exceeds its fair value, not to exceed the carrying amount of goodwill. We performed our goodwill impairment test in October 2022 and concluded that goodwill was impaired as the carrying amount of the reporting unit exceeded its fair value, including goodwill. As a result, we recorded an impairment of $0.8 million in the quarter ended September 30, 2022.

Indentifiable Intangible Assets

We have acquired an intangible asset through our recent business combination with Novosteo, Inc. When significant identifiable intangible assets are acquired, we engage an independent third party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows including revenues and operating profits resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair value that we assign to the intangible asset acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. No assurance can be given, however, that the underlying assumptions used to estimate expected cash flows will transpire as estimated. In addition, we are required to estimate the period of time over which to amortize the intangible assets, which requires significant judgment.

Impairment of Intangible Assets

Finite-lived intangible asset consist primarily of purchased developed technology and is amortized on a straight-line basis over their estimated useful lives. Indefinite lived intangible assets are not amortized, Intangible assets acquired in a business combination or an acquisition that are used in research and development activities (In-process research and development or IPR&D) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If the carrying value of the assets is not expected to be recovered, the assets are written down to their estimated fair values. As of December 31, 2022, we had $5.9 million of IPR&D and we have recorded no asset impairment charge for the year ended December 31, 2022. Please refer to Note 15, Intangible Assets to the Notes to Consolidated Financial Statements of this Annual Report on Form 10-K, for further information about our intangible assets as of December 31, 2022. As of December 31, 2022, management performed a quantitative impairment evaluation of IPR&D intangible asset. The quantitative evaluation included a

discounted cash flow analysis to determine if the intangible asset had decreased in value. In order to determine the fair value of the intangible asset, the Company utilized an average of a discounted cash flow analysis and comparable public company analysis. The key assumptions associated with determining the estimated fair value include projected future revenue growth rates, projected cost of revenue, operating expenses, future income tax rates, and after tax free cash flow, and the discount rate. The assumptions used in the discount rate calculation were based on a peer company metrics to determine the weighted average cost of capital. This quantitative analysis resulted in the intangible asset fair value being above its carrying value, resulting in no impairment.

Components of Operating Results

Operating Expenses

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the research and development of our research programs. These expenses include payroll and personnel expenses, including stock-based compensation, for our research and product development employees, laboratory supplies, product licenses, consulting costs, contract research, regulatory, quality assurance, preclinical and clinical expenses, allocated rent, facilities costs and depreciation. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments and deposits for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as an expense as the related services are performed.

To date, our research and development expenses have supported the advancement of atuzaginstat (COR388) and COR588 and to a lesser extent the clinical and regulatory development of NOV004. We expect our research and development expenses to decrease significantly from current levels until such time as we in-license a new product candidate. Predicting the timing or the costs to in-license a new drug candidate is difficult because of many factors.

In addition, the probability of success of any in-licensed product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will need to determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate’s commercial potential.

Because our product candidates have not been in-licensed the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidate or whether, or when, we may achieve profitability.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, insurance and accounting services, allocated rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will remain consistent until we in-license a new drug candidate. We anticipate an increase of our general and administrative expense after the successful in-licensing of a drug candidate as the size of our business and research and development operations grows to support additional research and development activities.

Interest Income

Interest income consists primarily of interest earned on our short-term and long-term investments portfolio.

Other Expense, net

Other Expense, net consists primarily of the effects of foreign currency exchange rates.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the periods indicated (dollars in thousands):

	Year Ended December 31,		Change	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 25,178	$ 60,795	$ (35,617)	(58.6) %
General and administrative	26,012	29,523	(3,511)	(11.9) %
Goodwill impairment charge	825	—	825	100.0 %
Loss from operations	(52,015)	(90,318)	(38,303)	(42.4) %
Interest income	1,068	620	448	72.3 %
Other expense, net	(997)	(247)	(750)	303.6 %
Net loss before income tax benefit	(51,944)	(89,945)	(38,001)	42.2 %
Income tax benefit	284	—	(284)	100.0 %
Net loss	$ (51,660)	$ (89,945)	$ (38,285)	(42.6) %

Research and Development Expenses

The following table summarizes our research and development expenses: (dollars in thousands)

	Year Ended December 31,		Change	
	2022	2021	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ 1,400	$ 25,639	(24,239)	(94.5) %
COR588	5,467	4,989	478	9.6 %
NOV004	1,834	—	1,834	100.0 %
Other direct research costs	1,510	3,503	(1,993)	(56.9) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	14,147	24,861	(10,714)	(43.1) %
Facilities and other research and development expenses	820	1,803	(983)	(54.5) %
Total research and development expenses	$ 25,178	$ 60,795	(35,617)	(58.6) %

Research and development expenses were $25.2 million for the year ended December 31, 2022, compared to $60.8 million for the year ended December 31, 2021, a decrease of $35.6 million. We anticipate our research and development expenses to decrease in the future until such time we acquire another clinical stage asset.

The costs for atuzaginstat (COR388) development, used in our GAIN Phase 2/3 clinical trial, decreased $24.2 million from the prior year due to the GAIN trial concluding in the fourth quarter of 2021. As a result, we experienced a decrease of $12.3 million in clinical trial costs, a $5.8 million decrease in drug manufacturing costs, a decrease in non-clinical studies and analysis related to the GAIN trial of $3.0 million, a $2.6 million decrease in consulting expenses related to atuzaginstat (COR388), a $0.3 million decrease in shipping expense related to shipments of COR388, and a decrease of $0.2 million related to the financing lease that was fully amortized in 2021.

Our Phase 1 SAD/MAD trial was completed in the second quarter of 2022 for our compound COR588 in healthy participants in Australia. As a result, the costs for COR588 increased by $0.5 million from the prior year. This increase was primarily

due to a $0.9 million increase for non-clinical studies and analysis to support COR588, offset by a decrease of $0.4 million in drug manufacturing costs and a decrease in consulting expenses of $0.1 million related to COR588.

As we sold our legacy protease inhibitor portfolio including COR388 and COR588 to Lighthouse Pharmaceuticals, Inc. in January 2023, we anticipate that any research and development expenses related to these assets to be minimal in the first quarter of 2023 and no additional expenses from the second quarter of 2023 onward.

For the year ended December 31, 2022, the costs for NOV004 increased by $1.8 million after the Novosteo, Inc. acquisition on May 19, 2022, primarily as a result of the increase in drug manufacturing costs as we prepared our compound for Phase 1 clinical trials. Due to the decision made on January 30, 2023 to align with our updated corporate strategy, our NOV004 costs will decrease significantly in 2023 from the current levels.

Additionally, other direct research costs decreased $2.0 million primarily due to the winddown of pipeline development of our two arginine gingipain inhibitors, COR788 and COR822, our 3CLpro inhibitor, COR803, COR852 and other preclinical research which were sold to Lighthouse Pharmaceutical in January 2023.

For the year ended December 31, 2022, we experienced a net decrease of $10.7 million in personnel related expenses due to a $8.7 million decrease in allocated stock-based compensation costs, a decrease of $4.4 million in wages and related personnel expenses as a result of our decreased headcount, offset by an increase in severance related expenses of $2.4 million as a result of our previously announced cost reduction program initiated in the first quarter of 2022.

Facilities and other research and development expenses decreased $1.0 million for the year ended December 31, 2022 primarily due to a $0.4 million decrease in the purchase of non-clinical supplies, a $0.3 million decrease in facilities and rent expense, a $0.2 million decrease in administration and depreciation expense, and a $0.1 million decrease in regulatory and quality assurance consulting costs.

General and Administrative Expenses

General and administrative expenses decreased by $3.5 million to $26.0 million for the year ended December 31, 2022 from $29.5 million for the year ended December 31, 2021. The decrease in general and administrative expenses was primarily due to an overall decrease in personnel expenses of $4.3 million, which is made up of a $4.6 million decrease in allocated stock-based compensation expense and $1.3 million decrease in personnel costs excluding stock based compensation related to our previously announced cost reduction program initiated in the first quarter of 2022, offset by increased severances expenses of $1.6 million. We also incurred a $2.1 million increase in legal, audit and other professional expenses related to the acquisition of Novosteo offset by a decrease of $0.6 million in marketing and investor relations expense and a $0.7 million decrease in consulting, corporate insurance expenses and other administrative expense due to our cost reductions efforts announced in the first quarter of 2022.

As a result of the previously mentioned cost reduction program, we anticipate our general and administrative expenses will decrease in 2023 compared to 2022 as we adjust our expenses to support our current in-licensing strategy.

Goodwill impairment charge

As of September 30, 2022, we conducted an impairment analysis of our goodwill that resulted from the purchase of Novosteo, Inc. in May 2022. That assessment included a qualitative assessment of deteriorating macro-economic conditions, including inflationary pressures, rising interest rates, and the continuing decline in our market capitalization from the date of acquisition. This qualitative assessment indicated that our goodwill was potentially impaired. To determine the extent, if any, by which our goodwill was impaired, we conducted additional quantitative analyses which resulted in our fair value being significantly below our current carrying value. As a result of the analyses, we recorded a non-cash goodwill impairment charge of $0.8 million for the year ended December 31, 2022.

Interest Income

For the year ended December 31, 2022, interest income increased $0.4 million or 72.3% due to increased yields on our investment portfolio which were partially offset by decreased average balances.

Other Expense

Other expense increased by $0.8 million for the year ended December 31, 2022, primarily due to unrealized losses resulting from changes in foreign exchange rates of $0.6 million, as well as a $0.2 million increase related to the San Diego lease impairment loss and loss on disposal of fixed assets.

Income tax

We recorded an $0.3 million income tax benefit for the year ended December 31, 2022 as a result of the acquisition of Novosteo, Inc. in May 2022.

Liquidity, Capital Resources and Plan of Operations

We have incurred cumulative net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of December 31, 2022, we had an accumulated deficit of $288.3 million. To date we have funded our operations primarily from the sales of our equity securities. As of December 31, 2022, we had cash, cash equivalents and investments of $93.8 million. Based on our current business plans, we believe that our existing capital resources will be sufficient to fund our projected operating requirements for at least the next twelve months. Our cash, cash equivalents, and marketable debt securities are held in a variety of deposit accounts, interest-bearing accounts, corporate bond securities, U.S government securities, debt securities in government-sponsored entities, and money market funds. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and credit risk.

On December 23, 2021, we entered into an Open Market Sales Agreement, with Jefferies, whereby we may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. During the year ended December 31, 2022, we sold 51,769 shares of common stock, resulting in net proceeds of approximately $0.6 million, after commissions and other offering costs.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to NOV004 and general and administrative expenditures. 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 and accrued expenses.

In January 2023 we successfully out-licensed our legacy protease inhibitors to Lighthouse Pharmaceuticals, Inc. and announced our intention to out-license our current preclinical drug candidate NOV004. We also intend to concentrate our efforts on in-licensing clinical-stage assets targeting debilitating and rare diseases. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our future product candidates or whether, or when, we may achieve profitability.

In the near term, our primary uses of cash will be to fund our operations, including business development activities, and administrative personnel related expenses. Our uses of cash beyond the next 12 months will depend on many factors, including the general economic environment in which we operate and our ability to progress on our out-licensing and in-licensing timelines, which are uncertain.

We may continue to require additional capital to develop our drug candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are able to in-license or acquire at least one clinical stage asset, we anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of any potential future trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;

- our need to expand our research and development activities in connection with any assets that we may in-license;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and drug candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other rights to our drug candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. However, based on our current business plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations through at least 2026, but does not include any costs or cash expenditures associated with in-licensing activities.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (44,038)	$ (62,932)
Investing activities	18,002	58,952
Financing activities	707	6,808
Effect of exchange rate changes on cash	184	55
Net (decrease) increase in cash and cash equivalents	$ (25,145)	$ 2,883

Operating Activities

Net cash used in operating activities was $44.0 million for the year ended December 31, 2022. Cash used in operating activities in the year ended December 31, 2022 was primarily due to our net loss for the period of $51.7 million, which included non-cash expenses of $17.5 million, including $16.6 million in stock-based compensation, and a net decrease in accounts payable and accrued expenses and other current liabilities of $12.6 million and decreases in our current assets of $2.8 million.

Net cash used in operating activities was $62.9 million for the year ended December 31, 2021. Cash used in operating activities in the year ended December 31, 2021 was primarily due to our net loss for the period of $89.9 million, which included non-cash expenses of $31.3 million, including $29.9 million in stock-based compensation, and a net decrease in accounts payable and accrued expenses and other current liabilities of $3.3 million and increases in our current assets of $1.0 million.

Investing Activities

Cash provided in investing activities was $18.0 million in the year ended December 31, 2022, primarily related to the purchase of investments of $75.0 million, maturities of investments of $82.5 million, cash acquired from the Novosteo, Inc. acquisition of $10.6 million, and the purchase of equipment of $0.1 million.

Cash used in investing activities was $59.0 million in the year ended December 31, 2021, primarily related to the purchase of investments of $38.8 million, maturities of investments of $98.0 million and the purchase of equipment of $0.2 million.

Financing Activities

Cash provided by financing activities was $0.7 million in the year ended December 31, 2022, which consisted of proceeds from the issuance of common stock in connection with an open market sales agreement, net of issuance costs as well as proceeds from the exercise of options.

Cash provided by financing activities was $6.8 million in the year ended December 31, 2021, which consisted of net proceeds from the exercise of stock options during the period.

Contractual Obligations and Commitments

Material contractual obligations arising in the normal course of business primarily consist of operating and finance leases, drug manufacturing, preclinical and clinical contract obligations. See Note 6 to the Consolidated Financial Statements for amounts outstanding for operating and finance leases on December 31, 2022.

We enter into contracts in the normal course of business with third party contract organizations for clinical trials, non-clinical studies and testing, manufacturing, and other services and products for operating purposes. The amount and timing of the payments under these contracts varies based upon the timing of the services. We have recorded accrued expense of approximately $0.9 million in our consolidated balance sheet for expenditures incurred by these vendors as of December 31, 2022. We have approximately $5.5 million in cancellable future operating expense commitments based on existing contracts as of December 31, 2022. These obligations will be satisfied in the normal course of business, but generally no longer than 12 months. In connection with the cost reduction plan, we estimate that we will incur expenses of approximately $0.6 million to $0.8 million, substantially all of which will be cash expenditures and other costs relating to the Plan through August 2023. We currently do not have any long-term contractual commitments.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of December 31, 2022 and December 31, 2021.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

Quince Therapeutics, Inc.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Quince Therapeutics, Inc.
South San Francisco, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Quince Therapeutics, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 the 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Intangible Assets Related to In-process Research and Development (IPR&D)

As disclosed in Note 14 and Note 15 to the consolidated financial statements, the Company completed its acquisition of Novosteo, Inc. in May 2022 for a purchase price of $16.5 million. As a result of acquisition, the Company acquired $5.9 million of IPR&D valued using discounted probable future cash flows. Significant assumptions used in determining the fair value of the IPR&D include revenue growth rates, risk adjusted discount rates and clinical trial success rate assumptions.

We identified the valuation of intangible assets related to IPR&D at the acquisition date as a critical audit matter. The principal considerations for our determination are the judgments and subjectivity required in assessing the fair value of the acquired IPR&D and certain significant assumptions, including revenue growth rates, discount rates and clinical trial success rate. Auditing these elements involved subjective auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skills or knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of the Company's determination of the fair value of Novesteo, Inc. as of the acquisition date to determine the reasonableness of the underlying fair values of the identifiable assets and liabilities acquired including IPR&D.
- Evaluating the reasonableness of certain significant assumptions by assessing whether these assumptions, including revenue growth rates are consistent with government agencies or medical publications.
- Utilizing professionals with specialized skill and knowledge to assist in (i) reviewing the purchase price consideration; (ii) assessing the appropriateness of valuation models used; and (iii) evaluating the reasonableness of certain significant assumptions incorporated into the various valuation models, including discount rates and clinical trial success rate.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2018.

San Jose, California

March 15, 2023

QUINCE THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 44,579	$ 69,724
Short term investments	45,602	37,078
Prepaid expenses and other current assets	3,567	4,871
Total current assets	93,748	111,673
Property and equipment, net	393	263
Operating lease right-of-use assets, net	291	1,165
Long term investments	3,578	19,933
Intangible asset	5,900	—
Other assets	—	194
Total assets	$ 103,910	$ 133,228
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 570	$ 4,911
Accrued expenses and other current liabilities	2,499	9,311
Total current liabilities	3,069	14,222
Long-term operating lease liabilities	—	420
Deferred tax liabilities	248	—
Total liabilities	3,317	14,642
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 36,136,480 and 30,074,412 issued and outstanding as of December 31, 2022 and 2021, respectively	36	30
Additional paid in capital	389,105	355,234
Accumulated other comprehensive loss	(289)	(79)
Accumulated deficit	(288,259)	(236,599)
Total stockholders' equity	100,593	118,586
Total liabilities and stockholders' equity	$ 103,910	$ 133,228

See accompanying notes to the consolidated financial statements

QUINCE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands except for share and per share amounts)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 25,178	$ 60,795
General and administrative	26,012	29,523
Goodwill impairment charge	825	—
Total operating expenses	52,015	90,318
Loss from operations	(52,015)	(90,318)
Interest income	1,068	620
Other expense, net	(997)	(247)
Net loss before income tax benefit	(51,944)	—
Income tax benefit	284	—
Net loss	(51,660)	(89,945)
Other comprehensive income (loss):		
Foreign currency translation adjustments	248	20
Unrealized gain (loss) on available for sales securities	(458)	(412)
Total comprehensive loss	$ (51,870)	$ (90,337)
Net loss per share - basic and diluted	$ (1.54)	$ (3.03)
Weighted average shares of common stock outstanding - basic and diluted	33,496,534	29,718,506

See accompanying notes to the consolidated financial statements

QUINCE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands except share amounts)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Shareholders' Equity
	Shares	Amount				
Balance January 1, 2021	29,543,222	$ 29	$ 318,574	$ 313	$ (146,654)	$ 172,262
Exercise of stock options	531,190	1	6,807	—	—	6,808
Stock based compensation	—	—	29,853	—	—	29,853
Foreign currency translation adjustment	—	—	—	20	—	20
Unrealized gain (loss) on available for sale investments	—	—	—	(412)	—	(412)
Net loss	—	—	—	—	(89,945)	(89,945)
Balance December 31, 2021	30,074,412	$ 30	$ 355,234	$ (79)	$ (236,599)	$ 118,586
Issuance of common stock in connection with open market sales agreement, net of issuance costs of $19	51,769	—	608	—	—	608
Issuance of common stock on exercise of stock options and vesting of restricted stock units	490,299	—	148	—	—	148
Stock based compensation	—	—	16,618	—	—	16,618
Share issuance in connection with acquisition of Novosteo, Inc.	5,520,000	6	16,497	—	—	16,503
Foreign currency translation adjustment	—	—	—	248	—	248
Unrealized gain (loss) on available for sale investments	—	—	—	(458)	—	(458)
Net loss	—	—	—	—	(51,660)	(51,660)
Balance December 31, 2022	36,136,480	$ 36	$ 389,105	$ (289)	$ (288,259)	$ 100,593

See accompanying notes to the consolidated financial statements

QUINCE THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net Loss	$ (51,660)	$ (89,945)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Non-cash rent expense	(29)	199
Stock based compensation	16,618	29,853
Depreciation and amortization	204	344
Impairment loss on operating lease	136	—
Loss on disposal of fixed assets	94	—
Non-cash goodwill impairment charge	825	—
Amortization of premium (discount) on available for sale investments	(113)	878
Change in deferred tax liabilities due to acquisition of Novosteo, Inc.	(284)	—
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other current assets	2,580	(829)
Other assets	194	(155)
Accounts payable	(5,943)	1,356
Accrued expenses and other current liabilities	(6,660)	(4,633)
Net cash used in operating activities	(44,038)	(62,932)
Cash flow from investing activities:		
Purchase of investments	(75,021)	(38,789)
Proceeds from maturities of investments	82,493	97,921
Cash acquired from Novosteo, Inc.	10,593	—
Proceeds from disposal of assets	70	—
Purchase of property and equipment	(133)	(180)
Net cash provided by (used in) investing activities	18,002	58,952
Cash flows from financing activities:		
Payments of finance leases	(49)	—
Proceeds from issuance of common stock upon exercise of stock options	148	6,808
Proceeds from issuance of common stock in connection with open market sales agreement, net of issuance costs	608	—
Proceeds from private placement offering, net of issuance costs	—	—
Net cash provided by financing activities	707	6,808
Effect of exchange rate changes on cash	184	55
Net (decrease) increase in cash and cash equivalents	(25,145)	2,883
Cash and cash equivalents at beginning of period	69,724	66,841
Cash and cash equivalents at end of period	$ 44,579	$ 69,724
Supplemental disclosures of non-cash information:		
Net assets acquired of Novosteo, Inc. in exchange for common stock	$ 16,503	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 411	$ 1,254
Right-of-use asset and operating lease liability reduction as a result of lease modification	$ (640)	$ —

See accompanying notes to the consolidated financial statements

Note 1. Organization

Description of Business

Effective August 1, 2022, Cortexyme Inc. changed its name to Quince Therapeutics, Inc (the "Company"). The Company was incorporated in the State of Delaware in June 2012 and is headquartered in South San Francisco, California. In April 2021, the Company established a wholly owned subsidiary in Australia, Cortexyme Australia, Pty Ltd. The Company is a preclinical stage biopharmaceutical company focused on advancing innovative precision therapeutics for debilitating and rare diseases. From the inception, the Company has been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. The predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis, or P. gingivalis, and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed the Company to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. At that time the Company changed our corporate name to Quince Therapeutics, Inc.

On January 30, 2023, the Company provided an update on its development pipeline and business outlook for 2023. The Company intends to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. The Company plans to out-license our bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

Novosteo, Inc. Acquisition

On May 9, 2022, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Novosteo, Quince Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Quince Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Company, Novosteo, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the securityholders' representative. The transaction closed on May 19, 2022. Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition ("Acquisition"), each share of capital stock of Novosteo that was issued and outstanding immediately prior to the Effective Time was automatically cancelled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company. The Company issued 5,520,000 shares and assumed 507,108 outstanding Novosteo options after conversion with the awards, retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition.

Pursuant to the Merger Agreement, upon the terms and subject to the conditions set forth therein, Merger Sub I merged with and into Novosteo (the "First Merger"), with Novosteo as the surviving entity in the First Merger (the "First Step Surviving Corporation"). Immediately following the First Merger, the First Step Surviving Corporation merged with and into Merger Sub II, with Merger Sub II surviving the Acquisition. Merger Sub II was renamed Novosteo, LLC and is a wholly-owned single member limited liability corporation. Novosteo, LLC has a wholly owned subsidiary in Australia, Novosteo Pty Ltd.

Liquidity and Capital Resources

The Company has incurred losses and negative cash flows from operations since inception and expects to continue to generate operating losses for the foreseeable future. As of December 31, 2022, the Company had an accumulated deficit of $288.3 million. Since inception through December 31, 2022, the Company has funded operations primarily with the net proceeds from the issuance of convertible promissory notes, from the issuance of redeemable convertible preferred stock, from the net proceeds from the IPO and from the net proceeds from the PIPE Financing. As of December 31, 2022, the Company had cash, cash equivalents, and short-term investments of $90.2 million, which it believes will be sufficient to fund its planned operations for a period of at least 12 months from the date of the issuance of the accompanying consolidated financial statements. The Company also has long-term investments of $3.6 million.

Management expects to incur additional losses in the future to fund the Company's operations and conduct product research and development and may need to raise additional capital to fully implement its business plan. The Company may raise additional capital through the issuance of equity securities, debt financings or other sources including out-licensing or partnerships, in order to further implement its business plan. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates.

Note 2. Summary of Significant Accounting Policies

Basis of Consolidation

The accompanying consolidated financial statements include the accounts of Quince Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

Basis of Presentation

The accompanying consolidated financial statements and the notes thereto have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") pursuant to the instructions of the SEC on Form 10-K through the rules and interpretive releases of the SEC under federal securities law.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as related disclosure of contingent assets and liabilities. The most significant estimates used in the Company's consolidated financial statements relate to the determination of the fair value of stock-based awards and other issuances, determination of the fair value of identifiable assets and liabilities in connection with the acquisition of Novosteo, Inc., including associated intangible assets and goodwill, accruals for research and development costs, useful lives of long-lived assets, stock-based compensation and related assumptions, the incremental borrowing rate for leases and income tax uncertainties, including a valuation allowance for deferred tax assets, eligibility of expenses for the Australia research and development refundable tax credits, impairment of intangible assets or goodwill; and contingencies. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes to be 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. Actual results could differ materially from the Company's estimates.

Foreign Currency Translation and Transactions

The functional currency of the Company's wholly-owned subsidiary is the Australian Dollar. Its financial results and financial position are translated into U.S. dollars using exchange rates at balance sheet dates for assets and liabilities and using average exchange rates for income and expenses. The resulting translation differences are presented as a separate component of accumulated other comprehensive loss, as a separate component of equity.

Foreign currency transactions are translated into the functional currencies using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses, resulting from the settlement of such transactions and from the re-measurement of monetary assets and liabilities denominated in foreign currencies using exchange rates at balance sheet date and non-monetary assets and liabilities using historical exchange rates, are recognized in the consolidated statements of operations and comprehensive income.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's drug candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers. The Company's drug candidates will require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any drug candidate will receive the necessary approvals. On January 25, 2022, the Company received a letter from the FDA Division of Neurology 1 placing a full clinical hold on atuzaginstat (COR388) IND application.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing therapeutics. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

Business Combinations

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business.

The Company accounts for business combinations using the acquisition method pursuant to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 805. This method requires, among other things, that results of operations of acquired companies are included in the Company's financial results beginning on the respective acquisition dates, and that identifiable assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Intangible assets acquired in a business combination are recorded at fair value using one of three valuation approaches, the income approach, the market approach or the cost approach. The Company reviewed the three valuation approaches and determined the income approach was the most appropriate model to approximate fair value for the Acquisition. The income approach model requires assumptions about the timing and amount of future net cash flows, the cost of capital and terminal values from the perspective of a market participant. Any excess of the fair value of consideration transferred (the "Purchase Price") over the fair values of the net assets acquired is recognized as goodwill. The fair value of identifiable assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other acquisition-related costs are expensed when incurred.

Intangible Assets

Intangible assets with a definite useful life are amortized on a straight-line basis over the estimated useful life of the related assets. Intangible assets with an indefinite useful life are not amortized. Intangible assets acquired in a business combination or an acquisition that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. Intangible assets acquired in a business combination are initially recorded at fair value. During the period that those assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment. Once the research and development efforts are completed or abandoned, the entity shall determine the useful life of the assets. An intangible asset shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount, If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the intangible asset. Qualitative factors to be considered include but are not limited to:

- Cost factors such as increases in raw materials, labor, or other costs that have a negative effect on future expected earnings and cash flows;
- Legal/regulatory factors or progress and results of clinical trials;
- Other relevant entity-specific events such as changes in management, key personnel, strategy, or customers; contemplation of bankruptcy; or litigation that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset;
- Industry and market considerations such as a deterioration in the environment in which an entity operates, an increased competitive environment;
- Macroeconomic conditions such as deterioration in general economic conditions, limitations on accessing capital, fluctuations in foreign exchange rates, or other developments in equity and credit markets that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset;

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired as of the acquisition date. Goodwill has an indefinite useful life and is not amortized. The Company reviews its goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of the Company may exceed its fair value. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the Company is less than its carrying amount, including goodwill. If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the goodwill.

Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments with maturities of three months or less when purchased to be cash equivalents. Cash equivalents include marketable securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase and at the end of each reporting period. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the balance sheet date are classified as short-term investments. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term investments. Collectively, cash equivalents, short-term investments and long-term investments are considered available-for-sale and are recorded at fair value. Unrealized gains and losses are recorded as a component of other comprehensive loss in the consolidated statements of operations and included as a separate component of consolidated statements of stockholders' equity (deficit). Realized gains and losses are included in interest income in the consolidated statements of operations and comprehensive loss.

Premiums (discounts) are amortized (accreted) over the life of the related investment as an adjustment to yield using the straight-line interest method. Dividend and interest income are recognized when earned. These amounts are recorded in "interest income" in the statements of operations and comprehensive loss.

Property and Equipment, Net

Property and equipment are stated at cost and reduced by accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful lives of the respective assets. Depreciation and amortization begin at the time the asset is placed in service. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

The useful lives of property and equipment are as follows:

Computer equipment	3 years
Lab equipment	5 years
Finance lease right of use assets	Shorter of estimated useful life or lease term
Leasehold improvement	Shorter of estimated useful life or lease term
Office furniture	3 years

Concentration of Credit Risk

Cash equivalents, short-term and long-term investments are financial instruments that potentially subject the Company to concentrations of credit risk. The Company invests in money market funds, repurchase agreements, treasury bills and notes, government bonds, and corporate notes. The Company limits its credit risk associated with cash equivalents, short-term and long-term investments by placing them with banks and institutions it believes are highly credit worthy and in highly rated investments.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment charge would be recorded when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows or other appropriate measures of fair value.

The Company recognized impairment charges of $0.2 million related to the San Diego lease impairment loss and loss on disposal of fixed assets for the year ended December 31, 2022. The Company did not recognize an impairment charge for the year ended 2021.

Leases

The Company determines if an arrangement includes a lease at inception. Right-of-use lease assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. The right-of-use lease asset includes any lease payments made and excludes lease incentives. Incremental borrowing rate is used in determining the present value of future payments. The Company applies a portfolio approach to the property leases to apply an incremental borrowing rate to leases with similar lease terms. The lease terms may include options to extend or terminate the lease. The Company recognizes the options to extend the lease as part of the right-of-use lease assets and lease liabilities only if it is

reasonably certain that the option would be exercised. Lease expense for minimum lease payments is recognized on a straight-line basis over the non-cancelable lease term.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of personnel costs for the Company's research and product development employees. Also included are non-personnel costs such as professional fees payable to third parties for preclinical and clinical studies and research services, laboratory supplies and equipment maintenance, product licenses, and other consulting costs. The Company estimates preclinical and clinical study and research expenses based on the services performed, pursuant to contracts with contract research organizations ("CROs") that conduct and manage preclinical and clinical studies and research services on its behalf. Expenses related to clinical studies are based on estimates of the services received and efforts expended pursuant to contracts with many research institutions, clinical research organizations and other service providers that conduct and manage clinical studies on the Company's behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts are mainly driven by time and materials incurred by these service providers. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered. Expenses related to clinical studies are generally recorded based on the timing of when services that have been performed on the Company's behalf by the service providers, clinical trial budgets and in accordance with the contracts and related amendments. The determination of timing involves reviewing open contracts and purchase orders, communicating with applicable personnel to identify the timing of when services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. The Company periodically confirms the accuracy of estimates with the service providers and makes adjustments if necessary. Examples of estimated clinical expenses include:

- fees paid to Contract Research Organizations, or CROs, in connection with clinical studies;
- fees paid to investigative sites in connection with clinical studies;
- fees paid to contract manufacturers in connection with the production of clinical study materials; and
- fees paid to vendors in connection with preclinical development activities.

If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the prepaid or accrual accordingly. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are expensed as incurred.

Patent Costs

The Company has no historical data to support a probable future economic benefit for the arising patent applications, filing and prosecution costs. Therefore, patent costs are expensed as incurred.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees in accordance with Accounting Standards Codification ("ASC") 718, Compensation—Stock Compensation. Stock-based awards granted include stock options with service-based vesting. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all stock-based payments. The Company's determination of the fair value of stock options with service-based vesting on the date of grant utilizes the Black-Scholes option-pricing model and is impacted by its common stock price as well as other variables including: but not limited to, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends. The fair value of a stock-based award is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense is recognized based on the fair value determined on the date of grant and is reduced for forfeitures as they occur. The Company uses a Monte Carlo Simulation model to estimate the grant date fair value of stock option awards with market-based performance conditions.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the consolidated financial statement reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect

when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company includes any penalties and interest expense related to income taxes as a component of other expense and interest expense, net, as necessary.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions and other events and circumstances from non-owner sources. The Company had an unrealized loss from its available-for sale securities and cumulative translation adjustment during the years ended December 31, 2022 and December 31, 2021, which are considered other comprehensive loss.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and common share equivalents of potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation and common stock options are considered to be potentially dilutive securities. Because the Company reported a net loss for the years ended December 31, 2022 and 2021, and the inclusion of the potentially dilutive securities would be antidilutive, diluted net loss per share is the same as basic net loss per share for both periods.

Recent Accounting Pronouncements Not Yet Adopted

The following are new accounting pronouncements that the Company is evaluating for future impacts on its financial statements:

Financial Instruments—Credit Losses: In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments which amends the principles around the recognition of credit losses by mandating entities incorporate an estimate of current expected credit losses when determining the value of certain assets. The guidance also amends reporting around allowances for credit losses on available-for-sale marketable securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which established that a one-time determination of the effective date for ASU 2016-13 would be based on the Company's SEC reporting status as of November 15, 2019. The Company was a "smaller reporting company" as defined by Item 10 of Regulation S-K, and therefore, ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company does not believe this will have a material impact on its financial statements.

All other newly issued accounting pronouncements not yet effective have been deemed either immaterial or not applicable.

Note 3. Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the company estimates would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of the assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date;

Level 2 - Inputs other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 - Inputs that are unobservable. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's financial instruments are carried in the accompanying consolidated balance sheets at amounts that approximate fair value.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the years ended December 31, 2022 and 2021.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of December 31, 2022 and 2021 are presented in the following tables (in thousands):

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 10,988	$ 10,988	$ —	$ —
Certificates of Deposit	6,102	—	6,102	—
Repurchase Agreements	9,000	—	9,000	—
Corporate notes	12,411	—	12,411	—
Government and agency notes	50,766	—	50,766	—
Municipal notes	506	—	506	—
Total	$ 89,773	$ 10,988	$ 78,785	$ —

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 15,954	$ 15,954	$ —	$ —
Certificates of Deposit	11,503	—	11,503	—
Repurchase Agreements	13,500	—	13,500	—
Corporate notes	38,397	—	38,397	—
Government and agency notes	5,178	—	5,178	—
Municipal notes	1,933	—	1,933	—
Total	$ 86,465	$ 15,954	$ 70,511	$ —

The Company classifies corporate notes, certificates of deposit, repurchase agreements, municipal notes, and government and agency notes as Level 2 investments as the Company uses quoted prices for similar assets sourced from certain third-party pricing services. The third-party pricing services generally utilize industry standard valuation models for which all significant inputs are observable, either directly or indirectly, to estimate the price or fair value of the securities. The primary input generally includes reported trades of or quotes on the same or similar securities. The Company does not make additional judgments or assumptions made to the pricing data sourced from the third-party pricing services.

Note 4: Cash, Cash Equivalents and Investments

The following tables categorize the fair values of cash, cash equivalents, short-term investments and long-term investments measured at fair value on a recurring basis on our balance sheets (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents:		
Cash	$ 3,986	$ 40,270
Money market funds	10,988	15,954
Repurchase agreements	9,000	13,500
Government and agency notes	20,605	—
Total cash and cash equivalents	$ 44,579	$ 69,724
Short-term investments:		
Certificates of deposit	$ 5,390	$ 6,928
Municipal notes	506	1,283
Corporate notes	12,411	25,675
Government and agency notes	27,295	3,192
Total short-term investments	$ 45,602	$ 37,078
Long-term investments		
Corporate notes	$ —	$ 12,722
Certificates of deposit	712	4,575
Municipal notes	—	650
Government and agency notes	2,866	1,986
Total long-term investments	$ 3,578	$ 19,933

The investments are classified as available-for-sale securities. As of December 31, 2022, the weighted average remaining contractual maturities of available-for-sale securities was approximately 5 months. At December 31, 2022 and 2021, the unrealized gain (loss) activity related to the Company's available-for-sale securities is included in the Company's accumulated other comprehensive income (loss). There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale securities for the years ended December 31, 2022 and 2021 and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income. Based on the Company's review of its available-for-sale securities, the Company has a limited number of available-for-sale securities in insignificant loss positions as of December 31, 2022. Management evaluates securities for other-than-temporary impairment (OTTI) on a quarterly basis, and more frequently when economic or market conditions warrant such an evaluation. Investment securities are generally evaluated for OTTI under FASB Accounting Standards Codification (ASC) Topic 320, Accounting for Certain Investments in Debt and Equity Securities. OTTI under the ASC Topic 320 model, management considers many factors, including: (1) the length of time and the extent to which the fair value has been less than cost, (2) the financial condition and near-term prospects of the issuer, (3) whether the market decline was affected by macroeconomic conditions, and (4) whether the entity has the intent to sell the debt security or more likely than not will be required to sell the debt security before its anticipated recovery. The assessment of whether an other-than-temporary decline exists involves a high degree of subjectivity and judgment and is based on the information available to management at a point in time. No other-than-temporary impairments on these securities were recognized for the years ended as of December 31, 2022 and 2021.

The following table summarizes the available-for-sale securities (in thousands):

	Fair Value Measurements at December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 10,988	$ —	$ —	$ 10,988
Certificates of Deposit	6,237	1	(136)	6,102
Repurchase Agreements	9,000	—	—	9,000
Corporate notes	12,575	—	(164)	12,411
Government and agency notes	51,020	4	(258)	50,766
Municipal notes	510	—	(4)	506
Total cash equivalents and investments	$ 90,330	$ 5	$ (562)	$ 89,773
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 40,593
Short-term investments (maturities within one year)				45,602
Long-term investments (maturities beyond 1 year)				3,578
Total cash equivalents and investments				$ 89,773

	Fair Value Measurements at December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 15,954	$ —	$ —	$ 15,954
Certificates of Deposit	11,511	12	(20)	11,503
Repurchase Agreements	13,500	—	—	13,500
Corporate notes	38,470	6	(79)	38,397
Government and agency notes	5,195	—	(17)	5,178
Municipal notes	1,934	—	(1)	1,933
Total cash equivalents and investments	$ 86,564	$ 18	$ (117)	$ 86,465
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 29,454
Short-term investments (maturities within one year)				37,078
Long-term investments (maturities beyond 1 year)				19,933
Total cash equivalents and investments				$ 86,465

Note 5: Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid expenses	$ 223	$ 333
Prepaid insurance	977	1,144
Prepaid research and development expenses	1,088	1,899
Australia research and development refundable tax credit	1,003	1,128
Other current assets	276	367
Total prepaid expenses and other current assets	$ 3,567	$ 4,871

Cortexyme Australia, Pty, Ltd, is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian R&D Tax Incentive Program (the "Australian Tax Incentive"). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the relevant expenditure has been incurred, the

amount can be reliably measured and that the Australian Tax Incentive will be received. The Company recognized reductions to R&D expense of $0.6 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively.

Novosteo Pty, Ltd is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian Tax Incentive as well. The Company is eligible to receive a refundable tax credit of $0.5 million and $0 million for the years ended December 31, 2022 and 2021, respectively.

Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2022	2021
Computer equipment	$ 18	$ 53
Lab equipment	415	528
Finance lease right of use assets	124	557
Leasehold improvement	21	58
Office furniture	—	26
Less: accumulated amortization and depreciation	(185)	(959)
Property and equipment, net	$ 393	$ 263

Depreciation expense for property and equipment was $204,000 and $344,000 for the years ended December 31, 2022 and 2021, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expense and other current liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Personnel expenses	$ 1,130	$ 820
Professional fees	234	462
Research and development expenses	497	7,108
Current portion of operating lease liabilities	377	741
Current portion of finance lease liability	76	—
Other	185	180
Total accrued expenses and other current liabilities	$ 2,499	$ 9,311

In response to the reprioritization of the Company's pipeline following the clinical hold on atuzaginstat (COR388) IND application, on February 2, 2022, the Board approved a cost reduction program to reorganize operations and allow continued support for the needs of the business. Under the cost reduction program, the Company lowered headcount through a reduction in workforce. The reduction in force was completed in July 2022. To be eligible for the severance payments, employees had to remain with the Company through their communicated severance date. The Company recognized the severance and related expenses over the requisite employment obligation period.

	For the year ended December 31,
	2022
Beginning accrued severance	$ —
Incurred during the period	3,942
Severance paid during the period	(3,942)
Ending accrued severance	$ —

Note 6. Leases

Real Estate Operating Leases

In June 2018, the Company entered into a three-year lease agreement with no renewal options with an investor in the Series B redeemable convertible preferred stock. The lease began on July 16, 2018 and provides office and laboratory space in South San

Francisco, California. The Company issued 114,437 shares of its Series B redeemable convertible preferred stock with a fair value of $1.1 million in exchange for the leased facility. No other payments were due under the lease. The common area maintenance and other operating costs are included in the base rent. 100% of the issued shares were initially subject to a repurchase option. Pursuant to the terms of the lease, each month beginning on the one-month anniversary of the commencement date of the lease, 1/36th of the total shares are released from the repurchase option until all shares are released over the lease period of three years. The scheduled release of shares ceased immediately upon the IPO which was a terminating event.

The Company completed its IPO on May 13, 2019 and as a result, pursuant to the terms of the lease agreement, all previously unvested shares were fully vested and as part of the IPO process, all outstanding shares of the Company's redeemable convertible preferred stock including the Series B redeemable convertible preferred stock issued in connection with the lease agreement were converted into shares of the Company's common stock on a 1-for-1 basis and the operating lease liability was extinguished.

In May 2019, the Company entered into an amendment to the lease agreement to rent additional space in the same facility under the same terms as its existing facility lease except the terms of payment. Under the terms of the amendment, the Company paid a one-time fee of approximately $63,000 for the additional space and the lease agreement will terminate in July 2021. No other payments are due under the lease agreement and no renewal option is available. As the entire lease is prepaid, there is no associated lease liability.

In May 2020, the Company entered into a second amendment to the lease agreement to rent additional space in the same facility under the same terms as its existing facility lease except the terms of payment. Under the terms of the amendment, the Company will pay rent monthly for the additional space and the lease agreement will terminate in July 2021. The Company recorded an operating lease asset and liability of $172,000.

In May 2021, the Company entered into a third amendment to the lease agreement to extend the term of its existing facility space to July 15, 2022 under the same terms as its existing facility lease except the terms of payment. The lease amendment provides for one-year extension period under the same terms. As a result of this amendment, the Company recognized an additional right-of-use asset and corresponding lease liability of $1.2 million. In the same agreement, the Company also agreed to rent additional space effective July 16, 2021 for a period of 12 months. The lease amendment provides for one-year extension period and was included in the lease term as it was reasonably certain that the Company would exercise the option. The Company recognized an additional right of use asset and corresponding lease liability of $44,000 in July 2021. Total payments under the third amendment to the lease including the additional space was approximately $1.3 million.

In March 2022, in response to the reprioritization of the Company's pipeline following the clinical hold on atuzaginstat (COR388) IND application, the Company has decided not to exercise the one-year extension period which was previously included in the determination of the lease term at the time the lease was modified in May 2021. This reduction in lease term was determined to be a lease modification and as such, the lease liability was re-measured and corresponding Right of use ("ROU asset") adjusted using an incremental borrowing rate at the date of modification. The Company reduced the ROU asset and lease liability by approximately $640,000.

In May 2020, the Company entered into a lease agreement to rent space in San Diego, California. The lease agreement is for three years, which commenced August 1, 2020. Total payments under the lease will be $337,000. In June 2022; the Company determined the San Diego facility was no longer required and intends to sublease the facility, if possible. As a result of this decision, the Company recorded an impairment loss of approximately $136,000 and $0 for the year ended December 31, 2022 and 2021, respectively, as it was determined that a sublease was improbable. The Company paid a security deposit of $29,000 which is included in Prepaid Expenses and Other Current Assets on the December 31, 2022 consolidated balance sheets and was included in Other Assets on the December 31, 2021 consolidated balance sheet.

In June 2022, the Company entered into a Sublease Agreement to rent office space in South San Francisco, California. The Sublease agreement commenced on June 18, 2022 and ends on November 30, 2023. The total payments under the term of the lease are expected to be approximately $271,000. The Company paid a security deposit of $17,000 which is included in Prepaid Expenses and Other Current Assets on the December 31, 2022 consolidated balance sheet and was not included on the December 31, 2021 consolidated balance sheet. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $256,000.

In October 2022, the Company entered into a lease agreement to rent space in West Lafayette, Indiana. The lease agreement amended the original lease to transfer liability to the Company due to the Acquisition. The lease agreement is for 15 months, which commenced on October 1, 2022 and ends on December 31, 2023. The total payments under the term of the lease are expected to be approximately $151,000. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $145,000.

In December 2022, the Company entered into an amendment to the lease agreement of the rental space in West Lafayette to rent additional space in the same facility under the same terms as its existing facility lease except the terms of payment. Under the terms of the amendment, the Company will pay rent monthly for the additional space. The Company recorded an operating lease right of use asset and liability of $10,000.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. As of December 31, 2022, total future rent expense from all real estate operating leases of $318,000 will be recognized over the remaining term of 12 months on a straight-line basis over the respective lease period.

Clinical Equipment Financing Lease

As part of the Acquisition the Company acquired a financing lease for lab equipment. The Company recognizes the depreciation expense in research and development expenses in the consolidated statements of operations and comprehensive loss and recognizes expense on a straight-line basis starting when the equipment is placed into service until the end of the remaining contract term of 18 months. Amortization expense of the financing lease right of use asset for the year ended December 31, 2022 was $50,000.

In 2021, the Company used certain vendor supplied equipment in connection with its clinical trial. The Company analyzed the vendor agreements and determined that they contained embedded finance leases. The Company recognized the depreciation expense in research and development expenses in the statements of operations and comprehensive loss and recognized expense on a straight-line basis starting when the equipment is placed into service until the end of the contract term ranging from 20 to 34 months. Amortization expense of the financing lease right of use asset for the year ended December 31, 2021 was $220,000.

Supplemental balance sheet information related to leases as follows (in thousands except lease terms and discount rates):

	December 31, 2022	December 31, 2021
Operating lease right of use asset, net	$ 291	$ 1,165
Short-term operating lease liability	377	741
Long-term operating lease liability	—	420
	$ 377	$ 1,161
Finance lease right of use asset	124	557
Finance lease accumulated amortization	(50)	(557)
Total finance lease right of use asset, net	$ 74	$ —
Weighted average remaining lease term		
Operating leases	0.9 years	1.6 years
Finance leases	1.0 year	— years
Weighted average discount rate		
Operating leases	5.71%	1.87%
Finance leases	4.45%	—%

Year ended December 31,	Operating Lease
2023	388
2024	—
Total lease payments	388
Less: imputed interest	(11)
Total remaining lease liability	377

Lease costs for the years ended December 31, 2022 and 2021 were approximately:

	Years ended December 31,	
	2022	2021
Lease costs:		
Finance lease amortization of right of use assets	$ 50	$ 220
Operating lease costs	572	729
Short-term lease costs	75	66
Total lease costs	$ 697	$ 1,015

Note 7. Commitments and Contingencies

Legal Matters

The Company's industry is characterized by frequent claims and litigation, including claims regarding intellectual property. As a result, the Company may be subject to various legal proceedings from time to time. The results of any future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. Management is not aware of any pending or threatened litigation.

Indemnification

As permitted under Delaware law and in accordance with the Company's bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its directors. The Company believes the fair value of the indemnification rights and agreements is minimal. Accordingly, the Company has not recorded any liabilities for these indemnification rights and agreements as of December 31, 2022 and 2021.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 8. Equity Incentive Plans

The Company operates three stock plans as of December 31, 2022.

- 2019 Equity Incentive Plan (Quince)
- 2019 Equity Incentive Plan (Novosteo)
- 2022 Inducement Plan (Quince)

2019 Equity Incentive Plan (Quince)

On December 4, 2014, the Company's stockholders approved the 2014 Stock Plan ("2014 Plan"), and on April 25, 2019 amended, restated and re-named the 2014 Plan as the 2019 Equity Incentive Plan (the "Quince 2019 Plan"), which became effective as of May 7, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. The remaining shares available for issuance under the 2014 Plan were added to the shares reserved for issuance under the Quince 2019 Plan.

The Quince 2019 Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Company's employees, directors, and consultants. The maximum aggregate number of shares that may be issued under the Quince 2019 Plan is 8,591,030 shares of the Company's common stock. In addition, the number of shares available for issuance under the Quince 2019 Plan will be annually increased on the first day of each of its fiscal years beginning with fiscal 2020, by an amount equal to the least of (i) 2,146,354 shares of common stock; (ii) 4% of the outstanding shares of its common stock as of the last day of its immediately preceding fiscal year; and (iii) such other amount as the Company's Board of Directors may determine.

The Quince 2019 Plan may be amended, suspended or terminated by the Company's Board of Directors at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the Quince 2019 Plan as required by applicable law or listing requirements. Unless sooner terminated by the Company's Board of Directors, the 2019 Plan will automatically terminate on April 23, 2029.

Stock Options

Activity for service-based stock options under the Quince 2019 Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2020	**4,790,327**	$ 25.47	8.69	$ 49,723
Options granted	1,436,116	35.20	—	—
Options exercised	(531,190)	12.82	—	—
Options cancelled / forfeited	(123,960)	47.09	—	—
Balance at December 31, 2021	**5,571,293**	$ 28.70	8.26	$ 15,687
Options granted	2,051,058	8.13	—	—
Options exercised	(102,152)	1.45	—	—
Options cancelled / forfeited	(4,200,488)	29.30	—	—
Balance at December 31, 2022	**3,319,711**	$ 16.07	4.77	$ 65
Options vested and expected to vest to December 31, 2022	3,319,711	16.07	4.77	65
Options exercisable at December 31, 2022	2,209,330	$ 20.13	2.52	$ 65

Aggregate intrinsic value represents the difference between the Company's estimated fair value of its common stock as of their respective balance sheet dates and the exercise price of outstanding options. The total intrinsic value of the Quince 2019 Plan options exercised was $1,393,000 and $22,512,000 for the years ended December 31, 2022 and 2021, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $6.05 and $25.66 per share, respectively. The total estimated grant date fair value of options vested during each of the years ended December 31, 2022 and 2021 was $31.8 million.

In 2022 and 2021 , the Company recognized $11,361,000 and $26,140,000, respectively, of stock-based compensation expense related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statement of operations for stock-based compensation arrangements. As of December 31, 2022, total unamortized employee stock-based compensation was $6.2 million, which is expected to be recognized over the remaining estimated vesting period of 2.27 years.

Performance Stock Options ("PSOs")

In December 2020, the Company granted 675,000 performance stock options ("PSOs") under the Stock Incentive Plan to its executive and senior officers. Vesting for the options is performance based and is based on continued employment at the vesting date, with the options vesting in two installments if the Company's average closing price in any 45 consecutive trading day period exceeds a certain amount per share prior to March 15, 2023 and March 15, 2024, respectively. PSOs represent a contingent right to purchase Common Stock upon achievement of specified market conditions.

In February 2022, the Company and certain executive officers agreed to voluntarily surrender 400,000 of the PSOs. As a result of the surrender, the Company accelerated the total remaining expense on these options and recognized approximately $3.6 million in compensation expense during the quarter ended March 31, 2022.

In February 2022, the Company's Chief Executive Officer and Chief Scientific Officer resigned from the Company. As a result, the unvested PSOs were cancelled and the life to date expense of approximately $1.6 million was reversed in the quarter ended March 31, 2022.

The following table summarizes activity under the Company's PSOs from the 2019 Plan and related information:

	Shares Subject to Outstanding PSOs	Weighted Average Exercise Price	Weighted average remaining contractual life (years)
Balance at December 31, 2021	675,000	$ 29.60	8.94
Surrendered	(675,000)	$ 29.60	
Vested	—	—	—
Balance at December 31, 2022	—	—	—

The Company recognized stock-based compensation expense of $2,044,000 and $3,713,000 in 2022 and 2021, respectively relating to these PSOs. The weighted-average grant date fair value of the PSOs granted during 2020 was $14.90 per share. As of December 31, 2022, there was no remaining unamortized stock-based compensation related to PSOs.

Restricted Stock Units ("RSUs")

The following table summarizes activity under the Company's RSUs from the Quince 2019 Plan and related information:

	Restricted Stock Units Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2021	**—**	**—**
RSUs granted	1,013,500	$ 4.30
RSUs vested	(388,147)	$ 4.30
RSUs cancelled	(594,477)	$ 4.30
Unvested - December 31, 2022	**30,876**	$ 4.30

The fair value of the RSUs is determined on the grant date based on the fair value of the Company's common stock. The fair value of the RSUs is recognized as expense ratably over the vesting period of two years. The total grant date fair value of the RSUs vested during the years ended December 31, 2022 and 2021 was $1.7 million and $0 million, respectively. The aggregate intrinsic value of the shares of the RSUs vested during the year ended December 31, 2022 was $1.1 million.

For the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense of $1,337,000 and $0, respectively, related to these RSUs. As of December 31, 2022, the total unamortized stock-based compensation related to RSUs was $0.1 million, which is expected to be recognized over the remaining estimated vesting period of 1.17 years.

2019 Equity Incentive Plan (Novosteo)

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed the 2019 Novosteo, Inc Equity Incentive Plan (the "2019 Novosteo Plan"). The 2019 Novosteo Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Novosteo legacy employees. On the closing date, each outstanding Novosteo stock option granted under Novosteo's equity compensation plans was converted into a corresponding stock option with the number of shares underlying such option and the applicable exercise price adjusted based and adjusted into the right to purchase 0.0911 shares of common stock. Each such converted stock option will continue to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo stock option prior to the Acquisition. The maximum aggregate number of shares that may be issued under the 2019 Novosteo Plan is 544,985 shares of the Company's common stock.

The 2019 Novosteo Plan may be amended, suspended or terminated by the Board at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the 2019 Novosteo Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board, the 2019 Novosteo Plan will automatically terminate on May 20, 2029.

Activity for service-based stock options under the 2019 Novosteo Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2021	—	—	—	—
Options assumed	507,648	$ 0.55	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(4,543)	0.55	—	—
Balance at December 31, 2022	**503,105**	$ 0.55	9.23	$ 44
Options vested and expected to vest as of December 31, 2022	503,105	0.55	9.23	44
Options exercisable as of December 31, 2022	—	—	—	—

For the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense of $245,000 and $0, respectively, related to options granted to employees and non-employees for the 2019 Novosteo plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2022, total unamortized employee stock-based compensation was $1.0 million, which is expected to be recognized over the remaining estimated vesting period of 3.23 years.

The total aggregate intrinsic value of the Novosteo 2019 Plan options exercised was $0 for the years ended December 31, 2022 and 2021. The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $2.51 and $0 per share, respectively. The total estimated grant date fair value of options vested during the years ended December 31, 2022 and 2021 was $0.3 million and $0 million, respectively.

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed a number of restricted stock awards ("RSAs") agreements with certain employees. Each outstanding Novosteo RSA was converted into a corresponding RSA with the number of shares underlying such RSA adjusted into 0.0911 shares of common stock. Each such converted RSA will continue to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo RSA prior to the Acquisition.

Restricted Stock Awards ("RSAs")

	Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2021	**—**	**—**
RSAs assumed	519,216	$ 3.30
RSAs vested	(91,815)	$ —
RSAs cancelled	-	$ —
Unvested - December 31, 2022	**427,401**	**$ 3.30**

For the years ended December 31, 2022 and 2021, the Company recognized stock-based compensation expense of $338,000 and $0, respectively, related to restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2022, total unamortized employee stock-based compensation was $1.4 million, which is expected to be recognized over the remaining estimated vesting period of 2.74 years.

2022 Inducement Plan

On May 9, 2022, the Company's board of directors approved 4,000,000 shares of the Registrant's common stock that may be offered or issued under the Quince Therapeutics, Inc. 2022 Inducement Plan. The 2022 Inducement Plan was adopted by the independent members of the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with rule awards under those plans may only be made to an employee who has not previously been an employee or member of the Board or of any board of directors of any parent or subsidiary of the Company, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The terms and conditions of the 2022 Inducement Plan are substantially similar to those of the Quince 2019 Plan.

As of December 31, 2022, the Company had 257,745 shares available for future issuance under the 2022 Inducement Plan.

Activity for service-based stock options under the 2022 Inducement Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2021	—	—	—	—
Options granted	3,744,255	$ 2.98	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(2,000)	2.98	—	—
Balance at December 31, 2022	**3,742,255**	$ 2.98	9.39	$ —
Options vested and expected to vest as of December 31, 2022	3,742,255	2.98	9.39	—
Options exercisable as of December 31, 2022	—	—	—	—

For the year ended December 31, 2022, the Company recognized stock-based compensation expense of $1,293,000, related to options granted to employees and non-employees for the 2022 Inducement plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2022, total unamortized employee stock-based compensation was $7.2 million, which is expected to be recognized over the remaining estimated vesting period of 3.39 years.

The total aggregate intrinsic value of the 2022 Inducement Plan options exercised was $0 for the year ended December 31, 2022. The weighted-average grant date fair value of options granted during the years ended December 31, 2022 was $2.26 per share. The total estimated grant date fair value of options vested during the year ended December 31, 2022 was $0 million. No options have vested or were exercised during 2022.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the years ended December 31, 2022 and 2021 and the allocation within the statements of operations and comprehensive loss (in thousands):

	2022	2021
General and administrative expense	$ 10,225	$ 14,792
Research and development expense	6,393	15,061
Total stock-based compensation	$ 16,618	$ 29,853

The Company estimates the fair value of its service-based stock option awards utilizing the Black-Scholes option pricing model, which is dependent upon several variables, such as expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine. Stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense, over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes compensation on a straight-line basis over the requisite vesting period for each award. Forfeitures are recognized as they occur. The following weighted average assumptions were used to calculate the fair value of stock-based compensation for the years ended December 31, 2022 and 2021:

	2022	2021
Expected volatility	89.98%	87.56%
Expected dividend yield	—%	—%
Expected term (in years)	6.23	6.23
Risk-free interest rate	2.67%	1.15%

Expected Term — The Company has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years). The expected term was estimated using the simplified method for employee stock options since the Company does not have adequate historical exercise data to estimate the expected term.

Expected Volatility—Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of its own stock and the stock of companies within its defined peer group. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options.

Expected Dividend — The Company has not issued any dividends in its history and does not expect to issue dividends over the life of the options and therefore has estimated the dividend yield to be zero.

Fair value of Common Stock — The fair value of the shares of common stock underlying the stock-based awards has historically been determined by the board of directors, with input from management. The board of directors uses the closing price of stock on the date of grant to determine the fair value. The board of directors intends all options granted to be exercisable at a price per share not less than the estimated per share fair value of common stock underlying those options on the date of grant.

The Company estimated the grant date fair value of its market-based performance stock option awards granted during the year ended December 31, 2021 using a Monte Carlo Simulation method by applying the following assumptions:

Expected share price volatility	95.0%
Contractual term, in years	10
Risk-free interest rate	0.90%

Employee Stock Purchase Plan

On April 24, 2019, the Company's Board of Directors adopted its 2019 Employee Stock Purchase Plan ("2019 ESPP"), which was subsequently approved by the Company's stockholders and became effective on May 7, 2019, the day immediately prior to the effectiveness of the registration statement filed in connection with the IPO. The 2019 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code (the "Code") for U.S. employees. In addition, the 2019 ESPP authorizes grants of purchase rights that do not comply with Section 423 of the Code under a separate non-423 component for non-U.S. employees and certain non-U.S. service providers. The Company has reserved 1,133,165 shares of common stock for issuance under the 2019 ESPP. In addition, the number of shares reserved for issuance under the 2019 ESPP will be increased automatically on the first day of each fiscal year for a period of up to ten years, starting with the 2020 fiscal year, by a number equal to the lesser of: (i) 536,589 shares; (ii) 1% of the shares of common stock outstanding on the last day of the prior fiscal year; or (iii) such lesser number of shares determined by the Company's Board of Directors. The 2019 ESPP is expected to be implemented through a series of offerings under which participants are granted purchase rights to purchase shares of the Company's common stock on specified dates during such offerings. The Company has not yet approved an offering under the 2019 ESPP.

Note 9. Common Stock

Equity Transactions

On December 23, 2021, the Company entered into an Open Market Sales Agreement, with Jefferies LLC ("Jefferies"), whereby the Company may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. During the years ended December 31, 2022 and 2021, the Company sold 51,769 and zero shares of common stock, respectively, under this agreement and received net proceeds of $0.6 and $0 million, respectively.

Common Stock

The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2022	2021
Options issued and outstanding under the Quince 2019 Stock Plan	3,319,711	6,246,293
Shares available for issuance under Quince 2019 Stock Plan	3,747,309	138,926
Shares available for issuance under the Employee Stock Purchase Plan	1,133,165	832,421
Options issued and outstanding under the Novosteo 2019 Plan	503,105	—
Shares available for issuance under Novosteo 2019 Plan	41,880	—
Options issued and outstanding under the 2022 Inducement Plan	3,742,255	—
Shares available for issuance under 2022 Inducement Plan	257,745	—
Total	12,745,170	7,217,640

The Company is authorized to issue 100,000,000 shares of common stock with a par value of $0.001 per share. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when and if declared by the board of directors, subject to the prior rights of holders of any preferred stock that may be outstanding at the time. The Company has never declared any dividends on common stock. As of December 31, 2022 and 2021, the Company had 36,136,480 and 30,074,412 shares of common stock issued and outstanding, respectively.

Note 10. Related Party Transactions

David Lamond, Chairperson of the Board of Quince Therapeutics, Inc. was a director and an equity holder in Novosteo, Inc. which Quince acquired on May 19, 2022. The shares of Novosteo, Inc. beneficially owned by Mr. Lamond were automatically cancelled and converted into the right to receive shares of Quince common stock in accordance with the terms of the Merger Agreement. The respective boards of directors of Quince and Novosteo have approved the Merger Agreement, and the Novosteo's stockholders adopted the Merger Agreement upon recommendation of the Novosteo board of directors. Mr. Lamond was not part of either company's special committees that evaluated the Acquisition and recused himself from board meetings where the Acquisition was discussed.

Philip Low, Board member of Quince Therapeutics, Inc., is employed as a professor at Purdue University. The Company rents a lab facility and office space from Purdue Research Foundation, a private, nonprofit foundation of Purdue University. Purdue Research Foundation also owns 154,497 shares of Quince Therapeutics, Inc. and has provided the Company an exclusive worldwide license under certain bone fracture repair and oncology therapeutics related patents and technology developed by the Purdue University and owned by Purdue Research Foundation. In addition, the Company is required to pay Purdue Research Foundation annual license maintenance fees, development milestones (up to $4.25 million for each licensed product), royalties on the gross receipts of the licensed products (subject to annual minimums), and a share of certain payments that the Company may receive from sublicensees. In addition, the Company also pays rent to Purdue University as the Company has a research and development lab on the campus. For the years ended December 31, 2022 and 2021, the Company has incurred total expenses of $195,000 and $0, respectively, related to these agreements. This is recorded in research and development expenses included in the Consolidated Statements of Operations and Comprehensive Loss.

In 2022, several executives and board members of the Company stepped down from their respective roles. In connection with their departure, the Company modified certain of their option awards to accelerate the vesting and extend the exercise period. As a result of these modifications, the Company recognized $2,115,000 of incremental stock-based compensation expense during the year ending December 31, 2022. The Company also made cash severance payments of $1,297,750 which are recorded in general

administrative expenses in the Consolidated Statements of Operations and Comprehensive Loss and $1,020,000 which are recorded in research and development expenses included in the Consolidated Statements of Operations and Comprehensive Loss.

Note 11. Income taxes

The components of the Company's loss before income taxes were as follows (in thousands):

	Year ended December 31,	
	2022	2021
United States	$ (48,191)	$ (87,907)
International	(3,753)	(2,038)
Total	$ (51,944)	$ (89,945)

The Company recorded a benefit for income taxes of $0.3 million for the year ended December 31, 2022 and did not record a provision or benefit for income taxes for the year ended December 31, 2021.

The provision for income taxes differs from the amount expected by applying the federal statutory rate to the loss before taxes as follows:

	Year ended December 31,	
	2022	2021
Federal statutory income tax rate	21.00 %	21.00 %
State income taxes	0.89	0.96
Income tax credits	1.49	2.17
Stock based compensation	(0.82)	1.68
Non-deductible expenses and others	(3.38)	0.26
Change in valuation allowance	(18.63)	(26.07)
	0.55 %	— %

As of December 31, 2022 and 2021, the components of the Company’s deferred tax assets are as follows (in thousands):

	Year ended December 31,	
	2022	2021
Deferred tax asset:		
Federal and State net operating loss carryforwards	$ 49,481	$ 44,933
Stock based compensation	9,667	6,853
Other accruals	515	396
Capitalized research and development expense	3,094	—
Tax credits	7,970	6,737
Gross deferred tax asset	70,727	58,919
Valuation allowance	(69,692)	(58,611)
Total deferred tax assets (liabilities)	1,035	308
Deferred tax liabilities:		
Property and equipment	(11)	(5)
Capitalized leases	(32)	(303)
IP R&D	(1,239)	—
Gross deferred tax liabilities	(1,282)	(308)
Net deferred tax liabilities	$ (247)	$ —

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and a deferred tax liability has been recorded as shown in the accompanying balance sheets. The valuation allowance increased by approximately $11.1 million and $23.6 million, respectively for the years ended December 31, 2022 and 2021.

At December 31, 2022, the Company has federal net operating loss carryforwards of approximately $225.4 million of which $209.5 million will not expire and $15.8 million begin expiring in 2034. The Company also has state net operating loss carryforwards of approximately $16.3 million which begin to expire in 2034. Additionally, the Company has federal tax credits of approximately $9.3 million which begin to expire in 2036 and state tax credits of approximately $3.0 million which do not expire.

At December 31, 2022, the Company has foreign net operating loss carryforwards of approximately $2.4 million, which have no expiration date.

Use of the net operating loss and credit carryforwards may be subject to a substantial annual limitation due to the ownership change provisions of U.S. tax law and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before use.

Pursuant to the Internal Revenue Code, as amended (the "Code") Sections 382 and 383, annual use of a company's NOL and research and development credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. If limited, the related tax asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. The Company has completed such an analysis pursuant to Sections 382 and 383 through December 31, 2021 and determined there was a change in control with an immaterial impact on the NOL available to offset future taxable income. The Company has reviewed the shareholder activity for the year ended December 31, 2022 and believe that no additional limitations have occurred.

Uncertain Tax Positions

The Company follows the provisions of the FASB ASC 740-10, Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in the consolidated financial statements of uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the consolidated financial statements due to the fact the liabilities have been netted against deferred attribute carryovers. It is the Company's policy to include penalties and interest related to income tax matters in income tax expense

The Company is subject to taxation in the United States and Australia. Because of the net operating loss and research credit carryforwards, all of the Company's tax years, from 2013 to 2022, remain open to U.S. federal, California, other state tax examinations. The Company's Australian subsidiaries remain open to examination from their inception to 2022. There were no interest or penalties accrued at December 31, 2022 and 2021. The Company does not expect that our uncertain tax positions will materially change in the next twelve months. The additional uncertain tax benefits would not impact our effective tax rate to the extent that we continue to maintain a full valuation allowance against our deferred tax assets.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year ended December 31,	
	2022	2021
Beginning balance	$ 3,249	$ 1,976
Additions for tax positions taken in a prior year	—	—
Additions for tax positions taken in a current year	439	1,273
Ending balance	$ 3,688	$ 3,249

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") into law. The Company reviewed the aspects of this law as it relates to income taxes and concluded that the CARES Act did not have a material impact to the Company's 2022 or 2021 provision for income taxes.

On August 16, 2022 the President signed into law the Inflation Reduction Act of 2022. The primary tax provisions in the new law include an alternative minimum tax (AMT) on certain large corporations, a tax on stock buybacks and certain energy-related tax credits each of which become effective after December 31, 2022. The provisions of the Inflation Reduction Act did not have a material effect on the Company's 2022 tax provision and related disclosures. The Company will continue to evaluate changes and revisions of the Inflation Reduction Act of 2022 and its impact on the Company's financial position, results of operations and cash flows.

Note 12. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands except for share and per share amounts):

	December 31,	
	2022	2021
Numerator:		
Net loss	$ (51,660)	$ (89,945)
Denominator:		
Weighted average common shares outstanding	33,496,534	29,718,506
Net loss per share, basic and diluted	$ (1.54)	$ (3.03)

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	December 31,	
	2022	2021
Stock options issued and outstanding	7,565,071	5,571,293
Restricted stock units	30,876	—
Restricted stock awards	427,401	—
Performance stock options	—	675,000
	8,023,348	6,246,293

Note 13. Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. This plan provides for pre-tax and post-tax contributions for all employees. Employee contributions are voluntary. Employees may contribute up to 100% of their annual compensation to this plan, as limited by an annual maximum amount as determined by the Internal Revenue Service. The Company may match employee contributions, and may make profit sharing contributions, in amounts to be determined at the Company's sole discretion. The Company made no contributions to the plan for the years ended December 31, 2022 and 2021, respectively.

Note 14. Business Combination

On May 19, 2022, the Company completed the Acquisition. Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition (the "Effective Time"), each share of capital stock of Novosteo (the "Novosteo Capital Stock") that was issued and outstanding immediately prior to the Effective Time was automatically cancelled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company (the "Company Common Stock"). These shares included options to purchase an aggregate of 507,108 shares of the Company Common Stock upon conversion of the outstanding Novosteo options based on the Company Option Exchange Ratio (as defined in the Merger Agreement), with the awards retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition. These options, as well as 519,216 unvested restricted shares were concluded to be post-combination expense and were excluded from purchase consideration.

The Company has included the financial results of Novosteo in the consolidated financial statements from the date of the Acquisition and recorded immaterial amounts of expenses and earnings since the period from May 19, 2022 through December 31, 2022. The transaction costs associated with the Acquisition were approximately $1.1 million and were recorded in general and administrative expense. The acquisition date fair value of the consideration transferred for Novosteo was approximately $16,502,587, which consisted of 5,000,784 shares at $3.30 per share.

The Company accounted for the Acquisition as a business combination in accordance with ASC Topic 805, Business Combinations ("ASC 805"). The Company applied the acquisition method, which requires the identifiable assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The following table summarizes the fair values of the identifiable assets acquired and liabilities assumed as the final determination of the date of acquisition (in thousands):

	May 19, 2022
Identifiable assets acquired and liabilities assumed:	
Cash and cash equivalents	$ 10,593
Prepaid expenses and other current assets	1,040
ROU asset	124
Property and equipment	279
In-process Research and Development	5,900
Accounts payable and accrued liabilities	(1,726)
Deferred tax liabilities	(532)
Net assets acquired	$ 15,678
Goodwill	$ 825

The final determination of the fair value of assets and liabilities have been completed within the one-year measurement period as required by ASC 805. As part of the valuation analysis, the fair value of the intangible assets was estimated by discounting forecasted risk adjusted cash flows at a rate that approximated the cost of capital of a market participant. Management's forecast of future cash flows was based on the income approach. Significant estimates, all of which are considered Level 3 inputs, were used in the fair value methodology, including the Company's forecast regarding its future operations and likeliness of obtaining approval to sell its products, as well as other market conditions. The Company recorded no measurement period adjustments for the year ended December 31, 2022. All subsequent adjustments will be recorded to earnings.

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill, which is primarily attributed to the assembled workforce and expanded market opportunities, for which there is no basis for U.S. income tax purposes. Goodwill amounts are not amortized but are rather tested for impairment at least annually, see Note 15 for this assessment. Goodwill is not deductible for tax purposes.

The Intangible asset balance above is attributable to in-process research and development with an indefinite useful life.

The unaudited pro forma revenue and net loss for the years ended December 31, 2022 and 2021 of the combined entity had the acquisition date been January 1, 2021 are as follows:

	For the year ended December 31,	
	2022	2021
Revenue	$ 262	$ 225
Net loss	(52,592)	(96,075)

The 2022 supplemental pro forma earnings were adjusted to exclude $2.2 million of acquisition-related costs incurred in 2022, the 2021 pro forma earnings were adjusted to include these charges. The Company’s consolidated statements of operations and comprehensive loss for the year ended December 31, 2022 include immaterial net revenue and net loss attributable to the Acquisition.

Note 15. Intangible Assets

The intangible asset acquired as a result of the Acquisition consists of in-process research and development ("IPRD") related to NOV004, the Company's bone targeting molecule designed to accelerate fracture repair. The value of the IPRD was determined using discounted probable future cash flows.

Significant assumptions used in determining the fair value of the IPR&D include revenue growth rates, risk adjusted discount rates, and clinical trial success rate.

All intangible assets acquired in a business combination that are used in research and development activities are capitalized as indefinite-lived intangible assets. During the period that those assets are considered indefinite lived, they are not amortized but are tested for impairment. Once the research and development efforts are completed, the asset will be amortized over its remaining useful life. If the research and development efforts are abandoned, the intangible asset will be expensed in that period.

As of December 31, 2022, management performed a quantitative impairment evaluation of IPR&D intangible asset. The quantitative evaluation included a discounted cash flow analysis to determine if the intangible asset had decreased in value. In order to determine the fair value of the intangible asset, the Company utilized an average of a discounted cash flow analysis and comparable public company analysis. The key assumptions associated with determining the estimated fair value include projected future revenue growth rates, after tax free cash flow, and the discount rate. The assumptions used in the discount rate calculation were based on a peer company metrics to determine the weighted average cost of capital. This quantitative analysis resulted in the intangible asset fair value being above its carrying value, resulting in no impairment.

Fair value determinations require considerable judgment and are sensitive to changes in underlying assumptions, estimates and market factors. Estimating the fair value of the Company's indefinite-lived intangible assets requires assumptions and estimates regarding the Company's future plans, as well as industry, economic, and regulatory conditions. These assumptions and estimates include projected future revenue growth rates, discount rates, relevant market multiples, royalty rates and other market factors. If current expectations of future growth rates, margins and cash flows are not met, or if market factors outside of the Company's control change significantly, then the reporting unit or indefinite-lived intangible assets might become impaired in the future, negatively impacting the Company's operating results and financial position.

The following table provides details of the carrying amount of the Company's indefinite-lived intangible asset (in thousands):

	As of December 31, 2022
Unamortized intangible assets:	
In-process research and development	$ 5,900

Goodwill

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill.

The following table sets forth the change in the carrying amount of goodwill for the Company as of and for the year ended December 31, 2022:

Balance at December 31, 2021	$ —
May 19, 2022	825
Impairment charge	(825)
Balance at December 31, 2022	—

As of September 30, 2022, management performed an impairment evaluation of goodwill after assessing qualitative factors that indicated a possible impairment of goodwill. Under the qualitative assessment, management considers relevant events and circumstances including but not limited to macroeconomic conditions, industry and market considerations, overall company performance and events directly affecting the Company. It was noted during our assessment that the Company's market capitalization was significantly below its carrying value and a further quantitative analysis was conducted to determine to the extent, if any, the Company's carrying value exceeded its fair value as of September 30, 2022. The quantitative analysis used fair value based on market capitalization adjusted for control premium based on market comparable transactions. This quantitative analysis resulted in the Company's fair value being significantly below its carrying value, resulting in a non-cash goodwill impairment charge of $0.8 million being recorded during the year ended December 31, 2022.

Note 16. Subsequent Events

On January 30, 2023, the Company announced the approved the cost reduction program to align operations with the Company's decision to cease internal development efforts on NOV004 and explore partnership and out-licensing opportunities. Under the cost reduction program, the Company will reduce headcount by approximately 47% through a reduction in its workforce. The reduction in force began in February 2023 and will be completed by April 2023.

In connection with the cost reduction program, the Company estimates that it will incur expenses of approximately $0.6 million to $0.8 million, substantially all of which will be cash expenditures and other costs relating to the Plan through August 2023. The Company may incur other charges, including contract termination costs, retirement of fixed assets and facility-related costs and

will record these expenses in the appropriate period as they are determined. These estimates are subject to a number of assumptions, and actual results may differ. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the cost reduction program.

On January 27, 2023, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Lighthouse Pharmaceuticals, Inc. ("Purchaser") for the sale of its legacy small molecule protease inhibitor portfolio for all uses and indications throughout the world (the "Transaction"), including COR388, COR588, COR803 and COR852, related drug substance, drug product and other related materials, related regulatory materials, and related intellectual property rights and contracts. The Transaction was also consummated on January 27, 2023.

Upon the consummation of the Transaction, the Company received shares of common stock of Purchaser ("Common Stock") equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by the Company and Purchaser on January 27, 2023 (the "Stock Agreement"). The Stock Agreement contains certain anti-dilution rights of the Company and certain transfer restrictions on the Common Stock, including a right of first offer in favor of Purchaser and certain restrictions with respect to non U.S. persons.

Pursuant to the terms of the Purchase Agreement, the Company is eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, the Company is eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

Each of the Company and Purchaser have made certain covenants in the Purchase Agreement with respect to the transfer of the assets, including requisite filings to be made with regulatory authorities, and the milestone, royalty and sublicense payments and have agreed to indemnify each other for any breaches of such party's covenants, assumed liabilities (in the case of Purchaser) and retained liabilities (in the case of the Company), subject to certain customary survival periods and mitigation requirements. In addition, Purchaser granted to the Company an exclusive option until June 30, 2023 to obtain worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license under the transferred intellectual property related to COR388 to research, develop, manufacture, use, commercialize and otherwise exploit COR388 in any animal health indication.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, of the effectiveness of our "disclosure controls and procedures" as of the end of the period covered by this Annual Report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Exchange Act. In connection with that evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms as of December 31, 2022. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management used the Committee of Sponsoring Organizations of the Treadway Commission Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 and has concluded that such internal control over financial reporting is effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting as long as we are a smaller reporting company pursuant to the provisions of Rule 12b-2 of the Exchange Act.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our fourth quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item will be included in our 2023 Proxy Statement under the caption "Proposal One: Election of Directors," which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all of the members of our board of directors, officers and employees. Information regarding our Code of Business Conduct and Ethics required by this item will be contained in our 2023 Proxy Statement under the caption "Code of Business Conduct and Ethics" and is hereby incorporated by reference. The full text of our Code of Business Conduct and Ethics is posted on the Investor Relations section of our website, which is located at https://ir.quincetx.com/investor-relations, by clicking on "Governance Documents" in the "Governance" section of our website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8 K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the location specified above.

Item 11. Executive Compensation

The information required by this item will be included in our 2023 Proxy Statement under the captions "Director Compensation," "Executive Compensation," which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management And Related Stockholder Matters

The information required in this item will be included in our 2023 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information," which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required in this item will be included in our 2023 Proxy Statement under the captions "Review, Approval or Ratification of Transactions with Related Parties" and "Independence of Directors," which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Our independent registered public accounting firm is BDO USA, LLP, Chicago, Illinois, PCAOB Auditor ID 243.

The information required in this item will be included in our 2023 Proxy Statement under the caption "Independent Registered Public Accounting Firm Fees and Services," which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements

See Index to Consolidated Financial Statements in Part II Item 8 of this Annual Report on Form 10-K.

2. Consolidated Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

3. Exhibits

The documents listed in the Exhibit Index are incorporated by reference or are filed with this report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
2.1	Agreement and Plan of Merger and Reorganization, dated as of May 9, 2022 by and among Cortexyme,Inc., Novosteo Inc., Quince Merger Sub I, Inc., Quince Merger Sub II, LLC and Fortis Advisors LLC	8-K	001-38890	2.1	5/12/2022	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38890	3.1	5/13/2019	
3.2	Certificate of Amendment to the registrant's Certificate of Incorporation, effective August 1, 2022	8-K	001-38890	3.1	8/1/2022	
3.3	Amended and Restated Bylaws	8-K	001-38890	3.2	8/1/2022	
4.1	Specimen Stock Certificate	S-1	333-230853	4.1	4/29/2019	
4.2	Amended and Restated Investors' Rights Agreement, dated May 23, 2018 by an among the Registrant and certain of its stockholders	S-1	333-230853	4.2	4/12/2019	
4.3	Description of Securities	10-K	001-36276	4.3	3/1/2021	
10.1**	License Agreement dated June 3, 2020, by and between Purdue Research Foundation and Novosteo Inc.	10-Q	001-38890	10.18	8/9/2022	
10.2**	Amendment No.1 to License Agreement dated March 21,2022, by and between Purdue Research Foundation and Novosteo Inc.	10-Q	001-38890	10.19	8/9/2022	
10.3**	Second Amendment to License Agreement, dated as of July 22, 2022, by and between Purdue Research Foundation and Novosteo, Inc	10-Q	001-38890	10.1	11/09/2022	
10.4+	Employment Offer Letter, by and between Cortexyme, Inc. and Brendan Hannah, dated May 9,2022	10-Q	001-38890	10.2	8/9/2022	
10.5+	Employment Offer Letter, by and between Cortexyme, Inc. and Karen Smith, dated May 9,2022	10-Q	001-38890	10.3	8/9/2022	
10.6+	Employment Offer Letter, by and between Cortexyme, Inc. and Dirk Thye, dated May 9,2022	10-Q	001-38890	10.4	8/9/2022	
10.7+	Form of Indemnification Agreement between Cortexyme, Inc. and each of its officers and directors	S-1/A	333-230853	10.2	4/29/2019	
10.8+	2014 Stock Plan, as amended as of November 28, 2018, and related forms of stock award agreements	S-1	333-230853	10.3	4/12/2019	
10.9+	2019 Equity Incentive Plan and forms of stock award agreements thereunder	S-1/A	333-230853	10.4	4/29/2019	
10.10+	2019 Employee Stock Purchase Plan	S-1/A	333-230853	10.5	4/29/2019	
10.11+	Executive Incentive Bonus Plan	S-1	333-230853	10.6	4/12/2019	
10.12+	Cortexyme, Inc. 2022 Inducement Plan	S-8	333-265109	99.1	5/20/2022	
10.13+	Forms of Stock Option Award Agreement, Notice of Stock Option Grant and Exercise Notice under Cortexyme, Inc. 2022 Inducement Plan	S-8	333-265109	99.2	5/20/2022	
10.14+	Forms of Restricted Stock Unit Award Agreement and Notice of Restricted Stock Unit Grant Cortexyme, Inc. 2022 Inducement Plan	S-8	333-265109	99.3	5/20/2022	
10.15+	Novosteo Inc. 2019 Equity Incentive Plan	S-8	333-265109	99.4	5/20/2022	

10.16+	Executive Change in Control and Severance Agreement by and between Cortexyme, Inc. and Brendan Hannah, dated May 19, 2022	10-Q	001-38890	10.10	8/9/2022	
10.17+	Executive Change in Control and Severance Agreement by and between Cortexyme, Inc. and Karen Smith, dated May 19, 2022	10-Q	001-38890	10.11	8/9/2022	
10.18+	Executive Change in Control and Severance Agreement by and between Cortexyme, Inc. and Dirk Thye, dated May 19, 2022	10-Q	001-38890	10.12	8/9/2022	
10.19+	Change in Control and Severance Agreement, by and between Cortexyme Inc. and Ted Monohon, dated as of September 21, 2021	10-Q	001-38890	10.1	10/29/2021	
10.20+**	Severance Agreement, dated February 1, 2022, between Casey Lynch and the Registrant	10-K	001-38890	10.1	3/1/2022	
10.21+	Change in Control and Severance Agreement, by and between Cortexyme Inc. and Caryn McDowell, Dated as of May 18, 2021	10-Q	001-38890	10.2	8/6/2021	
10.22+	Change in Control and Severance Agreement, by and between Cortexyme Inc. and Christopher Lowe, Dated as of May 18, 2021	10-Q	001-38890	10.3	8/6/2021	
10.23+	Change in Control and Severance Agreement, by and between Cortexyme Inc. and Leslie Holsinger, Dated as of May 18, 2021	10-Q	001-38890	10.4	8/6/2021	
10.24	Sublease Agreement, by and between Cortexyme, Inc. and ICON Clinical Research LLC, dated as of May 5, 2022	10-Q	001-38890	10.14	8/9/2022	
10.25	Consent to Sublease, by and between Cortexyme, Inc. and ICON Clinical Research LLC, dated as of June 8, 2022	10-Q	001-38890	10.15	8/9/2022	
10.26	Sub-Sublease Agreement by and between Cortexyme, Inc. and Verily Life Sciences LLC, dated June 18, 2018.	10-Q	333-230853	10.1	4/12/2019	
10.27	Amendment No. 1 to Sub-Sublease by and between Cortexyme, Inc. and Verily Life Sciences LLC dated April 2, 2019.	10-Q	001-38890	10.1	8/9/2019	
10.28	Second Amendment to Sub-Sublease by and between Cortexyme, Inc. and Verily Life Sciences LLC dated May 26, 2020	10-Q	001-38890	10.1	8/14/2020	
10.29	Third Amendment to Sub-Sublease by and between Cortexyme, Inc. and Verily Life Sciences LLC dated July 15,2021	10-Q	001-38890	10.7	8/6/2021	
10.30	Outside Director Compensation Policy adopted April 9,2019; Amended and Restated: June 7, 2022	10-Q	001-38890	10.17	8/9/2022	
10.31	Open Market Sales Agreement℠ dated December 23, 2021, by and between Cortexyme, Inc. and Jefferies LLC	8-K	001-38890	10.1	12/23/2021	
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K)					X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act					X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act					X

32.1#	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
32.2#	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X
101.INS	Inline XBRL Instance Document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	The cover page from this Annual Report on Form 10-K, formatted in Inline XBRL	

+ Management contract or compensatory plan or arrangement.

** Portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.

In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Quince Therapeutics, Inc.

Date: March 15, 2023

By: /s/ Dirk Thye
Dirk Thye

Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Dirk Thye and Ted Monohon, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Dirk Thye **Dirk Thye**	Chief Executive Officer, and Director (Principal Executive Officer)	March 15, 2023
/s/ Ted Monohon **Ted Monohon**	Chief Accounting Officer and Vice President, Finance (Principal Financial Officer and Principal Accounting Officer)	March 15, 2023
/s/ David A. Lamond **David A. Lamond**	Director	March 15, 2023
/s/ Margaret McLoughlin **Margaret McLoughlin, Ph.D.**	Director	March 15, 2023
/s/ Una Ryan **Una Ryan, OBE Ph.D.**	Director	March 15, 2023
/s/ Christopher J. Senner **Christopher J. Senner**	Director	March 15, 2023
/s/ Philip Low **Philip Low**	Director	March 15, 2023
/s/ June Bray **June Bray**	Director	March 15, 2023

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Quince Therapeutics, Inc.
South San Francisco, California

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 of Quince Therapeutics, Inc. of our report dated March 15, 2023, relating to the consolidated financial statements which appear in the Annual Report to Shareholders, which is incorporated by reference in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ BDO USA, LLP
San Jose, California

March 15, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dirk Thye, certify that:

1. I have reviewed this Annual Report on Form 10-K of Quince Therapeutics, Inc. for the fiscal year ended December 31, 2022;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 15, 2023

/s/ Dirk Thye

Dirk Thye
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ted Monohon, certify that:

1. I have reviewed this Annual Report on Form 10-K of Quince Therapeutics, Inc. for the fiscal year ended December 31, 2022;

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

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

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

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 15, 2023

/s/ Ted Monohon

Ted Monohon

Chief Accounting Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Annual Report of Quince Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof to which this Certification is attached as Exhibit 32.1 (the "Report"), I certify, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 15, 2023 By: /s/ Dirk Thye

Dirk Thye
President and Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Annual Report of Quince Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof to which this Certification is attached as Exhibit 32.1 (the "Report"), I certify, pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 15, 2023

By: /s/ Ted Monohon

Ted Monohon
Chief Accounting Officer
(Principal Financial Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.