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, 2024
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.)
611 Gateway Boulevard, Suite 273 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	The Nasdaq Stock Market LLC

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $23.2 million based on the closing price of the registrant's common stock, as reported by the Nasdaq Global Select Market on June 28, 2024 of $0.7500 per share.

As of March 13, 2025, the registrant had 44,001,643 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement (the "Proxy Statement") relating to its 2025 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, drug 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;
- 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 eDSP 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 approvals for our 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 drug candidates for their respective indications;
- whether regulatory authorities determine that additional trials or data are necessary in order to accept a new drug application for review and/or approval;
- the ability of any future clinical trials to demonstrate safety and efficacy of eDSP and other drug candidates, and other positive results;
- our financial performance;
- our ability to continue as a going concern, the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our expectations related to the use of our available cash;
- our ability to service our debt obligations and maintain compliance with associated covenants;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our drug candidates;
- our expectations regarding the potential market size and the size of the patient populations for our drug candidates, if approved for commercial use, and the potential market opportunities for commercializing our drug candidates;
- our plans relating to commercializing our drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any 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;
- dependence upon the integrity of our supply chain, including multiple single-source suppliers;
- our reliance on third-party suppliers for certain of our raw materials and components;
- our ability to expand our 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 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 drug candidates, and any related restrictions, limitations and/or warnings in the label of any approved drug candidate;
- our ability to obtain and maintain CE Certificates of conformity for the medical device components of our eDSP System in accordance with applicable legislation governing medical devices;
- our ability to transition CE Certifications under the previous Medical Device Directive, to a regulatory framework under MDR;
- 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 drug candidates and technology;
- potential claims relating to our intellectual property;
- our ability to grow our organization and increase the size of our facilities to meet our anticipated growth; and
- our ability to maintain compliance with Nasdaq listing requirements.

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 drug 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:

- We are substantially dependent on the success of our lead drug candidate, eDSP. The Phase 3 NEAT clinical trial of eDSP for A-T is being conducted under a protocol negotiated with FDA by EryDel and our execution of the trial may be slowed, may not be successful, and may not result in NDA approval, with adverse results for our business and share price.
- We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.
- There is substantial doubt regarding our ability to continue as a going concern. We will need to raise substantial additional funding, which may not be available on acceptable terms, to finance our operations and to develop and evaluate current and future drug candidates. If we are unable to raise this additional capital when needed or on acceptable terms, we may be forced to delay, limit, reduce, terminate or eliminate our drug development programs or other operations.
- We have and may be required to make additional milestone payments to (i) EryDel shareholders pursuant to the terms of the EryDel Acquisition or (ii) additional remuneration payments to EIB pursuant to the EIB Loan in connection with our commercialization of eDSP, which could adversely affect the overall profitability of eDSP, if approved.
- Clinical drug development is a lengthy, expensive and uncertain process. Results in preclinical studies and earlier clinical trials may not be indicative of future results, which may delay or prevent obtaining regulatory approval. 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 on a timely basis or at all.
- We will incur additional costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.
- Our drug candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.
- Clinical trials of our drug candidates may not uncover all possible AEs that patients may experience.
- If we are not able to successfully demonstrate a favorable differentiation between EryDex and currently available corticosteroids, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.
- Because the potential rare disease target patient populations of EryDex are small, and the addressable patient population even smaller, we may not be able to effectively complete clinical trials or commercialize the drug candidate.
- We are a clinical stage biotechnology company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.
- The terms of the EIB Loan place restrictions on our operating and financial flexibility.
- We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any current or future proposed clinical trial designs or to move directly to Phase 2 clinical trials in additional indications. Our drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.
- Clinical trials of our drug candidates have in the past been put on clinical holds by, and failed to demonstrate safety and efficacy to the satisfaction of, the FDA, and if any future clinical trials of our drug candidates are put on clinical holds by, or fail to demonstrate safety and efficacy to the satisfaction of, the FDA, the EMA, and the European Commission, or similar regulatory authorities outside the United States, or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.
- We currently rely and expect to continue to 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, clinical and commercial materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.

- If we or any of our third-party manufacturers or suppliers 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.
- Our stockholders may realize little or no value from the divestiture of our legacy assets, and as a result our stock price may decline, we could be subject to litigation, and our business may be adversely affected.
- We have in the past and may in the future fail to meet the requirements for continued listing on Nasdaq. If we fail to maintain compliance with the minimum listing requirements, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

DEFINED TERMS

Unless the context requires otherwise, references to "Quince," "the Company," "we," "us," or "our" in this Annual Report on Form 10-K refer to Quince Therapeutics, Inc. and its consolidated subsidiaries. We also have used several other terms in this Annual Report on Form 10-K, most of which are explained or defined below.

Abbreviated Term	Defined Term
2017 Tax Act	Tax Cuts and Jobs Act of 2017
3PLs	Third-party Logistics Providers
AE	Adverse Event
AIA	Leahy-Smith America Invents Act
AIDE	Autologous Intracellular Drug Encapsulation
ANDA	Abbreviated New Drug Application
ARB	Angiotensin Receptor Blockers
ASC	Accounting Standards Codification
ASU	Accounting Standards Update
A-T	Ataxia-Telangiectasia
ATTeST	Ataxia Telangiectasia Trial with the eDSP System
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
C-GIC	Clinical Global Impression of Change
Cmax	The highest (peak) concentration of a drug in the bloodstream or other part of the body after drug administration
CMC	Chemistry Manufacturing Controls
CMO	Contract Manufacturing Organization
CMS	Center for Medicare and Medicaid Services
the Code	Internal Revenue Code of 1986, as amended
COSO framework	Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission
COVID-19	Coronavirus disease
CPA	Certified Public Accountant
Credits	Tax credits
CRO	Contract Research Organization
CTA	Clinical Trial Application
CTR	European Union pharmaceutical legislation known as the Clinical Trials Regulation
Debt Agreement	Unsecured line of credit agreement between EryDel and the European Investment Bank, which the Company guaranteed on October 20, 2023 in connection with the EryDel Acquisition
DMD	Duchenne muscular dystrophy
DOJ	United States Department of Justice
DSMB	Data Safety Monitoring Board
DSP	Dexamethasone Sodium Phosphate
EC	European Commission
EMA	European Medicines Agency
EryDel	Quince Therapeutics, S.p.A (previously named EryDel S.p.A.)
eDSP	Encapsulated dexamethasone sodium phosphate encapsulated in patient's own red blood cells (previously referred to as EryDex)

eDSP System	Automated combination product to encapsulate dexamethasone sodium phosphate in red blood cells
EIB	European Investment Bank
EU	European Union
EIB Loan	Unsecured line of credit between EryDel and the European Investment Bank
Treatment Kit	Sterile, single-use kit component of the eDSP System
Exchange Act	Securities Exchange Act of 1934, as amended
FASB	Financial Accounting Standards Board
FCPA	Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977
FDA	United States Food and Drug Administration
GAAP	generally accepted accounting principles in the United States
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act of 2009
HPA	Hypothalamic-Pituitary-Adrenal (HPA) Axis
HTA	Health Technology Assessment
ICARS	International Cooperative Ataxia Rating Scale
IND	Investigational New Drug
IPO	Initial Public Offering
IPR&D	In-process Research and Development
IRA	Inflation Reduction Act of 2022
IRB	Institutional Review Board
ITT	Intent To Treat
Jefferies	Jefferies LLC
Lighthouse	Lighthouse Pharmaceuticals, Inc.
LSM	Least Square Mean
MAA	Marketing Authorization Application
MAD	Multiple Ascending Dose
MDD	Medical Devices Directive
MDR	Medical Devices Regulation 2017/745
Medicare Drug Price Negotiation Program	Program under the IRA which allows HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years 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
mICARS	Modified International Cooperative Ataxia Rating Scale
mITT	Modified intent-to-treat population
MHRA	United Kingdom Medicines and Healthcare Products Regulatory Agency
MPEEM	Multi-Period Excess Earnings Method
Nasdaq	The Nasdaq Stock Market LLC
NCE	New Chemical Entity
NDA	New Drug Application
NEAT	eDSP Phase 3 Clinical Trial (Neurological Effects of eDSP on Subjects with A-T)
NIH	National Institute of Health

NOL	Net Operating Loss
Novosteo	Novosteo, Inc.
Novosteo Acquisition	Acquisition of Novosteo, Inc.
OLE	Open-Label Extension Clinical Trial
PCAOB	Public Company Accounting Oversight Board
PCT	Patent Cooperation Treaty
PD	Pharmacodynamic
PDMA	Prescription Drug Marketing Act
Process solutions	(Hypotonic Solutions 1& 2 and Hypertonic Solution PIGPA) sterile solutions to allow drug encapsulation and restoring the physiological osmolarity during eDSP process
PP	Per Protocol Population is all patients who enrolled into the study and fulfilled all inclusion/exclusion criteria, did not have any major protocol violations, and completed the initial treatment period of the study as planned.
PK	Pharmacokinetic
PPACA	Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010
PRF	Purdue Research Foundation
PTE	Patent Term Extension
R&D	Research and Development
RCL	Red Cell Loader, the machine that encapsulates drug into red blood cells
REMS	Risk Evaluation and Mitigation Strategies
Registrational or pivotal trial	An adequate and well-controlled trial designed to be sufficient to apply for regulatory approval of a drug candidate, although notwithstanding the Company's design a regulatory agency may determine that further clinical studies or data are required
RmICARS	Rescored modified International Cooperative Ataxia Rating Scale
RBC	Red Blood Cell
RSA	Restricted Stock Awards
RSU	Restricted Stock Units
SAD	Single Ascending Dose
SAE	Serious Adverse Event
Sarbanes-Oxley Act	The Sarbanes-Oxley Act of 2002
SEC	United States Securities and Exchange Commission
Securities Act	Securities Act of 1933
SPA	Special Protocol Assessment
Syringe Kit	Device for anticoagulated blood collection and for the sterile connection to the treatment kit
TCA	Trade and Cooperation Agreement
TEAE	Treatment-Emergent Adverse Effect
UPC	Unified Patent Court
USPTO	The United States Patent and Trademark Office
VA	Veterans Affairs

PART I

Item 1. Business.

Overview

We are a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases. Our proprietary AIDE technology platform is an innovative drug/device combination that uses an automated process designed to encapsulate a drug into the patient's own red blood cells. Red blood cells have several characteristics that make them an excellent vehicle for drug delivery, potentially including better safety and tolerability, enhanced tissue biodistribution, reduced immunogenicity, and prolongation of circulating half-life. Our AIDE technology is designed to harness these benefits to allow for new and improved therapeutic options for patients living with high unmet medical needs. The AIDE technology platform is believed to confer several benefits over conventional therapies and can be applied to a broad range of small or large molecule drugs and biologics. Our lead asset, eDSP, uses our AIDE technology to encapsulate DSP into a patient's own red blood cells and is in a pivotal Phase 3 clinical trial to evaluate the treatment of a rare pediatric neurodegenerative disease, A-T. We began enrollment of the Phase 3 NEAT clinical trial of eDSP in patients with A-T in June 2024 and, as of March 24, 2025, 61 participants have been enrolled in the NEAT clinical trial and 24 participants have entered the 12-month open label extension trial study.

Strategy

We intend to focus our resources and capital toward the advancement of our proprietary AIDE technology platform and Phase 3 lead asset, eDSP.

eDSP is the first drug in development that leverages our AIDE technology and is composed of DSP encapsulated in autologous red blood cells for the treatment of A-T. DSP is a corticosteroid well-described for its anti-inflammatory properties, but is coupled with serious adverse effects, including potential long-term adverse effects due to adrenal suppression. eDSP is designed to maintain the efficacy of corticosteroids while reducing or eliminating the significant adverse effects associated with corticosteroid treatment. To date, there have been more than 7,800 infusions of eDSP in approximately 425 patients (>240 with A-T) who received at least one eDSP treatment through participation in our sponsored clinical trials or expanded access programs. 188 patients have received eDSP treatment for at least 12 months — and many for several consecutive years — without toxicities well-known to be associated with chronic corticosteroid use.

Currently, there are no approved treatments for A-T and the global market, based on our internal estimates and assumptions, represents a $1+ billion peak commercial opportunity. We believe this makes eDSP an ideal lead asset to demonstrate the clinical and commercial potential of our AIDE technology.

Our strategic priority is to complete the Phase 3 NEAT clinical trial of eDSP to evaluate its safety and efficacy for the treatment of A-T. We also plan to expand our development pipeline to include additional indications for eDSP where chronic corticosteroid treatment is or has the potential to become a standard of care. We selected DMD as our second development program. We consider DMD an excellent indication for eDSP as corticosteroids are the standard of care for this rare disease, and their utility is limited by significant toxicities. We expect to advance eDSP for DMD utilizing capital efficient study approaches and subject to receiving financial support from grant and/or opportunistic funding opportunities. We also intend to expand our development pipeline beyond A-T and DMD to target eDSP for the treatment of immunological and autoimmune focused rare disease indications, subject to additional funding.These priorities include the following activities and corporate milestones:

- Complete enrollment of our Phase 3 NEAT clinical trial in the second quarter of 2025.
- Report our Phase 3 NEAT clinical trial topline results in the fourth quarter of 2025.
- Initiate our DMD Phase 2 clinical trial in 2025, pending additional funding.
- Prepare for a U.S. NDA submission in 2026, provided we obtain positive NEAT study results.
- Prepare for a European MAA submission in 2026, provided we obtain positive NEAT study results.
- Initiate a Pediatric Investigational Plan to evaluate a younger population of patients with A-T in 2025.
- Advance U.S. commercial planning activities for eDSP for A-T.
- Select one to two additional immunological and autoimmune focused rare disease indications for eDSP.

- Evaluate potential strategic partnerships to out-license ex-U.S. rights for eDSP.

We benefit from a strong senior leadership team who possess a wide range of biotech expertise that encompasses all stages of drug development, regulatory submission and approval, and commercialization. Our team has previously been involved in drug programs that resulted in numerous FDA approvals, founded and sold companies, and participated in various public and private financings that resulted in hundreds of millions of dollars of company investment, in addition to a number of successful exits that generated billions of dollars in shareholder value. We believe this breadth of experience will meaningfully benefit the Company as we work to successfully execute our strategic priorities.

Fiscal Year 2024 Key Events

- Initiated the Phase 3 NEAT clinical trial of eDSP in A-T in June 2024 and the OLE study in December 2024.
- Selected DMD as our second development program and initiated work generating a Phase 2 clinical trial study designed to evaluate eDSP for the treatment of patients with DMD.
- Completed the evaluation process of other potential rare disease indications for eDSP beyond A-T and DMD that resulted in a prioritized list of immunological and autoimmune focused rare disease indications for potential new program development.
- Granted Fast Track designation from the FDA for our eDSP System for the treatment of patients with A-T in June 2024.
- Published efficacy and safety results from our Phase 3 ATTeST clinical trial evaluating eDSP for the treatment of A-T in peer-reviewed medical journal *The Lancet Neurology*.
- Participated at notable scientific conferences, including poster presentations at the 53rd Child Neurology Society (CNS) Annual Meeting and the 2024 International Congress for Ataxia Research (ICAR), where we presented results from our Phase 3 ATTeST clinical trial.
- Completed an initial patient sizing project based on third-party analysis from IQVIA Medical Claims (Dx), PharmetricsPlus (P+), and IQVIA Analytics, which confirmed that the number of diagnosed patients with A-T in the U.S. is estimated to be to approximately 4,600.
- Established a Scientific Advisory Board (SAB) comprised of leading experts in biochemistry, neurology, immunology, hematology, pharmacology, and clinical practice who are uniquely positioned to provide us with deep insights and advice to support advancement of our drug programs.

Proprietary AIDE Technology Platform

Our proprietary AIDE technology platform is a novel and innovative drug/device combination that uses an automated process designed to encapsulate a drug into the patient's own red blood cells. Red blood cells have several characteristics that make them a potentially ideal vehicle for drug delivery, including potentially better tolerability, enhanced tissue biodistribution, reduced immunogenicity, and prolongation of circulating half-life. Our AIDE technology is designed to harness these benefits to allow for the chronic administration of drugs that have limitations due to toxicity, poor biodistribution, suboptimal pharmacokinetics, or immune response. In this way, the flexibility of our AIDE technology is believed to confer several benefits over conventional therapies and can be applied to a broad range of small or large molecule drugs and biologics. Additionally, the AIDE technology's use of autologous red blood cells in the encapsulation process is different from standard cell therapies, such as synthetic or engineered cells, as well as distinct from typical blood transfusions that utilize donor red blood cells for drug administration to the patient. The use of autologous blood may minimize safety risks associated with the use of donor blood and may reduce the potential immunogenic risks associated with donor cells and synthetic cell therapies.

The AIDE technology drug/device combination consists of a proprietary CE marked non-invasive automated device called the RCL, along with a sterile single-use treatment kit. The automated drug encapsulation process and treatment are designed to be completed at the point-of-care and includes a series of steps which take approximately two hours from start to finish:

- Collection of 50mL of a patient's blood.
- Loading the patient's collected blood in the RCL using the sterile, single-use treatment kit.
- Autologous red blood cells in the RCL are swollen and their pores are "opened" using two hypotonic process solutions.

- Drug is added to the RCL and enters into the opened red blood cells.
- Physiological osmotic conditions are then restored by adding a hypertonic solution that "reseals" the red blood cells.
- Drug that is not encapsulated during the process is removed by extensive washing.
- Upon completion of the process, the drug encapsulated red blood cells are infused into the patient.

Our AIDE technology is the result of more than two decades of rigorous scientific research and $100 million of investment, which has resulted in innovation that creates high barriers to competitive entry. The RCL and single-use treatment kit are proprietary products and CE marked in the EU, in accordance with the MDR and MDD.

Potential Benefits of Drug Encapsulated in Patient's Own Red Blood Cells

Many efficacious drugs have limited therapeutic potential because of toxicity, while other drugs may have efficacy limitations due to biodistribution, pharmacokinetics, and pharmacodynamics. Our proprietary AIDE technology uses an automated process designed to encapsulate a drug into the patient's own red blood cells to deliver a therapy in a potentially more effective and safer method. Autologous red blood cells have several characteristics that make them an ideal vehicle for drug delivery:

- Potential for improved biodistribution as encapsulated drug in autologous red blood cells is designed to enable the slow release of the drug from the red blood cells while circulating through various tissue beds.
- Potential for improved pharmacokinetics and pharmacodynamics, including increasing circulating half-life and optimized drug-receptor interactions. The improved pharmacokinetics and pharmacodynamics of the red blood cell encapsulated drug may significantly increase the desired therapeutic effects and improve the safety profile of the therapy.
- Potential for avoiding issues with donor compatibility associated with heterologous cells.
- Potential for the encapsulation of small or large molecules, peptides, and proteins inside autologous red blood cells to limit biodegradability and immunogenicity.

eDSP — Encapsulated Dexamethasone Sodium Phosphate

One of the first drugs we encapsulated in autologous red blood cells was DSP. DSP is a corticosteroid well-described for its anti-inflammatory properties but is also coupled with serious adverse events, including adrenal suppression. eDSP is designed to maintain the well-described efficacy of DSP while reducing or eliminating the significant adverse events that accompany chronic corticosteroid treatment. The altered biodistribution, pharmacokinetics, and pharmacodynamics of eDSP enabled by autologous red blood cells may, therefore, improve the safety profile while maintaining and/or improving the desired therapeutic effects of DSP.

eDSP was previously evaluated in multiple early-stage investigator-initiated trials and clinical trials to evaluate safety and efficacy across a number of disease indications, including:

- Ataxia-Telangiectasia (A-T): We completed an open-label, single-arm, multicenter Phase 2 clinical trial in 2012 evaluating the efficacy and safety of eDSP on neurological symptoms and adaptive behavior in patients with A-T (NCT01255358). The study included 22 patients with A-T (mean age: 11.2 years) with confirmed diagnoses and partially supported or autonomous gait treated with monthly infusions of eDSP for six months and a 19-month extension for some participants. The primary endpoint utilized the rating scale ICARS to measure ataxia symptoms. The study results found a significant reduction in ICARS scores (mean reduction: 4 points for the intention-to-treat group and 5.2 points for the per-protocol group). A subgroup undergoing extended treatment showed a slower progression of the disease compared to untreated controls. eDSP was also well-tolerated with most adverse events being mild and unrelated to the treatment. No typical long-term corticosteroid side effects, such as weight gain or metabolic disruptions, were observed. The study concluded that eDSP significantly improved neurological symptoms and adaptive behavior in patients with A-T without well-described steroid-related side effects. These findings provided the basis for advancing eDSP into a Phase 3 study in A-T.

- Ulcerative colitis (UC): We completed a double-blind, randomized, placebo-controlled Phase 2 clinical trial in 2012 evaluating the efficacy and safety of eDSP in enabling oral corticosteroid withdrawal while maintaining remission in steroid-dependent patients with UC (NCT01171807). The study included 37 patients with corticosteroid-dependent UC randomized in two cohorts to receive eDSP (n=19) or placebo infusions (n=18) for

six months with the primary endpoint measuring the proportion of patients with UC who discontinued oral corticosteroids while maintaining remission. Secondary endpoints included reduction in corticosteroid-related adverse events and mucosal healing. Study results included: 1) efficacy measured by 68.4% of eDSP treated patients with UC successfully discontinuing oral corticosteroids while maintaining disease remission compared to 22.2% in the placebo group (p-value = 0.008), and 2) safety demonstrated by corticosteroid-related adverse events decreasing significantly in the treatment group to 26.3% versus 72.2% in placebo controls (p-value = 0.008). Relapse occurred shortly after eDSP treatment cessation, highlighting the need for ongoing therapy for long-term benefits. The study concluded that eDSP enabled effective corticosteroid withdrawal and reduced adverse events in patients with UC, presenting a promising alternative for managing corticosteroid dependency.

- Chronic obstructive pulmonary disease (COPD): We completed a Phase 1b/2a clinical trial in 2000 evaluating the efficacy and safety of eDSP in enabling a slow, prolonged release of corticosteroids as a novel approach managing COPD while potentially reducing well-described side effects and improving compliance. The study included 10 patients with severe COPD, all of whom were previously treated with systemic or inhaled corticosteroids and β2-agonists. Participants were randomized in three cohorts to receive eDSP as follows: 1) group A (n=5): single administration with varying doses, 2) group B (n=3): two infusions at 15-day intervals, and 3) group C (n=2): single infusion of eDSP monitored for pharmacokinetics. Following the administration of eDSP, all patients with COPD suspended previous systemic or inhaled corticosteroids and β2-agonists therapies and were requested to record the time at which they felt the need to take these drugs. The primary endpoint was measured by clinical improvement (e.g., reduced symptoms, decreased need for other medications) and pharmacokinetics of dexamethasone. Study results included: 1) efficacy as measured by significant clinical improvements in breathing, coughing, bronchospasm, and bronchostenosis, patient ability to avoid corticosteroids and β2-agonists for up to 30 days after infusions, and reduced symptoms of dyspnea and bronchial obstruction; 2) safety demonstrated by no significant side effects observed and lower doses of dexamethasone used (25–50 times less than conventional doses) thereby minimizing exposure and potential toxicity. The study concluded that eDSP provided a promising alternative for managing COPD, reducing drug burden and side effects while maintaining efficacy.

- Cystic fibrosis (CF): We completed a Phase 1b/2a clinical trial in 2004 evaluating the efficacy and safety of eDSP in patients with CF. The study included 17 patients with CF are homozygous for the ΔF508 mutation. Study results found that the procedure for loading red blood cells with DSP was safe and reproducible with no significant adverse effects observed, in addition to eDSP providing slow and prolonged release of DSP in the bloodstream, detectable for up to 28 days after infusion. Patients with CF treated with eDSP showed significant improvement in lung function (FEV1), significant reduction in infective relapses due to *Pseudomonas aeruginosa*, no significant changes in BMI, and a decrease in plasma levels of the inflammatory cytokine IL-8. The study concluded that eDSP offered a promising approach for reducing pulmonary inflammation and improving lung function in CF without the adverse effects commonly associated with conventional corticosteroid therapy.

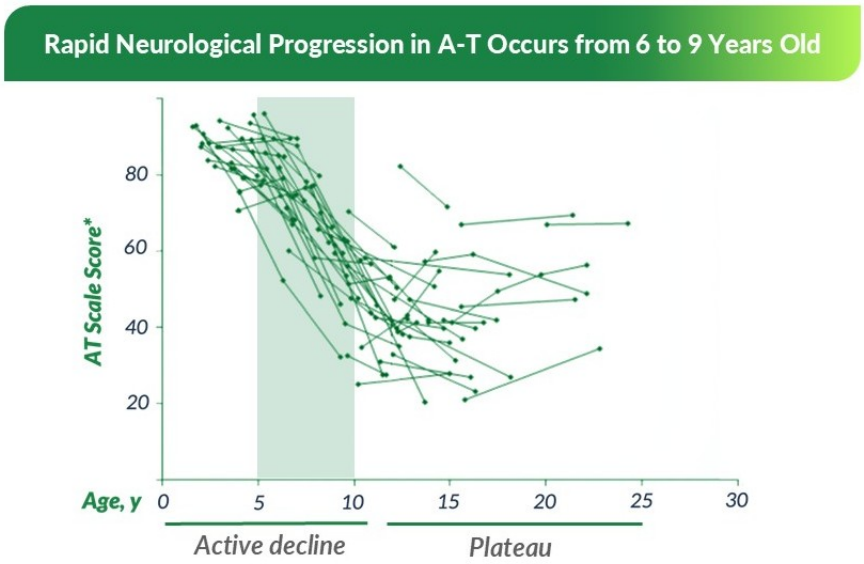
These previous clinical studies provide a robust set of efficacy and safety data upon which our development pipeline is informed. While each of these potential indications showed promising clinical study results, it was determined to advance eDSP for further evaluation of its efficacy and safety for the treatment of A-T primarily due to unmet need with no approved therapeutics for patients with A-T, previous literature showing a positive response to corticosteroids in the disease, a development path allowing for comparison to placebo control, favorable competitive landscape, and significant commercial opportunity.

Phase 3 Lead Asset – eDSP for the Potential Treatment of A-T

A-T Background and Prevalence

A-T is a rare inherited autosomal recessive neurodegenerative and immunodeficiency disorder caused by mutations in the ATM gene, which is responsible for cell homeostatic and cell division functions including but not limited to double-stranded DNA repair, cell cycle regulation, and oxidative stress response.

Typically, A-T is first diagnosed before the age of five as children begin to develop an altered gait and fall with greater frequency. As depicted below, neurological symptoms worsen and patients with A-T frequently become wheelchair-bound by adolescence with most of the clinical signs of neurodegeneration observed in patients with A-T before the age of 10. By the age of 12, the vast majority of patients with A-T have become non-ambulatory and the neurological signs of disease progression slow significantly.



*Scores based on the Crawford Quantitative Neurologic A-T Scale (100=normal). References: Rothblum-Oviatt C, et al. *Orphanet J Rare Dis.* 2016;11(1):159; Crawford TO, et al. *Neurology.* 2000;54(7):1505–1509.

Teenage years for patients with A-T are typically marked by repeated infections, pulmonary impairment, and malignancies. The median lifespan is approximately 25 to 30 years old with mortality due to infections and malignancy.

We completed a patient sizing project with third-party analysis from IQVIA Medial Claims (Dx), PharmetricsPlus (P+), and IQVIA Analytics, which confirmed that there are approximately 4,600 patients with A-T in the U.S. We estimate that there are and approximately 5,000 patients with A-T in the U.K. and EU4 countries. Currently, there are no approved therapeutic treatments for A-T and the global market, based on our internal estimates and assumptions, represents a more than $1 billion peak commercial opportunity.

Limitations of Chronic Corticosteroid Administration

DSP is a corticosteroid well known for its anti-inflammatory properties as well as its significant adverse toxicity, including long-term adverse effects due to adrenal suppression. The optimal efficacy of corticosteroids is the result of two pharmacokinetic characteristics: 1) an initial bolus to achieve a high Cmax that results in high levels of corticosteroid receptor occupation; and 2) sufficient sustained tissue concentrations that allow for continued receptor site occupancy over time. In order for conventional corticosteroids to achieve these characteristics, they must be dosed frequently, typically daily. However, the delivery of corticosteroids by either intravenous, intramuscular, subcutaneous, or oral routes result in multiple peaks and troughs. Although corticosteroids can readily achieve Cmax levels required to establish efficacy, frequent dosing regimens repeatedly exceeds toxicity thresholds associated with adverse events, leading to the chronic adverse effects such as hyperglycemia, immunosuppression, and suppression of the HPA axis. These chronic daily dosing regimens sufficient to ensure efficacy lead to debilitating long-term adverse effects associated with HPA axis suppression.

eDSP is designed to maintain the well-described efficacy of DSP while reducing or eliminating the significant adverse events that accompany chronic corticosteroid treatment. The improved tissue biodistribution, pharmacokinetics, and pharmacodynamics of eDSP enabled by autologous red blood cells may, therefore, significantly improve the safety profile and increase the desired therapeutic effects of DSP.

Based on many years of patients with A-T being treated monthly with eDSP, the eDSP may minimize the long-term serious adverse effects that are a major impediment to the chronic administration of corticosteroids. Corticosteroid therapy without significant long-term safety liabilities would represent a major advancement in the potential treatment of many chronic diseases where corticosteroids are already known to be beneficial.

Proposed eDSP Mechanism of Action in A-T

Similar to conventionally dosed corticosteroids, eDSP has a multimodal mechanism of action resulting in potent anti-inflammatory and immunosuppressive effects. Additionally, eDSP provides significant benefits due to the autologous encapsulated red blood cells, including a prolonged circulating half-life and improved tissue biodistribution.

Corticosteroids have a complex mechanism of action which collectively contribute to their powerful anti-inflammatory and immunosuppressive effects, making corticosteroids effective in treating various inflammatory and autoimmune conditions. Although a precise mechanism of action for DSP in A-T remains under investigation, we have summarized the key mechanisms by which we believe eDSP may play a synergistic therapeutic role in A-T:

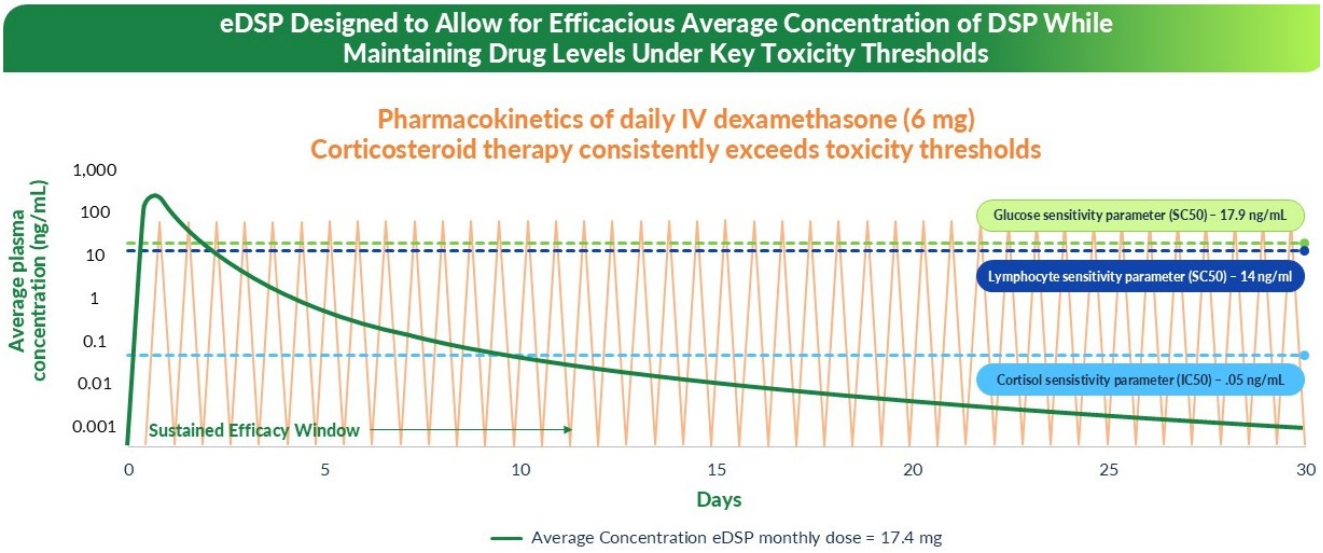
- **Saturation of the glucocorticoid receptor (GR) followed by maintenance of receptor occupancy.** DSP is a potent corticosteroid that plays a significant role in the treatment of various inflammatory and autoimmune conditions. Its mechanism of action is multifaceted and primarily involves the modulation of gene expression through the GR. The primary mechanism of action involves GR activation in the cytoplasm and translocation to the nucleus, ultimately leading to modulation of gene expression that results in potent anti-inflammatory and immunosuppressive effects. Infusion of eDSP into the patient results in an initial period with high plasma levels that achieve near maximal GR saturation. After this initial short-lived peak, eDSP is continuously released slowly from the encapsulated autologous red blood cells over an approximate one-month treatment period at exposures below toxicity thresholds, thereby avoiding the adverse side-effects observed with daily corticosteroid use. The plasma concentrations are sufficient to maintain receptor occupation throughout the one-month treatment period, leading to continuous modulation of gene expression and extending the therapeutic effects.

- **Enhanced biodistribution of DSP.** DSP encapsulated in autologous red blood cells have a prolonged circulation after infusion, resulting in the continuous release of eDSP to target tissues throughout the 21 to 30 day treatment period. We believe that eDSP has the potential to migrate through tissues and tight capillaries, allowing for enhanced delivery to previously excluded tissue (blood brain barrier-excluded central nervous system tissue). Moreover, direct intracellular delivery of the eDSP to phagocytic cells (primarily macrophages) that engulf senescent red blood cells encapsulated with eDSP may help migrate drug to tissues and sites of inflammation better than conventional therapy.

- **Genomic response hypothesis.** Currently under investigation is whether eDSP has a genomic response and is able to delay the onset of action of processes dependent on gene transcription and thereby inhibit inflammatory responses. Genomic responses to corticosteroids are believed to be their primary mechanism of action, potentially leading to modulation of gene expression that results in potent anti-inflammatory and immunosuppressive effects. This well-described anti-inflammatory process is primarily mediated through NFkB-dependent genomic effects and involves modulation of gene expression resulting in inhibition of pro-inflammatory mediators, including cytokines, prostaglandins, and leukotrienes. The genomic response to corticosteroids have a delayed onset of action since they are dependent on gene transcription. However, these effects are maintained throughout the treatment period with eDSP due to the continuous release of eDSP from encapsulated red blood cells. The degree of glucocorticoid receptor saturation is directly related to the intensity of the therapeutic corticosteroids genomic effects.

- **Non-genomic response hypothesis.** Corticosteroids are also known to have rapid non-genomic effects, within seconds to minutes, rapidly binding to membrane-bound glucocorticoid receptors, leading to rapid intracellular signaling cascades that do not involve changes in gene transcription (mRNA-independent). Corticosteroids are known for their anti-inflammatory and neuroprotective effects. Examples of non-genomic effects of corticosteroids include rapid activation of mitogen-activated protein kinase (MAPK) and phosphoinositide 3-Kinase (PI3K)/AKT pathways. These pathways are critical for neuronal plasticity and excitability, rapid modulation of ion channels and cell metabolism, and reduction in oxidative stress. Corticosteroids are known to rapidly modulate ion channel currents through membrane-associated GC receptors, which play a critical role in regulating neuronal excitability by allowing potassium ions to flow across the cell membrane in response to increased calcium and changes in action potential. Corticosteroids are also known to rapidly inhibit the ability of ATP to increase Ca2+ in neurons, thereby reducing glucose uptake and inducing calcium homeostasis. These rapid non-genomic responses result in improvements on mitochondrial calcium homeostasis, mitophagy, and ROS production in CNS.

As depicted below, eDSP achieves an initial Cmax required for efficacy in the first 24 hours after the initial infusion and then, over the following approximately 30 days, DSP is dephosphorylated by red blood cell intracellular phosphatases, resulting in the slow diffusion of DSP from the red blood cell.



Note: Pharmacokinetic (PK) curve from Population PK model (smoothed) based on company's prior studies of eDSP. Information represented does not reflect a completed comparative study of eDSP versus oral/IV administration of dexamethasone, but rather provides a comparison of published corticosteroid pharmacokinetic information relative to company data regarding eDSP. IC50 and SC50 refer to pharmacodynamic parameters of which IC50 reflects drug concentration eliciting 50% of the maximum inhibition and SC50 reflects drug concentration eliciting 50% of the maximum stimulation. References: Krzyzanski, *Journal of Pharmacokinetics and Pharmacodynamics* (2021) 48: 411-438; Montanha et al, *Frontiers in Pharmacology* (2022) 13: 814134; Krzyzanski et al, *Journal of Pharmacokinetics and Pharmacodynamics* (2021) 48: 411-438; and Świerczek A, Jusko WJ., *Clinical and Translational Science* (2023) 16(9):1667-1679.

ATTeST Phase 3 Clinical Trial Results in Patients with A-T

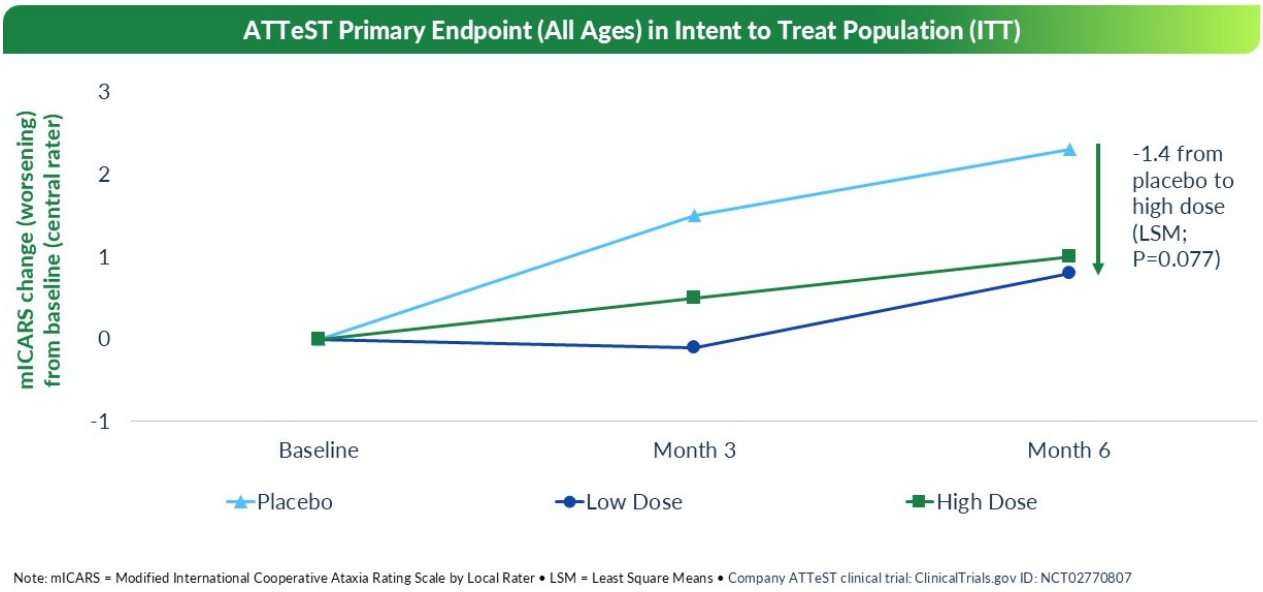
We completed the largest global clinical trial of patients with A-T in a Phase 3 clinical trial called ATTeST (**A**taxia **T**elangiectasia **T**rial with the **e**DSP **S**ys**T**em; NCT02770807 / IEDAT-02-2015). ATTeST was an international, multicenter, randomized, double-blind, placebo-controlled, Phase 3 clinical trial of patients ages six years and older. The objective of ATTeST was to evaluate the effect of two doses (Low Dose and High Dose eDSP infusion) of eDSP, compared to placebo, on central nervous system symptoms in subjects with A-T. The initial treatment period was six months. All participants who completed efficacy assessments over the initial six months were eligible to continue in an additional six-month, double blind, placebo-controlled treatment designed to collect longer-term safety and efficacy data. There were 176 patients randomized (1:1:1) between Low Dose (mean of 8.2 mg ± standard deviation of 3.3 mg), High Dose (mean of 17.4 mg ± standard deviation of 5.4 mg), and placebo. Participants received monthly doses for 12 months. At time points of month six and nine, one-third of participants on placebo switched to active drug, respectively. All participants who completed treatment in the ATTeST study were subsequently eligible to enroll in an open-label extension study (NCT03563053 / IEDAT-03-2018; OLE-IEDAT) with 104 participants receiving High Dose eDSP.

The primary efficacy endpoint of ATTeST was change in neurological symptoms from baseline to month six measured by mICARS and compared between eDSP active arms and the placebo control arm using a mixed model repeated measures analysis. The ICARS was developed to quantify the level of impairment as a result of ataxia as related to hereditary ataxias. The modified ICARS, or mICARS, was the result of discussions with the FDA. The key secondary efficacy endpoint of ATTeST was the change in participant's global clinical status from baseline until month six. This was measured by using the CGI-C. The safety objective was to evaluate the safety and tolerability of two dose levels of eDSP compared to placebo in participants based on the occurrence of AEs.

The primary efficacy endpoint was assessed in the mITT population,which included all randomly assigned participants who received at least one dose of study treatment and had at least one post-baseline assessment of the primary outcome. Efficacy was also assessed in the PP population, which included all participants who did not have any major protocol violations and completed the treatment period of the study within 228 days (allowed for only one missed dose). Of note, the majority of patients eliminated from the PP population were due to COVID-19. COVID-19 uniquely impacted this trial because of two critical factors: 1) participants received their infusion at hospitals where essential personnel were diverted to care for COVID patients, and 2) participants with A-T are immunocompromised and there was hesitation in taking them into a high risk setting for acquiring the infection.

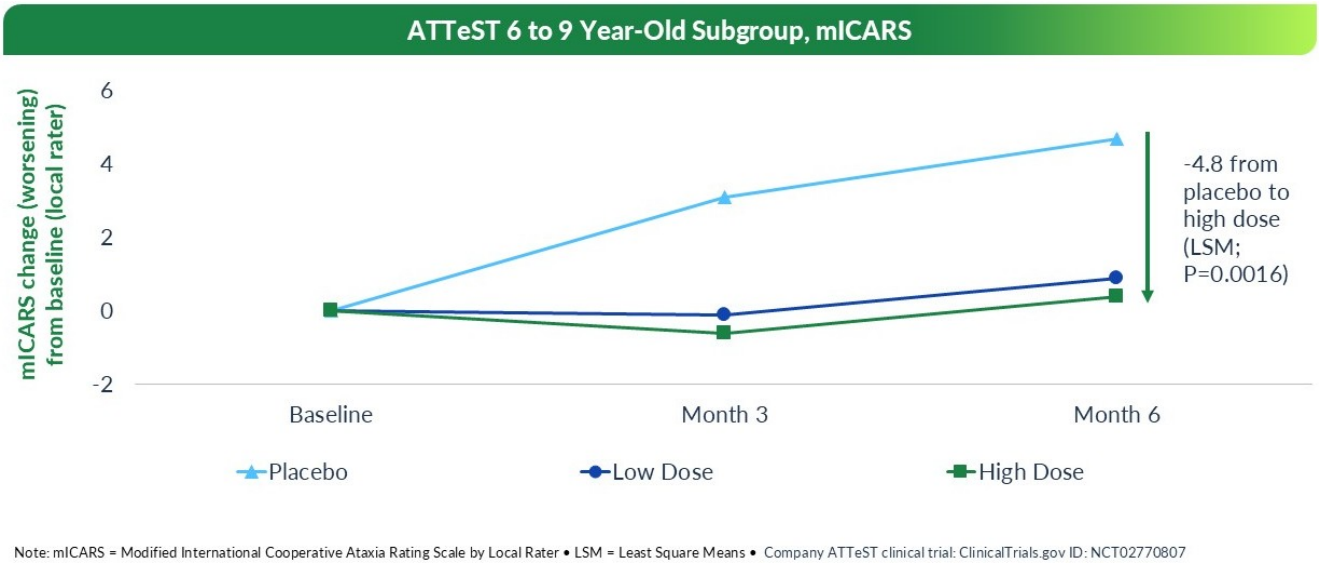
The mITT population comprised 164 participants (n = 56 in the Low Dose group, n = 54 in the High Dose group, and n = 54 in the placebo group). The point estimate of ATTeST's treatment effect LSM and a p-value are presented below. High

Dose eDSP missed the pre-specified primary efficacy endpoint with a p-value of 0.077. However, High Dose eDSP demonstrated statistical significance in the PP population with a p-value of 0.019.



Note: mICARS = Modified International Cooperative Ataxia Rating Scale by Local Rater • LSM = Least Square Means • Company ATTeST clinical trial: ClinicalTrials.gov ID: NCT02770807

Importantly, a notable benefit was demonstrated in the pre-specified subgroup analysis of the cohort aged six to nine years old treated with High Dose eDSP measured by mICARS change from baseline, suggesting an age-dependent therapeutic potential as most of the clinical signs of neurodegeneration are observed in patients with A-T before the age of 10. mICARS is focused on lower limb movement and published natural history data suggest two distinctive regression patterns between patients ages six to nine — and 10 years or older — with rapid neurological deterioration in the younger age group (six to nine years) compared to a much slower deterioration in older patients (10 years or older). These data underpin the treatment effect in the patient population where neurodegeneration is most pronounced. As depicted below, pre-specified subgroup analyses were performed in the six to nine year old subgroup in the mITT population with a statistically significant difference (p=0.0016) for mICARS in the High Dose group as compared to placebo.



Note: mICARS = Modified International Cooperative Ataxia Rating Scale by Local Rater • LSM = Least Square Means • Company ATTeST clinical trial: ClinicalTrials.gov ID: NCT02770807

After the initial six-month ATTeST clinical trial period, participants were eligible to continue an additional six months of double-blind, placebo-controlled treatment, designed to collect longer-term safety and efficacy data. All participants who completed treatment were eligible to enroll in an OLE study (IEDAT-03-2018) and receive High Dose eDSP.
The safety population included all participants who received at least one dose of study treatment. The safety and tolerability of treatment was based on the occurrence of TEAEs, SAEs, discontinuation of study treatment due to AEs, and changes in vital signs, laboratory parameters, electrocardiograms, and physical or neurological examinations.

In the ATTeST clinical trial, eDSP treatment in the initial six month treatment period was well tolerated with only mild to moderate and transient AEs that rapidly resolved without medical intervention in all dose groups. The only TEAE was severe anemia in one patient in the High Dose group, which resolved and treatment continued. Two participants discontinued study participation in the High Dose group owing to AEs. The descriptive safety data, which showed no difference in the frequency of TEAEs or SAEs between treated groups and the placebo group, indicate a favorable safety profile of eDSP. There were no clear, clinically significant differences in potential corticosteroid-related side effects observed between the treated and placebo groups; including adrenal insufficiency, cushingoid appearance, hyperglycemia, hirsutism, osteoporosis, growth and development through puberty, and serious systemic infections. No other clinically relevant adverse effects of treatment were noted in vital signs data, electrocardiograms, physical examinations, or neurological examinations.

ATTeST Safety Summary

Three patients discontinued from the study, all unrelated to corticosteroid toxicity

Two patients in high-dose group showed corticosteroid-related TEAEs of pyrexia and tachycardia / pain and pruritus

	ATTeST: Initial Treatment Period			ATTeST: Through Month 12		
	Low Dose (N=59)	High Dose (N=57)	Placebo (N=59)	Low Dose (N=59)	High Dose (N=57)	Non-switch Placebo (N=19)
Patients With Any TEAE (%)	73%	82%	73%	76%	88%	79%
Patients With Any Treatment–Related TEAE (%)	25%	37%	25%	32%	44%	26%
Patients With Any Serious TEAE (%)	10%	12%	12%	14%	16%	21%
Patients With Any Serious Treatment–Related TEAE (%)	0	2%	0	2%	2%	5%
Patients With Any TEAE Leading to Discontinuation (%)	0	4%	0	2%	4%	0
Patients With Any TEAE Leading to Death (%)	0	0	0	0	0	0

Note: TEAE = Treatment Emergent Adverse Event • Company ATTeST clinical trial: ClinicalTrials.gov ID: NCT02770807

ATTeST Data Publications, Presentations, and Ongoing Analysis

The data generated from our prior Phase 3 ATTeST clinical trial, the largest study in A-T completed to date, continues to provide opportunities for us to showcase the favorable safety profile of eDSP and its positive effect demonstrated in a subset of patients with A-T.

In August 2024, we announced the online publication of Phase 3 ATTeST data in *The Lancet Neurology* titled *The Lancet Neurology* publication entitled *Safety and efficacy of intra-erythrocyte dexamethasone sodium phosphate in children with ataxia-telangiectasia (ATTeST): a multicenter, randomized, double-blind, placebo-controlled phase 3 trial*. This publication highlighted key findings of the ATTeST study, including the favorable safety profile of eDSP and its positive effect of treatment in a subset of patients with A-T ages six to nine – the age range that typically experiences rapid clinical decline. Additionally, in January 2025, we announced the online publication of safety data from patients with A-T treated with eDSP for a minimum of 24 months in *Frontiers in Neurology* titled *Long-term safety of dexamethasone sodium phosphate encapsulated in autologous erythrocytes in pediatric patients with Ataxia-Telangiectasia*. The publication highlighted post-hoc analysis of patients with A-T treated over 24 to 61 months of dosing in our ATTeST and OLE study, which showed eDSP was administered without the chronic debilitating toxicities observed with standard corticosteroid treatment.

We also participated at notable scientific congresses where we presented additional post-hoc analysis from the ATTeST study. In November 2024, we presented two posters at the 2024 International Congress for Ataxia Research (ICAR). The objective of the first 2024 ICAR poster titled *Growth and Bone Mineral Density (BMD) in Children with Ataxia-Telangiectasia (A-T) Treated with Intra-Erythrocyte Dexamethasone (eDSP) for 24 months* describes that eDSP treatment did not adversely affect growth and bone mineral density in patients with A-T treated for 24 months. The objective of the second 2024 ICAR poster titled *Cross-sectional Analysis of International Cooperative Ataxia Rating Scale (ICARS) Subcomponent Scores in Children with Ataxia-Telangiectasia (A-T)* identifies ICARS subcomponents with reduced kinetic function domain best reflect progression of disease by age, and that mICARS and RmICARS analyses focused on a participant's posture and gait capture the fastest neurological symptom progression in patients with A-T between the ages

of six to 10 years old. At the 53rd Child Neurology Society (CNS) Annual Meeting in November 2024, we presented a poster highlighting ATTeST's safety data titled *Treatment-Emergent Adverse Events (TEAEs) in Children With Ataxia-Telangiectasia Treated for One Year With Intra-Erythrocyte Dexamethasone Sodium Phosphate (eDSP)* highlighting that eDSP treatment was generally well tolerated with most TEAEs being mild to moderate and transient, and generally similar between eDSP and placebo-treated patients. This CNS poster also noted the lack of side effects typically attributed to chronic steroid use, such as cushingoid features, hyperglycemia, hirsutism, or hypertension, which were not observed in eDSP treated patients with A-T,

Additionally, we have initiated transcriptomic profiling of whole blood samples from the Phase 3 ATTeST clinical trial as we continue to investigate mechanism of action and treatment-responsive biomarkers after treatment with eDSP compared to placebo treated patients. The sequencing of all ATTeST samples is underway with results expected later in 2025. Additionally, secondary confirmation of RNA sequencing results using an independent orthogonal method (long read DNA sequencing) is underway.

Pivotal Phase 3 NEAT Clinical Trial of eDSP in Patients with A-T

We gained valuable learnings from the ATTeST clinical trial. Treating patients early is an important factor in A-T because the rate of neurological deterioration is most pronounced between the ages of six to nine years old.

We began enrollment of a pivotal Phase 3 NEAT clinical trial of eDSP in patients with A-T in June 2024 and, as of March 24, 2025, 61 participants have been enrolled in the study and 24 participants have entered the OLE study. NEAT is an international, multicenter, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of eDSP in patients with A-T. We plan to enroll approximately 86 patients with A-T ages six to nine years old randomized (1:1) between eDSP or placebo, and approximately 20 patients with A-T ages 10 years or older. Participants who complete the full treatment period, complete the study assessments, and provide informed consent will be eligible to transition to an OLE program after trial completion. The primary efficacy endpoint for the NEAT study will be measured by the change from baseline to last visit completion in RmICARS. We expect to complete enrollment of our Phase 3 NEAT clinical trial by the end of second quarter of 2025 and report topline results in the fourth quarter of 2025.

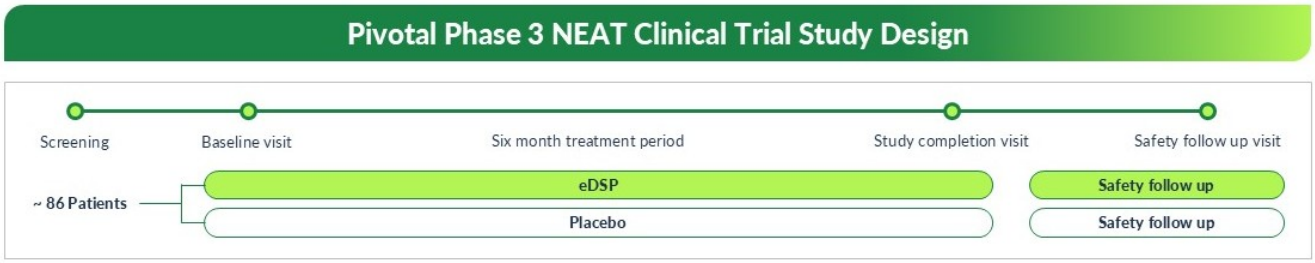


Figure: Phase 3 NEAT clinical trial study design

We plan to initiate a Pediatric Investigational Plan (PIP) to enroll approximately 12 evaluable children with A-T weighing at least 9 kg and less than 15 kg. The primary objective of the study is to examine the safety and pharmacokinetics of the eDSP in a younger patient population. We expect that this open label study will provide six months of eDSP with the option to continue treatment through a Compassionate Use Program or an Expanded Access Program.

Regulatory Interactions

The pivotal Phase 3 NEAT clinical trial is conducted under an SPA agreement with the FDA, which should allow for the submission of an NDA following completion of this study, provided we obtain positive results. The SPA agreement reflects the inclusion of the primary endpoint of RmICARS at the request of the FDA. Our plan is to submit an NDA in 2026 with expectations to submit a MAA to the EMA shortly thereafter. eDSP is regulated as a drug/device combination product by the FDA. We anticipate submitting a 505(b)(2) NDA to the FDA, which allows us to rely upon the agency's prior findings of safety and effectiveness for the active pharmaceutical ingredient DSP.

eDSP has received orphan drug designation for the treatment of A-T from the FDA and EC. The eDSP System's RCL is a CE marked non-invasive device that allows blood processing at the point of care, and the sterile, single-use treatment kit is a CE marked medical device in accordance with the MDR. Process Solutions are CE marked according to the MDD.

Phase 2 Candidate — eDSP for the Potential Treatment of DMD

We intend to investigate additional indications for eDSP where chronic corticosteroid treatment is or has the potential to become standard of care. We selected DMD as our second development program for eDSP.

DMD Background and Prevalence

DMD is an inherited severe muscle-wasting condition caused by X-linked recessive pattern gene mutations located on the X chromosome. The mutated dystrophin gene in DMD leads to a deficiency or absence of dystrophin protein in muscle cells. This disrupts muscle structure and function, causing progressive muscle weakness and degeneration. DMD is a progressive disease, meaning that muscle weakness worsens over time and is the most common and most severe form of muscular dystrophy diagnosed in childhood.

Typically, DMD symptoms begin in early childhood and the disease eventually affects all voluntary muscles, including the heart and respiratory muscles. Symptoms of DMD usually appear between the ages of two and six years of age. Progressive muscle weakness is the hallmark of DMD and typically starts in the hips and thighs, then spreads to other muscles. Patients with DMD may have delays in walking, running, or other motor skills and most patients with DMD require a wheelchair by their early teenage years. Heart muscle involvement (cardiomyopathy) is common in DMD and can lead to heart failure while weakness of respiratory muscles can cause breathing difficulties and increase susceptibility to respiratory infections. Without proper management, the median lifespan of patients with DMD is approximately 20 to 30 years old; however, with advancements in care, many now live longer.

DMD affects approximately one in every 3,500 to 5,000 male live births worldwide. We estimate that there are approximately 15,000 patients with DMD in the U.S. There are currently several corticosteroid treatments for DMD, including prednisone, prednisolone, betamethasone, deflazacort, vamorolone, and many in development that could allow for longer half-lives and less adverse events than approved corticosteroids. However, none of these therapeutics are designed to effectively eliminate the broad range of toxicities associated with chronic corticosteroid administration.

Limitations of Chronic Corticosteroid Administration in DMD

We consider DMD an ideal indication for eDSP as corticosteroids are the standard of care for this rare disease, but their utility is limited by significant chronic toxicity due to adrenal suppression. The standard delivery of corticosteroids by either intravenous, intramuscular, subcutaneous, oral routes for patients with DMD results in multiple peaks and troughs. Although corticosteroids can readily achieve Cmax levels required to establish efficacy, the frequent dosing repeatedly exceeds toxicity thresholds associated with adverse events, leading to debilitating serious adverse effects such as hyperglycemia, immunosuppression, and suppression of the HPA. As a result, corticosteroid treatment in patients with DMD is commonly interrupted during adolescence due to weight gain, growth suppression, cushingoid appearance, diabetes, osteoporosis, interference with sexual maturation, and delayed puberty.eDSP has the potential to provide efficacy in patients with DMD while avoiding these long-term toxicities associated with HPA axis suppression.

Phase 2 Candidate — eDSP for the Potential Treatment of DMD

We are currently in the process of generating a Phase 2 clinical trial study design to evaluate eDSP for the potential treatment of patients with DMD. We intend to initiate a Phase 2 clinical trial designed to evaluate eDSP for the potential treatment of patients with DMD in 2025, which we expect to conduct utilizing capital efficient study approaches and subject to receiving financial support from grant and/or opportunistic funding opportunities.

New Indications and Program Expansion Potential

The potential for robust program expansion and new indication targeting for eDSP alone is significant. We completed an evaluation of other potential indications for eDSP beyond A-T and DMD where chronic corticosteroid treatment is or has the potential to become standard of care. This evaluation process spanned across ataxia, neuromuscular, hematology, cancer, and autoimmune disease indications with a focus on rare diseases with compelling competitive advantages and significant commercial opportunities.

We prioritized a list of other potential rare disease targets under consideration, which include: 1) autoimmune hepatitis, 2) pulmonary sarcoidosis, 3) dermatomyositis, 4) pemphigus vulgaris, 5) Hashimoto’s encephalopathy, 6) Becker muscular dystrophy, 7) pediatric lupus, 8) juvenile idiopathic arthritis, 9) myasthenia gravis, 10) limb-girdle muscular dystrophy, and 11) chronic inflammatory demyelinating polyradiculoneuropathy.

As a next step, we intend to select the highest potential indications from this prioritized list of indications beyond A-T and DMD and begin advancement of additional new drug development programs for immunological and autoimmune focused rare disease indications for eDSP. Development activities would include the development of Phase 2 or Phase 3 clinical trial study designs to evaluate eDSP for the selected indications and are subject to additional financing.

Manufacturing

We currently operate one manufacturing facility in Medolla, Italy, which is authorized for the design and development, production, distribution, and servicing of our RCL machines, single-use treatment kits, and all proprietary medical devices. This production facility complies with EU ISO13485 and U.S. quality standards for medical device manufacturers. We also use several third-party manufacturers to produce key components and for final assemblies of the RCL and treatment kit. We believe our current leased space is sufficient to meet our current needs to ensure adequate supply in our ongoing and future clinical trials, as well as anticipated early commercial needs, if eDSP is approved for marketing.

We also rely on third-party providers to manufacture sterile process solutions and drug product. Under unilateral development of our drug candidates, we are responsible for our internal manufacturing efforts, as well as for those of our third-party contract manufacturers, and we expect to continue to rely on internal manufacturing and multiple external manufacturers. We believe there are multiple sources for all of the materials required for the manufacture of our drug candidates. We intend to identify and qualify additional manufacturers to provide both process solutions and bulk drug product manufacturing services prior to submission of an NDA to the FDA as necessary to provide adequate commercial quantities of each of the sterile solutions. As our drug candidates advance through development, we expect to enter into long-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure the ongoing and planned preclinical, clinical, and, if our drug candidates are approved for marketing, our commercial supply needs.

Commercialization Plan

We plan to establish a commercial infrastructure in the U.S. to support the launch of eDSP, provided we obtain positive results from the Phase 3 NEAT clinical trial and subsequent regulatory approval from the FDA.

If we receive FDA approval for eDSP for the treatment of A-T, we plan to utilize a specialty distribution model to support drug availability to patients. We will also utilize a patient-centered hub to support education, insurance coverage, and compliance.

Commercial infrastructure for rare disease drugs typically consists of a targeted specialty sales force responsible for a focused group of stakeholders, including physicians, specialty distributors, and patient groups. Each sales territory collaborates closely with a cross functional team, including sales management, medical liaisons, internal sales support, marketing, and distribution. One challenge unique to commercializing therapies for rare diseases is the difficulty in identifying eligible patients due to the very small and sometimes heterogeneous disease populations.

Additional capabilities important to the rare disease marketplace include the management of key accounts such as centers of excellence, managed care organizations, group-purchasing organizations, specialty distributors and pharmacies, and government accounts. To develop the required commercial infrastructure, we will have to invest significant financial and management resources. Some of these resources will be committed prior to any regulatory confirmation that any of our drug candidates will be approved.

Outside of the U.S., where appropriate and depending on the terms of contractual arrangements, we plan to commercialize eDSP through strategic partners. In certain instances, we may consider building our own commercial infrastructure.

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 currently no therapies approved for A-T on the global market. If eDSP is approved for the treatment of A-T, it has the potential to be the first treatment on the market for this indication, but it currently faces pipeline competition. Pipeline competition for this rare disease results in competition for patient recruitment, as well as investigators' time and

resources. There are drugs currently in development for A-T in the U.S., and other countries, including corticosteroids. Aqneursa (levacetylleucine) in development by IntraBio; GTX-102, an oral spray formulation of betamethasone, in development by Grace Therapeutics; MBM-01, an EPAS1/HIF1 inhibitor, in development by Matrix Biomed; splice-switching antisense oligonucleotide in development by the Boston Children's Hospital; triheptanoin, a medium-chain triglyceride marketed by Ultragenyx under the name Dojolvi, in development by The University of Queensland; and nicotinamide riboside, in development by Oslo University Hospital. In addition to drugs in development, there are many available corticosteroids, including prednisone, prednisolone, betamethasone, deflazacort, vamorolone, and many in development that could allow for longer half-lives and less AEs than approved corticosteroids.

If approved and launched commercially, eDSP may face competition from these drugs and drug candidates. Some of these drug candidates may enter the market prior to eDSP, and some of these drug candidates could limit the market or level of reimbursement available for eDSP, if it is commercialized.

Intellectual Property

The divesture of the numerous patents and patent applications relating to the compound NOV004 was completed on October 31, 2023. Under the Termination Agreement, we agreed to reimburse PRF for certain fees and costs incurred in connection with the prosecution of the licensed patents prior to termination. We also agreed to assign to PRF certain documents and materials developed by us in connection with the development of the licensed product under the License Agreement, subject to our retained right to use such documents and materials for internal research purpose. If during a specified period following the termination of the License Agreement, PRF assigns or grants any license, option or other rights under the licensed patents to certain third parties that we had identified in its prior efforts to pursue out-licensing opportunity, PRF would be required to pay us 35% of related payments received by PRF.

EryDel, our wholly owned subsidiary, owns numerous patents and patent applications covering eDSP and AIDE technology in the United States and in jurisdictions outside of the United States. Issued patents covering eDSP and the AIDE technology have been obtained in the United States, Europe, Japan, and a number of other jurisdictions outside of the United States. Our patent portfolio consists of six published patent families. Two patent families are directed to the eDSP System and the process for loading a drug into an erythrocyte. A third patent family is directed to the therapeutic use of drug-loaded erythrocytes in treating disease.

The first patent family consists of U.S. Patent No. 9,089,640 and select foreign counterparts. The '640 patent issued on July 28, 2015. The '640 patent is the U.S. national phase entry of International PCT Patent Appl. No. PCT/IB2011/000891, filed on April 26, 2011, which claims priority to U.S. Provisional Patent Appl. No. 61/373,018, filed on August 12, 2010. The patent has 154 days of PTA and will expire in 2031 (excluding PTE). The '640 patent was recorded as assigned to EryDel on January 4, 2013. The '640 patent discloses a portable and automated apparatus and kit for introducing compounds within erythrocytes. The apparatus has a reusable part provided with mechanical elements such as pumps and valves and electronic units such as a control unit, which introduces compounds into erythrocytes in an automated manner. The apparatus also has a disposable part which comes into contact with the sample containing the erythrocytes. The apparatus also provides for further concentration of the erythrocytes after they have been treated. There are foreign counterparts in the same family, including in Italy, Australia, Brazil, Canada, China, Israel, Japan, Mexico, Russia, Singapore, South Korea, and the EPO. The corresponding EPO patent is EP 2563343 B1. The claims of this patent cover the RCL and treatment kit. The first patent family consists of PCT Application No. PCT/IB2025/050489 and U.S. Patent Application No. 19/025657, both of which were filed on January 16, 2025. These applications claim priority to provisional patent applications 63/625,213, filed January 25, 2024, and 63/626,398, filed January 29, 2024. These applications have not yet published.

The second patent family consists of U.S. Patent No. 10,849,858 and select foreign counterparts. The '858 patent issued on December 1, 2020. The '858 patent was in the U.S. national phase entry of International PCT Patent Appl. No. PCT/IB2014/061338, filed on May 9, 2014, which claims priority to Italian Application numbers RM2013A0280 and RM2013A0610, filed May 10, 2013 and November 5, 2013, respectively. The '858 application was recorded as assigned to EryDel on December 11, 2015. The patent has 477 days of PTA and will expire in 2035 (excluding PTE). The '858 patent discloses a second swelling step that differentiates it from the method of the prior art which only has one swelling step. The second swelling step of the '858 patent leads to significant improvement in the viability and tunability of the erythrocytes before and after drug loading. U.S. Pat. Appl. No. 17/083,771, which is a continuation application of the '858 patent, was allowed by the USPTO on January 29, 2025. The allowed claims of the '771 application are directed to methods for treating A-T. The patent is expected to expire in 2036 with PTA, which has not been calculated yet. There are foreign

counterparts in the same family, including in Italy, Australia, Brazil, Canada, China, Israel, Japan, Mexico, Philippines, Russia, Singapore, South Korea, and the EPO. The corresponding EPO patent is EP 2994117 B1. This patent covers the planned method of operation of the eDSP System.

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.

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.

Products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific agency center as the lead reviewer. The FDA determines which center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. We anticipate that eDSP will be regulated as a drug, and that the FDA will permit a single regulatory submission seeking approval of eDSP. Even when a single marketing application is required for a combination product, such as an NDA for a combination pharmaceutical and device product, both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health may participate in the review. An applicant will also need to discuss with the agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, AE reporting and GMP, to their combination product.

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 GLP, regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with GCPs, to establish the safety and efficacy of the proposed drug product for each proposed indication;
- preparation and submission to the FDA of an 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 toxicology 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, 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 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 SAEs 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.

Special Protocol Assessment

A sponsor may request an SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins for an SPA to be approved. If a written agreement is reached, it will be documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA and made part of the administrative record.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding by the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. However, an SPA does not guarantee that a trial will be successful.

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 an 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 AEs, 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 AEs 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.

Medical Device Regulation

The medical device component of eDSP will be subject to additional FDA regulations, including:

- the FDA's Quality System Regulation, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- a requirement for Human Factors studies during development to support approval;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

- medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The Orphan Drug Act

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are Credits for certain research and a waiver of the NDA application user fee.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, certain drugs may obtain an additional six months of exclusivity in an indication, if the sponsor submits information requested in writing by the FDA in what is known as a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population. The six-month period of pediatric exclusivity attaches to the end of all existing marketing exclusivity and patent periods listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") at the time of granting.

To receive the six-month pediatric market exclusivity, a sponsor would have to receive a Written Request from the FDA and conduct the requested studies in accordance with a written agreement with the FDA. If there is no written agreement, studies would be conducted in accordance with commonly accepted scientific principles, and reports submitted of those studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request, agreement, or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric studies for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must include the evaluation of the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA, on its own initiative or at the request of the sponsor, may defer pediatric trial requirements for some or all of the pediatric subpopulations. A deferral may be granted by the FDA if it believes that additional safety or effectiveness data in the adult population need to be collected before the pediatric studies begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation. Unless otherwise

required by regulation, PREA generally does not apply to a drug for an indication for which orphan designation has been granted with the exception of orphan-designated drugs if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA has determined is substantially relevant to the growth or progression of a pediatric cancer.

Fast Track Designation, Accelerated Approval, and Priority Review

A sponsor may seek approval of its drug candidate under programs designed to accelerate the FDA's review and approval of NDAs. For example, Fast Track Designation may be granted to a drug intended for treatment of a serious or life-threatening disease or condition that has potential to address unmet medical needs for the disease or condition. The key benefits of Fast Track Designation are more frequent interactions with the FDA and rolling review (submission of portions of an application before the complete marketing application is submitted).

Under the accelerated approval programs, the FDA may approve an NDA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are required to verify the drug's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study.

Based on results of the Phase 3 clinical trials submitted in an NDA, upon the request of an applicant, the FDA may grant the NDA a Priority Review designation, which sets the target date for FDA action on the application at eight months after the NDA submission. Priority Review is granted where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for Priority Review, the application is subject to the standard FDA review period of twelve months after NDA submission. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

EU Drug Development

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022 repealing and replacing the former Clinical Trials Directive 2001/20, or CTD. The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

All new and ongoing trials are now subject to the provisions of the CTR, following the expiry of the transition period that ended on January 31, 2025. In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements. Medicines used in clinical trials, including ATMPs, must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

EU Review and approval process

In the EU, medicinal products can only be commercialized after a related marketing authorization, or MA, has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application, or MAA, either under a centralized procedure administered by the EMA, or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA (which is comprised of the 27 EU Member States plus Norway, Iceland and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures – Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Manufacturing Regulation in the EU

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. The manufacturing of medicinal products in the EU requires a manufacturing authorization and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance, including EU cGMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU Member States. Marketing authorization holders and/or

manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU Member States' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or bio similar application for eight years from the date of authorization of the innovative product, after which a generic or bio similar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or bio similar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Orphan Designation in the EU

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization must be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-authorization Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Clinical Trial Data Disclosure

Many jurisdictions have mandatory clinical trial information obligations incumbent on sponsors. In the EU, transparency requirements relating to clinical trial information are established in the CTR. The CTR establishes a general principle according to which information contained in CTIS shall be made publicly accessible unless confidentiality is justified on grounds of protecting personal data, or commercially confidential information, necessary to protect confidential communications between EU Member States in relation to the preparation of an assessment report, or necessary to ensure effective supervision of the conduct of a clinical trial by EU Member States. This confidentiality exception may be overruled if there is an overriding public interest in disclosure. The publication of data and documents in relation to the conduct of a clinical trial will take place in accordance with specific timelines. The timelines are established by the EMA and are determined based on the documents and the categorization of the clinical trial.

In addition, Regulation No. 1049/2001 on access to documents, or the ATD Regulation, and the related EMA policy 0043 on access to documents, provide for a wide right for EU-based interested parties to submit an access to documents request to the EMA to access certain information held by the EMA. Only very limited information is exempted from disclosure (i.e., commercially confidential information, which is construed increasingly narrowly and protected personal data). It is possible for competitors to access and use this data in their own research and development programs anywhere in the world, once these data are in the public domain.

Combination Products

The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which of the components of the combination has the primary mode of action.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal product is principal to that of the medical device are governed by the regulatory framework applicable to medicinal products. However, the General Safety and Performance Requirements, or GSPRs, of Annex I to Regulation (EU) 2017/745 on Medical Devices, or MDR, will be applicable to the safety and performance of the medical device part

of the product in the context of its use with the medicinal product. In these circumstances, an MAA must be submitted to the competent authorities responsible for evaluating the safety and effectiveness of medicinal products. As part of the MAA, the applicant must also submit, where available, the results of the assessment of the conformity of the medical device part of the product with the MDR contained in the manufacturer's EU Declaration of Conformity of the device or the relevant Certificate of Conformity issued by a Notified Body. If the MAA does not include the results of the conformity assessment, and where the conformity assessment of the device, if used separately, requires the involvement of a Notified Body, the competent authorities must require the applicant to provide a Notified Body Opinion on the conformity of the device with the relevant GSPRs. Based on this approach, the competent authorities responsible for medicinal products will review the specific aspects of the medical devices part of the product which are relevant to the safety and efficacy of the medicinal product and the Notified Body, where applicable, will evaluate the relevant GSPRs of the device.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to medical devices in accordance with the MDR. However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an EU Member State or from the EMA, depending on its nature and therapeutic intention, must be sought regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where a medical device incorporates a medicinal product as an integral part as a single use drug delivery system, which is intended exclusively for use in the given combination and which is not reusable, it is regulated as a medicinal product. In this case, the relevant General Safety and Performance Requirements, or GSPRs of the MDR will apply to the safety and performance of the device element.

By contrast, drug-device combination products which do not form a single integral product will be regulated separately. This may include, for example a drug-device combination product where a medical device and a medicinal product are co-packaged and the medical device is intended solely to be used for the administration of the co-packaged medicinal product. In these circumstances, the medicinal product will be governed by the regulatory framework applicable to medicinal products and the medical device will be governed by the MDR. However, the characteristics of a medical device used for the administration of a medicinal product may impact the quality, safety and efficacy profile of the medicinal product. As a result, as part of the MAA submitted to the competent authorities for the medicinal product, the applicant may need to provide additional information regarding the characteristics of the co-packaged medical device that may impact on the quality, safety and/or efficacy of the medicinal product. Similar requirements may apply where the products are not co-packaged but the medicinal product information makes an explicit reference to a specific medical device.

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 study that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical study could be expensive and result in delays in our commercialization efforts.

In the EU, 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 HTA) in order to obtain reimbursement or approval. This HTA process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. For example, the EU 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. EU 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 EU 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 EU. 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 EU 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 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 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 PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the CMS, within the 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;
- analogous state and foreign laws and regulations, such as state and foreign 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; and
- outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Some state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the 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 PPACA, which, among other things, includes changes to the coverage and payment for drug products under government healthcare programs.
Since its enactment, there have been amendments to and executive, legal and political challenges to certain aspects of the PPACA. On August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for

individuals purchasing health insurance coverage in PPACA 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 PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and additional healthcare reform measures of the second Trump administration will impact the PPACA 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 PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed 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, effective January 1, 2024.

In addition to the PPACA, 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, the IRA will, among other things (i) implement the Medicare Drug Price Negotiation Program 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. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

In the EU, in December 2021, Regulation No 2021/2282 on HTA, or HTA Regulation, was adopted. The HTA Regulation, which began to apply on January 12, 2025 through a phased implementation is intended to boost cooperation among EU

Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas, although individual EU Member States will continue to be responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technologies.

Employees

As of December 31, 2024, we had 36 total employees, of which 20 are in research and development and 16 are in general and administrative. Our employees are primarily located in South San Francisco, California, Medolla, Italy and Bresso Italy, and others work remotely from their residences located across the United States. 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. Effective August 1, 2022, the Company, previously named Cortexyme, Inc., changed its name to Quince Therapeutics, Inc. From inception, we have been focused on novel therapeutic approaches to improve the lives of patients with major, unmet medical needs. On January 30, 2023, we announced that we intended 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. On October 20, 2023, we completed our acquisition of EryDel, a privately held, late-stage biotechnology company (the "EryDel Acquisition") with a proprietary AIDE technology platform and Phase 3 lead asset, eDSP, that targets the potential treatment of a rare neurodegenerative disease, A-T, for which there are currently no approved treatments in any global market. EryDel is a variable interest entity and the Company is the primary beneficiary and sole shareholder. In addition, there are no restrictions on the use of the assets of EryDel.

Our principal executive offices are located at 611 Gateway Blvd, Suite 273, 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 Business

We are substantially dependent on the success of our lead drug candidate, eDSP.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and successfully commercialize our lead drug candidate, eDSP, which is under clinical development for A-T. eDSP is our only drug candidate in late-stage clinical development, and our business currently depends heavily on its successful development. The Phase 3 ATTeST trial did not meet its primary efficacy endpoint. The trial saw statistically significant results in the age group of six to nine years old. We initiated the NEAT clinical trial in this population in the second quarter 2024, and expect to announce the results of the NEAT clinical trial in the fourth quarter of 2025, but cannot guarantee that the results of this study will be positive or that they will allow further development in this therapeutic indication.

eDSP will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing

efforts before we can generate any revenue from product sales. We cannot be certain eDSP will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. In addition, because eDSP is our most advanced drug candidate, and because our other drug candidates are based on the same AIDE platform technology, if eDSP encounters safety or efficacy problems, developmental delays or regulatory issues or other problems, our development plans and business would be significantly harmed.

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, 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, 2024 and 2023, our net losses were $56.8 million and $31.4 million, respectively. We had an accumulated deficit of $376.5 million as of December 31, 2024.

Before we are able to generate any revenue, we will need to commit substantial funds to the anticipated clinical and development activities related to eDSP, 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 could take several years, if ever, before we may have a 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 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. However, we may never succeed in developing a commercial drug.

We expect to explore partnership and licensing opportunities to support the future development of eDSP and other drug candidates. 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.

There is substantial doubt regarding our ability to continue as a going concern. We will need to raise substantial additional funding, which may not be available on acceptable terms, to finance our operations and evaluate future drug candidates. If we are unable to raise this additional capital when needed or on acceptable terms, we may be forced to delay, limit, reduce, terminate or eliminate our drug development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations. We expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, including completion of the Phase 3 NEAT clinical trial and potential NDA submission, assuming positive study results. In addition, if we obtain marketing approval for eDSP or any future drug candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution.

As of December 31, 2024, we had $40.8 million in cash, cash equivalents and short-term investments. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the year ended December 31, 2024 are issued. Our existing capital resources, including term loans we received under the EIB Loan, will not be sufficient to enable us to complete our clinical development for eDSP. We will need to raise substantial additional funds in the future in order to complete the development of eDSP and seek regulatory approval thereof, to expand our manufacturing capabilities, and to commercialize eDSP, if approved by the FDA.

Further development of eDSP will require us to incur significant additional expenses. Moreover, we expect to require substantial additional funding to finance such payments and to advance the development and optimize the commercialization of eDSP, and there can be no assurance that such additional funding will be available on terms that are acceptable to us, or at all. We believe that our existing capital resources will be sufficient to fund our projected operations, which would include anticipated clinical and development activities related to eDSP through the Phase 3 NEAT clinical trial. 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 and our efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop our proprietary AIDE technology platform and Phase 3 lead asset, eDSP, to progress development of our product candidates or to advance our manufacturing processes.

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:

- the rate of progress in the development of and the conduct of clinical trials with respect to our product candidates;
- our ability to successfully identify partnership and licensing opportunities to support the future development of eDSP;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- our ability to manufacture sufficient quantities of our drug candidates and devices;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- 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;
- the costs to grow our organization and increase the size of our facilities to meet our anticipated growth;
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future; and
- our ability and timing of future milestones payments to EryDel shareholders and repayment of obligations in respect of the EIB Loan.

Additional funding may not be available to us on acceptable terms or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, the EIB Loan may prevent or limit our ability to incur additional indebtedness. As a result of geopolitical events, including the conflicts in Ukraine, inflation, high interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions.

If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements, we may be required to:

- significantly curtail, delay or discontinue one or more of our research or development programs, the development of our technology, including our AIDE platform technology, the commercialization of any product candidates or cease operations altogether;

- seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- forego expansion of our operations or refrain from pursuing business opportunities.

If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our financial statements, and investors may lose all or a part of their investment.

We have and may be required to make milestone payments to (i) the EryDel shareholders pursuant to the terms of the EryDel Acquisition or (ii) additional remuneration payments to EIB pursuant to the EIB Loan in connection with our development and commercialization of eDSP, which could adversely affect the overall profitability of eDSP, if approved.

In connection with the EryDel Acquisition, we have and may be required to make additional payments to EryDel shareholders of up to an aggregate of $485.0 million in potential cash payments, comprised of up to $5.0 million upon the achievement of first patient dosed in the Phase 3 NEAT clinical trial, which was achieved in the second quarter of 2024, $25.0 million at NDA acceptance, up to $60.0 million upon the achievement of specified approval milestones, and up to $395.0 million upon the achievement of specified on market and sales milestones, with no royalties paid to EryDel. These milestone obligations could impose substantial additional costs on us, divert resources from other aspects of our business, and adversely affect the overall profitability of eDSP, if approved. We may need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. In June 2024, we enrolled the first patient in the Phase 3 NEAT clinical trial and paid the cash milestone payment of $5 million to the former EryDel shareholders in accordance with the Purchase Agreement. We owe no further payments to EryDel shareholders for development-related milestones. The remaining potential contingent payments in connection with the EryDel Acquisition pertain to regulatory, on market and sales milestones.

We are required to make payments to EIB calculated based on a percentage of the revenue derived from the acquisition of EryDel on October 23, 2023, which will be payable annually on each June 30th. The additional remuneration is payable for seven years, during the period January 1, 2026, through December 31, 2032, with the first such payment becoming payable on June 30, 2027. The amount of additional remuneration to be paid is equal to 2.5% of revenue up to 125.0 million euros, plus 1.85% of revenue between 125.0 and 250.0 million euros, plus 1.0% of revenue in excess of 250.0 million euros, multiplied by a varying percentage based on how many tranches have been drawn. The varying percentage is equal to 30.0% in the event tranche A has been drawn, 50.0% in the event tranche A and B have been drawn, 80.0% in the event tranche A, B and C have been drawn, and 100.0% in the event all four tranches have been drawn.

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 and for which we obtain approval, 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, if approved, or devices. To achieve commercial success for any approved 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 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 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 our failure to educate adequate numbers of physicians on the benefits of 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, if approved, 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 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, if approved, to segments of the patient population;
- the lack of complementary drug candidates, if approved, 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, if approved, 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, if approved, we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our drug candidates, if approved, 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, if approved, 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 drug candidates if approved in the future.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and, if approved, through commercialization, we will need to expand our development, regulatory, quality assurance, manufacturing, commercialization, compliance, and administration capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to increase the responsibilities on members of management and manage any future growth effectively. Our failure to effectively manage our growth in this regard could prevent us from successfully implementing our strategy and maintaining the confidence of investors in our company.

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. We may enter into agreements with third parties for the development and commercialization of drug candidates in international markets. We also plan to seek regulatory approval of our drug candidates outside of the United States. 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;
- price controls on our drug products;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- potential third-party patent rights in countries outside of the United States;
- different United States and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indications for which our drug candidates are being developed;
- 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, bank failures, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, including withholding of payroll taxes, 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;
- 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; and
- compliance with evolving and expansive international data privacy laws, such as the EU GDPR.

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.

For example, the UK has voluntarily departed from the EU, commonly referred to as "Brexit." We do not know to what extent Brexit will impact the business and regulatory environment in the UK, the EU, or other countries. Changes impacting our ability to conduct business in the UK, or other EU countries, or changes to the regulatory regime in those countries, may impact certain portions of our research and general business operations in the UK and the EU.

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 previously 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.

Risks Related to the Development of Our Drug Candidates

The Phase 3 NEAT clinical trial of eDSP for A-T is being conducted under a protocol negotiated with FDA by EryDel and our execution of the trial may be slow, may not be successful, and may not result in NDA approval, with adverse results for our business and share price.

We initiated the Phase 3 NEAT clinical trial in the first half of 2024. The NEAT protocol is the subject of an SPA, agreement with FDA. The FDA may revoke or alter its SPA agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions, or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. An SPA, however, does not guarantee that a trial will be successful, and our execution of the Phase 3 NEAT clinical trial may be delayed and even if successful may not result in approval by the FDA.

Clinical drug development is a lengthy, expensive and uncertain process. Results in preclinical studies and earlier clinical trials may not be indicative of future results, which may delay or prevent obtaining regulatory approval. 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 on a timely basis or at all.

Clinical development 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. 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. Success in preclinical studies and early clinical trials may not be predictive of results in larger clinical trials, and previous results from early or small clinical trials may not be replicated or show as favorable an outcome in further clinical trials, even if successful. 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. For example, EryDel had previously endeavored to develop eDSP for the potential treatment of A-T. While we have not seen evidence of significant safety concerns throughout eDSP Phase 3 clinical development for A-T, it failed to meet the primary endpoint in the ATTeST trial, and was potentially, negatively affected by missing data during the COVID-19 pandemic, but showed statistically effective results in a certain population, six to nine years old. We are conducting the Phase 3 NEAT clinical trial in the population (*i.e.* six to nine years old) that was found to be statistically effective. However, further studies in this population may not replicate previous results. Accordingly, the previous clinical trials that EryDel conducted may not have uncovered safety issues, even if they exist. The biochemical pathways that we believe are affected by eDSP are implicated in a variety of biological processes and disease conditions, and it is possible that the use of our drug candidates to treat larger numbers of patients will demonstrate unanticipated AEs, which may negatively affect their safety profile.

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.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, or after achieving positive results in pivotal trials, and we have had, and may face, similar setbacks. In addition, the patient populations under investigation with eDSP have many co-morbidities that may cause severe illness or death, which may be attributed to eDSP in a manner that negatively affects the safety profile of our drug candidate. If the results of our ongoing or future clinical trials for eDSP are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or AEs that emerge during clinical trials, we may be prevented from or delayed in obtaining marketing approval, and even if we obtain marketing approval, any sales may suffer. 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.

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

The risk of failure is high for any drug candidates that are in clinical and preclinical development. The clinical trials and manufacturing of our drug candidates are, and the manufacturing and marketing of our 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 drug candidates, we must demonstrate thorough lengthy, complex and expensive preclinical testing and clinical trials that our 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 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. For example, on March 8, 2023, the FDA placed a partial clinical hold on the IND for eDSP related to extractables and leachables of new components used in the treatment kit. The FDA subsequently lifted the partial clinical hold on September 23, 2023. Additionally, the Phase 3 ATTeST study conducted by EryDel failed to meet the primary endpoint. 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;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including ability to find patients with a rare disease, meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates;
- 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 or positive ethics committee opinions 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 or devices required for a clinical trial;
- 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.

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 or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

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 drug candidates for their targeted indications or support continued clinical development of such drug 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 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 drug candidates.

If we are required to conduct preclinical studies, clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our 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 of efficacy concerns, we may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all or regulatory authorities may suspend, vary or withdraw marketing approvals for approved products;
- 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 drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our 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 drug candidates will harm our commercial prospects and our ability to generate revenues.

Our drug candidates may cause or have attributed to them undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by our drug candidates or that may be identified as related to our drug candidates by investigators conducting our clinical trials or even related to competing products in development that utilize a similar mechanism of action or act through a similar biological disease pathway could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. AEs and SAEs that emerge during treatment with our drug candidates or other compounds acting through similar biological pathways may be deemed to be related to our drug candidate. This may require longer and more extensive Phase 3 clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain our drug candidates and could result in negative labeling or a restrictive REMS or comparable foreign strategy. This may also result in an inability to obtain approval of our drug candidates.

The occurrence of any or all of these events may cause the development of our drug candidates to be delayed or terminated, which could materially and adversely affect our business and prospects. Our drug candidates have in the past and may in the future be deemed to cause AEs and SAEs.

Clinical trials of our drug candidates may not uncover all possible AEs that patients may experience.

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. By design, clinical trials are based on a limited number of subjects and are of limited duration of exposure to the product, to determine whether the drug candidate demonstrates the substantial evidence of efficacy and safety necessary to obtain regulatory approval. As with the results of any statistical sampling, we cannot be sure that all side effects of our drug candidates may be uncovered. It may be the case that only with a significantly larger number of patients exposed to the drug candidate for a longer duration may there be a more complete safety profile be identified. Further, even larger clinical trials may not identify rare SAEs, and the duration of such studies may not be sufficient to identify when those events may occur. Other products have been approved by the regulatory authorities for which safety concerns have been uncovered following approval. Such safety concerns have led to labeling changes, restrictions on distribution through use of a REMS, or comparable foreign strategy, or withdrawal of products from the market, and any of our drug candidates may be subject to similar risks.

Although to date we have not seen evidence of significant safety concerns with our drug candidates in the patient populations currently undergoing clinical trials with eDSP, if approved, may be associated with previously unreported adverse reactions, and it is possible that the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our drug candidates. If safety problems occur or are identified after our products, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our products, recall our products, or even withdraw approval for our products.

If we are not able to successfully demonstrate a favorable differentiation between eDSP and currently available corticosteroids, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Our business model is to pursue the development of off-patent drugs for which we would directly pursue the development of a red blood cell encapsulated formulation through the FDA's 505(b)(2) regulatory pathway. In order to receive sufficient reimbursement and utilization, our drug candidates, will require showing differentiation against currently available generic products. If we are not able to differentiate eDSP from currently available corticosteroids by showing a safety or efficacy benefit that is reflected in the approved label, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Because the potential rare disease target patient populations of EryDex are small, and the addressable patient population even smaller, we may not be able to effectively complete clinical trials or commercialize the drug candidate and we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth. If the market opportunities for our drug candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

eDSP is in development for rare disease. Our projections regarding the number of people affected by these rare and ultra-rare diseases, as well as the subset who may benefit from treatment, are based on our beliefs and estimates. These estimates, derived from various sources including scientific literature, patient foundations, and market research, may prove to be incorrect or contain errors. Furthermore, new studies may change the estimated incidence or prevalence of these diseases, reducing the number of patients who might benefit from treatment. As a result, we cannot accurately predict the number of patients who could be eligible for treatment. The limited size of the potentially addressable patient population may hinder our ability to enroll a sufficient number of participants in clinical trials, delaying or preventing their successful completion. Additionally, even if we obtain regulatory approval for EryDex or other drug candidates, achieving significant market share may prove challenging due to the small target populations. This limitation may prevent us from realizing a meaningful return on our investment or achieving profitability, even with substantial market penetration.

Our effort to identify patients who may benefit from our treatments is in its early stages and may become increasingly difficult over time. If we are unable to locate and reach a sufficient number of patients, our ability to enroll them in clinical trials or generate meaningful sales upon commercialization will be adversely affected. Financial assistance programs, which provide support to patients unable to afford treatment, could also negatively impact our profitability if a significant portion of patients continues to rely on these programs upon approval of our drugs.

If eDSP is approved for a narrowly defined subset of patients, such as those with A-T between six and nine years old, this could further constrain an already small potential market. As a result, our revenue, growth prospects, and overall business could suffer if market opportunities for our drug candidates are smaller than anticipated. Additionally, if we fail to successfully identify and reach patients, our ability to achieve profitability and growth will be further compromised.

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.

Even if we obtain regulatory approval for a 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 GMPs regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with GMP 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. We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third party manufacturers or suppliers must continually adhere to federal regulations setting forth GMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with GMP and foreign regulatory requirements, we and any of our third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory authorities and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of AEs and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices.

Failure to comply with these regulatory requirements could result in enforcement actions, including, but not limited to, significant civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations.

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 GMPs regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA or comparable foreign application. 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, as well as foreign regulatory authorities 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 and any products for which we receive approval. 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. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

The holder of an approved NDA or equivalent foreign application 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 authority discovers previously unknown problems with a drug or device, such as AEs 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, including if approved, such regulatory authority may impose restrictions on that drug candidate, an approved drug, or us, including requiring withdrawal of the approved drug from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- issue warning or untitled letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend, vary 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;
- 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 approved drugs; or
- require a drug candidate or approved drugs 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 suspended, varied or withdrawn, the value of our company and our operating results will be adversely affected.

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.

A Fast Track designation by the FDA, such as the Fast Track designations received for eDSP, does not guarantee marketing approval and may not lead to a faster development, regulatory review or approval process.

In June 2024, the FDA granted Fast Track designation for our eDSP System for the treatment of patients with A-T. Fast Track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review of the sponsor's NDA. Fast Track designation is intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. However, Fast Track designation does not accelerate conduct of clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that any potential eDSP NDA will be approved or that any approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track designation for any indication if it believes that the designation is no longer supported by data emerging from the eDSP clinical development program.

We may be unable to obtain and retain orphan drug designations for some of our drug candidates or to maintain the benefits associated with orphan drug designation status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. In the EU, the European Commission, following an opinion from the EMA's Committee for Orphan Medicinal Products may grant orphan drug designation to promote the development of products (i) that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating conditions; (ii) either such conditions affect not more than five in 10,000 persons in the EU community, or without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. In the EU, orphan drug designation provides a range of potential incentives for medicinal products that have been granted an orphan designation by the European Commission, including protocol assistance, access to the centralized authorization procedure and fee reductions.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if the FDA finds that the holder of the orphan product exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. A product may obtain orphan drug exclusivity for each indication that has been designated upon approval of the indication, subject to the qualifications above. Any orphan drug exclusivity granted for second or subsequent indications applies only to those subsequent indications and does not block approval of a product for the first indication once the initial period of exclusivity has expired. Moreover, even if one of our drug candidates receives orphan product exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease.

In the EU, upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is

extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application; (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

We have received orphan drug designation by the FDA and European Commission for eDSP for the treatment of A-T. We may seek orphan drug designation in the United States, the EU and other European countries for additional orphan indications in which there is a medically plausible basis, including other rare diseases. In the future, exclusive marketing rights in the United States, if granted, may be limited if we seek approval for an indication broader than the orphan drug designated indication and may be lost if the FDA later determines that the request for the orphan drug designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we have sought or intend to seek orphan drug designation, we may never receive approval for such designations.

Risks Relating to Our Financial Position

We are a clinical stage biotechnology company and have a limited history operating a newly acquired business, 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 Novosteo 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 the completion the acquisition of EryDel in October 2023. We have a limited history operating our newly acquired business, 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 two late-stage clinical trials, one of which was initiated by EryDel, and we 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 clinical stage biotechnology 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.

The terms of the EIB Loan place restrictions on our operating and financial flexibility.

In connection with the EIB Loan, we are subject to operating restrictions and covenants that restrict our ability to finance our operations, engage in business activities or expand or fully pursue its business strategies. For example, unless we get approval from EIB, the EIB Loan limits our ability to, among other things:

- incur additional debt or provide guarantees in respect of debt;
- incur liens;
- make investments, acquisitions, loans or advances;
- sell assets;
- make distributions to equity holders, including dividends and distributions on, and redemptions, repurchases or retirement of, our capital stock;

- enter into certain hedging transactions;
- enter into fundamental changes, including mergers and consolidations;
- enter into transactions with affiliates;
- change the nature of our business; and
- change our management.

In addition, the EIB Loan requires that we meet certain reporting and operating covenants, including an obligation to maintain a certain minimum unrestricted balance of cash or cash equivalents, which requirement EIB has temporarily waived for the duration of the Waiver Period pursuant to the terms of the Amendment, which requirement EIB has temporarily waived for the duration of the Waiver Period pursuant to the terms of the Amendment. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. Subject to grace periods commencing when the borrower learns of the occurrence of a breach, a breach of these covenants would give EIB the option to exercise remedies including to accelerate the outstanding balance under the EIB Loan.

The EIB Loan includes customary events of default, including failure to pay principal, interest or certain other amounts when due; material inaccuracy of representations and warranties; breach of covenants; cross-default to other indebtedness (resulting in a right of the other lender to accelerate such indebtedness after giving effect to any grace periods); certain bankruptcy and insolvency events; certain undischarged judgments; and material adverse change. A breach of any of these covenants could result in an event of default under the EIB Loan. If an event of default occurs and is ongoing under the terms of the Finance, EIB may accelerate all of the obligations of EryDel thereunder and demand payment from us pursuant to the guarantees. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

The occurrence of certain events of default under the EIB Loan, including failure to make payments as they become due (subject to a grace period of three (3) business days) to the EIB, would result in the EIB having the right to accelerate and demand immediate payment of all outstanding obligations, together with accrued interest, if any, and any prepayment fees, under the EIB Loan. We may need additional funding in order to make such payments.

The Debt Agreement requires the Company to maintain a minimum cash balance of 14.65 million euros ($15.3 million) until the outstanding obligations under the Debt Agreement, together with accrued interest and all other amounts accrued or outstanding under the agreement, is repaid in full (the “Minimum Cash Covenant”). In November 2024, we entered into the Amendment of the Debt Agreement with EIB which waives the Minimum Cash Covenant from January 1, 2025 and up to the earlier of December 31, 2025, or the date the Minimum Cash Covenant is restored (such period, the “Waiver Period”). Under the terms of the Amendment, we agreed to certain amendments, including, among other things, requiring monthly reporting of cash balances and additional limitations on certain permitted acquisitions. Additionally, during the waiver period, interest accruing at a rate of 2% on the outstanding principal balances of Tranches A and B are now payable quarterly solely during the Waiver Period, with the first such payment due on March 31, 2025. The amount of Deferred Interest Rate accruing on Tranches A and B during the Waiver Period will be correspondingly reduced by 2%, from 9% to 7%. Additionally, we paid a one-time fee of 20,000 euros to EIB in connection with the Amendment.

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets.

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with acquisitions. For example, during the quarter ended June 30, 2024, we incurred a $17.1 million goodwill impairment charge in connection with the EryDel Acquisition. Additionally, we incurred a $0.8 million goodwill impairment charge in the quarter ended September 30, 2022 and a $5.9 million IPR&D Intangible Asset impairment charge for the quarter ended March 31, 2023 in connection with the Novosteo Acquisition. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we assumed as a result of the EryDel 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.

Unstable market and global economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions, may have adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have experienced volatility, including as a result of the COVID-19 pandemic, changes in interest rates, and economic inflation, which has included diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability and changes in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, acts of terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could heighten market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Failure to secure any necessary financing in a timely manner could have a material adverse effect on our growth strategy, financial performance and stock price.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

Our failure to maintain certain tax benefits applicable to Italian biotechnology companies may adversely affect our results of operations, our cash flows and our financial condition.

Since we have an Italian biotechnology subsidiary, we have benefited from certain tax advantages, including, for example, the R&D tax credit, which is an Italian tax credit aimed at stimulating research and development. The R&D tax credit can offset payments of certain taxes and contributions (e.g., social contributions, VAT payables, registration fees, income and withholding taxes and all other tax-related items that companies usually pay monthly). For eligible research and development activities, the tax credits were equal to 20% of the costs incurred in fiscal years 2022 and 2021, with a maximum annual amount of $4.4 million (4 million euros). In 2023 the tax credit rate was decreased to 10% of the eligible expenses for certain activities, and the annual ceiling of the credit increased to $5.5 million (5 million euros). Expenses incurred by the Company for years ended December 31, 2024, 2023, and 2022 generated a total tax credit amounting to $1.7 million (1.6 million euros), 0.9 million (0.8 million euros), and $1.1 million (1 million euros), respectively. The Italian tax authorities may audit each research and development program in respect of which a R&D tax credit has been claimed and assess whether such program qualifies in its view for the R&D tax credit. The Italian tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions or deductions in respect of our research and development activities. Should the Italian tax authorities be successful, the R&D tax credit, may be reduced, which would have a negative impact on our results of operations and future cash flows. We believe, due to the nature of our business operations, that we will continue to be eligible to receive the R&D tax credit. However, if the Italian government decides to eliminate, or to reduce the scope or the rate of, the R&D tax credit, either of which it could decide to do at any time, our results of operations could be adversely affected.

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 current or future proposed clinical trial designs. Our 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 drug 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 drug candidates in the United States until we receive approval of an NDA from the FDA. Similar requirements apply in foreign countries. 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. We have not submitted any marketing applications for a drug candidate.

Because eDSP utilizes DSP, we believe it will qualify for FDA approval through the FDA's 505(b)(2) regulatory pathway and through corresponding regulatory paths in other foreign jurisdictions. The clinical requirements for a 505(b)(2) drug candidate can vary widely from product to product depending primarily on whether the drug candidate claims a new indication, provides for a different route of administration, or claims improved safety compared to the existing approved product, and may include bioequivalence trials, limited safety and efficacy trials, or full Phase 1 through 3 trials.

The submission of a successful NDA or comparable foreign applications is a complicated process. 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. 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 or comparable foreign applications. 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 may impose similar requirements and have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA or a comparable foreign regulatory authority 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 trials of our drug candidates have in the past been put on clinical holds by, and failed to demonstrate safety and efficacy to the satisfaction of, the FDA, and if any future clinical trials of our drug candidates are put on clinical holds by, or fail to demonstrate safety and efficacy to the satisfaction of, the FDA, the EMA, or similar regulatory authorities outside the United States, or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approvals for the commercial sale of any of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our 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. Clinical trials of our drug candidates have in the past been put on clinical holds imposed by, and failed to demonstrate safety and efficacy to the satisfaction of, the FDA, the EMA and the European Commission, or similar regulatory authorities outside of the United States. For example, on March 8, 2023, the FDA placed a partial clinical hold on the IND for eDSP related to extractables and leachables of new components used in the treatment kit. The FDA subsequently lifted the partial clinical hold on September 23, 2023. 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. Additionally, the results of preclinical studies of our 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 drug candidates may not be predictive of the results of later-stage clinical trials. For example, the Phase 3 ATTeST study conducted by EryDel failed to meet its primary endpoint. 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, the EMA, or other 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, the EMA, or other regulatory authorities. The FDA, the EMA, 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, the EMA, 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, the EMA, 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, the EMA, 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.

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 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(collectively, the “PPACA”) 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 amendments and executive, judicial and Congressional challenges to certain aspects of the PPACA. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the PPACA 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 PPACA, 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, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA 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 PPACA and our business.

Other legislative changes have been proposed and adopted since the PPACA 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 2032, unless additional Congressional action is taken. 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, the IRA will, among other things (i) implements the Medicare Drug Price Negotiation Program 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. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. 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.

Additional health reform measures may continue and affect our business in unknown ways, particularly given the recent changes in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMMI, to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, or Loper Bright, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. 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.

In the EU, the regulatory landscape related to clinical trials is also evolving. The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be

manufactured in accordance with the guidelines on GMP and in a GMP licensed facility, which can be subject to GMP inspections.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation and on 10 April 2024, the Parliament adopted its related position. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our drug candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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.

We currently rely and expect to continue to 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, clinical and commercial 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 currently rely on and expect to continue to rely on, third-party CMOs to manufacture and supply our preclinical, clinical and commercial 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 GCP regulations 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. Similar requirements and consequences may apply in countries outside the United States.

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 GMP 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 drug candidates.

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 medicinal products, producing additional losses and depriving us of drug revenue.

Failure (or perceived failure) to comply with health and data protection laws and regulations and other obligations (such as contracts, industry standards, and policies) could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, adverse publicity, and other adverse consequences that could negatively affect our operating results and business.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information and (collectively, "sensitive data"). As a result, we and third parties with whom we work are or may become subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security), contractual obligations, industry standards and policies.

In the United States, numerous federal and state laws and regulations including federal health information privacy laws, state comprehensive consumer 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 apply or could apply to our operations or the operations of entities with whom we work. Similar laws are being considered in various other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the collaborators upon whom we rely. 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 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we violate (or are perceived to violate) HIPAA.

Many jurisdictions, including the EU, its member states, the United Kingdom and Australia, among others, have also 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. Mechanisms to transfer such personal data to the United States or other countries may not be available to us. An inability or material limitation on our ability to transfer personal data across national borders could materially impact our business operations.

For example, the EU's GDPR imposes numerous 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 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, and as a result we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries. The GDPR may increase our responsibility and liability in relation to personal data that we process, and may also increase our costs of compliance. Additionally, the EU's Network and Information Security Directive ("NIS2") regulates resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2 may lead up to administrative fines of a maximum of 10 million Euros or up to 2% out of the total worldwide revenue of the preceding fiscal year.

These laws, and similar laws being considered in other countries, 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.

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 (or perceived failure) to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, adverse publicity and could otherwise negatively affect our operating results and business. Actual or perceived failure to comply with privacy laws may also cause 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, to limit our ability to collect, use and disclose personal 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.

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 VA hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our drug 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 drug 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 drug candidates, once approved, compared to existing products, pricing of existing products may limit the amount we will be able to charge for our drug candidates. 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 eDSP is still in 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. The EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on

the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and began on of January 12, 2025, through a phased implementation. The Regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and provides the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and permits EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for drug candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK MHRA is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium, the National Institute for Health and Care Excellence, and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products.

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 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 PPACA, 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 payor, including commercial insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require the registration of sales representatives; state and foreign laws that require drug manufacturers to file reports with states or foreign regulatory authorities 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.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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, if approved, outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above and comparable risks, 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 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 UK 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 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.

Risks Related to the Production and Manufacturing of our Drug Candidates and Future Products

Our production capacity could prove insufficient for our needs.

Our production capacity may prove insufficient in the future to meet the growth of our business, including producing sufficient quantities of drug candidates for clinical trials and, ultimately, our customers and distributors. There is no guarantee that we will or have properly estimated our required manufacturing capacities or that the third parties we rely on to provide required machinery and materials for the manufacturing process will be able to perform on our proposed timelines or meet our manufacturing demands, if at all. Also, if we must increase production capacity for any reason, we may need to make considerable investments that could lead to significant financing needs or require us to enter into subcontracting agreements in order to outsource part of the production.

We may not have access to the raw materials and other components, necessary for the manufacturing of our drug candidates.

We are dependent on third parties for the supply of various materials that are necessary to produce our drug candidates for clinical trials.

If our agreements with one or more of these suppliers were to be terminated or if one or more of these suppliers are unable to meet our demands, we could experience delays in our research or planned clinical trials or commercialization. We could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost.

In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products in a cost-effective and timely manner. If we encounter difficulties in the supply of these materials, chemicals or biological products, or if we were not able to maintain our supply agreements, or establish new supply agreements in the future, our product development and our business prospects could be significantly compromised.

Our manufacturing facilities are subject to significant government regulations and approvals. If we or our third-party manufacturers fail to comply with these regulations or maintain these approvals, our business will be materially harmed.

We currently partially manufacture our Red Cell Loader machines and treatment kit in our facility in Medolla, Italy. We and our third-party manufacturers are subject to ongoing regulation and periodic inspection by the FDA competent authorities of EU Member States and other regulatory bodies to ensure compliance with GMP, as part of our clinical trials. Any failure to follow and document our or their adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for commercial sale or clinical trials, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our products.

Failure to comply with applicable regulations could also result in the European Commission, FDA, the national authorities in the individual EU Member States, or other applicable regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring us to suspend or put on hold one or more of our clinical trials;
- suspending, varying or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring us to suspend manufacturing activities or product sales, imports or exports;
- requiring us to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving our products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to our reputation, business, financial condition or operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the United States, the EU or elsewhere, our suppliers will have to pass an audit by the applicable regulatory authorities. We are dependent on our suppliers' cooperation and ability to pass such audits, and the audits and any audit remediation may be costly. Failure to pass such audits by us or any of our suppliers would affect our ability to commercialize our drug candidates in the United States, the EU or elsewhere.

Our production costs may be higher than we currently estimate.

We manufacture our drug candidates according to manufacturing best practices applicable to drugs for clinical trials and to specifications approved by the applicable regulatory authorities. If any of our drug candidates are found to be non-compliant, we would be required to manufacture the drug candidates again, which would entail additional costs and may prevent delivery of the drug candidates to patients on time.

Other risks inherent in the production process may have the same effect, such as:

- contamination of the controlled atmosphere area;
- unusable premises and equipment;
- new regulatory requirements requiring a partial and/or extended stop to the production unit to meet the requirements;
- unavailable qualified personnel;
- power failure of extended duration;
- logistical error; and
- rupture in the cold chain, which is a system for storing and transporting blood and blood products within the correct temperature range and conditions.

In addition, a rise in direct or indirect energy rates may increase product manufacturing and logistical costs. Any of these risks, should they occur, could disrupt our activities and compromise our financial position, results, reputation or growth.

The manufacture of our products requires strict adherence to regulatory requirements governing medical devices and if we or our suppliers encounter problems our business could suffer.

The manufacture of our products must comply with strict regulatory requirements governing Class II medical devices in the U.S. and other regulatory requirements in foreign locations. Problems may arise during manufacturing, quality control, storage, or distribution of our products for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, manufacturing quality concerns, or problems with raw materials, electromechanical, software and other components, supplier issues, and natural disasters. If problems arise during production, the affected products may have to be discarded. In the EU, our RCL and treatment kit medical devices, syringe kit, and process solutions, are subject to periodic inspections by our Notified Body to maintain CE Certificates of Conformity permitting us to affix the CE mark to our medical devices. We may also be subject to unannounced audits by national competent authorities to ensure compliance with applicable regulatory requirements.

As a result of the transitional provisions in the MDR, some CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD from May 2017, and which remained valid on May 26, 2021 and have not since been withdrawn will, with certain exceptions, remain valid until December 31, 2027 for Class III and Class IIb implantable medical devices and until December 31, 2028 for other Class IIb, Class IIa and Class I devices with a measuring function or which are sterile. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the MDR and for which an EU Declaration of Conformity was issued in accordance with the MDD prior to May 26, 2021, can continue to be placed on the EEA market until December 31, 2028. Manufacturers of medical devices may only benefit from the above extended transitional provisions deadlines if the following conditions are fulfilled: (i) the devices continue to comply with the requirements of the MDD, (ii) there are no significant changes in the design and intended purpose, (iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, (iv) the manufacturer implemented a quality management system by May 26, 2024 which complies with the requirements of the MDR, (v) by May 26, 2024 an application was lodged with a Notified Body for conduct of the conformity assessment of the devices covered by the CE Certificate of Conformity, or the devices intended to substitute for such devices, in accordance with the MDR and a related written agreement is signed with the Notified Body by September 26, 2024, and (vi) from May 26, 2021, compliance with the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices is ensured in place of the corresponding requirements in the MDD.

In addition, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD from May 25, 2017, which were valid on May 26, 2021 and have not been withdraw since but which expired before March 20, 2023, will only

continue to be valid in accordance with the extended transitional deadlines above if either (i) the manufacturer signed a written agreement with a Notified Body for the conformity assessment of the device covered by the expired CE Certificate of Conformity, or the device intended to substitute that device, in accordance with the MDR before the date of expiry of the CE Certificate of Conformity, or (ii) a competent authority of an EU Member State has granted a derogation from the application conformity assessment procedure in accordance with Article 59(1) or Article 97(1) of the MDR.

Any failure to comply with any of these obligations may impact our activities in the EEA, the renewal of our existing CE Certificates of Conformity and future conformity assessment activities.

Manufacturing problems or delays could also lead to increased costs, lost sales, damage to customer relations, failure to supply penalties, time and expense spent investigating the cause and depending on the cause, similar losses with respect to other batches of products. If problems are not discovered before the product is released to the market, voluntary recalls, corrective actions, or product liability related costs may also be incurred. If unanticipated problems with our products arise, or if we or our suppliers fail to comply with regulatory requirements following CE marking, we may also become subject to enforcement actions such as restrictions on manufacturing processes, warning letters, suspension, variation or withdrawal of CE Certificates of Conformity, civil or criminal penalties. Should we encounter difficulties in the manufacture of our products or be subject to a product recall, our business could suffer materially.

If we or any of our third-party manufacturers or suppliers 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 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 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 drug candidates, or supply future commercial drug candidates or devices, 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 or devices 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 drug candidates or devices 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 supply of any of these materials used in treatment kits or RCLs may be limited or any of the supply manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of treatment kits and RCLs may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline. The same risks apply to our internal manufacturing facilities.

In addition, the manufacturing process for any drug candidates 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 GMPs, 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 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. Moreover, we, or our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, competent authorities of EU Member States or other comparable foreign regulatory authorities, to monitor and ensure compliance with GMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, competent authorities of EU Member States or other comparable foreign regulatory

authorities to be noncompliant with GMP regulations. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products, if approved, and significantly harm our business, financial condition, results of operations and prospects. 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 product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates, if approved.

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, if approved. 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, early access program, 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 our drug candidates or selling our drug candidates, if approved. 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, if approved; 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.

The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common stock.

Following Brexit, the UK and the EU signed a EU-UK TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. Among the changes that have occurred are that the United Kingdom is treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement.

Northern Ireland initially continued to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods but the Windsor Framework (as further discussed below) has ended the applicability of the vast majority of EU regulatory rules in Northern Ireland, although, notably, Northern Ireland is subject to EU regulations related to medical devices, as set out below. Regarding medicinal products, part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework". The Framework revised the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. The Windsor Framework, in so far as it applies to medicinal products, came into effect on January 1, 2025.
As it relates to marketing authorizations of medicinal products, the United Kingdom has a separate regulatory submission process, approval process and a separate national marketing authorization. The scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States no longer encompasses the UK. In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in the UK.

Regarding medical devices, in light of the fact that the CE Marking process is set out in EU law, which no longer applies in the United Kingdom, the United Kingdom has devised a new route to market culminating in a UKCA Mark to replace the CE Mark. Northern Ireland will, however, continue to be covered by the regulations governing CE Marks. The UK MHRA has established transitional provisions to recognize the acceptance of certain CE marked medical devices on the Great Britain market until June 30, 2030, at the latest, depending on the type of device and its classification. Accordingly, medical devices which, for example, meet all requirements of the EU MDD and have a valid CE Certificate of Conformity and EU Declaration of conformity issued under the MDD prior to May 26, 2021, may be placed on the market until the sooner of expiry of the CE Certificate of Conformity or June 30, 2028. Medical devices which meet all requirements of the EU MDR may be placed on the market until June 30, 2030. Manufacturers of medical devices located outside the UK, including manufacturers of CE marked medical devices, need to appoint a UK Responsible Person before the devices may be placed on the GB market. The UK government plans on introducing new legislation governing medical devices which will be delivered though secondary legislation. The first piece of legislation was laid in 2024 and updates post-market surveillance requirements. Additional instruments will follow in 2025 and 2026 to introduce new pre-market requirements including international reliance, and further enhancements to the regulations.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials, and which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation and such changes were brought forward in legislation laid before Parliament in December 2024. These resulting legislative amendments will determine how closely the UK regulations will align with the CTR and will be debated in 2025, such amendments are currently proposed to come into force in early 2026. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. The MHRA has also introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive

end of procedure outcome from the mutual recognition or decentralized procedures are considered to be authorizations for the purposes of the IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in UK, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the UK.

A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our drug candidates in the UK or the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our drug candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our drug candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our drug candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

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 previously 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 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.

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.

Should any of these events occur, they would significantly harm our business, results of operations and prospects.

We have applied, and we intend to continue applying, for patents covering aspects of our current drug candidates and device, any future drug candidates, any future improvements on the device 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.

Without patent protection on 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 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. 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 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 or commercializing eDSP, 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 biotechnology industry expands and more patents are issued, the risk increases that our drug 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 drug 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, drug 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, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications;

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. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and

developed intellectual property portfolios. 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. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other drug candidates, or enter into development partnerships that would help us bring our drug candidates to market. 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.

In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the UPC. Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the 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. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country.

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.

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 biotechnology 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 AIA, 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 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 trade names 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.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our drug candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our drug candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our drug candidates.

We cannot be certain that the claims in our pending patent applications directed to our drug candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our drug candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our drug candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not be successful in obtaining or maintaining necessary rights to our drug candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our drug candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our drug candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our drug candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our drug candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those drug candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future drug candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future drug candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future 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.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, drug candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, drug candidates, or future methods or products resulting 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.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

From time to time, we may be required to license technologies relating to our therapeutic research programs from additional 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.

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 products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products 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 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 and future drug candidates;
- collaborators may own or co-own intellectual property covering our products 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 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:

- our ability to complete clinical development of eDSP, on a timely basis or at all;
- our ability to continue as a going concern, the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- changes in our business strategy;
- timing and results of clinical trials;
- our ability to identify partnership and licensing opportunities to support the future development of eDSP;
- market opportunity for A-T and future indications;
- any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for drug candidates;
- regulatory actions with respect to our 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, including eDSP;
- 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;
- our ability to maintain compliance with Nasdaq minimum listing requirements;
- general economic and market conditions; 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 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. 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.

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.

In addition, we have filed a shelf registration statement on Form S-3, or the Shelf Registration Statement, which permits us to sell from time-to-time up to $200.0 million of additional shares of our common stock or other securities in one or more offerings. In particular, we may offer and sell up to $75.0 million shares of our common stock from time to time pursuant to the Controlled Equity Offering℠ Sales Agreement dated December 18, 2024, or the Sales Agreement, that we have entered into with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC. As of the filing date of this Annual Report, we have not sold any shares of our common stock pursuant to the Sales Agreement. Depending on market liquidity at the time, sales of our common stock pursuant to the Sales Agreement, or other sales of our common stock or other securities under the Shelf Registration Statement, may cause the trading price of our common stock to decline.

We have in the past and may in the future fail to meet the requirements for continued listing on Nasdaq. If we fail to maintain compliance with the minimum listing requirements, our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our common stock currently trades on the Nasdaq. The Nasdaq has requirements that a company must meet in order to remain listed on Nasdaq. For example, Nasdaq Listing Rule 5450(a)(1) requires listed securities to maintain a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement") and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive trading days.

Additionally, in December 2022, we received a written notice from the Nasdaq Listing Department notifying us that we were in noncompliance with the Minimum Bid Price Requirement and we regained compliance in April 2023. In December 2023, we again received a written notice from the Nasdaq Listing Department notifying us that we were in noncompliance with the Minimum Bid Price Requirement and regained compliance later in December 2023. In June 2024, we again received a written notice from the Nasdaq Listing Department notifying us that we were in noncompliance with the Minimum Bid Price Requirement and regained compliance later in November 2024. There can be no assurance that we will continue to meet the Minimum Bid Price Requirement, or any other Nasdaq requirements, in the future.

Furthermore, we may also be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

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.

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

We have sold our legacy small molecule protease inhibitor portfolio to Lighthouse, 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's 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's 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 previously announced change in our corporate strategy, including the termination of the license for 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 have attributed 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.

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.

If our internal information systems, those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences including, but not limited to, regulatory investigations or actions, litigation, fines/penalties, disruptions of our business operations, reputational harm, and loss of revenue or profits.

In the ordinary course of our business, we and the third parties upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," "hacktivists," individual threat actors, organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Despite the implementation of security measures designed to detect and mitigate vulnerabilities, our internal information systems and those of third parties with whom we work (such as our CROs and other contractors and consultants) are vulnerable to damage from sources including, but not limited to, malicious code (*e.g.*, computer viruses), malware, ransomware attacks, social engineering attacks, software or hardware failures or bugs, telecommunications failures, data loss, and unauthorized access (including as a result of personnel misconduct or error). In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network.

It is difficult and costly to detect, investigate, mitigate, contain and remediate security incidents. Our efforts to do so may not be successful. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Material information system failures or security breaches can cause interruptions in our operations which could result in a material disruption of our development programs and our business operations, as well as adverse consequences including, but not limited to, investigations, fines/penalties, litigation, and reputational harm, as well as triggering data breach notification obligations. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences. 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. Our reliance on third-party service providers could also introduce new cybersecurity risks and vulnerabilities, such as supply-chain attacks. To the extent that any disruption or security breach has in past or were in the future 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. Additionally, future or past business transactions could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, or that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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. NOLs generated in Italy are subject to Italian tax laws and deductibility of such Italian NOLs may be limited to 80% of taxable income.

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 1C. Cybersecurity.

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' Audit Committee is responsible for overseeing Company's our risk management processes, including oversight and mitigation of risks from cybersecurity threats. Management is responsible for the day-to-day administration of our risk management program and our cybersecurity policies, processes, and practices.

Cybersecurity Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data (including intellectual property, confidential information that is proprietary, strategic or competitive in nature (collectively, "Information Systems and Data").

We have implemented a cross-functional approach to assessing, identifying and managing material cybersecurity threats and incidents. Our Information Systems Representative and Chief Operating Officer identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment. We use various methods designed to accomplish this task including, for example: manual and automated tools, subscriptions to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, and evaluating threats reported to us.

Depending on the relevant information systems environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: incident detection and response strategies, systems monitoring, personnel training, cybersecurity insurance, data encryption strategies, network security controls, access controls, physical security controls, and asset management (such as tracking and disposal of Company information systems).

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our IT Department works with management in an effort to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use service providers to assist us from time to time in an effort to identify, assess, and manage material risks from cybersecurity threats, including, for example, cybersecurity software providers and professional services firms (including legal counsel). We also use service providers to perform a variety of functions throughout our business, such as application providers, data hosting providers, and CROs. We have a vendor management strategy designed to manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management strategies may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider, such as reviewing their information security documentation and imposing contractual obligations on them with respect to their information security controls.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including *If our internal information systems, those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences including, but not limited to, regulatory investigations or actions, litigation, fines/penalties, disruptions of our business operations, reputational harm, and loss of revenue or profits.*

Governance

Our Audit Committee receives regular presentations and reports on developments in the cybersecurity space, including risk management practices, recent developments, evolving standards, threats, risks and mitigation. Our Audit Committee also receives information regarding certain cybersecurity risks that meets pre-established reporting thresholds, as well as ongoing updates regarding any such risk.

Our Information Systems Representative, in coordination with senior management including our Chief Operating Officer works collaboratively across our company to implement a program designed to protect our information systems from cybersecurity threats and to promptly respond to any material cybersecurity incidents in accordance with our incident response and recovery plans. To facilitate the success of our cybersecurity program, cross-functional teams throughout our company address cybersecurity threats and respond to and escalate certain cybersecurity incidents. Through ongoing communications with these teams, the Information Systems Representative and senior management are informed about and monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents and report such threats and incidents to the Audit Committee when appropriate. The Information Systems Representative has served in various roles in information technology and information security for over 26 years, including serving as the Director of Information Technology of another public company. Our Chief Operating Officer has over 7 years of experience managing information technology, including cybersecurity and risk management.

Item 2. Properties.

Our corporate headquarters are currently located in South San Francisco, California, where we signed a lease agreement for a smaller office space pursuant to a lease agreement that expires in November 2025. We also have leases in Medolla, in the Province of Modena, Italy where we have our manufacturing facility pursuant to a lease agreement that expires in January 31, 2030 and in Bresso, in the Province of Milan, Italy, for office space pursuant to a lease agreement that expires in August 31, 2028. 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.

Market Information

Our common stock is listed on the Nasdaq under the trading symbol "QNCX".

Our common stock has been traded under the ticker symbol "CRTX" on the Nasdaq since May 9, 2019, and since August 1, 2022 under the ticker symbol "QNCX".

Stockholders

As of March 13, 2025, there were 41 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.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Additionally, the EIB Loan prohibits the payment of dividends. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions, and other factors that our board of directors may deem relevant.

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, and Item 1 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. Unless the context requires otherwise, references in this Annual Report on Form 10-K to the "Company," "Quince," "we," "us" and "our" refer to Quince Therapeutics, Inc.

Overview

We are a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases.

Our proprietary AIDE technology platform is an innovative drug/device combination platform that uses an automated process to encapsulate a drug into a patient's own red blood cells. Red blood cells have several characteristics that make them an excellent vehicle for drug delivery potential including better safety and tolerability, enhanced tissue distribution, reduced immunogenicity, and prolongation of circulating half-life. Our AIDE technology is designed to harness many of these benefits to allow for new and improved therapeutic options for patients living with high unmet medical needs. eDSP is the first product in development that leverages our AIDE technology and is composed of DSP encapsulated in autologous red blood cells targeted to treat A-T. DSP is a corticosteroid well-described for its anti-inflammatory properties, but is also coupled with serious adverse events, including adrenal suppression. eDSP is designed to maintain the well-described efficacy of DSP while reducing or eliminating the significant adverse events that accompany chronic corticosteroid treatment. The altered biodistribution, pharmacokinetics, and pharmacodynamics of eDSP enabled by autologous red blood cells may, therefore, improve the safety profile, and maintain or increase the desired therapeutic effect of DSP.

Currently, there are no approved treatments for A-T and the global market, based on our internal estimates and assumptions, represents a more than $1 billion peak commercial opportunity. We believe this makes eDSP an ideal lead asset to demonstrate the clinical and commercial potential of our AIDE technology.

We intend to focus our development expertise and financial resources toward advancing a Phase 3 NEAT clinical trial, which is an international multicenter, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of eDSP on patients with A-T. We plan to enroll approximately 86 patients with A-T aged six to nine years old and approximately 20 A-T patients aged 10 years or older. This pivotal clinical trial will be conducted under an SPA agreement with the FDA, which should allow for the submission of an NDA following completion of this study, provided we obtain positive results. As of March 24, 2025, 60 participants have been enrolled in the Phase 3 NEAT clinical trial of eDSP and 24 participants have entered the OLE study. We expect to report topline results from this trial in the fourth quarter of 2025, with potential NDA and MAA submissions in 2026, assuming positive study results.

Fiscal Year 2024 Key Events:

- Initiated the Phase 3 NEAT clinical trial of eDSP in A-T in June 2024 and the OLE study in December 2024.
- Selected DMD as our second development program and began work generating a Phase 2 clinical trial study designed to evaluate eDSP for the potential treatment of patients with DMD.
- Completed evaluation process of other potential rare disease indications for eDSP beyond A-T and DMD that resulted in a prioritized list of immunological and autoimmune focused rare disease indications for potential new program development.
- Granted Fast Track designation from the FDA for our eDSP System for the treatment of patients with A-T in June 2024.
- Published efficacy and safety results from our Phase 3 ATTeST clinical trial evaluating eDSP for the treatment of A-Tin peer-reviewed medical journal *The Lancet Neurology*.
- Participated at notable scientific conferences, including poster presentations at the 53rd Child Neurology Society (CNS) Annual Meeting and the 2024 International Congress for Ataxia Research (ICAR), where we presented data from our prior Phase 3 ATTeST clinical trial.

- Completed an initial patient sizing project based on third-party analysis from IQVIA Medical Claims (Dx), PharmetricsPlus (P+), and IQVIA Analytics, which confirmed that the number of diagnosed patients with A-T in the U.S. is estimated to be to approximately 4,600.
- Established a Scientific Advisory Board (SAB) comprised of leading experts in biochemistry, neurology, immunology, hematology, pharmacology, and clinical practice who are uniquely positioned to provide us with deep insights and advice to support advancement of our drug programs.

Financial Overview

Following our acquisition of EryDel in October 2023, we shifted our strategic focus to become a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology to deliver innovative therapeutics to those living with rare diseases.

Our strategic focus is to apply our resources and capital toward the advancement of our proprietary AIDE technology platform and Phase 3 lead asset, eDSP. The NEAT study is an international multicenter, randomized, double-blind, placebo-controlled study to evaluate the neurological effects of eDSP on patients with A-T. We plan to enroll approximately 86 patients with A-T aged six to nine years old and approximately 20 A-T patients aged 10 years or older. This pivotal clinical trial will be conducted under an SPA agreement with the FDA, which should allow for the submission of an NDA following completion of this study, provided we obtain positive results.

To expand our development pipeline, we also intend to initiate a DMD Phase 2 study in 2025 and will advance the development of immunology and autoimmune focused rare disease indications for eDSP, subject to additional financing.

Components of Results of Operations

Operating Expenses

Our operating expenses since inception have consisted primarily of R&D activities and G&A costs.

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.

Historically, 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. As we sold our legacy protease inhibitor portfolio including COR388 and COR588 to Lighthouse Pharmaceuticals, Inc. in January 2023, we did not incur any additional expenses related to these legacy assets from the second quarter of 2023 onward. Additionally, due to the decision made on January 30, 2023 to discontinue internal development of NOV004 and following the termination of the License Agreement with PRF on October 31, 2023, we have not and do not expect to incur any additional NOV004 costs.

We expect our research and development expenses to remain in the current levels as we continue our Phase 3 NEAT clinical trial and expand into new indications, including Phase 2 study in DMD.

General and Administrative

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.

Fair Value Adjustment for Contingent Consideration

We record fair value adjustment for contingent consideration primarily due to the expected timing of achieving various milestones, and the passage of time related to the contingent consideration earnout resulting from the EryDel Acquisition. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations.

Fair Value Adjustment for Long-term Debt

We record fair value adjustment for long-term debt primarily due to the passage of time and the interest accrued for the loan with the EIB.

Interest Income

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

Other Expense, net

Other income (expense), net consists primarily of the effects of foreign currency exchange rates.

Critical Accounting 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
- Business Combination
- Goodwill
- Identifiable Intangible Assets
- Contingent Consideration
- Long-term Debt

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 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.

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 FASB 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

When we acquire a business, the assets acquired and liabilities assumed are recorded at their respective fair values at the acquisition date. 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. 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. During 2024, we recognized a non-cash goodwill impairment charge of $17.1 million.

Identifiable Intangible Assets

We have acquired intangible assets through our business combinations with EryDel in 2023. 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 consists primarily of the tradename and is amortized on a straight-line basis over their estimated useful lives. Indefinite lived intangible assets are not amortized, Intangible assets related to IPR&D acquired in a business combination or an acquisition that are used in 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.

Contingent Consideration

We determine the acquisition date fair value of contingent consideration using a probability-weighted discounted cash flow model, with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC Topic 820, Fair Value Measurement. The significant inputs in the Level 3 measurement not supported by market activity included our probability assessments of expected future cash flows during the contingent consideration period, appropriately discounted considering the uncertainties associated with the earnout obligation, and calculated in accordance with the terms of the definitive agreement. The liabilities for the contingent consideration are established at the time of the acquisition and will be evaluated on a quarterly basis based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the earnings of that period. During the year ended December 31, 2024, we recorded a net $4.0 million adjustment to increase the fair value of its contingent consideration related to the acquisition of EryDel. The adjustment is reflected within operating loss on the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Significant increases or decreases in the inputs noted above in isolation would result in a significantly lower or higher fair value measurement.

Long-Term Debt

We determined that we are eligible for the fair value option election in connection with the EIB Loan (as defined below) as the instrument met the definition of a “recognized financial liability” which is an acceptable financial instrument eligible for the fair value option under ASC 825. At the date of inception of the EIB Loan through the EryDel Acquisition, the fair value for each instrument is derived from the instrument’s implied discount rate at inception.

Results of Operations

Comparison of the year ended December 31, 2024 to the year ended December 31, 2023

The following sets forth our results of operations for the year ended December 31, 2024 and 2023 (in thousands, except for percentages):

	Years Ended December 31,		Change	
	2024	2023	$	%
Operating expenses:				
Research and development	$ 18,590	$ 9,447	$ 9,143	97 %
General and administrative	17,580	17,695	(115)	(1)%
Goodwill impairment charge	17,130	—	17,130	
Intangible asset impairment charge	—	5,900	(5,900)	(100)%
Fair value adjustment for contingent consideration	3,985	1,578	2,407	153 %
Total operating expenses	57,285	34,620	22,665	65 %
Loss from operations	(57,285)	(34,620)	(22,665)	65 %
Fair value adjustment for long-term debt	(1,709)	(338)	(1,371)	406 %
Interest income	2,929	3,478	(549)	(16)%
Other expense, net	(676)	(102)	(574)	563 %
Net loss before income tax (expense) benefit	(56,741)	(31,582)	(25,159)	80 %
Income tax (expense) benefit	(87)	197	(284)	(144)%
Net loss	$ (56,828)	$ (31,385)	$ (25,443)	81 %

Research and Development Expenses *(in thousands, except for percentages):*

	Years Ended December 31,		Change	
	2024	2023	$	%
Direct research and development expenses:				
eDSP	$ 13,259	$ 1,655	$ 11,604	701 %
NOV004	—	2,048	(2,048)	(100)%
Other direct research costs	272	461	(189)	(41)%
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	4,593	4,619	(26)	(1)%
Facilities and other research and development expenses	466	664	(198)	(30)%
Total research and development expenses	$ 18,590	$ 9,447	$ 9,143	97 %

Research and development expenses were $18.6 million for the year ended December 31, 2024, compared to $9.4 million for the year ended December 31, 2023, an increase of $9.1 million.

The costs for eDSP development increased by $11.6 million compared to the same period from the prior year due to the start-up and ramping up costs related to our Phase 3 NEAT clinical trial. This increase was primarily due to clinical trial costs of $10.6 million and $1.0 million in manufacturing costs.

After the decision made on January 30, 2023 to discontinue internal development of NOV004 and following the termination of the License Agreement with PRF on October 31, 2023, we have not and do not expect to incur any additional NOV004 costs in the future.

Our personnel related costs remained consistent with a slight decrease of $26.0 thousand during the year ended December 31, 2024 as compared to the year ended December 31, 2023, mainly as a result of a $0.3 million decrease in allocated stock-based compensation costs, offset by a $0.3 million increase in personnel-related expenses

Facilities and other research and development expenses decreased by $0.2 million for the year ended December 31, 2024, as compared to the year ended December 31, 2023 primarily due to a decrease in storage and facilities expenses.

General and Administrative Expenses

General and administrative expenses decreased by $0.1 million for the year ended December 31, 2024 as compared to the year ended December 31, 2023. The change in general and administrative expenses is primarily due to a decrease of $1.5 million in legal fees, $0.7 million in consulting and professional fees expenses, and $0.3 million in corporate insurance expenses. These decreases were partially offset by an increase of $1.1 million in personnel-related expenses, $0.3 million in business development expenses, $0.2 million in audit and tax fees, and $0.8 million in other professional and administrative expenses year over year.

Goodwill Impairment Charge

During the year ended December 31, 2024, we conducted an impairment analysis of our goodwill that resulted from the acquisition of EryDel in October 2023. That assessment included a qualitative assessment of deteriorating macro-economic conditions, including inflationary pressures and high interest rates, and the continuing decline in our market capitalization from the date of the 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 $17.1 million for the year ended December 31, 2024.

Intangible Assets Impairment Charge

During the year ended December 31, 2023, we conducted an impairment analysis of our intangible asset IPR&D that resulted from the purchase of Novosteo, Inc. in May 2022. To determine the extent, if any, by which our IPR&D Intangible Asset was impaired, we conducted a quantitative analysis which resulted in our fair value being significantly below our current carrying value due to the assumptions changing as a result of the decision to hold this asset for sale in January 2023. As a result of the analyses, we recorded a non-cash intangible asset IPR&D impairment charge of $5.9 million for the year ended December 31, 2023.

Fair Value Adjustment for Contingent Consideration

For the year ended December 31, 2024, we recorded a fair value adjustment for contingent consideration which resulted in a $4.0 million increase primarily due the probability and expected timing of achieving various milestones and the passage of time. The Company owes no further payments to EryDel shareholders for development-related milestones.

Fair Value Adjustment for Long-term Debt

For the year ended December 31, 2024, we recorded a fair value adjustment for long-term debt which resulted in a $1.7 million charge primarily due to the passage of time and the interest accrued for the loan with the EIB.

Interest Income

Interest income decreased by $0.5 million for the year ended December 31, 2024, as compared to the year ended December 31, 2023. The change was due to decreased yields on our investment portfolio and decreased average balances.

Other Expense, net

Other expense, net increased by $0.6 million for the year ended December 31, 2024 primarily due to unrealized losses resulting from changes in foreign exchange rates.

Income Tax

We recorded tax expense of $0.1 million for the year ended December 31, 2024 and tax benefit of $0.2 million for the year ended December 31, 2023. Tax expense is primarily driven by foreign withholding tax, interest on uncertain tax position liability and net of tax benefit from decrease in EryDel's deferred tax liabilities.

Liquidity and Capital Resources

We have not generated any revenue and we have never been profitable. 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, 2024, we received net proceeds of approximately $304.1 million from the issuance of redeemable convertible preferred stock, convertible promissory notes and common stock.

We have incurred net losses since the commencement of our operations. As of December 31, 2024, we had an accumulated deficit of $376.5 million. We incurred a net loss of $56.8 million in the year ended December 31, 2024. 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.

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. We have incurred losses and generated negative operating cash flows since our inception and anticipate that we will continue to incur losses for at least the next several years. The transition to profitability is dependent upon the successful development, approval and commercialization of our product candidate, and the achievement of a level of revenues adequate to support our cost structure. As of December 31, 2024 and 2023, we had cash, cash equivalents and short-term investments of $40.8 million and $75.1 million, respectively. Based on our current operating plan, we believe that our cash and cash equivalents balance as of December 31, 2024 will not be sufficient to fund operations and capital expenditures for the twelve months following the filing of this Annual Report on Form 10-K, and we will need to obtain additional funding. We intend to obtain additional funding through available financing sources which may include additional public offerings of common stock, private financing of debt or equity, and/or the pursuit of strategic partnerships, licensing arrangements or collaborations. Management’s belief with respect to our ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management’s estimates, we may need to seek additional funding sooner than would otherwise be expected. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all. If we are unable to obtain sufficient funding, we may be required to delay development efforts, limit activities and reduce research and development costs, which could adversely affect our business prospects. Because of the uncertainty in securing additional funding and the insufficient amount of cash and cash equivalent resources as of December 31, 2024, we concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

Our cash, cash equivalents, and marketable debt securities are held in a variety of deposit accounts, interest-bearing accounts, 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. Our cash equivalents and short-term investments are held in money market funds, certificate of deposits, and government agency obligations.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations through Phase 3 NEAT topline results and into 2026, but that assumption does not include any costs or cash expenditures associated with initiating additional programs.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to eDSP, the initiation and continuation of the Phase 3 NEAT clinical trial, 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.

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. Following our acquisition of EryDel, 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 our Phase 3 NEAT clinical trial and any potential future trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- payment of future milestones to EryDel shareholders and payments to the EIB in respect of obligations under the EIB Loan;
- the number and characteristics of drug candidates that we pursue;
- 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, which would include anticipated clinical and development activities related to eDSP through completion of the Phase 3 NEAT clinical trial, but does not include any costs or cash expenditures associated with initiating additional programs. 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.

Financing

Equity Financing

On December 18, 2024, the Company entered into a Controlled Equity Offering℠ Sales Agreement, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, or the Agents, relating to the sale of shares of our common stock (the "Sales Agreement"). In accordance with the terms of the Sales Agreement, the Company may offer and sell up to $75.0 million of shares of common stock. During the year ended December 31, 2024, the Company did not sell any shares of common stock pursuant to the Sales Agreement.

Debt Financing

In connection with the acquisition of EryDel on October 20, 2023, we guaranteed the EIB Loan. The EIB Loan was amended and restated as of the acquisition date. The EIB Loan provides for maximum borrowings of 30.0 million euro through four tranches; tranche A, 3.0 million euro; tranche B, 7.0 million euro; tranche C, 10.0 million euro; and tranche D, 10.0 million euro. Each tranche is subject to conditions precedent related to our business and capitalization. As of December 31, 2024, only tranches A and B have been drawn. All amounts due under tranche A and B are payable on their maturity date of August 2026. Tranche C and D are payable in equal installments of principal together with all amounts

outstanding under the tranches on the repayment dates specified in the relevant disbursement offer. The first repayment date of tranche C shall fall not earlier than twelve months from the disbursement date of such tranche. The last repayment date of tranche C and tranche D shall fall not later than 5 years from the disbursement date of tranche C and tranche D, respectively. The EIB Loan bears interest at fixed rates for each tranche and both principal and interest are payable on the maturity date for each tranche (with the exception of 2% cash interest which shall accrue and be payable quarterly during fiscal year 2025 pursuant to the terms of the Amendment, which shall correspondingly reduce the deferred interest rate accruing during such period). The fixed rates range from 7.0% to 9.0% per annum. As of December 31, 2024, principal of 10.0 million euros ($10.4 million) was outstanding on the EIB Loan and it is recorded as Long-term debt on the consolidated balance sheet at fair value with imputed interest of 9.0% included.

We may voluntarily prepay, in whole or in part with a prepayment premium. In the event of an occurrence of an event of default, a change in control and certain other prepayment events, as specified in the Debt Agreement, we will be required to prepay the outstanding EIB Loan together with an additional remuneration buyout fee, as specified in the Debt Agreement. The Debt Agreement includes a provision for additional remuneration to be paid in addition to interest. The amount of additional remuneration to be paid is equal to 2.5% of revenue up to 125.0 million euros, plus 1.85% of revenue between 125.0 and 250.0 million euros, plus 1.0% of revenue in excess of 250.0 million euros, multiplied by a varying percentage based on how many tranches have been drawn. The varying percentage is equal to 30.0% in the event tranche A has been drawn, 50.0% in the event tranche A and B have been drawn, 80.0% in the event tranche A, B and C have been drawn, and 100.0% in the event all four tranches have been drawn. The additional remuneration is payable for seven years, during the period January 1, 2026, through December 31, 2032. In the event of an occurrence of an event of default or prepayment, we may be required to pay an additional remuneration buyout fee.

The Debt Agreement requires us to maintain a minimum cash balance of 14.65 million euros ($15.3 million) until the outstanding obligations under the Debt Agreement, together with accrued interest and all other amounts accrued or outstanding under the agreement, is repaid in full (the “Minimum Cash Covenant”). In November 2024, we entered into an amendment (the “Amendment”) of the Debt Agreement with EIB which waives the Minimum Cash Covenant from January 1, 2025, and up to the earlier of December 31, 2025, or the date the Minimum Cash Covenant is restored (such period, the “Waiver Period”). Under the terms of the Amendment, we agreed to amendments requiring monthly reporting of cash balances and additional limitations on certain permitted acquisitions. Additionally, solely during the waiver period, 2% cash interest on the outstanding principal amounts of tranches A and B are payable on March 31, 2025, June 30, 2025, September 30, 2025 and December 31, 2025, reducing the total deferred interest on tranches A and B to 7% for the duration of the Waiver Period, and a one-time fee of 20,000 euros in connection with the Amendment. As of December 31, 2024, we have been in compliance with all covenants under the Debt Agreement.

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):

	Years Ended December 31,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (31,904)	$ (18,292)
Investing activities	21,908	(5,758)
Financing activities	(4,775)	143
Effect of exchange rate changes on cash	231	80
Net decrease in cash and cash equivalents	$ (14,540)	$ (23,827)

Operating Activities

Net cash used in operating activities was $31.9 million for the year ended December 31, 2024. Cash used in operating activities was primarily due to our net loss of $56.8 million for the period, adjusted for $25.4 million of non-cash items, including $17.1 million goodwill impairment charge, $4.7 million in stock-based compensation, $4.0 million change in the fair value of contingent consideration liabilities, $1.7 million change in the fair value of the EIB Loan and a net increase in our operating assets of $2.6 million, offset by a net increase in our accounts payable, and accrued expenses and other current liabilities of $2.1 million.

Net cash used in operating activities was $18.3 million for the year ended December 31, 2023. Cash used in operating activities in the year ended December 31, 2023 was primarily due to our net loss for the period of $31.4 million, which included non-cash expenses of $11.2 million, including $5.2 million in stock-based compensation, and a net decrease in accounts payable and accrued expenses and other current liabilities of $2.3 million, offset by increases in our current assets of $4.2 million.

Investing Activities

Cash provided by investing activities was $21.9 million for the year ended December 31, 2024, primarily related to the maturities of short-term investments of $111.7 million, and the purchase of investments of $89.6 million.

Cash used in investing activities was $5.8 million in the year ended December 31, 2023, primarily related to the purchase of investments of $113.8 million, offset by maturities of investments of $111.2 million, transaction costs related to the EryDel acquisition net of cash acquired of $2.1 million, the advance of the note receivable to EryDel prior to the close of the acquisition of $1.0 million, and the purchase of equipment of $0.2 million.

Financing Activities

Cash used in financing activities was $4.8 million for the year ended December 31, 2024, which consisted of a cash milestone payment of $5 million in accordance with the purchase agreement entered into in connection with EryDel Acquisition, partially offset by proceeds of $0.2 million from the exercise of stock options in the period.

Cash provided by financing activities was $0.1 million in the year ended December 31, 2023, which consisted of net proceeds from the exercise of stock options in the period.

Contractual Obligations and Commitments

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations.

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 $1.8 million in our consolidated balance sheet for expenditures incurred by these vendors as of December 31, 2024. We have approximately $23.1 million in cancellable future operating expense commitments based on existing contracts as of December 31, 2024. These obligations will be satisfied in the normal course of business, but generally no longer than 12 months. As of December 31, 2024, the fair value of the EIB Loan is $14.3 million and it is recorded as long-term debt on the consolidated balance sheet at fair value. As of December 31, 2024, the fair value of long-term contingent consideration on our books for the earnout related to the EryDel Acquisition is $56.7 million, refer to Note 3 to the consolidated financial statements for further details.

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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Shareholders 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, 2024 and 2023, 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, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

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 the 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 a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Contingent Consideration

As disclosed in Notes 2, 3 and 13 to the consolidated financial statements, the Company's consolidated contingent consideration balance was $56.7 million at December 31, 2024, and the Company recorded a change in fair value of $4.0 million for the year ended December 31, 2024. At December 31, 2024 the contingent consideration arrangement related to

the Company's 2023 acquisition of EryDel is comprised of payments up to $25.0 million at NDA acceptance, up to $60.0 million upon the achievement of specified approval milestones, and up to $395.0 million upon the achievement of specified on market and sales milestones. The Company estimated the fair value of the contingent consideration using a probability-weighted discounted cash flow model.

We identified the valuation of contingent consideration as a critical audit matter. Under the probability-weighted discounted cash flow model, the key estimates and assumptions used in the valuation of the contingent consideration include management's determination of the expected timing of milestone achievement, particularly related to NDA acceptance, special approval milestones and specified on market milestones. Changes to these key estimates and assumptions could have a significant impact on the fair value of the contingent consideration. Auditing these assumptions involved especially challenging and subjective auditor judgment due to the nature and extent of auditor effort required to address this matter.

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

- Assessing management's expected timing of milestone achievements by corroborating with personnel knowledgeable with the current progression of the product candidates and comparing with relevant industry studies.
- Corroborating management's estimated timing of milestone achievement by reviewing the Company's internal product development timeline.
- Assessing management's ability to forecast milestone achievement dates by analyzing the historical accuracy of these forecasts.

/s/ BDO USA, P.C.
We have served as the Company's auditor since 2018.
San Jose, California

March 24, 2025

QUINCE THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands except share amounts)

	December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,212	$ 20,752
Short-term investments	34,572	54,307
Prepaid expenses and other current assets	3,252	2,381
Total current assets	44,036	77,440
Property and equipment, net	315	234
Operating lease right-of-use assets	498	385
Goodwill	—	17,625
Intangible assets	60,045	63,672
Other assets	9,584	8,544
Total assets	$ 114,478	$ 167,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,903	$ 2,033
Short-term contingent consideration	—	4,103
Accrued expenses and other current liabilities	4,375	3,436
Total current liabilities	7,278	9,572
Long-term debt	14,321	13,429
Long-term operating lease liabilities	394	321
Long-term contingent consideration	56,691	53,603
Deferred tax liabilities	4,963	5,304
Other long-term liabilities	685	587
Total liabilities	84,332	82,816
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 44,001,643 and 42,973,215 issued and outstanding as of December 31, 2024 and December 31, 2023, respectively.	44	43
Additional paid in capital	406,609	401,638
Accumulated other comprehensive income (loss)	(35)	3,047
Accumulated deficit	(376,472)	(319,644)
Total stockholders' equity	30,146	85,084
Total liabilities and stockholders' equity	$ 114,478	$ 167,900

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

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

	Years Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 18,590	$ 9,447
General and administrative	17,580	17,695
Goodwill impairment charge	17,130	—
Intangible asset impairment charge	—	5,900
Fair value adjustment for contingent consideration	3,985	1,578
Total operating expenses	57,285	34,620
Loss from operations	(57,285)	(34,620)
Fair value adjustment for long-term debt	(1,709)	(338)
Interest income	2,929	3,478
Other expense, net	(676)	(102)
Net loss before income tax (expense) benefit	(56,741)	(31,582)
Income tax (expense) benefit	(87)	197
Net loss	(56,828)	(31,385)
Other comprehensive loss:		
Foreign currency translation adjustments	(3,160)	2,789
Unrealized gain on available-for-sale securities	78	547
Total comprehensive loss	$ (59,910)	$ (28,049)
Net loss per share - basic and diluted	$ (1.31)	$ (0.84)
Weighted average shares of common stock outstanding - basic and diluted	43,262,269	37,237,149

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

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

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	36,136,480	36	389,105	(289)	(288,259)	100,593
Issuance of common stock on exercise of stock options and vesting of restricted stock units	374,713	—	167	—	—	167
Restricted stock award retirement	(63,293)	—	(18)	—	—	(18)
Stock based compensation	—	—	5,220	—	—	5,220
Share issuance in connection with acquisition of EryDel S.p.A	6,525,315	7	7,164	—	—	7,171
Foreign currency translation adjustment	—	—	—	2,789	—	2,789
Unrealized gain (loss) on available for sale investments	—	—	—	547	—	547
Net loss	—	—	—	—	(31,385)	(31,385)
Balance as of December 31, 2023	42,973,215	$ 43	$ 401,638	$ 3,047	$ (319,644)	$ 85,084
Issuance of common stock on exercise of stock options and vesting of restricted stock units	303,391	—	225	—	—	225
Stock based compensation	—	—	4,746	—	—	4,746
Release of indemnity holdback shares in connection with acquisition of EryDel S.p.A	725,037	1	—	—	—	1
Foreign currency translation adjustment	—	—	—	(3,160)	—	(3,160)
Unrealized gain (loss) on available for sale investments	—	—	—	78	—	78
Net loss	—	—	—	—	(56,828)	(56,828)
Balance as of December 31, 2024	44,001,643	$ 44	$ 406,609	$ (35)	$ (376,472)	$ 30,146

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

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

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net Loss	$ (56,828)	$ (31,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	4,746	5,220
Depreciation and amortization	186	322
Impairment loss on operating lease	—	66
Gain on sale of legacy assets	—	(78)
Loss on disposal of fixed assets	—	37
Change in the fair value of contingent consideration liabilities	3,985	1,578
Change in fair value of long-term debt	1,709	338
Non-cash goodwill and intangible asset impairment charge	17,130	5,900
Amortization of discount on available-for-sale investments	(2,348)	(2,019)
Change in deferred tax liabilities due to acquisition of Novosteo, Inc.	—	(248)
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other current assets	(1,711)	4,246
Right of use assets, operating leases and operating lease liabilities	(135)	—
Other assets	(741)	(9)
Accounts payable	927	(288)
Accrued expenses and other current liabilities	1,176	(1,972)
Net cash used in operating activities	(31,904)	(18,292)
Cash flow from investing activities:		
Purchase of investments	(89,562)	(113,781)
Proceeds from maturities of investments	111,727	111,209
Advancement of note receivable	—	(1,000)
Cash paid in acquisition of EryDel S.p.A. net of cash acquired	—	(2,116)
Proceeds from disposal of assets	—	90
Purchase of property and equipment	(257)	(160)
Net cash provided (used) by investing activities	21,908	(5,758)
Cash flows from financing activities:		
Payment of contingent consideration	(5,000)	—
Proceeds from issuance of common stock upon exercise of stock options	225	149
Payments of finance leases	—	(6)
Net cash (used in) provided by financing activities	(4,775)	143
Effect of exchange rate changes on cash	231	80
Net decrease in cash and cash equivalents	(14,540)	(23,827)
Cash and cash equivalents at beginning of period	20,752	44,579
Cash and cash equivalents at end of period	$ 6,212	$ 20,752
Supplemental disclosures of non-cash information:		
Net assets acquired of EryDel S.p.A. in exchange for common stock	$ —	63,732
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 216	—
Right-of-use asset and financing lease liability reduction as a result of lease modification	$ —	(70)

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

QUINCE THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Organization

Description of Business

Quince Therapeutics, Inc. is a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases.

The Company's proprietary AIDE technology platform is an innovative drug/device combination platform that uses an automated process to encapsulate a drug into a patient's own red blood cells. Our Phase 3 lead asset, eDSP, leverages the AIDE technology to encapsulate DSP into a patient's own red blood cells, and is targeted to treat a rare pediatric neurodegenerative disease, A-T.

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, 2024, the Company had an accumulated deficit of $376.5 million. Since inception through December 31, 2024, 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 Company's initial public offering (the "IPO") and from the net proceeds of the private investment in public equity transaction ("PIPE Financing"). As of December 31, 2024, the Company had cash, cash equivalents, and short-term investments of $40.8 million.

The Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. The transition to profitability is dependent upon the successful development, approval and commercialization of our product candidate, and the achievement of a level of revenues adequate to support our cost structure. Based on our current operating plan, the Company believes that its cash and cash equivalents balance as of December 31, 2024 will not be sufficient to fund operations and capital expenditures for at least the twelve months following the issuance of these consolidated financial statements, and we will need to obtain additional funding. We intend to obtain additional funding through available financing sources which may include additional public offerings of common stock, private financing of debt or equity, and/or the pursuit of strategic partnerships, licensing arrangements or collaborations. Management's belief with respect to our ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional funding sooner than would otherwise be expected. There can be no assurance that we will be able to obtain additional funding on acceptable terms, if at all. If we are unable to obtain sufficient funding, we may be required to delay development efforts, limit activities and reduce research and development costs, which could adversely affect our business prospects. Because of the uncertainty in securing additional funding and the insufficient amount of cash and cash equivalent resources as of December 31, 2024, management concluded that substantial doubt exists with respect to our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

In connection with the acquisition of EryDel on October 20, 2023 (the "EryDel Acquisition"), the Company became a guarantor in respect of an unsecured line of credit between EryDel and the European Investment Bank (the "EIB Loan" or "Debt Agreement"). As of December 31, 2024, the principal of 10.0 million euros ($10.4 million) was outstanding on the EIB Loan. The Debt Agreement requires the Company to maintain a minimum cash balance of 14.65 million euros ($15.3 million) until the outstanding obligations under the Debt Agreement, together with accrued interest and all other amounts accrued or outstanding under the agreement, is repaid in full (the "Minimum Cash Covenant") Furthermore, the Company may at any time voluntarily prepay, in whole or in part, together with certain fees as set forth in the Debt Agreement, the outstanding obligations under the Debt Agreement. In the event of a default or a change in control, as specified in the Debt Agreement, EIB may, subject to certain grace periods, accelerate the outstanding obligations under the EIB Loan.

In November 2024, the Company entered into an amendment (the "Amendment") of the Debt Agreement with EIB which waives the Minimum Cash Covenant from January 1, 2025 and up to the earlier of December 31, 2025, or the date the Minimum Cash Covenant is restored. Under the terms of the Amendment, the Company agreed to amendments requiring monthly reporting of cash balances and additional limitations on certain permitted acquisitions. Additionally, during the waiver period, the Company agreed to convert 2% out of the total 9% deferred interest on Tranches A and B to be payable quarterly, with the first payment due on March 31, 2025, and a one-time fee of 20,000 euros in connection with the Amendment.

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 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 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.

Risks 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 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.

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 identifiable assets and liabilities in connection with business combinations including associated intangible assets and goodwill, contingent consideration, 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, including 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 subsidiaries are the Euro and Australian Dollar. The Company's 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 loss.

Segment Information

The Company manages its business activities on a consolidated basis and operates as one operating and reportable segment, which is the business of developing and commercializing the Company's proprietary AIDE technology platform. The key factors used to identify the reportable segments are the organization of our business and alignment of the Company's internal operations and the nature of our AIDE technology. Operating segments are defined as components of an enterprise for which discrete financial information is available and is evaluated regularly by the CODM, in deciding how to allocate resources and assess performance.

The Company’s Chief Executive Officer, who is the CODM, reviews financial information on a consolidated basis for purposes of allocating and evaluating financial performance. The CODM evaluates the Company’s performance and resource allocation by analyzing consolidated financial information. See Note 15 Segment Information for further details.

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 FASB 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 EryDel 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

Definite lived 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. The Company regularly reviews whether current conditions or events suggest that the carrying values of its acquired definite lived intangible assets might not be recoverable. When such conditions are identified, an estimate of the undiscounted future cash flows from these assets, or relevant asset groupings, is compared to their carrying value to determine if an impairment exists. If an impairment is identified, the loss is calculated as the difference between the

carrying value of the intangible asset and its fair value, which is based on the net present value of the estimated future cash flows.

Indefinite lived Intangible 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 indefinite lived 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.

During 2024, the Company recognized a non-cash goodwill impairment charge of $17.1 million.

Contingent Consideration

The Company determines the acquisition date fair value of contingent consideration using a probability-weighted discounted cash flow method, with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC Topic 820, Fair Value Measurement. The significant inputs in the Level 3 measurement not supported by market activity included our probability assessments of expected future cash flows related to the Company's acquisition of EryDel in October 2023, during the contingent consideration period, appropriately discounted considering the uncertainties associated with the earnout obligation, and calculated in accordance with the terms of the definitive agreement. The liabilities for the contingent consideration are established at the time of the acquisition and will be evaluated on a quarterly basis based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the earnings of that period. During the year ended December 31, 2024, the Company recorded a net $4.0 million adjustment to increase the fair value of its contingent consideration related to the acquisition of EryDel. The adjustment is reflected within operating loss on the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions

with respect to the likelihood of achieving the various contingent payment obligations. Significant increases or decreases in the inputs noted above in isolation would result in a significantly lower or higher fair value measurement.

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 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 consolidated 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 consolidated 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. However, cash balances in excess of Federal Deposit Insurance Corporation (FDIC) insured limit of $0.3 million are at risk.

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.

During the year ended December 31, 2024, the Company recognized no impairment charges. During the year ended December 31, 2023, the Company recognized an impairment charge of $0.1 million for the Purdue lease.

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 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 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 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. Stock options exercised are issued new shares of our common stock.

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, net 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 gain and loss from its available-for sale securities and cumulative translation adjustment during the years ended December 31, 2024 and 2023, respectively, 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, 2024 and 2023, 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.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued *ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, requiring public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in

ASC 280 on an interim and annual basis. The Company adopted ASU 2023-07 during the year ended December 31, 2024. See Note 15 Segment Information for further detail.

Recent Accounting Pronouncements Not Yet Adopted

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

ASU 2023-09, *Improvements to Income Tax Disclosures (ASC 740).* In December 2023, the FASB issued this ASU to establish new income tax disclosure requirements in addition to modifying and eliminating certain existing requirements. Under this ASU, entities must consistently categorize and provide greater disaggregation of information in the rate reconciliation. They must also further disaggregate income taxes paid. The ASU is effective beginning after December 2024 under a prospective approach. Early adoption is permitted. The Company is evaluating the disclosure requirements related to the new standard.

ASU 2024-03, *Disaggregation of Income Statement Expenses ("DISE")*. In November 2024, the FASB issued a new accounting standard to improve the disclosures about an entity's expenses and address requests from investors for more detailed information about the types of expenses included in commonly presented expense captions. The new standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with retrospective application permitted. The Company is evaluating the disclosure requirements related to the new standard.

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 that it 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, 2024 and 2023.

The Company elected the fair value option for the EIB Loan guaranteed by the Company in connection with the EryDel Acquisition. The Company adjusted the EIB Loan to fair value through the change in fair value of debt in the accompanying consolidated statements of operations and comprehensive loss. Subsequent unrealized gains and losses on items for which the fair value option is elected are reported in earnings. The Company will breakout any change in value due to credit loss in accumulated other comprehensive loss. For the years ended December 31, 2024 and 2023, there was no change in value due to credit loss.

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, 2024 and 2023 are presented in the following tables (in thousands):

	Fair Value Measurements as of December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 3,702	$ 3,702	$ —	$ —
Government and agency notes	34,572	—	34,572	—
Total Assets	$ 38,274	$ 3,702	$ 34,572	$ —
Liabilities:				
Contingent consideration	56,691	—	—	56,691
Long-term debt	14,321	—	—	14,321
Total	$ 71,012	$ —	$ —	$ 71,012

	Fair Value Measurements as of December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 4,285	$ 4,285	$ —	$ —
Certificates of Deposit	729	—	729	—
Government and agency notes	68,524	3,971	64,553	—
Total Assets	$ 73,538	$ 8,256	$ 65,282	$ —
Liabilities:				
Contingent consideration	57,706	—	—	57,706
Long-term debt	13,429	—	—	13,429
Total	$ 71,135	$ —	$ —	$ 71,135

The Company classifies certificates of deposit 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.

Level 3 Assets and Liabilities

Contingent Consideration

The following table reflects the changes in present value of acquisition related accrued earnouts of contingent consideration liability using significant unobservable inputs (Level 3) for the year ended December 31, 2024 and 2023:

	(in thousands)
Balance as of December 31, 2022	**$ —**
Acquisition date fair value of contingent consideration	56,128
Change in fair value of contingent consideration	1,578
Balance as of December 31, 2023	**$ 57,706**
Payout of contingent earnout based on milestone achievement	(5,000)
Change in fair value of contingent consideration	3,985
Balance as of December 31, 2024	**$ 56,691**

During the year ended December 31, 2024, the Company enrolled the first patient in the Phase 3 NEAT clinical trial. In accordance with the purchase agreement entered into in connection with EryDel Acquisition, the Company notified the former EryDel shareholders of this achievement within 45 days of achieving this milestone and paid the cash milestone payment of $5 million to the former EryDel shareholders. The Company owes no further payments to EryDel shareholders for development-related milestones. The remaining potential contingent payments in connection with the EryDel Acquisition pertain to approval, on market and sales milestones.

To estimate the fair value of the contingent consideration, the Company used a probability-weighted discounted cash flow model with an expected present value valuation technique with significant unobservable fair value inputs and is therefore classified as a Level 3 measurement. The estimates of fair value are uncertain and changes in the estimated inputs may result in significant adjustments to the fair value. The unobservable inputs consisted of the expected timing of milestone completion dates, probability of achievement, and discount rate. The change in the fair value of the contingent consideration is primarily driven by the expected timing of achieving various milestones, and the passage of time related to the contingent consideration earnout.

The following table summarizes the assumptions used in the valuation of the contingent consideration as of December 31, 2024 and 2023 (in thousands except for percentages):

	December 31,	
	2024	2023
Expected timing of milestones completion dates	2026 - 2038	2024 - 2037
Discount rate	14.5%	15%
Probability of achievement	1% - 56.5%	0% - 100%

Long-term Debt

The following table presents the changes in the fair value of the Level 3 EIB Loan for the year ended December 31, 2024 and 2023:

	(in thousands)
Balance as of December 31, 2022	**$** —
Acquisition of EIB Loan	12,564
Change in fair value	338
Due to foreign currency translation	527
Balance as of December 31, 2023	**$ 13,429**
Change in fair value	1,709
Due to foreign currency translation	(817)
Balance as of December 31, 2024	**$ 14,321**

To estimate the fair value of the EIB Loan, the Company used an expected present value valuation technique with significant unobservable inputs resulting in classification as a Level 3 measurement. The estimate of fair value is uncertain and changes in the estimated inputs may result in significant adjustments to the fair value. The unobservable inputs consisted of discount rate which includes the credit quality of the Company and credit spreads for comparable debt.

The following table summarizes the assumptions including the unobservable inputs related to the Company's long-term debt as of December 31, 2024 and 2023(in thousands except for percentages):

	December 31,	
	2024	2023
Discount rate	13%	13%

Note 4. Cash, Cash Equivalents and Investments

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

	December 31,	
	2024	2023
Cash and cash equivalents:		
Cash	$ 2,510	$ 1,521
Money market funds	3,702	4,285
Government and agency notes	—	14,946
Total cash and cash equivalents	$ 6,212	$ 20,752
Short-term investments:		
Certificates of deposit	$ —	$ 729
Government and agency notes	34,572	53,578
Total short-term investments	$ 34,572	$ 54,307

The Company's investments are classified as available-for-sale securities. As of December 31, 2024, the weighted average remaining contractual maturities of available-for-sale securities was approximately 4 months. The unrealized gain (loss) activity related to the Company’s available-for-sale securities is included in the Company’s accumulated other comprehensive income. 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, 2024 and 2023, 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 no available-for-sale securities in loss positions as of December 31, 2024. No other-than-temporary impairments on these securities were recognized for the years ended December 31, 2024 and 2023.

The Company periodically assesses its investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses is determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. There have been no impairment and credit losses related to available-for-sale securities for the years ended December 31, 2024 and 2023.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security’s amortized cost basis is written down to fair value and recognized in interest and other income, net in the statement of operations and comprehensive loss. If neither criteria is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in interest and other income, net.

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income, net of tax as a separate component of stockholders’ equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in interest and other income, net in the statement of operations and comprehensive loss.

For purposes of identifying and measuring credit-related impairments, the Company’s policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded in other current assets on the balance sheets.

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

	Fair Value Measurements as of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 3,702	$ —	$ —	$ 3,702
Government and agency notes	34,503	69	—	34,572
Total cash equivalents and investments	$ 38,205	$ 69	$ —	$ 38,274
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 3,702
Short-term investments (maturities within one year)				34,572
Total cash equivalents and investments				$ 38,274

	Fair Value Measurements as of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 4,285	$ —	$ —	$ 4,285
Certificates of Deposit	735	—	(6)	729
Government and agency notes	68,528	13	(17)	68,524
Total cash equivalents and investments	$ 73,548	$ 13	$ (23)	$ 73,538
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 19,231
Short-term investments (maturities within one year)				54,307
Total				$ 73,538

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2024	2023
Prepaid research and development expenses	$ 1,300	$ 133
Short-term Italian research and development refundable tax credit	882	993
Prepaid insurance	629	809
Prepaid expenses	357	365
Other current assets	84	81
Total prepaid expenses and other current assets	$ 3,252	$ 2,381

The Company is eligible to obtain an R&D tax credit as companies in Italy that invest in eligible research and development activities, regardless of the legal form and economic sector in which they operate, can benefit from a R&D tax credit. Such tax credits can only be used to offset payments of certain taxes and contributions (e.g., social contributions, VAT payables, registration fees, income and withholding taxes and other tax-related items that companies usually pay monthly). The Company recognized reductions to R&D expense of $1.7 million for the year ended December 31, 2024, and $0.2 million reductions for the year ended December 31, 2023.

Novosteo Pty, Ltd, a wholly-owned subsidiary of Novosteo, LLC, is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian Tax Incentive. During the year ended December 31,

2024, the Company received $0 refundable tax credit. During the year ended December 31, 2023, the Company received a refundable tax credit of $0.5 million, which reduced prepaid expenses and other current assets by $0.5 million.

Other Assets

Other assets consisted of the following (in thousands):

	December 31,	
	2024	2023
Long-term Italian research and development refundable tax credit	$ 4,053	$ 4,993
Value-Added Tax receivable	5,453	3,463
Equity investments in Lighthouse Pharmaceuticals, Inc.	78	78
Assets held for sale	—	10
Total other assets	$ 9,584	$ 8,544

Property and Equipment, Net

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

	December 31,	
	2024	2023
Computer equipment	$ 55	$ 36
Computer Software	28	30
Lab equipment	635	486
Leasehold improvement	34	36
Office furniture	202	153
Less: accumulated amortization and depreciation	(639)	(507)
Property and equipment, net	$ 315	$ 234

Depreciation expense for property and equipment was $0.2 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Personnel expenses	$ 2,482	$ 2,340
Research and development expenses	1,029	564
Professional fees	460	211
Current portion of operating lease liabilities	96	64
Other	308	257
Total accrued expenses and other current liabilities	$ 4,375	$ 3,436

For the years ended December 31, 2024 and 2023, the severance accrual activity was as follows (in thousands):

	2024	2023
Beginning accrued severance	$ 341	$ —
Incurred during the period	38	770
Severance paid during the period	(379)	(429)
Ending accrued severance	$ —	$ 341

On January 30, 2023, in response to the reprioritization of the Company's pipeline following the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company's Board of Directors 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 Company recognized the severance of $0.3 million and related expenses of $0.1 million over the requisite employment obligation period. The reduction in force was completed in April 2023.

On August 4, 2023, the Company entered into a transition and separation agreement with Karen Smith, M.D., Ph.D., (the “Separation Agreement”) in connection with Dr. Smith’s transition and departure from the Company as the Company's Chief Medical Officer, effective as of September 1, 2023. Pursuant to the Separation Agreement, the Company is required to pay cash severance, equal to her annual salary, in the aggregate amount of $0.5 million, of which $0.3 million was paid during the year ended December 31, 2024. The severance is to be paid on regular payroll schedule through the third quarter of 2024. Additionally, pursuant to the Separation Agreement, the Company paid an additional cash bonus severance payment equal to 100% of Dr. Smith’s target annual bonus opportunity for 2023 on a prorated basis, an additional cash severance payment equal to 12 months of the monthly premiums for health care continuation benefits, and provided for 50% accelerated vesting with respect to Dr. Smith’s equity award. The acceleration of 612,141 options and 54,757 RSAs resulted in a stock-based compensation expense of approximately $0.1 million that was recorded in 2023.

Note 6. Leases

In October 2023, as part of the EryDel Acquisition the Company acquired operating leases in which the Company recorded an operating lease right of use asset and liability in total of $0.4 million. This includes a lease agreement renting office space in Bresso, in the Province of Milan, Italy. The Lease Agreement commenced on September 1, 2016 and will end on August 31, 2028. At acquisition date, the Company recorded an operating lease right of use asset and liability of $0.1 million. This also includes a lease agreement renting office space in Medolla, in the Province of Modena, Italy. The Lease Agreement commenced on June 18, 2018, with a duration of 12 years, until January 31, 2030. At acquisition date, the Company recorded an operating lease right of use asset and liability of $0.2 million. The acquired lease agreements also included other operating leases two of which are car leases and the other a printing press.

In January 2024, the above-mentioned Lease Agreement for the office space in Medolla was renegotiated. The new Lease Agreement includes an additional space and commenced on February 1, 2024, and will end on January 31, 2030, substituting the Lease Agreement commenced in June 2018. The Company recorded an additional $0.2 million of operating lease right of use asset and liability during the year ended December 31, 2024.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. During the year ended December 31, 2024 and 2023, the Company recorded lease expense of $0.1 million and $0.4 million, respectively.

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

	December 31,	
	2024	2023
Assets:		
Operating lease right of use asset, net	$ 498	$ 385
Liabilities:		
Short-term operating lease liability	96	64
Long-term operating lease liability	394	321
Total lease liabilities	$ 490	$ 385
Other information:		
Weighted average remaining lease term	4.6 years	5.4 years
Weighted average discount rate	9.11%	7.95%

Future minimum lease payments under lease agreements as of December 31, 2024, were as follows (in thousands):

Fiscal Year	
2025	$ 135
2026	132
2027	126
2028 and thereafter	203
Total lease payments	596
Less: imputed interest	(106)
Total remaining lease liability	$ 490

In February 2023, as a result of the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company entered into a sublease agreement as the lessor for the majority of the West Lafayette facility. The lease commenced on March 17, 2023 and ended on December 31, 2023. The Company recorded an impairment loss of approximately $66,000 which is included in other expense, net per the consolidated statement of operations and comprehensive loss for the year ended December 31, 2023.

Note 7. Long-term Debt

In connection with the acquisition of EryDel on October 20, 2023, the Company became a guarantor in respect of the EIB Loan. The EIB Loan was amended and restated as of the acquisition date. The EIB Loan provides for maximum borrowings of 30.0 million euro through four tranches; tranche A, 3.0 million euro; tranche B, 7.0 million euro; tranche C, 10.0 million euro; and tranche D, 10.0 million euro. Each tranche is subject to conditions precedent related to the Company's business and capitalization. As of December 31, 2024, only tranches A and B have been drawn. All amounts due under tranche A and B are payable on their maturity date of August 2026. Tranche C and D are payable in equal installments of principal together with all amounts outstanding under the tranches on the repayment date. The first repayment date of tranche C shall fall not earlier than twelve months from the disbursement date of such tranche. The last repayment date of tranche C and tranche D shall fall not later than 5 years from the disbursement date of tranche C and tranche D, respectively. The EIB Loan bears interest at fixed rates for each tranche and is payable on the maturity date for each Tranche (with the exception of 2% cash interest which shall accrue and be payable quarterly during fiscal year 2025 pursuant to the terms of the Amendment, which shall correspondingly reduce the deferred interest rate accruing during such period). The fixed rates range from 7.0% to 9.0% per annum. As of December 31, 2024, principal of 10.0 million euros ($10.4 million) was outstanding on the EIB Loan and it is recorded as Long-term debt on the consolidated balance sheet at fair value with imputed interest of 9.0% included.

The Debt Agreement requires the Company to maintain a minimum cash balance of 14.65 million euros ($15.3 million) until the outstanding obligations under the Debt Agreement, together with accrued interest and all other amounts accrued or outstanding under the agreement, is repaid in full (the "Minimum Cash Covenant") . Furthermore, the Company may at any

time voluntarily prepay, in whole or in part, together with certain fees as set forth in the Debt Agreement, the outstanding obligations under the . In the event of a default or a change in control, as specified in the Debt Agreement, EIB may, subject to certain grace periods, accelerate the outstanding obligations under the EIB Loan.

In November 2024, the Company entered into an amendment (the "Amendment") of the Debt Agreement with EIB which waives the Minimum Cash Covenant from January 1, 2025 and up to the earlier of December 31, 2025, or the date the Minimum Cash Covenant is restored. Under the terms of the Amendment, the Company agreed to amendments requiring monthly reporting of cash balances and additional limitations on certain permitted acquisitions. Additionally, during the waiver period, the Company agreed to convert 2% out of the total 9% deferred interest on Tranches A and B to be payable quarterly, with the first payment due on March 31, 2025, and a one-time fee of 20,000 euros in connection with the Amendment.

The Debt Agreement includes a provision for additional remuneration to be paid in addition to interest. The amount of additional remuneration to be paid is equal to 2.5% of revenue up to 125.0 million euros, plus 1.85% of revenue between 125.0 and 250.0 million euros, plus 1.0% of revenue in excess of 250.0 million euros, multiplied by a varying percentage based on how many tranches have been drawn. The varying percentage is equal to 30.0% in the event tranche A has been drawn, 50.0% in the event tranche A and B have been drawn, 80.0% in the event tranche A, B and C have been drawn, and 100.0% in the event all four tranches have been drawn. The additional remuneration is payable for seven years, during the period January 1, 2026, through December 31, 2032. In the event of an occurrence of an event of default or prepayment, the Company may be required to pay an additional remuneration buyout fee.

The Company elected to account for the EIB Loan at fair value, which requires the EIB Loan to be recorded at fair value at issuance and at the end of each reporting period. Gains or losses upon remeasurement are to be recorded in other expense, net in the consolidated statements of operations and comprehensive income. The Company presents separately in other comprehensive income the portion of the total change in the fair value of the EIB Loan that results from a change in instrument-specific credit risk. The EIB Loan's fair value at the date it was assumed adjusted its carrying value based on using a discounted cash flow analysis with a discount rate based on a yield curve that was adjusted for credit rating. The change in fair value as of December 31, 2024 was determined using a discounted cash flow analysis discounted at the market yield. The significant inputs used to measure the market yield as of December 31, 2024 relative to the date the EIB Loan was assumed was the change in credit quality of the Company, the change in credit spreads for comparable debt instruments, and the change in the risk-free rate. As of December 31, 2024, the fair value of the EIB Loan is $14.3 million, which includes a fair value adjustment of $1.7 million and foreign currency translation of $0.8 million during the year ended December 31, 2024.

Future minimum principal payments, as of December 31, 2024 are as follows (in thousands):

Year Ended December 31, 2024	Amount
2025	$ —
2026	10,413
2027 and thereafter	—
Total future payments	10,413
Imputed interest and fair value adjustments	3,908
Total Debt as of December 31, 2024	$ 14,321

Note 8. 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, 2024 and 2023.

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 9. Common Stock

Equity Transactions

On December 18, 2024, the Company entered into a Controlled Equity Offering[SM] Sales Agreement, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, or the Agents, relating to the sale of shares of our common stock, par value $0.001 per share. In accordance with the terms of this agreement, the Company may offer and sell up to $75.0 million of shares of common stock. During the year ended December 31, 2024, the Company sold zero shares of common stock.

Common Stock

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

	December 31,	
	2024	2023
Options issued and outstanding under the Quince 2019 Stock Plan	7,408,005	4,267,178
Shares available for issuance under Quince 2019 Stock Plan	2,428,575	4,005,784
Shares available for issuance under the Employee Stock Purchase Plan	1,924,262	1,494,530
Options issued and outstanding under the Novosteo 2019 Plan	163,839	310,431
Shares available for issuance under Novosteo 2019 Plan	246,797	246,797
Options issued and outstanding under the 2022 Inducement Plan	2,333,306	2,333,306
Shares available for issuance under 2022 Inducement Plan	1,666,694	1,666,694
Total	16,171,478	14,324,720

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, 2024 and 2023, the Company had 44,001,643 and 42,973,215 shares of common stock issued and outstanding, respectively.

Note 10. Stock-Based Compensation

The Company operates three stock plans as of December 31, 2024:

- 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. As of December 31, 2024, the maximum aggregate number of shares that may be issued under the 2019 Plan is 11,755,418 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 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 Board may determine.

The Quince 2019 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 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.

As of December 31, 2024, the Company had 2,428,575 shares available for future issuance under the Quince 2019 Plan.

Stock Options

Stock options under the 2019 Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant. If, at the time of grant, the optionee directly owns stocks representing more than 10% of the voting power of all our outstanding capital stock, the exercise price for these options must be at least 110% of the fair value of the underlying common stock. Stock options granted to employees and non-employees generally have a maximum term of ten years and vest over four years from the vesting commencement date, of which 25% vest on the one-year anniversary of the vesting commencement date, and 75% vest in equal monthly installments over the remaining three years or monthly vesting over 3 to 4 years. We may grant options with different vesting terms from time to time. Unless an employee's or non-employee's termination is due to cause, disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the termination date or expiration of the option, whichever is earlier.

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, 2022	**3,319,711**	$ 16.07	4.77	$ 65
Options granted	3,346,958	1.03	—	—
Options exercised	(258,705)	0.42	—	240
Options cancelled / forfeited	(2,140,786)	16.52	—	—
Balance as of December 31, 2023	**4,267,178**	$ 5.00	8.85	$ 197
Options granted	3,674,500	1.25	—	—
Options exercised	(155,311)	0.93	—	65
Options cancelled / forfeited	(378,362)	6.28	—	—
Balance as of December 31, 2024	**7,408,005**	$ 3.16	8.37	$ 4,285
Options vested and expected to vest as of December 31, 2024	7,408,005	3.16	8.37	4,285
Options exercisable as of December 31, 2024	2,716,401	$ 6.34	7.52	$ 1,162

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 $0.1 million and $0.2 million for the years ended December 31, 2024 and 2023, respectively. The weighted-average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $1.04 and $0.82 per share, respectively. The total estimated grant date fair value of options vested during each of the years ended December 31, 2024 and 2023 was $12.4 million and $11.1 million, respectively.

For the years ended December 31, 2024 and 2023, the Company recognized stock-based compensation expense of $2.9 million and $2.6 million, respectively, 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 consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2024, total unamortized employee stock-based compensation was $4.8 million, which is expected to be recognized over the remaining estimated vesting period of 2.59 years.

Restricted Stock Units ("RSUs")

RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. The fair value of RSUs is based upon the closing sales price of the Company's common stock on the grant date. RSUs granted to employees generally vest over a 2 – 4 year period.

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, 2023	**1,488**	**$ 4.30**
RSUs granted	—	—
RSUs vested	(1,488)	4.30
RSUs cancelled	—	—
Unvested - December 31, 2024	**—**	**$ —**

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.

For the years ended December 31, 2024 and 2023, the Company recognized stock-based compensation expense of $4.4 thousand and $37.0 thousand respectively, related to these RSUs. As of December 31, 2024, total unamortized stock-based compensation related to RSUs was $0.

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 on the exchange ratio of 0.0911. Each such converted stock option continues 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.

Stock options under the 2019 Novosteo Plan may be granted for periods of up to 10 years and at prices no less than 100% of the fair market value of the shares on the date of grant. If, at the time of grant, the optionee directly owns stocks representing more than 10% of the voting power of all our outstanding capital stock, the exercise price for these options must be at least 110% of the fair value of the underlying common stock. Stock options granted to employees and non-employees generally have a maximum term of ten years and vest over four years from the vesting commencement date, of which 25% vest on the one-year anniversary of the vesting commencement date, and 75% vest in equal monthly installments over the remaining three years or monthly vesting over 3 to 4 years. We may grant options with different vesting terms from time to time. Unless an employee's or non-employee's termination is due to cause, disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the termination date or expiration of the option, whichever is earlier.

As of December 31, 2024, the Company had 246,797 shares available for future issuance under the 2019 Novosteo Plan.

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, 2022	**503,105**	$ 0.55	9.23	$ 44
Options granted	—	—	—	—
Options exercised	(105,808)	0.55	—	40
Options cancelled / forfeited	(86,866)	0.55	—	—
Balance as of December 31, 2023	**310,431**	$ 0.55	8.22	$ 155
Options granted	—	—	—	—
Options exercised	(146,592)	0.55	—	94
Options cancelled / forfeited	—	—	—	—
Balance as of December 31, 2024	**163,839**	$ 0.55	7.23	$ 216
Options vested and expected to vest as of December 31, 2024	163,839	0.55	7.23	216
Options exercisable as of December 31, 2024	66,827	$ 0.55	7.23	$ 88

For the years ended December 31, 2024 and 2023, the Company recognized stock-based compensation expense of $0.2 million and $0.3 million, 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, 2024, total unamortized employee stock-based compensation was $0.2 million, which is expected to be recognized over the remaining estimated vesting period of 1.22 years.

Restricted Stock Awards

	Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2023	**175,763**	**$ 3.30**
RSAs granted	—	—
RSAs vested	(97,346)	3.30
RSAs cancelled	—	—
Unvested - December 31, 2024	**78,417**	**$ 3.30**

For the years ended December 31, 2024 and 2023, the Company recognized stock-based compensation expense of $0.3 million and $0.5 million, respectively, related to restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the award holder. No income tax benefits have been recognized in the consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. The fair value of vested restricted stock awards was $0.3 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, total unamortized employee stock-based compensation was $0.2 million, which is expected to be recognized over the remaining estimated vesting period of 0.74 years.

2022 Inducement Plan

On May 9, 2022, the Company's Board of Directors approved 4,000,000 shares of common stock that may be offered or issued under the Quince Therapeutics, Inc. 2022 Inducement Plan (the "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 (“Nasdaq Rule 5635(c)(4)”). In accordance with Nasdaq Rule 5635(c)(4), awards under those plans may only be made to an employee who has not previously been an employee or member of the Board of Directors 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.

Options under the 2022 Inducement Plan may be granted for periods of up to 10 years at prices no less than 100% of the fair market value of the shares on the date of grant. Options granted to employees may have different performance goals or other vesting provisions (including continued employment) in accordance with the applicable award agreement. Unless an employee's termination service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of the three months from the date of termination or expiration of the option, whichever is earlier.

As of December 31, 2024, the Company had 1,666,694 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, 2022	**3,742,255**	$ 2.98	9.39	—
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(1,408,949)	2.98	—	—
Balance as of December 31, 2023	**2,333,306**	$ 2.98	8.39	—
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of December 31, 2024	**2,333,306**	$ 2.98	7.39	—
Options vested and expected to vest as of December 31, 2024	2,333,306	2.98	7.39	—
Options exercisable as of December 31, 2024	1,506,925	$ 2.98	7.39	—

For the years ended December 31, 2024 and 2023, the Company recognized stock-based compensation expense of $1.3 million and $1.8 million, respectively, related to options granted to 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 for stock-based compensation arrangements. As of December 31, 2024, total unamortized employee stock-based compensation was $1.8 million, which is expected to be recognized over the remaining estimated vesting period of 1.39 years.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the years ended December 31, 2024 and 2023 and the allocation within the consolidated statements of operations and comprehensive loss (in thousands):

	Years Ended December 31,	
	2024	2023
General and administrative expense	$ 3,876	$ 4,003
Research and development expense	870	1,217
Total stock-based compensation	$ 4,746	$ 5,220

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. The following weighted average assumptions were used to calculate the fair value of stock-based compensation for the years ended December 31, 2024 and 2023:

	2024	2023
Expected volatility	106.05%	106.36%
Expected dividend yield	—%	—%
Expected term (in years)	6.21	6.22
Risk-free interest rate	3.78%	4.01%

Expected Term — The Company uses 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 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.

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 1,924,262 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 11. Income taxes

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

	Years Ended December 31,	
	2024	2023
United States	$ (22,397)	$ (27,375)
International	(34,344)	(4,207)
Total	$ (56,741)	$ (31,582)

The components of the Company's benefit for income taxes were as follows:

(in thousands)	Years Ended December 31, 2024	2023
Current expense (benefit):		
Federal	$ 44	$ —
State	—	—
Foreign	88	61
Total current expense (benefit):	132	61
Deferred expense (benefit):		
Federal	—	(248)
State	—	—
Foreign	(45)	(10)
Total deferred expense (benefit):	(45)	(258)
Total income tax expense (benefit)	$ 87	$ (197)

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, 2024	2023
Federal statutory income tax rate	21.00 %	21.00 %
State income taxes	0.34	4.47
Income tax credits	0.18	1.07
Stock based compensation	(1.49)	(26.35)
Foreign rate differential	3.96	0.89
Change in fair value - deferred consideration	(2.30)	(1.05)
Impairment of Goodwill	(8.25)	—
Other	(0.27)	(1.09)
Change in valuation allowance	(13.32)	1.68
	(0.15) %	0.62 %

As of December 31, 2024 and 2023, the components of the Company's deferred tax assets are as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Deferred tax asset:		
Federal and State net operating loss carryforwards	$ 87,188	$ 81,881
Stock based compensation	2,529	2,401
Other accruals	581	527
Capitalized research and development expense	3,127	3,220
Tax credits	8,545	8,343
Disallowed interest expense carryforward	1,194	1,043
Gross deferred tax asset	103,164	97,415
Valuation allowance	(91,488)	(85,111)
Total deferred tax assets	11,676	12,304
Deferred tax liabilities:		
Capitalized leases	(120)	—
IPR&D	(16,519)	(17,608)
Gross deferred tax liabilities	(16,639)	(17,608)
Net deferred tax liabilities	$ (4,963)	$ (5,304)

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 $6.4 million and $15.4 million, respectively for the years ended December 31, 2024 and 2023.

As of December 31, 2024, the Company has federal net operating loss carryforwards of approximately $251.6 million of which $235.8 million will not expire and $15.8 million begin expiring in 2034. The Company also has state net operating loss carryforwards of approximately $34.8 million which begin to expire in 2034. Additionally, the Company has federal tax credits of approximately $10.1 million which begin to expire in 2036 and state tax credits of approximately $3.0 million which do not expire.

As of December 31, 2024, the Company has foreign net operating loss carryforwards, primarily in Italy, of approximately $131.0 million, which have no expiration date.

Pursuant to the Code Sections 382 and 383, annual use of a company's U.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 in prior years which determined that ownership changes occurred on December 22, 2015 and May 13, 2019, which had no impact on the NOLs available to offset future income. The Company had rolled forward the analysis through December 31, 2023 and no additional ownership changes had occurred.

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. 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, Australia, and Italy. Because of the net operating loss and research credit carryforwards, all of the Company's tax years, from 2013 to 2024, remain open to U.S. federal, California, and other state tax examinations. The Company's Australian subsidiaries remain open to examination from their inception to 2024. The Company's Italian subsidiary remain open to examination from their inception to 2024. The majority of our unrecognized tax benefits would not impact our effective tax rate due to a valuation allowance offsetting our deferred tax assets. The impact on our effective tax rate of recognizing unrecognized tax benefits is approximately $0.1 million. There were interest and penalties of $0.2 million and $0.1 million accrued as of December 31, 2024 and 2023, respectively. The Company does not expect that our uncertain tax positions will materially change in the next twelve months.

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

	Years Ended December 31,	
	2024	2023
Beginning balance	$ 4,339	$ 3,688
Additions for tax positions taken in a prior year	—	200
Additions for tax positions taken in a current year	91	451
Ending balance	$ 4,430	$ 4,339

Note 12. Net Loss Per Share

Basic and diluted net loss per common share is determined by dividing the net loss by the weighted-average common shares outstanding during the period, as follows (net loss in thousands):

	Years Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (56,828)	$ (31,385)
Denominator:		
Weighted average common shares outstanding	43,262,269	37,237,149
Net loss per share, basic and diluted	$ (1.31)	$ (0.84)

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

	December 31,	
	2024	2023
Stock options issued and outstanding	9,905,150	6,910,915
Restricted stock units	—	1,488
Restricted stock awards	78,417	175,764
Total	9,983,567	7,088,167

Note 13. Business Combination

EryDel Business Combination

On October 20, 2023, the Company completed its acquisition of EryDel, a privately held, late-stage biotechnology company with a lead Phase 3 lead asset, eDSP, that targets the potential treatment of a rare neurodegenerative disease, A-T. The acquisition will drive Quinces' next stage of growth, as EryDel's proprietary drug-device combination technology platform and promising late-stage clinical asset represents an opportunity for the Company to expand into several debilitating rare diseases where chronic corticosteroid treatment is – or has the potential to become – a standard of care if there were not corticosteroid-related safety concerns. The Company accounted for this acquisition in accordance with ASC 805, Business Combinations, which requires the assets acquired and the liabilities assumed to be measured at fair value at

the date of the acquisition. As part of the acquisition of EryDel, the Company recorded deferred tax liability of $5.1 million and uncertain tax position liability of $0.5 million.

The acquisition date fair value of the consideration transferred for EryDel was approximately $66.9 million, which consisted of the following (in thousands):

	Fair Value of Consideration
Cash	$ 2,615
Quince Therapeutics common stock (7,250,352 shares)	7,164
Contingent consideration	56,128
Settlement of preexisting notes receivable	1,000
Fair value of total consideration transferred	$ 66,907

The fair value of the Company's common stock was determined based on the closing market price of the Company's common stock of $0.989 per share on the acquisition date. The aggregate stock consideration consists of 6,525,315 shares of Company's common stock issued at closing and 725,037 shares of common stock (the "Indemnity Holdback Shares") were withheld by the Company until October 2024 for general representations and warranties. The Company has included the total fair value of the stock consideration within additional-paid-in capital and common stock.

In October 2024, upon the first anniversary of the closing of the EryDel Acquisition (the "Holdback Release Date"), and in accordance with the purchase agreement entered into in connection with EryDel Acquisition, the Indemnity Holdback Shares were released to the EryDel shareholders. As of the Holdback Release Date, no indemnification claims were made by the Company. No further stock consideration is available for issuance and no additional shares will be issued in connection with the EryDel Acquisition.

The contingent consideration arrangement requires the Company to pay $485.0 million of additional consideration in cash, comprised of up to $5.0 million upon the enrollment of the first patient in the Phase 3 NEAT clinical trial, which was paid in the third quarter of 2024, $25.0 million at NDA acceptance, up to $60.0 million upon the achievement of specified approval milestones, and up to $395.0 million upon the achievement of specified on market and sales milestones. The Company estimated the fair value of the contingent consideration using a probability-weighted discounted cash flow model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in ASC 820. The key assumptions in applying the income approach are as follows: 15% discount rate, probability of achievement, 0% to 100%, each of the milestones and future revenues from commercialization over the contingent consideration period. No contingent consideration is payable unless and until the milestones are achieved. The fair value of each milestone after the acquisition is reassessed, with the subsequent change in fair value recorded in the Company's consolidated statements of operations and comprehensive loss.

During the year ended December 31, 2024, the Company enrolled the first patient in the Phase 3 NEAT clinical trial and paid the cash milestone payment of $5 million to the former EryDel shareholders in accordance with the purchase agreement entered into in connection with EryDel Acquisition.

The following table summarizes the allocation of the consideration paid for EryDel to the estimated fair value of the assets acquired and liabilities assumed at the acquisition date, with the excess recorded to goodwill (in thousands):

	Purchase Price Allocation
Assets acquired:	
Cash	$ 560
Tax assets	10,187
Other current assets	644
Property and equipment, net	238
Operating lease right-of-use assets, net	383
Other non-current assets	14
Intangible assets	61,096
Goodwill	16,929
Total assets acquired	90,051
Liabilities assumed:	
Trade payables	(1,685)
Accrued expenses and other current liabilities	(2,943)
Debt, non-current	(12,564)
Other non-current liabilities	(854)
Deferred tax liability	(5,098)
Total liabilities assumed	(23,144)
Fair value of total consideration transferred	$ 66,907

The Company has finalized the purchase price allocation, reflecting estimates of the fair values of assets acquired and liabilities assumed as of the acquisition date.

The fair value of identifiable acquired IPR&D intangible assets was $60.6 million. IPR&D was determined using the Multi-Period Excess Earnings Method (the "MPEEM") under the income approach. MPEEM calculates the economic benefits by determining the income attributable to an intangible asset after the returns are subtracted for contributory assets such as working capital, assembled workforce, and fixed assets. The resulting after-tax net earnings were discounted at 16.6%, a rate commensurate with the risk inherent in the economic benefit projections of the assets. The probability-weighted, projected cash flows were calculated based on projections of revenues and expenses related to the asset and were assumed to extend through a multi-year projection period. The IPR&D has an indefinite useful life, and as such, is not amortized but rather tested for impairment at least annually.

The fair value of trade name intangible assets was $0.5 million. The trade name intangible assets were derived using the relief from royalties method under the income approach, utilizing royalty rate of 0.3%. This approach is used to estimate the cost savings that accrue for the owner of an intangible asset who would otherwise have to pay royalties or licensing fees on revenues earned through the use of the asset if they had not owned the rights to use the assets. The probability-weighted, net after-tax royalty savings are calculated for each year in the remaining economic life of the intangible asset and discounted to present value using a discount rate of 16.6%. The trademark has a useful life of 21 years. The trademark is amortized on a straight-line basis over the useful life.

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 global market opportunities. None of the goodwill is expected to be deductible for income tax purposes. Goodwill is not amortized but is tested for impairment at least annually. During the year ended December 31, 2024, the Company recorded a full goodwill impairment, resulting in non-cash charge of $17.1 million. Please refer to Note 14 for this assessment.

The transaction costs associated with the acquisition were approximately $2.5 million, of which $2.3 million were recorded in general and administrative expenses and $0.2 million were recorded in research and development expenses in the consolidated statement of operations and comprehensive loss for the year-ended December 31, 2023. No transaction expenses were incurred during the year ended December 31, 2024.

The Company has included the financial results of EryDel in the consolidated financial statements from the date of acquisition. From October 21, 2023 through December 31, 2023, the Company recognized no revenue and a net loss of $3.7 million attributable to EryDel.

The following unaudited pro forma information gives effect to the acquisition of EryDel as if it had been completed on January 1, 2022 (the beginning of the comparable prior reporting period), including pro forma adjustments primarily related to amortization of acquired intangible assets, tax benefit from release of the valuation allowance and the inclusion of acquisition-related expenses reflected in the revenue and net loss (in thousands):

	For the year ended December, 31
	2023
Revenue	$ —
Net Loss	(40,265)

The 2023 supplemental pro forma earnings were adjusted to exclude $2.5 million of acquisition-related costs incurred in 2023.

Following the finalization of the purchase price allocation, the Company does not anticipate incurring any additional acquisition-related expenses or changes to the fair values of the assets acquired and liabilities assumed as of the acquisition date.

Note 14. Intangible Assets

EryDel Intangible Assets

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

	(in thousands)
In-process research and development:	
Balance as of December 31, 2022	**$ —**
Acquisition date fair value of in-process research and development	60,636
Foreign currency translation adjustments	2,561
Balance as of December 31, 2023	**$ 63,197**
Foreign currency translation adjustments	(3,578)
Balance as of December 31, 2024	**$ 59,619**

The following table provides details of the carrying amount of the Company's finite-lived intangible asset (in thousands, except useful life):

		As of December 31, 2024			As of December 31, 2023		
	Useful life	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite life intangible assets:							
Trade name	21 years	$ 460	$ (26)	$ 434	$ 460	$ (4)	$ 456
Foreign currency translation adjustments				(8)			19
Total				$ 426			$ 475

The Company performs annual impairment reviews of its intangible assets during the fourth fiscal quarter or more frequently if appropriate. As of December 31, 2024, the Company did not incur any impairment losses related to its EryDel intangible assets. The remaining amortization period for the trade name is 19.8 years as of December 31, 2024.

Novosteo Intangible Assets

In January 2023, the Company decided to abandon internal development of NOV004 and pursue out-licensing opportunities. As a result, several of the assumptions used in determining the initial fair value have changed including discount rate and expected cash flows and thus triggered the need for an interim impairment assessment as required under ASC 350. And so, the Company performed a fair value assessment of the Intellectual Property as of March 31, 2023, and based upon this assessment, the fair value was determined to be significantly below its carrying value and resulted in an asset impairment charge of $5.9 million during the year ended December 31, 2023.

Goodwill

As part of the EryDel Acquisition, the Company recorded goodwill, the excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired.

The Company evaluates goodwill at least annually, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. As of June 30, 2024, the Company 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 the 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 June 30, 2024. 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 $17.1 million being recorded during the year ended December 31, 2024.

The following table summarizes the changes in the carrying amount of goodwill (in thousands):

Balance as of December 31, 2022	**$**	**—**
Goodwill addition related to the acquisition of EryDel		16,929
Foreign currency translation adjustments		696
Balance as of December 31, 2023	**$**	**17,625**
Impairment charge		(17,130)
Foreign currency translation adjustments		(495)
Balance as of December 31, 2024	**$**	**—**

Note 15. Segment Information

The Company manages its business activities on a consolidated basis and operates as one operating and reportable segment, which is the business of developing and commercializing the Company's proprietary AIDE technology platform. The key factors used to identify the reportable segments are the organization of our business and alignment of the Company's internal operations and the nature of our AIDE technology. Operating segments are defined as components of an enterprise for which discrete financial information is available and is evaluated regularly by the CODM, in deciding how to allocate resources and assess performance.

The Company’s Chief Executive Officer, who is the CODM, reviews financial information on a consolidated basis for purposes of allocating and evaluating financial performance. The CODM evaluates the Company’s performance and resource allocation by analyzing consolidated net loss, as reported on the consolidated statement of operations. This assessment involves comparing net loss across prior periods, the Company's forecast, and total expenditures related to eDSP product development and the ongoing Phase 3 NEAT clinical trial.

The measure of segment assets reviewed by the CODM is the consolidated total assets, as reported on the consolidated balance sheet. The following table presents the measure of segment assets regularly provided to the CODM (in thousands):

	December 31,	
	2024	2023
Cash, cash equivalents and short-term investments	40,784	75,059

The following table presents financial information, including significant segment expenses, which are regularly provided to the CODM and included within consolidated net loss (in thousands):

	Years Ended December 31,	
	2024	2023
Research and development:		
Personnel	$ 3,724	$ 3,402
Stock-based compensation	870	1,217
Clinical and contract manufacturing	16,006	4,278
Other	(2,010)	550
General and administrative:		
Personnel	5,218	3,968
Stock-based compensation	3,876	4,003
Consulting and professional costs	5,115	7,100
Other	3,371	2,624
Goodwill impairment charge	17,130	—
Intangible asset impairment charge	—	5,900
Fair value adjustment for contingent consideration	3,985	1,578
Total operating expenses	57,285	34,620
Loss from operations	(57,285)	(34,620)
Other segment items	457	3,235
Net loss	$ (56,828)	$ (31,385)

Other segment items within net loss include fair value adjustment for long-term debt, interest income, other expense, net, and income tax (expense) benefit.

The Company's long-lived assets consist primarily of property, plant and equipment, net, and operating lease right-of-use assets are maintained in Italy. As of December 31, 2024 and 2023, no individual country other than the U.S. accounted for 10% or more of these assets.

Note 16. Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its US employees. This plan provides for pre-tax and post-tax contributions for all US 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 amount of contributions that the Company made to the 401(k) Plan during the years ended December 31, 2024 and 2023 was $0.1 million and $0.1 million, respectively.

The Company has defined benefit plans, regulated by the Italian laws in which the Company's non-US employees participate. The benefits due to employees under the defined benefit plans are calculated based on the employee compensation and the duration of the employment relationship and are paid to the employee upon termination of the employment relationship or retirement. The costs of the defined benefit plans reported in the Company's consolidated statements of operations and comprehensive loss is determined by an actuarial calculation performed on an annual basis. The actuarial valuation is performed using the "Projected Unit Credit Method" based on the employees' expected date of separation or retirement.

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, 2024. 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, 2024 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

During the three months ended December 31, 2024, our management integrated internal controls for the acquired EryDel business into our existing controls. Other than the controls enhanced or implemented to integrate the EryDel business, 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), 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 2025 Proxy Statement under the captions "Proposal One: Election of Directors," "Insider Trading Policy" and "Delinquent Section 16(a) Reports," 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 2025 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 2025 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 2025 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 2025 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, P.C., Chicago, Illinois, PCAOB Auditor ID 243.

The information required in this item will be included in our 2025 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).

Exhibit Index

		Incorporated by reference				Filed or furnished herewith
Exhibit No.	Exhibit title	Form	File No.	Exhibit No.	Filing date	
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	
4.3	Description of Securities					X
10.1+	Employment Offer Letter, by and between Cortexyme, Inc. and Brendan Hannah, dated May 9,2022	10-Q	001-38890	10.2	8/9/2022	
10.2+	Employment Offer Letter, by and between Cortexyme, Inc. and Dirk Thye, dated May 9,2022	10-Q	001-38890	10.4	8/9/2022	
10.3+	Offer Letter between Quince Therapeutics, Inc. and Charles Ryan, dated as of August 1, 2023	10-Q	001-38890	10.3	11/14/2023	
10.4+	Form of Indemnification Agreement between Cortexyme, Inc. and each of its officers and directors	S-1/A	333-230853	10.2	4/29/2019	
10.5+	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	
10.6+	2019 Equity Incentive Plan and forms of stock award agreements thereunder	10-K	001-38890	10.6	4/1/2024	
10.7+	2019 Employee Stock Purchase Plan	S-1/A	333-230853	10.5	4/29/2019	
10.8+	Cortexyme, Inc. 2022 Inducement Plan	S-8	333-265109	99.1	5/20/2022	
10.9+	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	
10.10+	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	

10.11+	Novosteo Inc. 2019 Equity Incentive Plan	S-8	333-265109	99.4	5/20/2022	
10.12+	Executive Change in Control and Severance Agreement by and between Cortexyme, Inc. and Brendan Hannah, dated May 19, 2022	10-Q	001-38890	10.1	8/9/2022	
10.13+	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	
10.14+	Executive Change in Control and Severance Agreement between Quince Therapeutics, Inc. and Charles Ryan, dated as of September 1, 2023	10-Q	001-38890	10.4	11/14/2023	
10.15	Outside Director Compensation Policy adopted April 9,2019; Amended and Restated: December 2, 2024					X
10.16	Controlled Equity Offering℠ Sales Agreement, by and among the Company, Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, dated as of December 18, 2024	S-3	333-283897	1.2	12/18/2024	
10.17**	Accession, Amendment and Restatement Agreement to the Finance Contract relating to the Finance Contract dated 24 July 2020, as amended from time to time, by and between the Company, EryDel Italy, Inc., EryDel US, Inc., EryDel USA, Inc. EryDel S.p.A, and the European Investment Bank, dated as of October 20, 2023	10-K	001-38890	10.26	4/1/2024	
10.18**	Autonomous First Demand Guarantee (*Garanzia Autonoma a Prima Richiesta*) by and between the Company, EryDel Italy, Inc., EryDel US, Inc., EryDel S.p.A, and the European Investment Bank, dated as of October 20, 2023	10-K	001-38890	10.27	4/1/2024	
19.1	Insider Trading Policy					X
21.1	List of subsidiaries					X
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
97.1	Incentive Compensation Recoupment Policy	10-K	001-38890	97.1	4/1/2024	
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.

Item 16. Form 10-K Summary

None.

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 24, 2025

By: /s/ Dirk Thye

Dirk Thye

Chief Executive Officer and Chief Medical Officer

POWER OF ATTORNEY AND SIGNATURES

Each person whose signature appears below constitutes and appoints Dirk Thye and Brendan Hannah, 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, Chief Medical Officer and Director (Principal Executive Officer)	March 24, 2025
/s/ Brendan Hannah **Brendan Hannah**	Chief Business Officer, Chief Operating Officer and Chief Compliance Officer (Principal Financial Officer and Principal Accounting Officer)	March 24, 2025
/s/ David A. Lamond **David A. Lamond**	Director	March 24, 2025
/s/ Margaret McLoughlin **Margaret McLoughlin, Ph.D.**	Director	March 24, 2025
/s/ Una Ryan **Una Ryan, OBE Ph.D.**	Director	March 24, 2025
/s/ Christopher J. Senner **Christopher J. Senner**	Director	March 24, 2025
/s/ Luca Benatti **Luca Benatti**	Director	March 24, 2025
/s/ Rajiv Patni **Rajiv Patni**	Director	March 24, 2025
/s/ June Bray **June Bray**	Director	March 24, 2025

Exhibit 4.3

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Quince Therapeutics, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended ("1934 Act"): our common stock. The following summary description of our capital stock is based upon our amended and restated certificate of incorporation and our amended and restated bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated certificate of incorporation, our amended and restated bylaws and the applicable provisions of the Delaware General Corporation Law ("DGCL") for more information.

General

Under our amended and restated certificate of incorporation, we have authority to issue 100,000,000 shares of our common stock, par value $0.001 per share, and we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 10,000,000 shares of preferred stock, par value $0.001 per share, in one or more series.

Description of Common Stock

Voting Rights

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and our amended and restated bylaws contain certain provisions that could have the effect of delaying, deterring or preventing another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate more favorable terms with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

Undesignated Preferred Stock

Pursuant to our amended and restated certificate of incorporation, our board of directors has the authority to designate the rights, preferences, privileges and restrictions of each such series, including dividend rights, preferences, privileges and restrictions of each such series, including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences, sinking fund terms and the number of shares constituting any series.

The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of the company without further action by the stockholders.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting

Our amended and restated certificate of incorporation provides that our stockholders may not act by written consent, which may lengthen the amount of time required to take stockholder actions. As a result, a holder controlling a majority of our capital stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws. In addition, our amended and restated bylaws provides that special meetings of the stockholders may be called only by the chairperson of the board, the Chief Executive Officer, the lead independent director, or at the request of a majority of our board of directors. Stockholders may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Board Classification

Our board of directors is divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board.

No Cumulative Voting

Our amended and restated certificate of incorporation and amended and restated bylaws do not permit cumulative voting in the election of directors. Cumulative voting allows a stockholder to vote a portion or all of its

shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

Amendment of Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws Provisions

The amendment of the above provisions of our amended and restated certificate of incorporation will require approval by holders of at least two thirds of our outstanding capital stock entitled to vote generally in the election of directors. The amendment of our amended and restated bylaws will require approval by the holders of at least two thirds of our outstanding capital stock entitled to vote generally in the election of directors.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Choice of Forum

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 will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us 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. 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, employees or agents 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.

Exhibit 10.15

QUINCE THERAPEUTICS, INC.
OUTSIDE DIRECTOR COMPENSATION POLICY ADOPTED: APRIL 9, 2019; ORIGINALLY EFFECTIVE: MAY 8, 2019 (the "*Effective Date*")
AMENDED AND RESTATED: DECEMBER 2, 2024

Each member of the Board of Directors (the "***Board***") of **Quince Therapeutics, Inc.** (the "***Company***") who is not an employee of the Company (each such member, an "***Outside Director***") will receive the compensation described in this Outside Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service following the Effective Date.

The Director Compensation Policy may be amended at any time in the sole discretion of the Board.

Annual Cash Compensation

Each Outside Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts (the "***Annual Cash Compensation***") will be payable in arrears, in equal quarterly installments following the end of each fiscal quarter of the Company in which the service occurred. Any amount payable for a partial quarter of service will be pro-rated by multiplying such amount by a fraction, the numerator of which will be the number of days of service that the Outside Director provided in such quarter and the denominator of which will be the number of days in such quarter inclusive. All annual cash fees are vested upon payment. For purposes of clarity, the first quarterly installment of the annual retainers set forth below shall be paid for the first quarter that ends on or after the Effective Date, with the amount of such payment equal to the full quarterly installment, pro-rated as applicable based on the days of service that the Outside Director provided in such quarter regardless of whether such service was before or after the Effective Date.

1. Annual Board Member Service Retainer:
   a. All Outside Directors: **$38,000**.
   b. Outside Director serving as Lead Independent Director: **$14,500** (in addition to above).
   c. Outside Director serving as Chairperson of the Board: **$14,500** (in addition to above).

2. Annual Committee Member Service Retainer:
   a. Member of the Audit Committee: **$7,500**.
   b. Member of the Compensation Committee: **$5,500**.
   c. Member of the Nominating and Corporate Governance Committee: **$4,000**.

3. Annual Committee Chair Service Retainer (in lieu of Annual Committee Member Service Retainer):
   a. Chairperson of the Audit Committee: **$15,000**.
   b. Chairperson of the Compensation Committee: **$11,000**.
   c. Chairperson of the Nominating and Corporate Governance Committee: **$8,000**.

Each Outside Director may elect to receive a stock option in lieu of all of the Annual Cash Compensation, subject to the election procedures and other terms and conditions set forth under subsection (a) of "Equity Compensation" below.

Equity Compensation

Equity awards will be granted under the Company's 2019 Equity Incentive Plan or any successor equity incentive plan adopted by the Board and the stockholders of the Company (the "***Plan***").

(a) Stock Options Granted In lieu of Annual Cash Compensation. Each Outside Director may elect to receive all of the Annual Cash Compensation, beginning with the Annual Cash Compensation to be received for services provided on and after January 1, 2025, in the form of a stock option (a "***Retainer Option***") to purchase shares of the Company's common stock ("***Common Stock***") in lieu of cash, subject to executing and timely delivering an election form provided by the Company (the "***Retainer Option Election***").

(i) *Election Timing.* An Outside Director must deliver a Retainer Option Election to the Company by no later than December 31 of the year preceding the calendar year to which the Retainer Option Election relates (e.g., an election to receive 2025 Annual Cash Compensation in the form of a Retainer Option must be delivered by no later than December 31, 2024); provided, that an Outside Director who is elected or appointed as an Outside Director on or after the beginning of a calendar year (a "***Newly Eligible Director***"), subject to the following sentence, must deliver a Retainer Option Election with respect to such calendar year within thirty (30) days following the commencement of such service (as applicable, the "***Election Deadline***"). Any Retainer Option Election delivered following the applicable Election Deadline, and any Retainer Option Election submitted by a Newly Eligible Director who was elected or appointed as an Outside Director during the final quarter of a calendar year, will become effective with respect to Annual Cash Compensation to be paid for future calendar years (e.g., an election delivered on January 1, 2025 would apply beginning with 2026 Annual Cash Compensation).

(ii) *Applicable Compensation.* A Retainer Option Election for a calendar year will apply to no less than 100% of the Annual Cash Compensation earned with respect to such calendar year; provided, that for Newly Eligible Directors, such election will apply only to the portion of the Annual Cash Compensation that would otherwise be payable for services provided starting in the first full quarter of such calendar year commencing after the date such election is made.

(iii) *"Evergreen" Election; Termination.* A Retainer Option Election cannot be altered with respect to a calendar year once the calendar year begins (or once submitted, for Newly Eligible Directors elected or appointed in the first three quarters of the calendar year) and once made, will be "evergreen" in nature and will apply to all subsequent calendar years, unless and until terminated. An Outside Director may terminate a Retainer Option Election by submitting notice to the Company's Chief Operating Officer (or such other individual as the Company designates), which termination shall be effective with respect to the Annual Cash Compensation earned beginning on the first day of the next following calendar year after such termination notice is submitted and will apply to all future Annual Cash Compensation that the Outside Director is

eligible to receive, unless and until the Outside Director makes a new Retainer Option Election in accordance with the procedures set forth above.

(iv) *Grant Timing.* Without any further action of the Board, (1) each Outside Director (other than a Newly Eligible Director) who has properly and timely delivered a Retainer Option Election to the Company as described above will automatically be granted a Retainer Option on the first business day of the calendar year to which the Retainer Option Election relates, and (2) each Newly Eligible Director who has properly and timely delivered a Retainer Option Election to the Company as described above will automatically be granted a Retainer Option on the first business day of the first full quarter of the calendar year to which the Retainer Option Election relates.

(v) *Grant Value and Conversion.* Each Retainer Option will have a grant date value, calculated based on the aggregate Black-Scholes Value, equal to the Annual Cash Compensation in lieu of which such Retainer Option is being granted, provided that the number of shares covered by such Retainer Option will be rounded down to the nearest whole share. For purposes of this Director Compensation Policy, "***Black-Scholes Value***" means the per share fair value of the Retainer Option determined as of the date of grant using the Black-Scholes or other option pricing model that the Company most recently applied when valuing grants of options with service-based vesting conditions for purposes of preparing its (audited or unaudited) consolidated financial statements that have been filed with the Securities and Exchange Commission and using as inputs into such model (1) the closing price of one share of the Company's Common Stock on the date of grant and (2) such other assumptions as determined by the Company's principal accounting officer on or before such date of grant.

(vi) *Vesting.* Each Retainer Option will vest and become exercisable in substantially equal installments on the last day of each calendar quarter over the number of quarters to which the Retainer Option Election applies, subject to the Outside Director's continued service as a member of the Board through each vesting date.

(b) Annual Grant for Continuing Outside Directors. Without any further action of the Board, at the close of business on the date of each annual meeting of the Company's stockholders (an "***Annual Meeting***") following the IPO, each continuing Outside Director shall be granted a stock option award under the Plan covering the total shares of the Company's Common Stock set forth below (each, a "***Continuing Director Annual Option***"):

(i) If the Outside Director's appointment to the Board was more than 6 months prior to the Annual Meeting, the stock option shall cover **27,000** shares of the Company's Common Stock.

(ii) If the Outside Director's appointment to the Board was between 3 and 6 months prior to the Annual Meeting, the stock option shall cover **13,500** shares of the Company's Common Stock.

(iii) If the Outside Director's appointment to the Board was less than 3 months prior to the Annual Meeting, the Outside Director shall not receive a stock option on the date of the Annual Meeting.

Each Continuing Director Annual Option shall vest 100% on the one-year anniversary of the grant date, subject to the applicable Outside Director's continued service as a member of the Board through each such vesting date.

(c) Initial Grant for New Outside Directors. Without any further action of the Board, each person who, after the Effective Date, is elected or appointed for the first time to be an Outside Director will automatically, upon the date of his or her initial election or appointment to be an Outside Director, be granted, a stock option award under the Plan covering **54,000** shares of the Company's Common Stock (a "***New Director Initial Option***"). That each New Director Initial Option shall vest in equal annual installments over the 3-year period following the grant date, subject to the applicable Outside Director's continued service as a member of the Board through each such vesting date.

(d) Change in Control Vesting Acceleration. Notwithstanding anything stated herein, for each Outside Director who remains in continuous service as a member of the Board until immediately prior to the closing of a "***Change in Control***" (as defined in the Plan), any unvested portion of any stock option award granted in consideration of such Outside Director's service as a member of the Board shall vest in full immediately prior to, and contingent upon, the consummation of the Change in Control.

(e) Remaining Terms. Each stock option granted under this Director Compensation Policy will be a nonstatutory stock option, will have an exercise price equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of an Outside Director's continued service as a member of the Board. The remaining terms and conditions of each stock option award granted under this Director Compensation Policy will be as set forth in the Plan and the Company's standard form of stock option award agreement, as amended from time to time by the Board or the Compensation Committee of the Board, as applicable.

Expenses

The Company will reimburse each Outside Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at, and participation in, Board and committee meetings; provided, that the Outside Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Exhibit 19.1

Quince Therapeutics, Inc.
Insider Trading Policy
(adopted July 25, 2023)

Introduction

During the course of your relationship with Quince Therapeutics, Inc. ("***Quince***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about Quince or other publicly traded companies that Quince has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in Quince's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Quince securities and in the securities of other applicable publicly traded companies, in each case by our employees, directors and consultants and the other persons or entities subject to this policy as described below.

Statement of Policy

It is the policy of Quince that an employee, director or consultant of Quince (or any other person or entity subject to this policy) who is aware of material nonpublic information relating to Quince **may not**, directly or indirectly:

1. engage in any transactions in Quince's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any Quince's securities;
3. disclose material nonpublic information to persons within Quince whose jobs do not require them to have that information, or outside of Quince to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Quince's policies regarding the protection or authorized external disclosure of information regarding Quince; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to Quince at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Quince's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Quince that no employee, director or consultant of Quince (or any other person or entity subject to this policy) may either (a) recommend to another person or entity that they buy, hold or sell Quince's securities **at any time** or (b) disclose material nonpublic information to persons within Quince

whose jobs do not require them to have that information, or outside of Quince to other persons (unless the disclosure is made in accordance with Quince's policies regarding the protection or authorized external disclosure of information regarding Quince).

In addition, it is the policy of Quince that no person subject to this policy who, in the course of his or her relationship with Quince, learns of any confidential information that is material to another publicly traded company, including but not limited to a partner or collaborator of Quince or an economically-linked company such as a competitor of Quince, may trade in that other company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted above or below.

Transactions Subject to this Policy

This policy applies to all transactions in securities issued by Quince, as well as derivative securities that are not issued by Quince, such as exchange-traded put or call options or swaps relating to Quince's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Quince's common stock in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

Persons Subject to this Policy

This policy applies to you and all other employees, directors and consultants of Quince and its subsidiaries. This policy also applies to members of your family who reside with you, any other persons with whom you share a household, any family members who do not live in your household but whose transactions in Quince's securities are directed by you or are subject to your influence or control and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

Material Nonpublic Information

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;

- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for Quince's securities;
- gain or loss of a significant licensor, licensee or supplier; and
- changes or new corporate partner relationships or collaborations.
- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- employee layoffs;
- a disruption in Quince's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, Quince may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

Quarterly Trading Blackouts

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and consultants will possess material nonpublic information at certain points during the year. To minimize even the appearance of insider trading among our employees, directors and consultants we have established "quarterly trading blackout periods" during which Quince employees, directors, consultants and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Quince securities. That means that, except as described in this policy, all Quince employees, directors, consultants and their Related Persons will be able to trade in Quince securities only during limited open trading window periods that generally will begin after two full trading days have elapsed since the public dissemination of Quince's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Quince securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the day that is fifteen (15) days before the end of each fiscal quarter and end after two full trading days have elapsed since the public dissemination of Quince's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer, Principal Financial Officer, or Compliance Officer, there exists undisclosed information that would make trades by Quince employees, directors and consultants inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Quince employee, director or consultant who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the Compliance Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Compliance Officer concludes that the person is not in fact aware of any material nonpublic information relating to Quince or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

Event-Specific Trading Blackouts

From time to time, an event may occur that is material to Quince and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Executive Officer, Principal Financial Officer, or Compliance Officer may not trade in Quince's securities. In that situation, Quince will notify the designated individuals that neither they nor their Related Persons may trade in the Quince's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

Exceptions to this Policy

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option Exercises***. This policy does not apply to the exercise of options granted under Quince's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to Quince to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of options or other equity awards granted under Quince's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3. ***ESPP***. This policy does not apply to the purchase of stock by employees under Quince's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.

4. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by Quince, employees, directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Quince securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of Quince securities pursuant to that Trading Plan are not subject to this policy. To be properly established, a Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of Quince at a time when Quince was not in a trading blackout period and they were not otherwise aware of any material nonpublic information relating to Quince. Moreover, all Trading Plans must be reviewed and approved by Quince before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.

Special and Prohibited Transactions

1. ***Inherently Speculative Transactions.*** No Quince employee, director or consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to Quince's stock

2. ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Quince employee, director or consultant to continue to own Quince's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Quince employee, director or consultant may no longer have the same objectives as Quince's other stockholders. Therefore, Quince employees, directors and consultants are prohibited from engaging in any such transactions.

3. ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Quince employee, director or consultant is in possession of material nonpublic information. Quince therefore discourages placing standing or limit orders on Quince's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

Pre-Clearance and Advance Notice of Transactions

In addition to the requirements above, officers, directors and other applicable members of management face a further restriction. Even during an open trading window, they may not engage in any transaction in Quince's securities without first obtaining pre-clearance of the transaction from Quince's Compliance Officer or his or her designee at least two business days in advance of the proposed transaction. The Compliance Officer or his or her designee will then determine whether the transaction may proceed and, if so, will (or direct his or her designee to) help such officer, director or other applicable member of management to comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. Quince may choose to shorten this period.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Compliance Officer. Once any transaction takes place, the officer, director or applicable member of management must immediately notify the Compliance Officer or his or her designee, so that Quince may assist in any Section 16 reporting obligations.

Short-Swing Trading, Control Stock and Section 16 Reports

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), and any notices of sale required by Rule 144.

Policy's Duration

This policy continues to apply to your transactions in Quince's securities and the securities of other applicable public companies as more specifically set forth in this policy, even after your relationship with Quince has ended. If you are aware of material nonpublic information when your relationship with Quince ends, you may not trade Quince's securities or the securities of other applicable publicly traded companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Quince during a trading blackout period, then you may not trade Quince's securities or the securities of other applicable companies until the trading blackout period has ended.

Individual Responsibility

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about Quince and to not engage in transactions in Quince's securities or the securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Quince or any employee or director of Quince pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Quince for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

Penalties

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Quince, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Quince's Compliance Officer. Please also see Frequently Asked Questions, which are attached as **Exhibit A**.

Amendments

Quince is committed to continuously reviewing and updating its policies and procedures. Quince therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the Quince's policies regarding insider trading may be obtained by contacting the Compliance Officer.

Exhibit A
Insider Trading Policy
Frequently Asked Questions

1. ***What is insider trading?***

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If, during the course of your relationship with Quince, you become aware of material nonpublic information about Quince and you trade in Quince's securities, you have broken the law and violated our insider trading policy. In addition, our insider trading policy provides that if in the course of your relationship with Quince, you learn of any confidential information that is material to another publicly traded company, including but not limited to a partner or collaborator of Quince or an economically-linked company such as a competitor of Quince, you may not trade in that other company's securities until the information becomes public or is no longer material to that other company. For example, if you learn of nonpublic information during the course of your relationship with Quince that could affect the stock price of a Quince competitor, you may not trade in that competitor's stock until the information becomes public or is no longer material.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, directors and others who don't even work at Quince. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. ***Does Quince have an insider trading policy?***

A: Yes, the insider trading policy is available to read in the Company's internal Human Resources folder, which is also available upon request to the Compliance Officer.

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Quince director, employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside Quince, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with Quince's policies regarding the protection or authorized external disclosure of information regarding Quince). This includes anonymous discussions on the internet about Quince or companies with which Quince does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell Quince's common stock or any derivative security related to Quince's common stock, since that could be a form of tipping.

9. ***What are the sanctions if I trade on material nonpublic information or tip off someone else?***

A: In addition to disciplinary action by Quince—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than Quince, for example a partner or competitor of Quince?***

A: Yes, you may be restricted from doing so due to your awareness of material nonpublic information. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. You should be particularly conscious of this restriction if, through your position at Quince, you sometimes obtain sensitive, material information about other companies and their business dealings with Quince. Please also refer to Question 1 above and our insider trading policy with respect to restrictions on trading in the securities of other public companies.

12. ***So if I do not trade Quince securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Quince stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my Quince securities?***

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **Even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period**. Our insider trading policy describes the quarterly trading blackout period, and additional event-driven trading blackout periods may be announced by email.

14. ***If I have an open order to buy or sell Quince securities on the date a blackout period commences, am I required to cancel the open order and avoid executing the trade?***

A: Unless it is in connection with a 10b5-1 trading plan (see Question 24 below), if you have any open orders when a blackout period commences, it is your responsibility to cancel these orders with your broker to avoid violating our insider trading policy and potentially insider trading laws.

15. ***Am I allowed to trade derivative securities of Quince's common stock?***

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

16. ***Why does Quince prohibit trading in derivative securities and short selling?***

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short-term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

17. ***Can I pledge my Quince shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

1. ***Can I hedge my ownership position in Quince?***

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own Quince's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as Quince's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

2. ***Can I exercise options granted to me under Quince's equity compensation plans during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the options for cash (or via net exercise transaction with the company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information

3. ***Am I subject to trading blackout periods if I am no longer an employee or consultant of Quince?***

A: It depends. If your employment with Quince ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with Quince ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave Quince, you should not trade in Quince securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

4. ***What if I purchased publicly traded options or other derivative securities before I became a Quince employee or consultant?***

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

5. ***May I own shares of a mutual fund that invests in Quince?***

A: Yes.

6. ***Are mutual fund shares holding Quince common stock subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding Quince common stock at any time.

7. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Yes, subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stockbroker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our Compliance Officer.

8. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with Quince. In addition, you may be subject to criminal and civil sanctions.

9. ***Who should I contact if I have questions about our insider trading policy or specific trades?***

A: You should contact our Compliance Officer.

Exhibit 21.1

List of Subsidiaries of Quince Therapeutics, Inc.

Quince Therapeutics, Inc. subsidiaries as of December 31, 2024, are listed below.

Subsidiary	Jurisdiction of Incorporation
Cortexyme Australia Pty Ltd	Australia
Novosteo, LLC	Delaware
Novosteo Pty Ltd	Australia
EryDel US, Inc.	Delaware
EryDel USA, Inc.	New Jersey
EryDel Italy, Inc.	Delaware
Quince Therapeutics, S.p.A	Italy

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-231307, 333-237199, 333-253743, 333-263186, 333-265109, 333-270577 and 333-278440) and Registration Statement on Form S-3 (No. 333-283897) of Quince Therapeutics, Inc. of our report dated March 24, 2025, relating to the consolidated financial statements which appears in this Annual Report on Form 10-K for the year ended December 31, 2024. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, P.C.

San Jose, California

March 24, 2025

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, 2024;

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 the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 24, 2025

/s/ Dirk Thye

Dirk Thye

Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Brendan Hannah, certify that:

1. I have reviewed this Annual Report on Form 10-K of Quince Therapeutics, Inc. for the fiscal year ended December 31, 2024;

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 the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: March 24, 2025

/s/ Brendan Hannah

Brendan Hannah

Chief Business Officer, Chief Operating Officer, and Chief Compliance 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, 2024 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-149b) 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 24, 2025

By: /s/ Dirk Thye

Dirk Thye
Chief Executive Officer and Chief Medical 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, 2024 as filed with the Securities and Exchange Commission on the date hereof to which this Certification is attached as Exhibit 32.2 (the "Report"), I certify, pursuant to Rule 13a-149b) 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 24, 2025

By: /s/ Brendan Hannah

Brendan Hannah

Chief Business Officer, Chief Operating Officer, and Chief Compliance 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.