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, 2025

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 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $64.0 million, based on the closing price of the registrant's common stock, as reported by the Nasdaq Global Select Market on June 30, 2025 of $1.65 per share.

As of April 9, 2026, the registrant had 163,007,943 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 2026 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, including our ability to pursue strategic alternatives, such as completing a reverse merger or selling assets;
- 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 debt service requirements;
- the accuracy of our estimates regarding expenses, liquidity 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;
- our ability to attract and retain key personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- potential claims relating to our intellectual property; and
- our ability to maintain compliance with Nasdaq listing requirement.

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.

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
CODM	Chief Operating Decision Maker
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 biotechnology company and, prior to the completion of our NEAT Phase 3 trial, described below, focused our development activities on 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, used our AIDE technology to encapsulate DSP into a patient's own red blood cells. In January 2026 we completed our pivotal Phase 3 NEAT clinical trial to evaluate the treatment of a rare pediatric neurodegenerative disease, A-T. In the NEAT study, the primary endpoint, which measured the change from baseline to last efficacy visit at month six using the Rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo, did not reach statistical significance. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T and we will be unable to continue development of eDSP in this or other therapeutic indications. We have no other current product candidates and do not have sufficient resources to pursue further research and development activities at this time. We are currently focused on preserving cash while we evaluate available strategic alternatives.

On February 9, 2026, we engaged LifeSci Capital as our exclusive financial advisor to assist in restructuring activities and an evaluation of strategic alternatives aimed at maximizing shareholder value. Based on our initial evaluation, we plan to focus our efforts with respect to strategic alternatives, including effecting a reverse merger. We do not currently have any agreements or commitments to effect any such transactions and may not be able to execute such transactions on terms favorable to us and our stockholders, or at all. While we may also sell assets relating to our previous product candidates and other intellectual property, we do not expect to receive any meaningful consideration from such sale, if any.

In order to fund our current efforts to pursue strategic alternatives, including a reverse merger, we intend to obtain additional funding through available financing sources, which may include additional public offerings of common stock, including sales of common stock, under a Controlled Equity Offering^{SM} Sales Agreement, dated December 18, 2024, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, or private financing of debt or equity. If we are successful in obtaining any such additional funding, we may use all or a portion of the net proceeds to repay outstanding indebtedness, as well as for general corporate purposes and to support our activities with respect to strategic alternatives, including effecting a reverse merger. There can be no guarantee that we will be able to obtain such additional funding on terms favorable to us or our stockholders, or at all.

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:

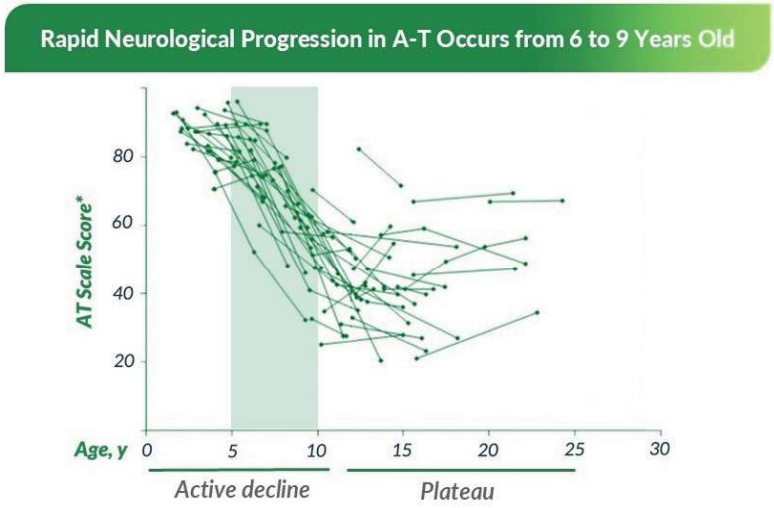
- Potential for improved biodistribution as encapsulated drug in autologous red blood cells is designed to enable the slow release of the drug from the red blood cells while circulating through various tissue beds.
- Potential for improved pharmacokinetics and pharmacodynamics, including increasing circulating 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.

Previous Candidate Development Activities

eDSP for the Potential Treatment of A-T

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.

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.

In the NEAT study, the primary endpoint, which measured the change from baseline to last efficacy visit at month six using the RmICARS compared to placebo, did not reach statistical significance. The mean change from baseline to month six was 0.94 in the active arm compared to 2.24 in the placebo arm (difference -1.30) with a p-value of 0.0851. Furthermore, the study did not meet its key secondary endpoint of improvement in Clinical Global Impression of Severity (CGI-S) measured from baseline to month six with a p-value of 0.522. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T.

eDSP was generally well tolerated and there were no clinically meaningful safety concerns identified. The most common adverse events reported in the eDSP arm included pruritis and pyrexia.

Phase 2 Candidate — eDSP for the Potential Treatment of DMD

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.

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.

Manufacturing

We currently have 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.

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

While we have discontinued all activities relating to developing product candidates, we remain subject to laws and rules in the United States and foreign jurisdictions relating to 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.

Strategic Alternatives

On February 9, 2026, we engaged LifeSci Capital as our exclusive financial advisor to assist in restructuring activities and an evaluation of strategic alternatives aimed at maximizing shareholder value. Based on our initial evaluation, we plan to focus our efforts with respect to strategic alternatives, including effecting a reverse merger. We do not currently have any agreements or commitments to effect any such transactions and may not be able to execute such transactions on terms favorable to us and our stockholders, or at all. While we may also sell assets relating to our previous product candidates, we do not expect to receive any meaningful consideration from such sale, if any.

In order to fund our current efforts to pursue strategic alternatives, including a reverse merger, we intend to obtain additional funding through available financing sources, which may include additional public offerings of common stock, including sales of common stock, under a Controlled Equity Offering^{SM} Sales Agreement, dated December 18, 2024, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, or private financing of debt or equity. If we are successful in obtaining any such additional funding, we may use all or a portion of the net proceeds to repay outstanding indebtedness, as well as for general corporate purposes and to support our activities with respect to strategic alternatives, including effecting a reverse merger. There can be no guarantee that we will be able to obtain such additional funding on terms favorable to the Company or our stockholders, or at all.

Employees

As of December 31, 2025, we had 38 total employees, of which 25 are in research and development and 13 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 and Financial Condition

Our lead drug candidate, eDSP, did not meet primary or secondary endpoints in the NEAT clinical trial and we do not have resources to pursue further operations. Therefore, we have limited operations and the only opportunity for a return on an investment in our common stock is based on our ability to execute a reverse merger transaction.

We recently completed our NEAT clinical trial for our lead drug candidate, eDSP, which did not meet primary or secondary endpoints. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T and we will be unable to continue development of eDSP in A-T or other therapeutic indications. We have no other current product candidates and do not have sufficient resources to pursue further research and development activities. Therefore, we have limited operations and the only opportunity for a return on an investment in our common stock is based on our ability to execute a reverse merger transaction.

While we have engaged a financial advisor to support our Board of Directors in exploring strategic transactions, there can be no assurance that we will be able to engage in a strategic alternative transaction, including a reverse merger, or even if we do so, that any such transaction will result in favorable terms and conditions for us or our shareholders. If we are unsuccessful in engaging in a reverse merger, we will need to liquidate our business and you will not realize any return on an investment in our common stock.

In the event of a reverse merger transaction, your ability to realize a return on an investment in our common stock will depend on, among other things, the terms of such reverse merger transaction and the future performance of the target company in such transaction. There can be no guarantee that you will realize any benefit even if we are able to execute a reverse merger transaction.

Nasdaq may delist our securities from its exchange, which could adversely affect our ability to execute a strategic transaction and limit our stockholders' liquidity.

Our common stock is currently listed on the Nasdaq Global Select Market, which has qualitative and quantitative listing criteria. However, we cannot assure you that our common stock will continue to be listed on Nasdaq in the future. In order to continue listing our common stock on Nasdaq, we must maintain certain financial, distribution and stock price levels. Generally, we must maintain a minimum amount in stockholders' equity, a minimum number of holders of our common stock, a $1.00 minimum bid price per share for our common stock, and certain governance requirements relating to the composition of the committees of our Board of Directors.

In March 2026, we received notices from Nasdaq indicating that we are no longer in compliance with Nasdaq's continued listing requirements relating to maintaining (i) a minimum bid price of our common stock equal to $1.00 per share pursuant to Nasdaq Listing Rule 5550(a)(2) and (ii) a minimum market value of listed securities equal to $50,000,000. While we have an initial period of 180 days, until September 14, 2026, to regain compliance with such

requirements, there is no guarantee that we will be able to regain compliance. In addition, as of December 31, 2025, our total stockholders' deficit was approximately $35.7 million.

If we are unable to comply with Nasdaq continued listing requirements, our common stock may be subject to delisting. If Nasdaq delists our common stock from trading on its exchange or if we decide to voluntarily delist from Nasdaq and/or deregister our common stock under the federal securities laws, we could face significant material adverse consequences, including but not limited to (i) a limited availability of market quotations for our common stock; (ii) reduced liquidity for our common stock; (iii) a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; (iv) a limited amount of news and analyst coverage, and in the event of deregistration of our common stock, less public disclosure about us; and (v) a decreased ability to issue additional securities or obtain additional financing in the future. In addition, if our common stock is delisted from Nasdaq our ability to execute a reverse merger transaction will be adversely affected.

If we are unable to execute a strategic transaction, may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including under Chapters 7 or 11 of the U.S. Bankruptcy Code.

Under the EIB Loan, the occurrence of a Material Adverse Change (as defined in the EIB Loan) gives the Bank (as defined in the EIB Loan) the right to declare amounts outstanding under the EIB Loan immediately due and payable. The Bank has not purported that a Material Adverse Change has occurred at this time. However, there can be no guarantee that the Bank will not invoke such provision in the future, or that we will not experience other Material Adverse Changes, or otherwise breach our financial or other covenants under the EIB Loan, that could give rise to an acceleration of our obligations under the EIB Loan.

If we are unable to execute a strategic transaction in a way that resolves our outstanding liabilities, we will be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including protection ("Bankruptcy Protection") under Chapters 7 or 11 of the U.S. Bankruptcy Code. Holders of our common stock will likely not receive any value or payments in a restructuring or similar scenario.

Under Chapter 7 of the United States Bankruptcy Code, a Chapter 7 trustee would be appointed or elected to liquidate our assets for distribution in accordance with the priorities established by the United States Bankruptcy Code. We believe that liquidation under Chapter 7 would result in significantly smaller distributions being made to our stakeholders than those we might obtain under Chapter 11 primarily because of the likelihood that the assets would have to be sold or otherwise disposed of in a distressed fashion over a short period of time rather than in a controlled manner and as a going concern.

We have no drug candidates approved for commercial sale, and we expect to continue to generate net losses as we work to evaluate strategic alternatives.

We have no drug candidates approved for sale, have never generated any revenue from sales and have never been profitable. Based on the results of our NEAT Phase 3 clinical trial, we have discontinued all development activities and do not expect to generate any revenue. While we may also sell assets relating to our previous product candidates, we do not expect to receive any meaningful consideration from such sales, if any. We have incurred net losses in each year since our inception. For the years ended December 31, 2025 and 2024, our net losses were $84.0 million and $56.8 million, respectively. We had an accumulated deficit of $460.5 million as of December 31, 2025.

We anticipate that we will continue to incur net losses as we evaluate strategic alternatives. 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.

There are numerous risks and uncertainties, and we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to execute a strategic transaction, such as a reverse merger.

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. If we are unable to raise this additional capital when needed or on acceptable terms, we may not be able to successfully execute a strategic transaction and our stockholders will not realize any value from an investment in our business.

Since our inception, we have used substantial amounts of cash to fund our operations. As of December 31, 2025, we had $17.8 million in cash, cash equivalents and short-term investments. Following December 31, 2025, and through the issuance of these financial statements, we raised net proceeds of approximately $20.4 million by issuing 105,285,000 shares of common stock under the ATM program, with approximately $47.5 million remaining available for issuance. 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, 2025 are issued.

We will need additional funding to support our operations as we seek to execute a strategic transaction, such as a reverse merger. 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. While we may also sell assets relating to our previous product candidates, we do not expect to receive any meaningful consideration from such sales, if any.

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 you may lose all or a part of your investment.

We may become a "shell company" in the future, which would significantly limit our flexibility to raise capital, reduce the liquidity of our securities, and adversely affect our stockholders.

We are in the process of evaluating strategic alternatives, including the disposition of operating assets, restructuring activities, or other transactions that could significantly reduce or eliminate our ongoing business operations. As a result of such actions, we could in the future be deemed a "shell company" under applicable rules of the SEC.

If we were to become a shell company, we would be subject to significant regulatory restrictions that could materially impair our ability to operate as a public company and pursue strategic transactions. In particular, our ability to raise capital would be significantly constrained, the resale of our securities would be more restricted, and we would also face limitations on our ability to use equity-based compensation, which could hinder our ability to attract and retain key personnel. Our status as a shell company could also negatively affect investor confidence, reduce analyst coverage, and increase volatility in our stock price.

Moreover, if we were to seek to combine with an operating business in the future, including through a reverse merger or similar transaction, we would be required to provide extensive disclosure comparable to that required in a Form 10 registration statement. This would increase the cost, complexity and time required to complete such a transaction and could discourage potential counterparties.

In addition, our potential transition to a shell company could heighten the risk that we fail to meet the continued listing requirements of The Nasdaq Stock Market, which could result in the delisting of our common stock. Any such delisting would likely have a material adverse effect on the liquidity and market value of our securities.

The determination of whether we are a shell company requires significant judgment and is based on the particular facts and circumstances at the time. Accordingly, there can be no assurance as to when or if we may be deemed a shell company. If we are deemed to be a shell company, the foregoing risks, individually or in the aggregate, could have a material adverse effect on our business, financial condition, results of operations, and the value of our securities.

We have and may be required to make milestone payments to the EryDel shareholders pursuant to the terms of the EryDel Acquisition or 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 may be exposed to a variety of international risks that could materially adversely affect our business.

We subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States. We are also subject to regulatory authorities 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 personnel due to the intense competition for qualified personnel and consultants among 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 will experience constraints that will significantly impede 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, 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, and have undertaken further reductions in force, resulting in the termination of most of our remaining management team, as we seek to conserve cash while we evaluate strategic alternatives. Further reductions 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 retain key personnel in the future and increase the risk that we may not be able to execute our strategic plans.

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.

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.

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

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

instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our 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.

We anticipate that additional impairment changes may be recorded in the first quarter of 2026 relating to the negative outcome of the NEAT study.

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 general R&D 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). In 2023 to 2025, the Company generated R&D tax credit under Article 31 of Decree-Law No. 73/2021, for Pharmaceutical/Vaccine R&D tax credit, which has tax credits equal to 20% of cost incurred in the fiscal year and annual ceiling of the credit of $23.4 million (20 million euros). Expenses incurred by the Company for years ended December 31, 2025, 2024, and 2023 generated a total tax credit amounting to $1.9 million (1.7 million euros), $1.7 million (1.6 million euros), and $0.9 million (0.8 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 Legal Compliance Matters

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 have relied 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 have relied 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 have also relied on third-party CMOs to manufacture and supply our preclinical, clinical and commercial materials.

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. Failure to comply with these requirements 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.

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.

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.

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.

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. We will also need to acquire tail insurance policies, including coverage relating to our directors and officers, which will require the payment of additional premiums, which may be significant.

Risks Relating to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our proprietary technology and assets, 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 the value of such assets may be adversely affected.

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. In addition, we may choose to allow some patents to lapse, as we seek to conserve cash while we evaluate available strategic alternatives.

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 and prospects.

We have applied for patents covering aspects of our drug candidates and device and their uses that we deem appropriate. However, such patent coverage 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 drug candidates or methods involving the use of these candidates in a particular 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.

It is 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. Any of these factors could adversely affect the value of our intellectual property in a potential strategic transaction or sale of such assets.

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.

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 and the value of our intellectual property.

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.

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.

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 intellectual property.

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 enforce our existing patents, which could adversely affect the value of our intellectual property.

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.

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.

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 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;
- 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;
- changes in laws or regulations applicable to our drug candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- 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. 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 of shares of our common stock from time to time pursuant to the Controlled Equity Offering^{SM} 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. During the year ended

December 31, 2025, we utilized our ATM program to raise net proceeds of $6.3 million by issuing 4,823,859 shares of common stock. 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.

Furthermore, we have warrants currently outstanding which may be immediately exercised to purchase shares of common stock. To the extent that these warrants are exercised, or to the extent we issue additional shares of common stock in the future, as the case may be, there will be further dilution to holders of shares of the common stock.

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.

Our outstanding warrants include put rights upon the occurrence of a fundamental transaction, which could make it difficult for us to complete a fundamental transaction that would otherwise be beneficial to our stockholders.

Our outstanding warrants include provisions that, in the event of certain fundamental transactions defined in the relevant agreements, provide the holders of such warrants with the right to require us, or the successor company in such transaction, to repurchase any unexercised portion of such warrants from the holder at their Black-Scholes value. In some circumstance this repurchase must be made in cash. Such Black-Scholes value may be significant and the requirement to pay such amount could prevent us from completing a transaction which would otherwise be accretive to shareholders or make such transaction more costly and reduce the value of such transaction to holders of our common stock.

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 are 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 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 8 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 2026. 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 April 9, 2026, there were 28 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 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, 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 rare pediatric neurodegenerative disease, 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.

Results of Phase 3 NEAT clinical trial of eDSP for A-T

In the NEAT study, our pivotal Phase 3 international, multicenter, randomized, double-blind, placebo-controlled study (n=105), the primary endpoint, which measured the change from baseline to last efficacy visit at month six using the Rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo, did not reach statistical significance. The mean change from baseline to month six was 0.94 in the active arm compared to 2.24 in the placebo arm (difference -1.30) with a p-value of 0.0851. Furthermore, the study did not meet its key secondary endpoint of improvement in Clinical Global Impression of Severity (CGI-S) measured from baseline to month six with a p-value of 0.522. eDSP was generally well tolerated and there were no clinically meaningful safety concerns identified. The most common adverse events reported in the eDSP arm included pruritis and pyrexia. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T and we will be unable to continue development of eDSP in this or other therapeutic indications. We have no other current product candidates and do not have sufficient resources to pursue further research and development activities at this time. We are currently focused on preserving cash while we evaluate available strategic alternatives.

Recent Development

Strategic Alternatives

On February 9, 2026, we engaged LifeSci Capital as our exclusive financial advisor to assist in restructuring activities and an evaluation of strategic alternatives aimed at maximizing shareholder value. Based on our initial evaluation, we plan to focus our efforts with respect to strategic alternatives, including effecting a reverse merger. We do not currently have any agreements or commitments to effect any such transactions and may not be able to execute such transactions on terms favorable to us and our stockholders, or at all. While we may also sell assets relating to our previous product candidates, we do not expect to receive any meaningful consideration from such sale, if any.

In order to fund our current efforts to pursue strategic alternatives, including a reverse merger, we intend to obtain additional funding through available financing sources, which may include additional public offerings of common stock, including sales of common stock, under a Controlled Equity Offering[SM] Sales Agreement, dated December 18, 2024, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, or private financing of debt or equity. If we are successful in obtaining any such additional funding, we may use all or a portion of the net proceeds to repay outstanding indebtedness, as well as for general corporate purposes and to support our activities with respect to strategic alternatives, including effecting a reverse merger. There can be no guarantee that we will be able to obtain such additional funding on terms favorable to the Company or our stockholders, or at all.

Financial Overview

We recently completed our NEAT clinical trial for our lead drug candidate, eDSP, which did not meet primary or secondary endpoints. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T and we will be unable to continue development of eDSP in this or other therapeutic indications. We have no other current product candidates and do not have sufficient resources to pursue further research and development activities. With cash, cash equivalents, and short-term investments of $17.8 million as of December 31, 2025 and net proceeds of approximately $20.4 million by issuing 105,285,000 shares of common stock under the ATM program that we raised after December 31, 2025, we expect to fund operations into the second quarter of 2026, or into the second half of 2026 if common warrants from the Company's financing in June 2025 are exercised in full for cash. However, there can be no guarantee as to when such warrants may be exercised, if at all.

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 would 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.

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 Debt

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

Fair Value Adjustment for Warrants

We record fair value adjustment for warrant liability calculated using the Black-Scholes option pricing model, adjustments are due to changes in the Company's stock price, the expected term, volatility, risk-free interest rate, and expected dividends.

Warrant Issuance Costs

Warrant issuance costs consist of expenses incurred in connection with the offering of our private placement warrants, which are classified as liabilities.

Interest Income

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

Other Income (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 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
- Impairment of Intangible Assets
- Contingent Consideration
- Debt
- Warrant Liability
- Income Taxes

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.

Impairment of Intangible Assets

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. We evaluate these assets for impairment by comparing their estimated fair value to their carrying value, and if the carrying value exceeds the estimated fair value, an impairment charge is recognized for the difference.

The determination of the fair value of IPR&D assets requires management to exercise judgment and make estimates and assumptions regarding the future development and commercialization of the underlying assets. These estimates involve inherent uncertainties and are based on factors such as the status and expected timing of development efforts and other considerations relevant to the associated research and development activities.

The significant inputs used in the impairment assessment are not observable in the market and therefore represent Level 3 fair value measurements as defined in ASC Topic 820, Fair Value Measurement. Changes in these assumptions could have a material impact on the estimated fair value of the assets and the amount of any impairment charge. Significant increases or decreases in these inputs in isolation would result in a significantly higher or lower fair value measurement and could result in the recognition of an impairment charge in future periods.

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, 2025, we recorded a net $7.6 million adjustment to increase the fair value of our 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.

Debt

We determined that we are eligible for the fair value option election in connection with the EIB Loan 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. Subsequent to initial recognition, the EIB Loan is remeasured at fair value at each reporting period using a discounted cash flow model, which includes significant inputs that are not observable in the market and therefore represents a Level 3 fair value measurement as defined in ASC Topic 820, Fair Value Measurement. The fair value is determined based on the present value of expected future cash flows, including principal, accrued interest, and end-of-term payments, discounted at 13% as of December 31, 2025. Changes in the fair value of the EIB Loan are recorded in the consolidated statement of operations within fair value adjustment for debt in the period in which the changes occur. During the year ended December 31, 2025, we recorded a net $2.0 million adjustment to increase the fair value of the EIB Loan. Significant increases or decreases in the discount rate or changes in the timing of expected cash flows in isolation would result in a significantly lower or higher fair value measurement.

Warrant Liability

Accounting for liability classified warrants requires management to exercise judgment and make estimates and assumptions regarding their fair value, 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.

We issued Pre-Funded Warrants and Common Warrants in connection with the June 2025 Private Placement. Due to certain provisions, including purchase rights that could result in holders receiving securities that more than offset or neutralize the effect of a distribution event, these warrants do not meet the indexation guidance under ASC 815 and are classified as liabilities. For more information about the material inputs and assumptions used to value the liability classified warrants, see Note 10 to the consolidated financial statements.

The warrant liabilities are initially recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting date, with changes recognized in the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2025, we recognized a $21.5 million loss related to the change in fair value of the warrant liabilities. Changes in the fair value of the warrant liabilities may result from changes in facts and circumstances, including those related to the terms of the warrants and other factors affecting their valuation.

Changes in the fair value of the liability classified warrants will continue to be recognized until the warrants are settled, and such changes may be material to our results of operations in the period in which they are recognized. The fair value of the

Pre-Funded Warrants and Common Warrants is determined at issuance and at each reporting date and requires the use of valuation techniques that incorporate significant inputs and assumptions. These estimates involve inherent uncertainties and the application of management judgment. Significant increases or decreases in the inputs and assumptions used in the valuation in isolation would result in a significantly higher or lower fair value measurement.

Income Taxes

We account 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 we determine it is more likely than not that some or all of the tax benefits will not be realized. In making this assessment, we consider the availability of loss carryforwards, projected reversals of deferred tax liabilities, projected future taxable income, and ongoing prudent and feasible tax planning strategies.

We use estimates in determining the amount of unrecognized tax benefits associated with uncertain tax positions. Significant judgment is required in evaluating tax law and measuring the benefits likely to be realized. Uncertain tax positions are periodically re-evaluated and adjusted as more information about their ultimate realization becomes available. In December 2025, we completed an intercompany transfer of certain intellectual property from our Italian subsidiary to the United States parent entity. The tax impact of the intellectual property transfer has been adjusted for associated unrecognized tax benefits, consistent with ASC 740, Income Taxes. The fair value of the intellectual property was determined using an Acquisition Price Method (‘APM’) based on unobservable inputs and includes judgments such as, but not limited to, discount rates, control premium and residual returns. Our estimate of fair value is based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		Change	
	2025	2024	$	%
Operating expenses:				
Research and development	$ 35,382	$ 18,590	$ 16,792	90%
General and administrative	15,047	17,580	(2,533)	(14)%
Goodwill impairment charge	—	17,130	(17,130)	(100)%
Fair value adjustment for contingent consideration	7,639	3,985	3,654	92%
Total operating expenses	58,068	57,285	783	1%
Loss from operations	(58,068)	(57,285)	(783)	1%
Fair value adjustment for debt	(2,043)	(1,709)	(334)	20%
Fair value adjustment for warrants	(21,470)	—	(21,470)	
Warrant issuance costs	(914)	—	(914)	
Interest income	1,244	2,929	(1,685)	(58)%
Other income (expense), net	486	(676)	1,162	(172)%
Net loss before income tax expense	(80,765)	(56,741)	(24,024)	42%
Income tax expense	(3,214)	(87)	(3,127)	3594%
Net loss	$ (83,979)	$ (56,828)	$ (27,151)	48%

Research and Development Expenses

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

	Year Ended December 31,		Change	
	2025	2024	$	%
Direct research and development expenses:				
eDSP	$ 27,641	$ 13,259	$ 14,382	108%
Other direct research costs	323	272	51	19%
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	6,991	4,593	2,398	52%
Facilities and other research and development expenses	427	466	(39)	(8)%
Total research and development expenses	$ 35,382	$ 18,590	$ 16,792	90%

Research and development expenses were $35.4 million for the year ended December 31, 2025, compared to $18.6 million for the year ended December 31, 2024, an increase of $16.8 million.

The costs for eDSP development increased by $14.4 million compared to the same period from the prior year due to the ramping up and continuation costs related to our Phase 3 NEAT clinical trial and OLE. This increase was primarily due to an increase in clinical trial costs of $13.3 million, an increase in eDSP consulting offset by a decrease in commercial spend of $1.7 million, an increase in other research and development costs of $0.2 million, and a decrease in manufacturing costs of $0.8 million.

Our personnel related costs increased by $2.4 million during the year ended December 31, 2025 as compared to the year ended December 31, 2024, mainly as a result of an increase of $0.9 million in allocated stock-based compensation costs and a $1.5 million increase in other personnel related expenses, including payroll taxes and benefits.

Facilities and other research and development expenses decreased by $39 thousand for the year ended December 31, 2025, as compared to the year ended December 31, 2024 primarily due to a decrease in rent, storage and facilities expenses.

General and Administrative Expenses

General and administrative expenses decreased by $2.5 million to $15.0 million for the year ended December 31, 2025, from $17.6 million for the year ended December 31, 2024. The decrease in general and administrative expenses is primarily due to decreases of $0.7 million in allocated stock-based compensation and personnel related expenses, $1.1 million in consulting and professional costs and $0.7 million decrease 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.

Fair Value Adjustment for Contingent Consideration

For the year ended December 31, 2025, we recorded a fair value adjustment for contingent consideration which resulted in a loss on the change in the fair value of the 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.

Fair Value Adjustment for Debt

For the year ended December 31, 2025, we recorded a fair value adjustment for debt which resulted in an increase in loss on the change in the fair value of the debt primarily due to the passage of time and the interest accrued and paid for the loan with the EIB.

Fair Value Adjustment for Warrants

For the year ended December 31, 2025, we recorded a fair value adjustment for warrants which resulted in a $21.5 million charge primarily due to the issuance of the warrants and change in the price of our common stock.

Interest Income

Interest income decreased by $1.7 million for the year ended December 31, 2025, as compared to the year ended December 31, 2024. The change was due to decreased yields on our investment portfolio and decreased average balances.

Other Income (Expense), net

Other income (expense), net increased by $1.2 million for the year ended December 31, 2025 primarily due to realized gains resulting from changes in foreign exchange rates.

Income Tax Expense

We recorded $3.2 million of tax expense for the year ended December 31, 2025 and $0.1 million for the year ended December 31, 2024. Tax expense is primarily driven by tax expense associated with the intercompany sale of intellectual property offset by the associated release of 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 our securities. From inception through December 31, 2025, we received net proceeds of approximately $322.1 million from the issuance of redeemable convertible preferred stock, convertible promissory notes, common warrants, pre-funded warrants, and common stock.

We have incurred net losses since the commencement of our operations. As of December 31, 2025, we had an accumulated deficit of $460.5 million. We incurred a net loss of $84.0 million in the year ended December 31, 2025. We do not expect to generate revenue unless and until we complete a reverse merger or other strategic transaction and the post-transaction company generates revenue, and we cannot assure you that a transaction will be completed or that the combined company 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. In January 2026, we ceased clinical development of eDSP as the primary and secondary endpoints did not achieve statistical significance in our Phase 3 NEAT clinical trial. As of

December 31, 2025, we had cash, cash equivalents and short-term investments of $17.8 million. Based on our current operating plan, we believe that our cash and cash equivalents balance as of the date of this filing 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, including sales of common stock, under a Controlled Equity Offering℠ Sales Agreement, dated December 18, 2024, with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, and/or private financing of debt or equity. 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. Because of the uncertainty in securing additional funding and the insufficient amount of cash and cash equivalent resources, 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, if any, 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 and government agency obligations.

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. While we have engaged a financial advisor to support our board of directors in exploring strategic transactions, there can be no assurance that we will be able to engage in a strategic alternative transaction, including a reverse merger, or even if we do so, that any such transaction will result in favorable terms and conditions for us or our stockholders. If we are unable to execute a strategic transaction, may be required to pursue a reorganization proceeding under applicable bankruptcy or insolvency laws, including under Chapters 7 or 11 of the U.S. Bankruptcy Code.

Financing

Equity Financing

ATM Program

On December 18, 2024, we 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, par value $0.001 per share. In accordance with the terms of this agreement, we may offer and sell up to $21.9 million of shares of common stock. In October 2025, we increased the total amount available under the ATM program to $75.0 million.

During the year ended December 31, 2025, we utilized our ATM program to raise net proceeds of approximately $6.3 million by issuing 4,823,859 shares of common stock. As of December 31, 2025, $68.5 million remained available to be sold under the ATM program.

June 2025 Private Placement

On June 12, 2025, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement"), with certain institutional investors (the "Investors") and certain members of our management (together with the Investors, the "Purchasers") pursuant to which we issued and sold to the Purchasers in a private placement (the "Private Placement"): (i) 6,671,928 shares (the "Shares") of our common stock, par value $0.001 per share, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 2,000,000 shares of common stock, and (iii) accompanying warrants

to purchase up to an aggregate of 8,671,928 shares of common stock (the "Common Warrants"), for aggregate gross proceeds of approximately $11.5 million (excluding up to approximately $10.4 million of aggregate gross proceeds that may be received in the future upon the cash exercise in full of the Common Warrants issued in the Private Placement), before deducting placement agent fees and other expenses payable by us. Each Share and each Pre-Funded Warrant sold pursuant to the Securities Purchase Agreement was accompanied by one Common Warrant. The combined purchase price of each Share and accompanying Common Warrant was $1.325 (which included $0.125 per Common Warrant in accordance with the rules and regulations of Nasdaq). The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrant was $1.324 (equal to the combined purchase price per Share and accompanying Common Warrant, minus $0.001).

Debt

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, 2025, 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 (as defined below), 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, 2025, principal of 10.0 million euros ($11.8 million) was outstanding on the EIB Loan and classified as current portion of 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 ($17.2 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 thousand euros in connection with the Amendment. In September 2025, we entered into a second amendment (the "Second Amendment"), providing that (i) for the period from

January 1, 2026 to March 31, 2026 (the "Second Amendment Period"), our required minimum cash balance will be reduced to 5.0 million euros and (ii) during the Second Amendment Period, out of the overall 9% deferred interest rate due in respect of Tranche A and Tranche B under the EIB Facility, 1% will be converted into Fixed Rate to be paid on March 31, 2026 in respect of Tranche A and Tranche B. As of December 31, 2025, we have been in compliance with all covenants under the Debt Agreement.

On March 27, 2026, we entered into a loan settlement agreement (the "Settlement Agreement") with the EIB in connection with the EIB loan. Pursuant to the Settlement Agreement, effective immediately upon our payment of 4.8 million euros ($5.5 million), our outstanding obligations to the EIB were settled in full and all of our obligations were satisfied and discharged.

Cash Flows

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

	Year Ended December 31,		
	2025	2024	Change
Net cash (used in) provided by:			
Operating activities	$ (41,425)	$ (31,904)	$ (9,521)
Investing activities	23,227	21,908	1,319
Financing activities	17,909	(4,775)	22,684
Effect of exchange rate changes on cash	(114)	231	(345)
Net increase (decrease) in cash and cash equivalents	$ (403)	$ (14,540)	$ 14,137

Operating Activities

Net cash used in operating activities increased by $9.5 million during the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to higher operating payments driven by increased clinical development activities. Net cash used in operating activities was $41.4 million for the year ended December 31, 2025. Cash used in operating activities was primarily due to our net loss of $84.0 million for the period, adjusted for $29.7 million of non-cash items, including $21.5 million change in the fair value of warrants, $5.1 million in stock-based compensation, $7.6 million change in the fair value of contingent consideration liabilities, $1.8 million change in the fair value of the EIB Loan, $5.0 million change in deferred tax liabilities, and a net increase in our operating assets of $7.3 million and a net increase in our accounts payable, and accrued expenses and other current liabilities of $5.6 million.

Investing Activities

Cash provided by investing activities was $23.2 million for the year ended December 31, 2025, primarily related to the proceeds from maturities of short-term investments of $58.0 million, and the purchase of investments of $34.4 million.

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.

Financing Activities

Cash provided by financing activities was $17.9 million for the year ended December 31, 2025, which consisted of gross proceeds of $11.4 million from the issuance of common stock, Common Warrants, and Pre-Funded Warrants in connection with June 2025 Private Placement, $6.3 million from the issuance of common stock in connection with the ATM offerings, and $0.2 million from the exercise of stock options in the period.

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.

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 $10.6 million in our consolidated balance sheet for expenditures incurred by these vendors as of December 31, 2025. We have approximately $16.7 million in cancellable future operating expense commitments based on existing contracts as of December 31, 2025. These obligations will be satisfied in the normal course of business, but generally no longer than 12 months. As of December 31, 2025, the fair value of the EIB Loan is $18.0 million and classified as current portion of debt on the consolidated balance sheet at fair value. In March 2026, we entered into a Settlement Agreement with the EIB to settle our outstanding obligations in full with a single payment of 4.8 million euros ($5.5 million). Following such payment, all of our obligations to the EIB were satisfied and discharged. As of December 31, 2025 the fair value of long-term contingent consideration on our books for the earnout related to the EryDel Acquisition is $52.0 million. However, in March 2026, it was determined that the criteria for the contingent consideration payouts will not be met, resulting in the related liability being reduced to zero. As of December 31, 2025, the fair value of warrants issued in connection with the private placement is $32.2 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.
Index to Consolidated Financial Statements

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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) 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, 2025 and 2024, 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 and 3 to the consolidated financial statements, the Company has a contingent consideration balance

of $64.3 million at December 31, 2025, and recorded a change in fair value of $7.6 million for the year ended December 31, 2025. At December 31, 2025, 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 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, regulatory approval milestones and commercialization 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 third-party sources.
- 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 the forecast.

/s/ BDO USA, P.C.

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

San Jose, California

April 10, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,809	$ 6,212
Short-term investments	11,943	34,572
Prepaid expenses and other current assets	5,144	3,252
Total current assets	22,896	44,036
Property and equipment, net	595	315
Operating lease right-of-use assets	453	498
Intangible assets	67,819	60,045
Other assets	1,760	9,584
Total assets	$ 93,523	$ 114,478
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 2,223	$ 2,903
Accrued expenses and other current liabilities	10,608	4,375
Current portion of debt	18,026	—
Short-term contingent consideration	12,369	—
Total current liabilities	43,226	7,278
Debt	—	14,321
Long-term operating lease liabilities	330	394
Long-term contingent consideration	51,961	56,691
Deferred tax liabilities	—	4,963
Warrant liabilities	32,150	—
Other long-term liabilities	1,570	685
Total liabilities	129,237	84,332
Commitments and contingencies (Note 8)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of December 31, 2025 and 2024, respectively.	—	—
Common stock, $0.001 par value, 250,000,000 shares authorized, 55,725,291 and 44,001,643 issued and outstanding as of December 31, 2025 and 2024, respectively.	55	44
Additional paid in capital	418,932	406,609
Accumulated other comprehensive income (loss)	5,750	(35)
Accumulated deficit	(460,451)	(376,472)
Total stockholders' (deficit) equity	(35,714)	30,146
Total liabilities and stockholders' equity (deficit)	$ 93,523	$ 114,478

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)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 35,382	$ 18,590
General and administrative	15,047	17,580
Goodwill impairment charge	—	17,130
Fair value adjustment for contingent consideration	7,639	3,985
Total operating expenses	58,068	57,285
Loss from operations	(58,068)	(57,285)
Fair value adjustment for debt	(2,043)	(1,709)
Fair value adjustment for warrants	(21,470)	—
Warrant issuance costs	(914)	—
Interest income	1,244	2,929
Other income (expense), net	486	(676)
Net loss before income tax expense	(80,765)	(56,741)
Income tax expense	(3,214)	(87)
Net loss	(83,979)	(56,828)
Other comprehensive loss:		
Foreign currency translation adjustments	5,849	(3,160)
Unrealized gain (loss) on available-for-sale securities	(64)	78
Total comprehensive loss	$ (78,194)	$ (59,910)
Net loss per share - basic and diluted	$ (1.68)	$ (1.31)
Weighted average shares of common stock outstanding - basic and diluted	50,096,897	43,262,269

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

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

	Common Stock		Additional Paid in	Accumulated Other Comprehensive Income /	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	(Loss)	Deficit	Equity
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
Issuance of common stock and warrants in private placement offering, net	6,671,928	6	740	—	—	746
Issuance of common stock in connection with the ATM offerings, net	4,823,859	5	6,258	—	—	6,263
Issuance of common stock on exercise of stock options	227,861	—	220	—	—	220
Stock based compensation	—	—	5,105	—	—	5,105
Foreign currency translation adjustment	—	—	—	5,849	—	5,849
Unrealized gain (loss) on available for sale investments	—	—	—	(64)	—	(64)
Net loss	—	—	—	—	(83,979)	(83,979)
Balance as of December 31, 2025	55,725,291	$ 55	$ 418,932	$ 5,750	$ (460,451)	$ (35,714)

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

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

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net Loss	$ (83,979)	$ (56,828)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	5,105	4,746
Depreciation and amortization	142	186
Change in the fair value of contingent consideration liabilities	7,639	3,985
Change in fair value of debt, net	1,809	1,709
Change in fair value of warrants	21,470	—
Non-cash goodwill impairment charge	—	17,130
Reclassification of cumulative translation adjustment to net income	(477)	—
Amortization of discount on available-for-sale investments	(1,014)	(2,348)
Change in deferred tax liabilities	(4,963)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,957	(1,711)
Right of use assets, operating leases and operating lease liabilities	104	(135)
Other assets	4,204	(741)
Accounts payable	(940)	927
Accrued expenses and other current liabilities	5,776	1,067
Other liabilities	742	109
Net cash used in operating activities	(41,425)	(31,904)
Cash flow from investing activities:		
Purchase of investments	(34,418)	(89,562)
Proceeds from maturities of investments	57,997	111,727
Purchase of property and equipment	(352)	(257)
Net cash provided by investing activities	23,227	21,908
Cash flows from financing activities:		
Payment of contingent consideration	—	(5,000)
Proceeds from issuance of common stock, common warrants, and pre-funded warrants pursuant to private placement offering, net of issuance costs	11,426	—
Proceeds from issuance of common stock upon public offering, net of issuance costs	6,263	—
Proceeds from issuance of common stock upon exercise of stock options	220	225
Net cash provided by (used in) financing activities	17,909	(4,775)
Effect of exchange rate changes on cash	(114)	231
Net decrease in cash and cash equivalents	(403)	(14,540)
Cash and cash equivalents at beginning of period	6,212	20,752
Cash and cash equivalents at end of period	$ 5,809	$ 6,212
Supplemental disclosures of cash flow and non-cash information:		
Interest payment on debt	$ 234	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 216

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. ("Quince" or the "Company") is a late-stage biotechnology company dedicated to unlocking the power of a patient's own biology for the treatment of rare diseases.

Quince's proprietary AIDE technology 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. In January 2026 the Company completed its pivotal Phase 3 NEAT clinical trial to evaluate the treatment of A-T. In the NEAT study, the primary endpoint, which measured the change from baseline to last efficacy visit at month six using the Rescored modified International Cooperative Ataxia Rating Scale (RmICARS) compared to placebo, did not reach statistical significance. Based on the results of the NEAT clinical trial, eDSP does not appear to be an effective treatment for A-T and the Company will be unable to continue development of eDSP in this or other therapeutic indications. As a result, the Company has engaged LifeSci Capital as its exclusive financial advisor to assist in restructuring activities and to evaluate strategic alternatives aimed at maximizing shareholder value.

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, 2025, the Company had an accumulated deficit of $460.5 million. Since inception through December 31, 2025, the Company has funded operations primarily with the net proceeds from the sale of our securities, 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, 2025, the Company had cash, cash equivalents, and short-term investments of $17.8 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. In January 2026, the Company ceased clinical development of eDSP as the primary and secondary endpoints did not achieve statistical significance in its Phase 3 NEAT clinical trial. Based on its current operating plan, the Company believes that its cash and cash equivalents balance 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 the Company will need to obtain additional funding. The Company has no other current product candidates and does not have sufficient resources to pursue further research and development activities at this time. The Company is currently focused on preserving cash while it evaluates available strategic alternatives. Because of the uncertainty in securing additional funding and the insufficient amount of cash and cash equivalent resources as of the issuance of these consolidated financial statements, management concluded that substantial doubt exists with respect to the Company's 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, 2025, the Company had 10.0 million euros ($11.8 million) outstanding on the EIB Loan, with an original requirement to maintain a minimum cash balance of 14.65 million euros ($17.2 million) until full repayment (the "Minimum Cash

Covenant"). The Company could voluntarily prepay, and in cases of default or change in control, EIB could accelerate the debt. In November 2024, the Company amended the Debt Agreement (the "Amendment"), waiving 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 cash balance reporting, restrictions on acquisitions, quarterly payments of 2% out of the total 9% deferred interest during the waiver period, and a one-time fee of 20 thousand euros ($22 thousand). In September 2025, the Company entered into a second amendment (the "Second Amendment"), providing that (i) for the period from January 1, 2026 to March 31, 2026 (the "Second Amendment Period"), the required minimum cash balance will be reduced to 5.0 million euros and (ii) during the Second Amendment Period, out of the overall 9% deferred interest rate due in respect of Tranche A and Tranche B under the EIB Facility, 1% will be converted into Fixed Rate to be paid on March 31, 2026 in respect of Tranche A and Tranche B. As of December 31, 2025, the Company is in compliance with its covenants under the Second Amendment. The amendments were accounted for as a modification with minimal impact due to fair value option election. See Note 17 for subsequent events regarding EIB loan.

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. Certain prior year amounts have been reclassified for consistency with the current period presentation with an immaterial impact on the consolidated financial statements.

Risks and Uncertainties

Based on the results of the NEAT clinical trial, the Company will be unable to continue development of eDSP. The Company has no other current product candidates and does not have sufficient resources to pursue further research and development activities.

While the Company engaged LifeSci Capital as its exclusive financial advisor to assist in restructuring activities and evaluate strategic alternatives aimed at maximizing shareholder value, the Company does not currently have any agreements or commitments to effect any such transactions and may not be able to execute such transactions on terms favorable to the Company or its stockholders, or at all.

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, the Company's ability to maintain sufficient funding while evaluating strategic alternatives or successfully effect a strategic transaction.

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, the fair value of contingent consideration, warrant liabilities and debt, 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, 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 income (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 its business and alignment of the Company's internal operations and the nature of its 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 for further details.

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. See Note 17 for discussion of subsequent events related to impairment of indefinite lived assets.

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, or a more 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.

See Note 17 for discussion of subsequent events related to impairment of indefinite lived assets.

Contingent Consideration

The Company determines the fair value of contingent consideration related to the Company's acquisition of EryFel in October 2023 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 include 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 liability for the contingent consideration were initially established at the time of the acquisition and are 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, 2025, the Company recorded adjustments of $7.6 million 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 statements 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. Collectively, cash equivalents and short-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 income (loss) in the consolidated statements of operations and included as a separate component of consolidated statements of stockholders' (deficit) equity. 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.

Warrants

The Company accounts for warrants as equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms. The assessment considers whether the warrants are freestanding financial instruments, meet the definition of a liability, and whether the warrants meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For warrants that meet all criteria for equity classification, the warrants are recorded as a component of additional paid-in capital in the consolidated balance sheets at the time of issuance. For warrants that do not meet all the criteria for equity classification, the warrants are recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized within the consolidated statements of operations. The fair value of the warrants is estimated using the Black-Scholes option pricing model (see Note 10).

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
Computer software	3 years
Lab equipment	5 years
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 $0.4 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 years ended December 31, 2025 and 2024, the Company recognized no impairment charges. See Note 17 for discussion of subsequent events related to impairment of long-lived assets.

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, restricted stock awards, and employee stock purchase plan awards. 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 income (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, 2025 and 2024, 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, common stock options, warrants, and restricted stock awards are considered to be potentially dilutive securities. For the years ended December 31, 2025 and 2024, the inclusion of potentially dilutive securities would be antidilutive, therefore diluted net loss per share is the same as basic net loss per share for both periods.

Recent Accounting Pronouncements Adopted

ASU 2023-09, *Improvements to Income Tax Disclosures (ASC 740)*. In December 2024, 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 and income taxes paid. They must also further disaggregate income taxes paid. The Company adopted this new standard for the year ended December 31, 2025. These amendments have been applied on a prospective basis in the financial statements. See Note 12 for the inclusion of new disclosures required.

Recent Accounting Pronouncements Not Yet Adopted

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

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.

ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements.* In December 2025, the FASB issued a new accounting standard to clarify the applicability of interim reporting guidance under GAAP, provide a comprehensive list of interim disclosure requirements within Topic 270, and introduce a disclosure principle requiring entities to provide information about events and changes occurring after the end of the most recent annual reporting period that have a material impact on the entity. The ASU does not change the fundamental nature of interim reporting or expand or reduce existing interim disclosure requirements. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027 for public business entities, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its interim financial reporting and related disclosures.

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 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, 2025 and 2024.

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 break out any change in value due to credit loss in accumulated other comprehensive loss. For the years ended December 31, 2025 and 2024, 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, 2025 and 2024 are presented in the following tables (in thousands):

	Fair Value Measurements as of December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds	$ 4,402	$ 4,402	$ —	$ —
Government and agency notes	11,943	—	11,943	—
Total Assets	$ 16,345	$ 4,402	$ 11,943	$ —
Liabilities:				
Short-term contingent consideration	$ 12,369	$ —	$ —	$ 12,369
Long-term contingent consideration	51,961	—	—	51,961
Debt	18,026	—	—	18,026
Common warrants	25,452	—	—	25,452
Pre-Funded warrants	6,698	—	—	6,698
Total Liabilities	$ 114,506	$ —	$ —	$ 114,506

	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
Debt	14,321	—	—	14,321
Total	$ 71,012	$ —	$ —	$ 71,012

The Company classifies 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 years ended December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Beginning balance	$ 56,691	$ 57,706
Change in fair value	7,639	3,985
Payout of contingent earnout based on milestone achievement	—	(5,000)
Ending balance	$ 64,330	$ 56,691

The contingent consideration arrangement requires the Company to pay up to $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 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 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. As of December 31, 2025, no approval, on market, or sales milestones were met. See Note 17 for discussion of subsequent events related to contingent consideration.

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 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.

The following table summarizes the assumptions used in the valuation of the contingent consideration (in thousands except for percentages):

	December 31, 2025	December 31, 2024
Expected timing of milestones completion dates	2026 - 2038	2026 - 2038
Discount rate	14.2%	14.5%
Probability of achievement	1% - 56.5%	1% - 56.5%

Debt

The following table presents the changes in the fair value of the Level 3 EIB Loan for the years ended December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Beginning balance	$ 14,321	$ 13,429
Change in fair value	2,043	1,709
Interest payment	(234)	—
Due to foreign currency translation	1,896	(817)
Ending balance	$ 18,026	$ 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 debt:

	December 31, 2025	December 31, 2024
Discount rate	13%	13%

Warrants

During the year ended December 31, 2025, the Company issued common and pre-funded warrants which are classified as liabilities based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 815. The Company estimates the fair value of the common and pre-funded warrants utilizing the Black-Scholes option pricing model, which is dependent upon several level 3 inputs that are not observable in active markets, such as expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires judgment to determine.

The following table summarizes key inputs used in the valuation of the liability classified warrants as of the issuance date and as of December 31, 2025:

	As of issuance date	As of December 31, 2025
Expected term	5.0 years	4.45 years
Common stock market price	$ 1.20	$ 3.35
Common warrants exercise price	$ 1.20	$ 1.20
Pre-Funded warrants exercise price	$ 0.001	$ 0.001
Risk-free interest rate	3.97%	3.63%
Expected volatility	108.35%	110.96%

The following table presents the changes in the fair value of the Level 3 liability classified warrants for the year ended December 31, 2025:

	(in thousands)
Balance as of December 31, 2024	$ —
Issuance of warrants	10,680
Change in fair value of warrants	21,470
Balance as of December 31, 2025	$ 32,150

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 the consolidated balance sheets (in thousands):

	December 31, 2025	December 31, 2024
Cash and cash equivalents:		
Cash	$ 1,407	$ 2,510
Money market funds	4,402	3,702
Total cash and cash equivalents	$ 5,809	$ 6,212
Short-term investments:		
Government and agency notes	$ 11,943	$ 34,572
Total short-term investments	$ 11,943	$ 34,572

The Company's investments are classified as available-for-sale securities. As of December 31, 2025, the weighted average remaining contractual maturities of available-for-sale securities was approximately 1 month. The unrealized gain (loss) activity related to the Company's available-for-sale securities is included in the Company's accumulated other comprehensive income (loss). There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale securities for the years ended December 31, 2025 and 2024, and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income (loss). 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, 2025. No other-than-temporary impairments on these securities were recognized for the years ended December 31, 2025 and 2024.

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 impairments or credit losses related to available-for-sale securities for the years ended December 31, 2025 and 2024.

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 consolidated 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 consolidated balance sheets.

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

	Fair Value Measurements as of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 4,402	$ —	$ —	$ 4,402
Government and agency notes	11,938	5	—	11,943
Total cash equivalents and investments	$ 16,340	$ 5	$ —	$ 16,345
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 4,402
Short-term investments (maturities within one year)				11,943
Total cash equivalents and investments				$ 16,345

	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

Note 5: Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31, 2025	December 31, 2024
Prepaid research and development expenses	$ 578	$ 1,300
Short-term Italian research and development refundable tax credit	—	882
Short-term VAT receivable	3,622	—
Prepaid insurance	635	629
Prepaid expenses	255	357
Other current assets	54	84
Total prepaid expenses and other current assets	$ 5,144	$ 3,252

The Company was 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 $2.0 million and $1.7 million for the years ended December 31, 2025 and 2024, respectively.

Other Assets

Other assets consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Long-term Italian research and development refundable tax credit	$ —	$ 4,053
Long-term VAT receivable	1,682	5,453
Equity investments in Lighthouse Pharmaceuticals, Inc.	78	78
Total other assets	$ 1,760	$ 9,584

Property and Equipment, Net

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

	December 31, 2025	December 31, 2024
Computer equipment	$ 66	$ 55
Computer software	32	28
Lab equipment	1,076	635
Leasehold improvement	38	34
Office furniture	227	202
Less: accumulated amortization and depreciation	(844)	(639)
Property and equipment, net	$ 595	$ 315

Depreciation and amortization expense for property and equipment was $0.1 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31, 2025	December 31, 2024
Personnel expenses	$ 3,138	$ 2,482
Research and development expenses	6,966	1,029
Professional fees	181	460
Current portion of operating lease liabilities	115	96
Other	208	308
Total accrued expenses and other current liabilities	$ 10,608	$ 4,375

Note 6. Leases

In January 2024, the Medolla Lease Agreement for the office space was renegotiated. The new Medolla Lease Agreement includes an additional space and commenced on February 1, 2024, and will end on January 31, 2030, substituting the Medolla Lease Agreement commenced in June 2018.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. During the year ended December 31, 2025 and 2024, the Company recorded lease expense of $0.2 million and $0.1 million, respectively.

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

	December 31, 2025	December 31, 2024
Assets:		
Operating lease right of use asset, net	$ 453	$ 498
Liabilities:		
Short-term operating lease liability	115	96
Long-term operating lease liability	330	394
Total lease liabilities	$ 445	$ 490
Other information:		
Weighted average remaining lease term	3.7 years	4.6 years
Weighted average discount rate	9.12%	9.11%

Future minimum lease payments under lease agreements as of December 31, 2025, were as follows (in thousands):

Fiscal Year	
2026	$ 149
2027	142
2028	128
2029 and thereafter	101
Total lease payments	520
Less: imputed interest	(75)
Total remaining lease liability	$ 445

Note 7. 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, 2025, 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, 2025, principal of 10.0 million euros ($11.8 million) was outstanding on the EIB Loan and is classified as current portion of debt on the consolidated balance sheet at fair value with imputed interest of 9.0% included.

The original Debt Agreement requires the Company to maintain the Minimum Cash Covenant of 14.65 million euros ($17.2 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. 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 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 payments made on March 31, 2025, June 30, 2025, September 30, 2025, and a one-time fee of 20 thousand euros ($22 thousand) in connection with the Amendment.

In September 2025, the Company entered into a second amendment (the "Second Amendment"), providing that (i) for the period from January 1, 2026 to March 31, 2026 (the "Second Amendment Period"), the required minimum cash balance will be reduced to 5.0 million euros and (ii) during the Second Amendment Period, out of the overall 9% deferred interest rate due in respect of Tranche A and Tranche B under the EIB Facility, 1% will be converted into Fixed Rate to be paid on March 31, 2026 in respect of Tranche A and Tranche B. As of December 31, 2025, the Company is in compliance with its covenants under the Second Amendment. The amendments were accounted for as a modification with minimal impact due to fair value option election. See note 17 for subsequent events related to EIB loan.

For the year ended December 31, 2025, the Company paid 0.2 million euros ($0.2 million) in interest payments.

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 income (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, 2025 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, 2025 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, 2025, the fair value of the EIB Loan is $18.0 million, which includes a fair value adjustment of $2.0 million and foreign currency translation of $1.9 million during the year ended December 31, 2025.

Future minimum principal payments, as of December 31, 2025 are as follows (in thousands):

Fiscal Year	Amount
2026	$ 11,756
Total future payments	11,756
Imputed interest and fair value adjustments	6,270
Total Debt as of December 31, 2025	$ 18,026

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, 2025 and 2024.

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

Common Stock

On June 4, 2025, the Company's shareholders approved an amendment to the Company's certificate of incorporation to increase the total number of authorized shares of Common Stock from 100,000,000 to 250,000,000.

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

	December 31,	
	2025	2024
Options issued and outstanding under the Quince 2019 Stock Plan	10,299,981	7,408,005
Shares available for issuance under Quince 2019 Stock Plan	1,071,074	2,428,575
Shares available for issuance under the Employee Stock Purchase Plan	2,364,278	1,924,262
Options issued and outstanding under the Novosteo 2019 Plan	161,568	163,839
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	18,143,698	16,171,478

The Company is authorized to issue 250,000,000 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, 2025 and 2024, the Company had 55,725,291 and 44,001,643 shares of common stock issued and outstanding, respectively.

ATM Program

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 the Company's 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, 2025, the Company utilized its ATM program to raise net proceeds of approximately $6.3 million by issuing 4,823,859 shares of common stock. As of December 31, 2025, $68.5 million remained available to be sold under the ATM program. See Note 17 for discussion of subsequent events related to the ATM program.

June 2025 Private Placement

On June 12, 2025, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement"), with certain institutional investors (the "Investors") and certain members of the Company's management (together with the Investors, the "Purchasers") pursuant to which the Company issued and sold to the Purchasers in a private placement ("June 2025 Private Placement"): (i) 6,671,928 shares (the "Shares") of its common stock, par value $0.001 per share (the "Common Stock"), (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 2,000,000 shares of Common Stock, and (iii) accompanying warrants to purchase up to an aggregate of 8,671,928 shares of Common Stock (the "Common Warrants"), for aggregate gross proceeds of approximately $11.5 million (excluding up to approximately $10.4 million of aggregate gross proceeds that may be received in the future upon the cash exercise in full of the Common Warrants issued in the Private Placement), before deducting placement agent fees and other expenses payable by the Company.

Note 10. Warrants

Warrants Issued with June 2025 Private Placement

On June 12, 2025, in connection with the sale and issuance of common stock as part of the June 2025 Private Placement, the Company issued Pre-Funded Warrants to purchase up to an aggregate of 2,000,000 shares of Common Stock at an exercise price of $0.001 per share, and Common Warrants to purchase up to an aggregate of 8,671,928 shares of Common Stock at an exercise price of $1.20 per share. Each Share and each Pre-Funded Warrant sold pursuant to the Securities Purchase Agreement was accompanied by one Common Warrant. The combined purchase price of each Share and accompanying Common Warrant was $1.325 (which included $0.125 per Common Warrant in accordance with the rules and regulations of Nasdaq). The combined purchase price of each Pre-Funded Warrant and accompanying Common Warrant was $1.324 (equal to the combined purchase price per Share and accompanying Common Warrant, minus $0.001).

The Common Warrants can be exercised into either common stock or Pre-Funded Warrants at the holders' option, and both Common Warrants and Pre-Funded Warrants contain purchase rights that could result in holders receiving securities that more than offsets or neutralizes the effect of a distribution event. As a result of the aforementioned provisions, both Common Warrants and Pre-Funded Warrants fail the indexation guidance under ASC 815 and are classified as liabilities. The Pre-Funded Warrants and Common Warrants liabilities were recorded at fair value as of the issuance date and December 31, 2025, and subject to adjustment to estimated fair value at each balance sheet date until the warrants are settled.

The proceeds from June 2025 Private Placement were first allocated to the full fair value of the Pre-Funded Warrants and Common Warrants due to the liability classification. As disclosed in Note 3, the fair value of the Pre-Funded Warrants and Common Warrants at issuance was $10.7 million. The remaining proceeds of $0.8 million, before issuance costs, were allocated to the Common Stock.

During the year ended December 31, 2025, the Company recognized a fair value loss on warrant liability of $21.5 million. Proceeds from the June 2025 Private Placement are shown as cash from financing transactions and the loss on the change in fair value of the warrant liability is included as an adjustment to reconcile the net loss to net cash used in operating activities in the statements of cash flows for the year ended December 31, 2025.

Offering expenses of $0.9 million out of total offering expenses of $1.0 million related to the June 2025 Private Placement were expensed immediately as the proceeds were allocated to the warrant liability. The offering expenses were allocated to each instrument based on their respective fair value at issuance.

All of the Pre-Funded Warrants and Common Warrants issued in connection with the June 2025 Private Placement remained outstanding as of December 31, 2025. The following table is a summary of the Company's warrants outstanding as of December 31, 2025:

	Number of Common Stock Issuable	Exercise Price	Expiration Date
Pre-Funded Warrants	2,000,000	$ 0.001	None
Common Warrants	8,671,928	$ 1.20	June 12, 2030

Note 11. Stock-Based Compensation

The Company operates three stock-based compensation plans as of December 31, 2025.

- 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, 2025, the maximum aggregate number of shares that may be issued under the Quince 2019 Plan is 13,515,484 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 of Directors may determine.

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

As of December 31, 2025, the Company had 1,071,074 shares available for future issuance under the Quince 2019 Plan.

Stock Options

Stock options under the Quince 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 as of December 31, 2024	**7,408,005**	$ 3.16	$ 8.37	$ 4,285
Options granted	3,287,256	1.58	—	—
Options exercised	(225,590)	0.97	—	146
Options cancelled / forfeited	(169,690)	1.04	—	—
Balance as of December 31, 2025	**10,299,981**	$ 2.74	$ 7.97	$ 18,856
Options vested and expected to vest as of December 31, 2025	10,299,981	2.74	7.97	18,856
Options exercisable as of December 31, 2025	5,086,553	$ 4.12	$ 7.44	$ 8,634

Aggregate intrinsic value represents the difference between the Company's 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 for both the years ended December 31, 2025 and 2024. The weighted-average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $1.35 and $1.04 per share, respectively.

For the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense of $3.3 million and $2.9 million, respectively, related to options granted to employees and non-employees for the Quince 2019 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 statements of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2025, total unamortized employee stock-based compensation was $5.7 million, which is expected to be recognized over the remaining estimated vesting period of 1.90 years.

2019 Equity Incentive Plan (Novosteo)

On May 19, 2022, in accordance with the terms of Agreement and Plan of Merger and Reorganization between the Company, Novosteo, Inc., and the other parties thereto, 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 of Directors at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the 2019 Novosteo Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board of Directors, 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, 2025, 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 as of December 31, 2024	**163,839**	$ 0.55	7.23	$ 216
Options granted	—	—	—	—
Options exercised	(2,271)	0.02	—	8
Options cancelled / forfeited	—	—	—	—
Balance as of December 31, 2025	**161,568**	$ 0.55	6.23	$ 452
Options vested and expected to vest as of December 31, 2025	161,568	0.55	6.23	452
Options exercisable as of December 31, 2025	142,164	$ 0.55	6.23	$ 398

The total intrinsic value of the 2019 Novesteo Plan options exercised was $8 thousand and $0.1 million for the years ended December 31, 2025 and 2024.

For the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense of $0.2 million and $0.2 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, 2025, total unamortized employee stock-based compensation was $0.1 million, which is expected to be recognized over the remaining estimated vesting period of 0.22 years.

Restricted Stock Awards

	Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2024	**78,417**	**$ 3.30**
RSAs granted	—	—
RSAs vested	(78,417)	3.30
RSAs cancelled	—	—
Unvested - December 31, 2025	**—**	**$ —**

For the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense of $0.3 million and $0.3 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 $0.3 million and year ended December 31, 2025, and December 31, 2024, respectively. As of December 31, 2025, there is no remaining unamortized employee stock-based compensation.

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 of Directors 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, 2025, 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 as of December 31, 2024	**2,333,306**	$ 2.98	7.39	—
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	—	—	—	—
Balance as of December 31, 2025	**2,333,306**	$ 2.98	6.39	863
Options vested and expected to vest as of December 31, 2025	2,333,306	2.98	6.39	863
Options exercisable as of December 31, 2025	2,090,252	$ 2.98	6.39	773

For both the years ended December 31, 2025 and 2024, the Company recognized stock-based compensation expense of $1.3 million, related to options granted to employees and non-employees for the 2022 Inducement plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of December 31, 2025, total unamortized employee stock-based compensation was $0.5 million, which is expected to be recognized over the remaining estimated vesting period of 0.39 years.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the years ended December 31, 2025 and 2024 and the allocation within the consolidated statements of operations and comprehensive loss (in thousands):

	Years Ended December 31,	
	2025	2024
General and administrative expense	$ 3,382	$ 3,876
Research and development expense	1,723	870
Total stock-based compensation	$ 5,105	$ 4,746

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, 2025 and 2024:

	2025	2024
Expected volatility	110.53%	106.05%
Expected dividend yield	— %	— %
Expected term (in years)	6.16	6.21
Risk-free interest rate	4.28%	3.78%

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—The Company has based its estimate of expected volatility on the historical volatility of its own stock. The historical volatility data was computed using the daily closing price during the 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 2,364,278 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 12. Income taxes

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

	Year ended December 31,	
	2025	2024
United States	$ (56,470)	$ (22,397)
International	(24,295)	(34,344)
Total	$ (80,765)	$ (56,741)

The components of the Company's expense (benefit) for income taxes were as follows (in thousands):

	Year ended December 31,	
	2025	2024
Current expense (benefit):		
Federal	$ 241	$ 44
State	(9)	—
Foreign	8,571	88
Total current expense (benefit):	8,803	132
Deferred expense (benefit):		
Federal	—	—
State	—	—
Foreign	(5,589)	(45)
Total deferred expense (benefit):	(5,589)	(45)
Total income tax expense (benefit)	$ 3,214	$ 87

A reconciliation of the Company’s effective tax rate to the statutory U.S. federal rate is as follows (in thousands, except percentages):

	Year ended December 31, 2025	
	Amount	Percentage
U.S. federal taxes at statutory rate	$ (16,961)	21.00%
State tax, net of federal income tax benefit	1	—
Effect of cross-border tax laws		
Global intangible low-taxed income (GILTI)	6,544	(8.10)
R&D tax credit	(311)	0.38
Change in valuation allowance	(403)	0.50
Nondeductible items		
Stock based compensation	681	(0.84)
Change in fair value - warrants and contingent consideration	6,113	(7.57)
Other	194	(0.24)
Worldwide changes in unrecognized tax benefits	17,846	(22.10)
Other		
Acquisition-related deferred tax adjustment	216	(0.27)
Foreign tax effects		
Italy		
Rate differential	(2,010)	2.49
Change in valuation allowance	(7,315)	9.06
Australia		
Rate differential	592	(0.73)
Change in valuation allowance	(1,973)	2.44
	$ 3,214	(3.98)%

	Year ended December 31, 2024
Federal statutory income tax rate	21.00%
State income taxes	0.34
Income tax credits	0.18
Stock based compensation	(1.49)
Foreign rate differential	3.96
Change in fair value - deferred consideration	(2.30)
Impairment of Goodwill	(8.25)
Other	(0.27)
Change in valuation allowance	(13.32)
	0.15%

As of December 31, 2025 and December 31, 2024, the components of the Company's deferred tax assets are as follows (in thousands):

	Year ended December 31,	
	2025	2024
Deferred tax asset:		
Federal and State net operating loss carryforwards	$ 59,688	$ 87,188
Stock based compensation	2,898	2,529
Other accruals	604	581
Capitalized research and development expense	725	3,127
Tax credits	8,010	8,545
Disallowed interest expense carryforward	—	1,194
IPR&D	13,253	—
Gross deferred tax asset	85,178	103,164
Valuation allowance	(85,069)	(91,488)
Total deferred tax assets	109	11,676
Deferred tax liabilities:		
Capitalized leases	(109)	(120)
IPR&D	—	(16,519)
Gross deferred tax liabilities	(109)	(16,639)
Net deferred tax liabilities	$ —	$ (4,963)

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. The valuation allowance decreased by approximately $6.4 million and increased by approximately $6.4 million, respectively for the years ended December 31, 2025 and 2024.

As of December 31, 2025, the Company has federal net operating loss carryforwards of approximately $253.3 million, of which $237.5 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 $10.4 million which begin to expire in 2036 and state tax credits of approximately $3.0 million which do not expire.

As of December 31, 2025, the Company has foreign net operating loss carryforwards, primarily in Italy, of approximately $119.0 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 has rolled forward the analysis through December 31, 2023 and no additional ownership changes had occurred. The Company has not completed a Section 382/383 analysis for the period subsequent to December 31, 2023. Subsequent ownership changes may further affect the limitation in future years.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law in the U.S. which contains a broad range of tax reform provisions affecting businesses. The Company evaluated the impact of the OBBBA and determined that it did not have a material impact on the Company's financial statements for the year ended December 31, 2025.

The Company's subsidiaries in Australia received cash payments of R&D tax incentives in prior periods, a qualifying condition of which was that the related R&D expenditure was 'at risk'. During the quarter ended June 30, 2025, the Australian entities were dissolved. It is reasonably possible that the Australian tax authorities may determine that the initial R&D expenditures were not 'at risk' and seek to recover the related incentives previously paid to the Company of $0 up to $2.7 million. The outcome of a potential recoupment of amounts by the Australian Tax Authorities is inherently unpredictable and involves a series of complex assessments by management about future events.

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 2014 to 2025, 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 2025. The Company's Italian subsidiary remain open to examination from their inception to 2025. The cash paid for income taxes (net of refunds) during the year was zero for all jurisdictions.

The Company's foreign subsidiaries are in accumulated deficit positions. Accordingly, the Company has not accrued any provision for taxes associated with the repatriation of undistributed earnings from its foreign subsidiaries as of December 31, 2025.

In December 2025, the Company completed an intercompany transfer of certain intellectual property from its Italian subsidiary to the United States parent entity. Prior to the sale the Company had a $16.4 million deferred tax liability related to the difference between book and tax basis of the intellectual property. As a result of the transfer the deferred tax liability was released and a deferred tax asset recorded of $13.4 million. The deferred tax assets represents the value of future deductions for amortization of the asset in the US, and is offset by the valuation allowance. The tax impact of the intellectual property transfer has been adjusted for associated unrecognized tax benefits, consistent with ASC 740, Income Taxes. The fair value of the intellectual property was determined using an Acquisition Price Method ('APM') based on unobservable inputs and includes judgments such as, but not limited to, discount rates, control premium and residual returns. Management's estimate of fair value is based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. The increase in the gross unrecognized tax benefits and the unrecognized tax benefit at December 31, 2025 are primarily due to the positions taken with respect to this intercompany transaction. Included in the balance of gross unrecognized tax benefits as December 31, 2025 are potential benefits of $6.4 million that would reduce the Company's effective tax rate. The remainder of our unrecognized tax benefits would not impact our effective tax rate due to a valuation allowance offsetting our deferred tax assets. There were interest and penalties of $0.2 million and $0.2 million accrued as of December 31, 2025 and 2024, respectively.

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

	Year ended December 31,	
	2025	2024
Beginning balance	$ 4,430	$ 4,339
Reductions for tax positions taken in a prior year	(37)	—
Lapse of the applicable statute of limitations	(24)	—
Additions for tax positions taken in the current year	31,507	91
Ending balance	$ 35,876	$ 4,430

Note 13. 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,	
	2025	2024
Numerator:		
Net loss	$ (83,979)	$ (56,828)
Denominator:		
Weighted average common shares outstanding	50,096,897	43,262,269
Net loss per share, basic and diluted	$ (1.68)	$ (1.31)

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,	
	2025	2024
Stock options issued and outstanding	12,794,855	9,905,150
Common warrants	8,671,928	—
Pre-Funded warrants	2,000,000	—
Restricted stock awards	—	78,417
Total	23,466,783	9,983,567

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, 2023	$ 63,197
Foreign currency translation adjustments	(3,578)
Balance as of December 31, 2024	$ 59,619
Foreign currency translation adjustments	$ 7,742
Balance as of December 31, 2025	$ 67,361

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, 2025			As of December 31, 2024		
	Useful life	Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite life intangible assets:							
Trade name	21 years	$ 460	(53)	$ 407	$ 460	(26)	$ 434
Foreign currency translation adjustments				51			(8)
Total				$ 458			$ 426

The Company performs annual impairment reviews of its intangible assets during the fourth fiscal quarter or more frequently if appropriate. As of December 31, 2025, the Company did not incur any impairment losses related to its EryDel intangible assets. The remaining amortization period for the trade name is 18.8 years as of December 31, 2025. See Note 17 for discussion of subsequent events related to impairment of indefinite and long-lived assets.

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 fiscal year 2024.

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

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 its 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,	
	2025	2024
Cash, cash equivalents and short-term investments	17,752	40,784

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

	Year Ended December 31,	
	2025	2024
Research and development:		
Personnel	$ 5,269	$ 3,724
Stock-based compensation	1,723	870
Clinical and contract manufacturing	30,066	16,006
Other	(1,676)	(2,010)
General and administrative:		
Personnel	5,029	5,218
Stock-based compensation	3,382	3,876
Consulting and professional costs	4,006	5,115
Other	2,630	3,371
Goodwill impairment charge	—	17,130
Fair value adjustment for contingent consideration	7,639	3,985
Total operating expenses	58,068	57,285
Loss from operations	(58,068)	(57,285)
Fair value adjustment for debt	(2,043)	(1,709)
Fair value adjustment for warrants	(21,470)	—
Other segment items	(2,398)	2,166
Net loss	$ (83,979)	$ (56,828)

Other segment items within net loss include warrant issuance costs, interest income, other income (expense), net, and income tax expense.

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, 2025 and 2024, 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, 2025 and 2024 was $45 thousand 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.

Note 17. Subsequent Events

In January 2026, the Company issued 2,000,000 shares of common stock related to pre-funded warrant holders exercising their warrants at an exercise price of $0.001. The Company reclassified the pre-funded warrant liability to equity.

As a result of the clinical readout of the Phase III NEAT study in January 2026 (see Note 1), the Company expects substantially all of the IPR&D to be impaired. Additionally, the criteria for the contingent consideration payments are not expected to be met, resulting in the related liability being reduced to zero.

Following December 31, 2025, and through the issuance of these financial statements, the Company raised net proceeds of approximately $20.4 million by issuing 105,285,000 shares of common stock under the ATM program, with approximately $47.5 million remaining subject to available shares for issuance.

In February 2026, the Company engaged in restructuring activities and evaluation of strategic alternatives aimed at maximizing shareholder value. As such, the Company incurred severance costs of $1.4 million related to personnel separation.

In March 2026, the EIB agreed to a full settlement of all obligations associated with the loan with a single payment of 4.8 million euros ($5.5 million) which was paid on March 30, 2026.

On April 2, 2026, the Company's board of directors determined to effect a reverse stock split of 1-for-10 for the Company's outstanding shares of common stock and approved an amendment to the Company's Amended and Restated Certificate of Incorporation to effect the reverse stock split. The Company anticipates the reverse stock split to be effective on April 10, 2026 at approximately 11:59 p.m. Eastern Time. Trading will begin on a split-adjusted basis on April 13, 2026. Following the reverse stock split, the Company's issued and outstanding shares of common stock will decrease from approximately 163.0 million pre-split shares to 16.3 million post-split shares, subject to adjustment for fractional shares. Proportionate adjustments will be made to the number of shares of common stock underlying the Company's outstanding equity awards, warrants, the number of shares issuable under its equity incentive plans and other existing agreements, as well as the exercise or conversion price, as applicable. This reverse stock split will result in proportionate adjustment to the basic and diluted earnings per share. The reverse stock split will not affect the number of authorized shares of common stock or the par value of the common stock.

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, 2025. 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, 2025 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, 2025, 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

10b5-1 Plans

On December 22, 2025, Brendan Hannah, our Chief Operating Officer, adopted a Rule 10b5-1 trading plan. Mr. Hannah's Rule 10b5-1 trading plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) and provides for the potential exercise and sale of up to 500,000 shares of the Company's common stock subject to stock options held by Mr. Hannah at specified limit prices ranging from $15.00 to $35.00 per share until April 6, 2027.

On December 22, 2025, Charles Ryan, our President, adopted a Rule 10b5-1 trading plan. Mr. Ryan's Rule 10b5-1 trading plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) and provides for the potential sale of up to 122,461 shares of the Company's common stock and the exercise and sale of up to 527,290 shares subject to stock options held by Mr. Ryan at specified limit prices ranging from $9.90 to $29.90 per share until April 6, 2027.

The Rule 10b5-1 plans described above each included a representation from the director or officer to the broker administering the plan that he or she was not in possession of any material nonpublic information regarding the Company or the securities subject to the plan. A similar representation was made to the Company by each individual in a certification provided in connection with the adoption of the plan under the Company's insider trading policy. These representations were made as of the date of adoption of each Rule 10b5-1 plan and speak only as of those dates. In making these representations, there can be no assurance with respect to any material nonpublic information of which the individual was unaware, or with respect to any material nonpublic information acquired by the individual or the Company after the applicable date of the representation.

Amendment to Bylaws

On April 8, 2026, the Board of Directors adopted and approved an amendment to the Company's Amended and Restated Bylaws (the "Bylaws Amendment") to change the number of stockholders required to constitute a quorum at a meeting of stockholders from a majority to one-third of the outstanding shares entitled to vote, present in person or represented by proxy. The Bylaws Amendment became effective immediately.

The foregoing description of the Bylaws Amendment does not purport to be complete and is qualified in its entirety by the text of the Bylaws Amendment, which is filed as Exhibit 3.4 to this Annual Report and is incorporated herein by reference.

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 2026 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 2026 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 2026 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 2026 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 2026 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 2026 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

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		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	
3.4	Amendment to Amended and Restated Bylaws					X
4.1	Specimen Stock Certificate	S-1	333-230853	4.1	4/29/2019	
4.2	Description of Securities	10-K	001-38890	4.3	03/16/2020	
4.3	Form of Pre-Funded Warrant	8-K	001-38890	4.1	6/13/2025	
4.4	Form of Common Warrant	8-K	001-38890	4.2	6/13/2025	
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 Employee Stock Purchase Plan	S-1/A	333-230853	10.5	4/29/2019	
10.7+	Cortexyme, Inc. 2022 Inducement Plan	S-8	333-265109	99.1	5/20/2022	
10.8+	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	
10.9+	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	
10.10+	Novosteo Inc. 2019 Equity Incentive Plan	S-8	333-265109	99.4	5/20/2022	
10.11+	Executive Change in Control and Severance Agreement by and between Cortexyme, Inc. and Brendan Hannah, dated May 19, 2022	10-Q	001-38890	10.10	8/9/2022	
10.12+	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	
10.13+	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	
10.14	Outside Director Compensation Policy adopted April 9,2019; Amended and Restated: December 2, 2024	10-K	001-38890	10.15	3/24/2025	
10.15	Controlled Equity Offering[SM] 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	
10.16**	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	10-K	001-38890	10.26	4/1/2024	

	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					
10.17**	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	
10.18	Form of Securities Purchase Agreement, dated June 12, 2025, by and among Quince Therapeutics, Inc. and each of the several purchasers signatory thereto.	8-K	001-38890	10.1	6/13/2025	
10.19	Form of Registration Rights Agreement, dated June 12, 2025, by and among Quince Therapeutics, Inc. and each of the several purchasers signatory thereto.	8-K	001-38890	10.2	6/13/2025	
10.20	Amendment to Accession, Amendment, and Restatement Agreement to the Finance Contract dated September 25, 2025 by and between Quince Therapeutics, Inc., EryDel Italy, Inc., EryDel US, Inc., EryDel USA, Inc., EryDel S.p.A., and the European Investment Bank	10-Q	001-38890	10.1	11/12/2025	
19.1	Insider Trading Policy	10-K	001-38890	19.1	3/24/2025	
21.1	List of subsidiaries	10-K	001-38890	21.1	3/24/2025	
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	001-388909	97.1	4/1/2024	
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents					X
104	The cover page from this Annual Report on Form 10-K, formatted in Inline XBRL and contained in Exhibit 101					

+ 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: April 10, 2026

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)	April 10, 2026
/s/ Brendan Hannah **Brendan Hannah**	Chief Business Officer and Chief Operating Officer and Chief Compliance Officer (Principal Financial Officer and Principal Accounting Officer)	April 10, 2026
/s/ David A. Lamond **David A. Lamond**	Director	April 10, 2026
/s/ Christopher J. Senner **Christopher J. Senner**	Director	April 10, 2026

Exhibit 3.4

AMENDMENT TO THE AMENDED AND RESTATED BYLAWS OF QUINCE THERAPEUTICS, INC.

The undersigned, in his capacity as the Chief Executive Officer of Quince Therapeutics, Inc. (the "*Corporation*"), hereby certifies on behalf of the Corporation that the following Amendment to the Amended and Restated Bylaws of the Corporation (the "*Bylaws*") was duly adopted by the Board of Directors of the Corporation on April 8, 2026:

1. Section 1.5 of the Bylaws is hereby amended and restated in its entirety to read as follows:

"Section 1.5: Quorum. Except as otherwise provided by applicable law, the Certificate of Incorporation or these Bylaws, at each meeting of stockholders the holders of one-third (1/3) of the voting power of the shares of stock issued and outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of stock is required by applicable law or the Certificate of Incorporation, the holders of one-third (1/3) of the voting power of the shares of such class or classes or series of the stock issued and outstanding and entitled to vote on such matter, present in person or represented by proxy at the meeting, shall constitute a quorum entitled to take action with respect to the vote on such matter. If a quorum shall fail to attend any meeting, the chairperson of the meeting or, if directed to be voted on by the chairperson of the meeting, the holders of a majority of the voting power of the shares entitled to vote who are present in person or represented by proxy at the meeting may adjourn the meeting. Shares of the Corporation's stock belonging to the Corporation (or to another corporation, if a majority of the shares entitled to vote in the election of directors of such other corporation are held, directly or indirectly, by the Corporation), shall neither be entitled to vote nor be counted for quorum purposes; provided, however, that the foregoing shall not limit the right of the Corporation or any other corporation to vote any shares of the Corporation's stock held by it in a fiduciary capacity and to count such shares for purposes of determining a quorum. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum."

2. All other provisions of the Bylaws remain in full force and effect.

Date: April 8, 2026

By: /s/ Dirk Thye
Dirk Thye
Chief Executive Officer

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Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-283897 and 333-288971) and Form S-8 (Nos. 333-231307, 333-237199, 333-253743, 333-263186, 333-265109, 333-270577, 333-278440 and 333-286063) of Quince Therapeutics, Inc. (the Company) of our report dated April 10, 2026, relating to the consolidated financial statements which appears in this Annual Report on Form 10-K. 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
April 10, 2026

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, 2025;

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: April 10, 2026

/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, 2025;

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: April 10, 2026

/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, 2025 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: April 10, 2026

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, 2025 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: April 10, 2026

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.