UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

or

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

FOR THE TRANSITION PERIOD FROM TO .

Commission File Number 001-38356

VYNE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-3757789**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

685 Route 202/206 N, Suite 301
Bridgewater, New Jersey 08807
(Address of principal executive offices, including zip code)

(800) 775-7936
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001	VYNE	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 Section 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 and post such files).

Yes ☒ No ☐

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

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

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

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

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 corrects 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 Exchange Act Rule 12b-2).

Yes ☐ No ☒

As of June 30, 2024, the last business day of the registrant's last completed second quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $28.2 million based on the closing price of the registrant's common stock, as reported by the Nasdaq Capital Market, on such date.

As of February 27, 2025, there were 15,209,862 shares of the registrant's Common Stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

VYNE THERAPEUTICS INC.
FORM 10-K
TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These statements are often identified by the use of words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "if," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "until," "will," "would," and similar expressions or variations.

These forward-looking statements include, but are not limited to, statements regarding the following matters:

- our ability to successfully execute our business strategy, including our ability to successfully develop our bromodomain and extra-terminal domain ("BET") inhibitor platform for immuno-inflammatory conditions;
- the timing of commencement of future preclinical studies and clinical trials and timing of data from those studies and trials;
- our ability to enroll patients and successfully complete, and receive favorable results in, clinical trials for our product candidates;
- the regulatory approval process for our product candidates, including any delay or failure in obtaining requisite approvals;
- our pursuit of, and ability to successfully identify and execute, strategic transactions;
- estimates of our expenses, capital requirements, our needs for additional financing and our ability to obtain additional capital on acceptable terms or at all;
- the potential market size of treatments for any diseases and market adoption of our products, if approved or cleared for commercial use, by physicians and patients;
- disruptions related to macroeconomic conditions on our ability to initiate and retain patients in our clinical trials and progress preclinical studies and the ability of our suppliers to manufacture and provide materials for our product candidates;
- our ability to create and or in-license in intellectual property and the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and programs, including the projected terms of patent protection;
- developments and projections relating to our competitors and the markets in which we compete, including competing drugs and therapies, particularly if we are unable to receive exclusivity;
- our ability to comply with various regulations applicable to our business;
- our ability to successfully challenge intellectual property claimed by others;
- our intentions and our ability to establish collaborations or obtain additional funding;
- our ability to attract and retain key scientific or management personnel;
- risks and uncertainties arising out of the completed divestiture of our commercial business;
- our defense of any future litigation that may be initiated against us;
- our expectations regarding licensing, business transactions and strategic operations; and
- our future financial performance and liquidity.

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. Forward-looking statements involve known and unknown risks,

uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in "Risk Factors" and elsewhere in this Annual Report on Form 10-K as well as our other filings made with the Securities and Exchange Commission ("SEC"). Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

COMPANY REFERENCES

Throughout this Annual Report on Form 10-K, "VYNE," the "Company," "we," "us" and "our" refer to VYNE Therapeutics Inc. and its subsidiaries.

TRADEMARKS

The trademarks and registered trademarks of VYNE Therapeutics Inc. and our subsidiaries referred to in this Annual Report on Form 10-K include VYNE Therapeutics®, InhiBET™, our logo and our name and logo used together. Third-party products and company names mentioned herein may be the trademarks of their respective owners.

Risk Factors Summary

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- Our business is substantially dependent on the successful development of our BET inhibitor product candidates;
- We may encounter delays in enrolling patients and successfully completing clinical trials for our product candidates, and may be delayed in, or prevented from, commencing such trials due to factors that are largely beyond our control;
- Clinical drug development is very expensive, time-consuming and uncertain. Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates, which could prevent or delay regulatory approval and commercialization as well as prevent or delay our ability to pursue strategic alternatives for our product candidates;
- New chemical entities may require more time and resources for development, testing and regulatory approval;
- Results obtained in preclinical studies and completed clinical trials may not predict success in later clinical trials;
- Top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as additional data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- We have a limited history as a clinical-stage biopharmaceutical company developing product candidates for immuno-inflammatory conditions, which may make it difficult to assess our future viability;
- We may spend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- We have not obtained regulatory approvals to market our other pipeline product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize these product candidates;
- Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business;
- We may engage in strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management;
- We may decide not to continue developing any of our product candidates at any time during development or of any of our products after approval, which would reduce or eliminate our potential return on investment for those product candidates or products;
- We are subject to various U.S. federal, state, local and foreign health care fraud and abuse laws, including anti-kickback, self-referral, false claims and fraud laws, health information privacy and security, and transparency laws, and any violations by us of such laws could result in substantial penalties or other consequences including criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business;
- Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market, and distribute our products after clearance or approval is obtained;
- We are subject to various risks and uncertainties arising out of the completed divestiture of our commercial business, any of which could materially and adversely affect our business, operations and stock price; and
- The trading price of the shares of our common stock is volatile, and stockholders could incur substantial losses.

PART I

ITEM 1 — BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on developing differentiated therapies to treat chronic inflammatory and immune-mediated conditions with high unmet need.

We have exclusive worldwide rights to research, develop and commercialize products containing small molecule bromodomain and extra-terminal domain ("BET") inhibitors for the treatment of any disease, disorder or condition in humans, which we licensed from Tay Therapeutics Ltd., formerly known as In4Derm Ltd ("Tay"). BET proteins are epigenetic enablers of transcription that regulate the expression of specific genes. Each BET protein consists of two bromodomains ("BD1" and "BD2") and one end terminal ("ET") domain. Through our transaction with Tay, we obtained access to a library of new small molecule BET inhibitor compounds including those that inhibit both BD1 and BD2 ("pan-BD" BET inhibitor) and that selectively inhibit BD2 ("BD2-selective" BET inhibitor). Through our access to this library of new BET inhibitors, which comprise our InhiBET™ portfolio, we plan to develop product candidates for a diverse set of therapeutic indications. We have chosen to initially focus our development efforts with these molecules on immune-mediated inflammatory diseases, which are not being targeted by current BET inhibitors in development.

Our lead program is repibresib gel (also known as VYN201), a topically administered, small molecule pan-BD BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. In preclinical testing, repibresib produced consistent reductions in pro-inflammatory and disease-related biomarkers and improvements in disease severity across a variety of inflammatory and fibrotic preclinical models. In November 2022, we initiated a Phase 1 clinical trial evaluating a topical formulation of repibresib first in healthy volunteers (Phase 1a) and then in subjects (Phase 1b) with nonsegmental vitiligo (NSV), an immune-mediated condition that has a high unmet need and only one approved therapy. In the first quarter of 2023, we announced positive preliminary safety and tolerability, including hematology data, and predicted pharmacokinetic results (minimal systemic exposures) from the Phase 1a portion of the trial. We initiated the Phase 1b portion of the trial in NSV subjects in January 2023 and announced positive data from the Phase 1b trial in October 2023. We showed significant clinical improvements in vitiligo involving the face, which has the greatest psychosocial impact on patients, after 16 weeks of treatment using the Facial-Vitiligo Area Scoring Index ("F-VASI"). We initiated a Phase 2b trial with repibresib gel in NSV subjects in June 2024. The Phase 2b trial is a randomized, double-blind, vehicle-controlled trial evaluating the efficacy, safety and pharmacokinetics of once-daily repibresib gel in NSV subjects in three dose cohorts (1%, 2% or 3% concentrations) compared to vehicle over 24 weeks, followed by a 28-week active treatment extension with subjects on vehicle crossing over to active doses. We enrolled approximately 45 patients in each arm and expect to report top-line results from the 24-week double-blind portion of the trial in mid-2025.

Our second program is VYN202, an oral, small molecule BD2-selective BET inhibitor. Prior studies have shown that while BD1 modulates cell-cycling and homeostatic functions, BD2 regulates gene expression of pro-inflammatory mediators in cells. VYN202 has been designed to achieve potential class-leading potency and selectivity for BD2 vs. BD1. By maximizing BD2 selectivity, we believe VYN202 has the potential to be a potent oral immunomodulator option for both acute control and chronic management of immune-mediated inflammatory conditions, without the hematologic and gastrointestinal adverse effects associated with earlier generation systemic pan-BD BET inhibitors that were being developed in oncologic settings. We have completed a Phase 1a single ascending dose/multiple ascending dose ("SAD/MAD") trial of VYN202 in healthy volunteers and announced positive data from this trial in December 2024. We observed that VYN202 had a favorable safety and tolerability profile with no drug-related adverse events historically associated with earlier generation, less BD2-selective BET inhibitors. VYN202 also demonstrated robust pharmacodynamic activity including evidence of target engagement and inhibition of several inflammatory biomarkers relevant to immune-mediated disorders in ex vivo stimulation assays. We initiated a Phase 1b trial in February 2025 in adult subjects with moderate-to-severe plaque psoriasis. The Phase 1b trial is a randomized, double-blind, placebo-controlled trial of once daily treatment with VYN202 capsules dosed for

12 weeks, to primarily evaluate the safety of VYN202 across four cohorts (0.25 mg, 0.5 mg, 1 mg doses and placebo), with secondary objectives that include pharmacokinetics and preliminary evidence of efficacy via endpoints evaluating improvements from baseline in psoriasis area and severity index (PASI) scores. The trial will also include a 4-week safety follow-up visit after completion of the 12-week dosing period. We expect to enroll approximately 80 subjects with moderate-to-severe plaque psoriasis and to report top-line results from the placebo-controlled trial by the end of 2025. Additionally, we anticipate that the data from the Phase 1b trial in plaque psoriasis subjects will provide key insights into VYN202's potential activity across a range of immune-mediated diseases.

We intend to advance our product candidates through further phases of clinical development toward regulatory approval. As part of our strategy to maximize the value of our pipeline, we may partner with larger pharmaceutical companies to expand and accelerate the development of our programs and explore other indications and therapeutic areas outside of our core focus in immune-mediated diseases.

BET Proteins: Key Epigenetic Regulators of NF-kB, an Orchestrator of Inflammation

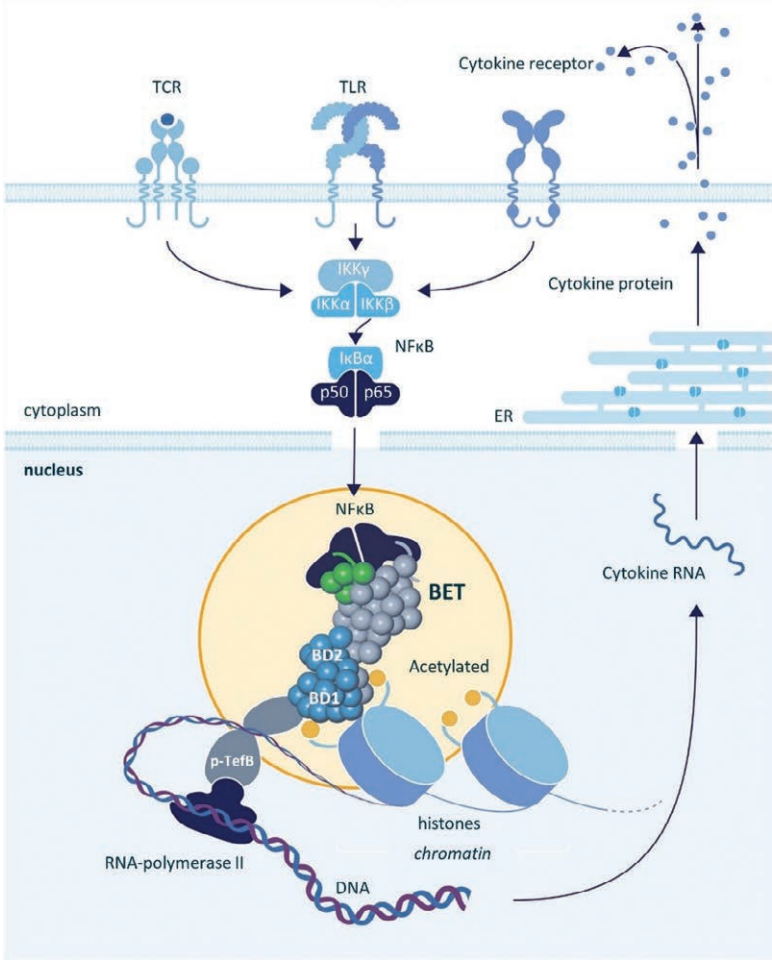
BET proteins are epigenetic enablers of transcription that regulate the expression of specific genes. In some cases, BET proteins can activate oncogenes via BD1, thereby leading to increased cell proliferation and survival that may lead to formation of solid tumors and hematologic malignancies. BET inhibitors have the potential to downregulate the expression of such oncogenes. These observations have resulted in the generation and clinical investigation of BET inhibitors in several cancer subtypes by various pharmaceutical companies, including large pharmaceutical companies.

In addition, BET proteins can regulate the expression of a wide range of pro-inflammatory genes, primarily through the NF-kB pathway. NF-kB is a critical transcription factor in inflammation that orchestrates production of key inflammatory cytokines and activation of multiple immune cell types. The dysregulation of NF-kB pathway activation can lead to several chronic immune-mediated conditions.

BET Inhibition: A Potential Novel Mechanism for the Treatment of Immune-Mediated Conditions

Inhibition of BET proteins can prevent the continual dysregulated/hyperactivated signaling of the NF-kB pathway which occurs in many autoimmune diseases. A known family of drugs, corticosteroids, have demonstrated efficacy in treating inflammation predominantly by inhibiting the NF-kB pathway. These are a widely used class of anti-inflammatory and immunosuppressive drugs, but their therapeutic use when given systemically is limited by many endocrine and metabolic side effects mediated by other pathways that are also impacted by these agents. By inhibiting the NF-kB pathway through the specific bromodomain BD2, BET inhibition could be a novel, non-steroidal, mechanism for the treatment of immune-mediated diseases without the non-immune side effects of corticosteroids. Because most of such diseases are heterogenous and driven by multiple immune pathways, BET inhibition has the potential to address a broad range of immune-mediated diseases due to its potential impact on many of these pathways.

The diagram below depicts the role of BET proteins in gene transcription via the NF-kB pathway, and the subsequent effect of disrupting this process on expression of inflammatory cytokines.



Our Platform and Product Candidates

InhiBET™ BET Inhibitor Platform

Through our partnership with Tay, we have exclusive worldwide rights to research, develop and commercialize products containing certain BET inhibitor compounds for the treatment of any disease, disorder or condition in humans. See "Development and License Agreements — Tay License Agreements." Utilizing our InhiBET platform and through our preclinical and clinical activities, we are evaluating the impact that BET inhibitor compounds have on regulating proinflammatory cytokines. We are targeting indications whose pathogenesis is linked to excessive production of these cytokines. We have selected development candidates and are developing formulations that are designed to maximize the anti-inflammatory effect of the drugs while minimizing safety concerns. Through our InhiBET development platform, we believe we can demonstrate the potential utility of these BET inhibitor compounds and develop therapies for a variety of immune-mediated diseases.

Repibresib — Locally Administered Pan-BD BET Inhibitor

Our lead BET inhibitor candidate in development is repibresib gel, which was developed using the InhiBET platform and is a topically-administered BET inhibitor. It is a first-in-class "soft" pan-BD BET inhibitor that is being developed to address diseases involving multiple, diverse inflammatory cell signaling pathways. Our goal with the repibresib program is to develop a therapy that delivers potent, localized anti-inflammatory effects and can be rapidly cleared through the body's metabolic processes to avoid systemic

effects. We have conducted several preclinical studies which have demonstrated repibresib's anti-fibrotic and anti-inflammatory activities and the ability to significantly reduce the expression of key cytokines relevant to certain autoimmune diseases, including vitiligo, psoriasis, rheumatoid arthritis, and idiopathic pulmonary fibrosis. In October 2023, we announced positive data from our Phase 1b trial of repibresib gel in subjects with NSV, which demonstrated clinical proof-of-concept for the use of this BET inhibitor to treat an immune-mediated disease. We initiated a Phase 2b trial with repibresib gel in NSV subjects in June 2024. Based on data generated to date, we believe repibresib has the potential to be highly versatile across multiple indications by serving as a locally-acting therapy with low systemic exposure.

Nonsegmental Vitiligo (NSV)

Vitiligo is a chronic autoimmune depigmenting disorder of the skin, characterized by the loss of pigment-producing cells known as melanocytes. Vitiligo is the most common depigmenting skin condition, with a prevalence estimated at 0.5 – 2.0% of the world population. An article published in the scientific journal, JAMA Dermatology, in 2021 estimated that there were between 1.9 million and 2.8 million cases of vitiligo in the United States. Approximately 90% of vitiligo cases are characterized as nonsegmental, in which white patches appear symmetrically on both sides of the body. There is currently only one drug, OPZELURA® (ruxolitinib) cream, approved by the FDA for the treatment of NSV. That product includes a boxed safety warning on its label. Based on preclinical and clinical data generated to date, we believe that repibresib gel has the potential to offer a targeted, efficacious, and a safe treatment option for NSV that lowers the disease recurrence rate and can be effective for all skin phototypes with few side effects.

Phase 1 Clinical Trial

Based in part on the data we observed from the preclinical vitiligo model described below, we commenced a Phase 1 clinical trial evaluating repibresib topical ointment for the treatment of NSV in November 2022. The trial was conducted at U.S.-based clinical centers. In the Phase 1a portion of the trial, single ascending and multiple ascending doses of repibresib were applied topically once daily to 30 healthy volunteers in five dose cohorts for two weeks with a one-week safety follow-up visit to evaluate the safety, tolerability and pharmacokinetics of repibresib. Evaluated doses included 0.025%, 0.1%, 0.5%, 1.0% and 2.0% concentrations. There were no serious adverse events and no dose adjustments were required. There were no clinically-relevant treatment emergent adverse events, abnormal clinical laboratory results or electrocardiogram findings, and no discontinuations. We selected the 0.5%, 1.0% and 2.0% doses for further evaluation in the Phase 1b portion of the trial.

The Phase 1b portion was a 16-week open-label trial assessing the safety, tolerability and pharmacokinetics of once-daily repibresib in 29 patients across the three dose cohorts. Exploratory efficacy of repibresib was also evaluated, including its ability to arrest the progression of skin depigmentation and support skin repigmentation in patients with active disease using F-VASI scoring. In October 2023, we announced positive results from the Phase 1b portion of the trial. Significant clinical improvement was observed in the 1.0% and 2.0% cohorts with rapid onset of action and a dose-dependent response. Mean percentage reduction in F-VASI score from baseline after 16 weeks of treatment was 7.5%, 30.2% and 39.0% for the 0.5%, 1.0% and 2.0% cohorts, respectively. There were no clinically-relevant treatment emergent adverse events in any cohort.

Phase 2 Clinical Trial

Last year, we reformulated repibresib in a once-daily gel for our Phase 2b trial in subjects with NSV, which we initiated in the second quarter of 2024. The ongoing Phase 2b trial is a randomized, double-blinded, vehicle-controlled trial evaluating subjects with NSV for 24 weeks, followed by a separate active treatment extension phase for an additional 28 weeks, with vehicle subjects crossing over to active doses at Week 24. The trial is evaluating four arms (three active arms, one vehicle arm) of once-daily repibresib gel, with each arm enrolling approximately 45 subjects with active or stable NSV. The primary efficacy endpoint of the trial is an evaluation of the proportion of subjects achieving F-VASI50 at Week 24 compared to vehicle. In January 2025, we announced the completion of enrollment in the trial. We anticipate top-line results from the 24-week double-blind portion of the trial to be available in mid-2025.

Preclinical Studies for Multiple Indications

Vitiligo

We conducted a preclinical study using an ex vivo skin model of vitiligo. The objectives of this study were to evaluate the potential of repibresib to:

- reduce matrix metalloproteinase-9 ("MMP-9") secretion, which allows for melanocyte stabilization and limits loss of melanocytes/depigmentation in vitiligo;
- reduce the soluble adhesion molecule, E-cadherin, which is a biomarker of melanocyte loss due to degradation of matrix-bound E-cadherin by MMP-9;
- minimize the loss of melanocytes by assessing melanin pigment content; and
- increase the expression of genes commonly associated with melanogenesis (melanin synthesis, melanosome maturation and transport).

In the preclinical study, repibresib reduced the expression of key pro-inflammatory biomarkers relevant to the pathogenesis of vitiligo and resulted in marked reduction in melanocyte loss. Repibresib produced a dose-dependent reduction in MMP-9 and soluble E-cadherin and substantially reduced the loss of melanin pigment in the basal layers of skin at the 0.1% and 1.0% concentrations. In addition, repibresib significantly upregulated WNT16, a member of the WNT family of genes, suggestive of increased melanogenesis. The WNT/β-catenin signaling pathway is known to be dysregulated in vitiligo and is believed to play a key role in melanocyte regeneration.

In additional in vitro assays using human CD8+ t-cells with repibresib:

- Repibresib was found to potently inhibit the differentiation of CD8+ T-cells that are known to induce both a cytotoxic and destabilizing effect on melanocytes, the primary cell type that produces melanin in skin.
- Repibresib inhibited the release of interferon-gamma which is a cytokine known to drive differentiation of CD8+ T-cells.

Plaque Psoriasis

We evaluated the impact of repibresib on Th17-mediated inflammation in an established preclinical animal model of psoriasis and an ex vivo human tissue study. T-helper 17, or Th17, cells are a CD4+ T-cell subset characterized by production of the inflammatory cytokine, interleukin-17, or IL-17. Th17 cells play an important role in the pathogenesis of a diverse group of immune-mediated diseases, including psoriasis, psoriatic arthritis, inflammatory bowel disease, and multiple sclerosis. In the animal model, depilated mice were topically dosed with imiquimod cream to induce a psoriasis phenotype over a 7-day induction phase. A further 7-day treatment phase evaluated three doses of repibresib (0.001%, 0.01% and 0.1% concentrations) compared to a highly potent topical corticosteroid (clobetasol propionate 0.05% cream) used as a positive control, and a vehicle control. An imiquimod-naive control group (healthy control group) was also included for vehicle treatment. In these studies, treatment with repibresib significantly reduced the expression of several key proinflammatory cytokines relevant to Th17-mediated autoimmune diseases. A dose-dependent improvement in the signs of inflammation was observed in repibresib treatment groups, and treatment with repibresib at all concentrations was well tolerated in the study.

Idiopathic Pulmonary Fibrosis

We evaluated an inhaled formulation of repibresib in an established mouse model of idiopathic pulmonary fibrosis. Lung fibrosis was induced in mice using a single intratracheal dose of bleomycin. Fibrosis was left to develop for seven days, and thoracic tomography images were obtained to stage fibrotic development. Animals were assigned to six treatment groups: untreated and unstimulated control, placebo, and one of four doses of repibresib (0.1, 0.2, 0.5, and 1.0 mg/mL), with six mice in each group. Each treatment group was dosed intratracheally every other day for 14 days. Changes in blood oxygen saturation, Ashcroft scoring (a standardized numerical scale used to quantify the extent of lung fibrosis in histological samples), lung hydroxyproline (a tissue biomarker for fibrosis), and volumetric lung function were assessed. Treatment

with repibresib at 0.5 mg/mL and 1 mg/mL resulted in statistically significant reductions in Ashcroft scores and levels of hydroxyproline compared to the placebo control group at Day 21. In addition, mean blood oxygen saturation for the repibresib 1 mg/mL group was 92.4% at Day 21, an 8.8% improvement compared to the placebo group (83.6%). Mean blood oxygen saturation for the untreated and unstimulated control group was 95.2%. Thoracic tomography revealed that repibresib treatment groups experienced a dose-dependent improvement in functional lung volume compared to the placebo control group.

Rheumatoid Arthritis

We conducted a preclinical study showing that intra-articular injections of repibresib resulted in significant inhibition of inflammation in a validated animal model of rheumatoid arthritis. In the preclinical study, inflammatory arthritis was induced in BALB/c mice. Each treatment group of seven mice was injected with either (i) an intra-articular dose of vehicle, (ii) an intra-articular dose of repibresib (with one of four concentrations ranging from 0.01 to 10 mg/kg), (iii) an intra-articular dose of dexamethasone (1 mg/kg) or (iv) a systemic dose of dexamethasone (1 mg/kg, via intraperitoneal injection). The intra-articular doses were administered on days 0, 3, 6 and 9 while the dexamethasone systemic injections were given daily beginning at day 0 through 11. Each animal treated with the intra-articular injections received the injection in the ankle of one rear paw. The untreated rear paw was assessed to evaluate any potential anti-inflammatory systemic effect. Treatment response was evaluated based on an assessment of paw thickening or swelling (in millimeters) and arthritis scoring based on a five-point composite severity scale of redness, swelling of the ankles and wrists, and paw thickness. Scoring in this model ranges from 0 (normal) to 4 (extensive signs and symptoms of arthritis).

Treatment with repibresib resulted in marked inhibition of paw thickening at the 1 and 10 mg/kg doses. At both doses, the inhibition of paw thickening was statistically significant in the treated paw relative to the untreated rear paw on Day 12 ($p<0.01$). In addition, limbs treated with repibresib at the 1 and 10 mg/kg dose levels had an average arthritis score of 0.57 and 0.67, respectively, or near normal. The arthritis score was significantly lower in the treated paw at both doses relative to the non-treated paws on Day 12 ($p<0.05$).

VYN202 — Oral BD2-Selective BET Inhibitor

VYN202 is an oral, small molecule BD2-selective BET inhibitor that has been designed to achieve potential class-leading potency and selectivity for BD2 vs. BD1. Systemic BET inhibitors have historically targeted both BD1 and BD2 less selectively, which we believe caused gastrointestinal toxicity and bone marrow suppressive effects like thrombocytopenia. By maximizing BD2 selectivity, we believe VYN202 may alleviate the toxicities observed by other less BD2-selective BET inhibitors in development for oncology and have the potential to be a potent, oral immunomodulator option for both acute control and chronic management of immune-mediated conditions, where the damaging effects of unrestricted inflammatory signaling activities are common.

Phase 1a SAD/MAD Clinical Trial

We have completed a Phase 1a SAD/MAD trial of VYN202 in healthy volunteers and announced positive data from this trial in December 2024. We observed that VYN202 had a favorable safety and tolerability profile with no drug-related adverse events historically associated with earlier generation, less BD-selective BET inhibitors. VYN202 also demonstrated robust pharmacodynamic activity including evidence of target engagement and inhibition of several inflammatory biomarkers relevant to immune-mediated disorders in ex vivo stimulation assays. In February 2025, we initiated a Phase 1b trial in adult subjects with moderate-to-severe plaque psoriasis. The Phase 1b trial is a randomized, double-blind, placebo-controlled trial to primarily evaluate the safety of VYN202 administered orally once a day across four cohorts (0.25 mg, 0.5 mg, 1 mg doses and placebo), with secondary objectives that include pharmacokinetics and preliminary evidence of efficacy via endpoints evaluating improvements from PASI scores after 12 weeks. We expect to enroll approximately 80 subjects with psoriasis and to report top-line results from the placebo-controlled trial by the end of 2025. Additionally, we anticipate that the data from the Phase 1b trial in psoriasis subjects will provide key insights into VYN202's potential activity across a range of immune-mediated diseases.

Preclinical Data in Multiple Indications

Plaque Psoriasis

We evaluated VYN202 in an established mouse model of psoriasis that was used earlier with repibresib gel (see above). After inducing a psoriasis phenotype in BALB/c mice, treatment was administered intraperitoneally with VYN202 doses, deucravacitinib (an allosteric TYK2 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis), or placebo. VYN202 and deucravacitinib at equivalent dosing resulted in comparable onset of action and efficacy. Mice receiving VYN202 3 mg/kg had approximately 95% mean reduction in PASI score from baseline by day 7 of treatment, which was consistent with the results in the deucravacitinib 3 mg/kg group. Treatment with VYN202 3 mg/kg reduced the expression of IL-17A, a major effector cytokine involved in the pathogenesis of psoriasis, by 93% compared to placebo. Treatment with VYN202 at all doses also resulted in a marked reduction of other disease-related cytokines (IL-1β, IL-6, IL-22, IL-23, and TNF-α) compared to the placebo group.

Rheumatoid Arthritis

We evaluated VYN202 in two preclinical models of rheumatoid arthritis. In a 21-day collagen-induced arthritis (CIA) model, signs and symptoms of inflammatory arthritis were induced in Lewis rats. Each treatment group orally received placebo, GSK620 (an early generation less BD2-selective BET inhibitor) at 10 mg/kg, or VYN202 at one of three different dose strengths (1, 3, or 10 mg/kg). Daily treatment with VYN202 10 mg/kg resulted in a 71% reduction in the overall signs and symptoms of rheumatoid arthritis at day 21 and a 79% lower paw volume (a measure of swelling) compared to mice receiving placebo. Of the animals treated with the highest dose of VYN202, 75% presented with normal joint histopathology at the end of the study, whereas animals treated with placebo experienced marked inflammatory cell infiltrate, granulation tissue, bone erosion and cartilage ulceration. The administration of VYN202 10 mg/kg also achieved a 98% lower expression of anti-collagen II antibody compared to placebo.

In a 21-day adjuvant-induced arthritis (AIA) model in Lewis rats, test animals were randomly assigned to 7 groups: two vehicle groups, dexamethasone, upadacitinib, and VYN202 at one of three different dose strengths (0.1, 1, or 10 mg/kg). All but one of the vehicle groups were induced with the adjuvant to replicate signs and symptoms of inflammation on the paws and joints of the animals. Induced animals were then orally administered either vehicle, reference compound or VYN202 doses for 15 consecutive days. Compared to the vehicle+adjuvant group, all strengths of VYN202 had a significant effect on inhibiting inflammation in the paws, comparable to the reference compound, upadacitinib. The highest concentration of VYN202 resulted in an approximately 88% reduction in paw volume compared to the vehicle group. Histopathology scores showed VYN202 had a significant effect on preventing ankle inflammation compared to the control group with VYN202 10 mg/kg having a 67% reduction compared to control and upadacitinib 10 mg/kg demonstrating a 56% reduction compared to control.

Manufacturing

We currently contract with third party manufacturers for all of our required raw materials, active ingredients and finished products for our preclinical studies and clinical trials for our product candidates. We currently have no plans to establish our own manufacturing capabilities and plan to continue to rely on third-party manufacturers for any future trials of our product candidates.

Together with contract manufacturing organizations ("CMOs"), we have developed the validation processes, methods, tests and/or controls that we believe are suitable for the manufacturing of our product candidates and for defining their properties. Development stage quantities of any products that we develop need to be manufactured in facilities and by processes that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we may seek approval. We require all of our CMOs to comply with these requirements and currently employ internal and external resources to manage our manufacturing contractors. The relevant manufacturers of our product candidates for our current preclinical and clinical trials have advised us that they are compliant with both the FDA's Good Laboratory Practices ("GLP") and the FDA's current Good Manufacturing Practice ("cGMP") guidances.

Development and License Agreements

Agreements with Tay

Evaluation and Option Agreement

In April 2021, we entered into an Evaluation and Option Agreement (the "Option Agreement") with Tay. Pursuant to the Option Agreement, Tay granted us an exclusive option to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's BET inhibitor compounds for the treatment of any disease, disorder or condition in humans. Pursuant to the Option Agreement, we agreed to use commercially reasonable efforts to develop and manufacture a product with a pan-BD BET inhibitor as its active ingredient, and Tay agreed to provide a mutually agreed data package and select a new chemical entity development candidate from its Oral BETi Compounds. We paid a $1.0 million non-refundable cash payment to Tay upon execution of the Option Agreement.

Under the terms of the Option Agreement, our option (the "Oral Option") with respect to the Oral BETi Compounds was to expire on June 30, 2022, but in June 2022, we and Tay entered into a letter agreement to extend the option term to February 28, 2023. In February 2023, we and Tay entered into an additional letter agreement pursuant to which the option term was further extended to April 30, 2023. We exercised the Oral Option for VYN202 on April 28, 2023 as described below. See "Part II — Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Development and License Agreements — Agreements with Tay Therapeutics — Evaluation and Option Agreement" for a discussion regarding payments made to Tay in connection with the extension of the term for the Oral Option.

License for Locally Administered Pan-BD BET Inhibitor Program (Repibresib)

In August 2021, we exercised our option with respect to the repibresib program and entered into a License Agreement (the "Repibresib License Agreement") granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion. We are required to use commercially reasonable efforts to develop and, if approved, commercialize such products. Pursuant to the Repibresib License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products. Pursuant to the Repibresib License Agreement, we may develop a product that contains or incorporates a specific BET inhibitor, whether alone or in combination with other active ingredients, in any form, formulation, presentation, or dosage, and for any mode of administration.

We made a $0.5 million cash payment to Tay in 2021 in connection with entering into the Repibresib License Agreement. Pursuant to the Repibresib License Agreement, we agreed to make cash payments to Tay upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed topical product in the United States of up to $15.75 million for all indications, of which $1.8 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products we commercialize under the Repibresib License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales of licensed products under the Repibresib License Agreement and the VYN202 License Agreement, subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Pursuant to the Repibresib License Agreement, we were granted a sublicense under certain intellectual property which was licensed to Tay by the University of Dundee ("Dundee") pursuant to a certain license agreement between Tay and Dundee effective as of July 24, 2020 and amended and restated on October 8, 2021 (the "Head License"). On February 13, 2025, Tay and Dundee entered into an agreement for the termination of the Head License and assignment of such intellectual property from Dundee to Tay. Upon

termination of the Head License, the Repibresib License Agreement was accordingly amended to reflect the assignment of the intellectual property to Tay upon its payment in full to Dundee. The amendment does not change any of Tay's or VYNE's rights or obligations under the Repibresib License Agreement, except that any obligations owed by VYNE to Dundee with respect to repibresib are now owed to Tay.

License for Selective BET Inhibitor Program (VYN202)

On April 28, 2023, we exercised the Oral Option and entered into a license agreement (the "VYN202 License Agreement") with Tay granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's Oral BETi Compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion, and shall use commercially reasonable efforts to develop and, if approved, commercialize such products. We may sublicense our rights to a third party without Tay's consent. Pursuant to the VYN202 License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products.

We made a cash payment of $3.75 million to Tay in connection with entering into the VYN202 License Agreement. Pursuant to the terms of the VYN202 License Agreement, we agreed to make cash payments to Tay of up to $43.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed oral product in the United States for all indications, of which $1.3 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products we commercialize under the VYN202 License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales of licensed products under the VYN202 License Agreement and the Repibresib License Agreement, subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Intellectual Property

Our intellectual property and proprietary technology are essential to the development of our product candidates. We are committed to protecting our intellectual property rights, core technologies and other know-how through a combination of patents, trademarks, domain names, trade dress, trade secrets, copyrights, non-disclosure and confidentiality agreements, common interest agreements to protect privileged confidential information, licenses, assignments of invention and other contractual arrangements with our employees, scientific advisors, consultants, partners, suppliers, customers and others. These agreements and rights may, however, be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets and other proprietary and confidential information may otherwise become known or be independently discovered by competitors. To the extent that our employees, scientific advisors, consultants, partners, or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our success will also depend at least in part on not infringing the proprietary rights of third parties. While we are diligent in our efforts to investigate proprietary rights of third parties, no search is completely exhaustive. For example, a relevant patent or published application could escape detection because of unusual terminology or use of terminology that is still evolving in developing technological fields. Also, databases used in the searches may not be entirely complete. It is uncertain whether the issuance of any third party patent would require us to alter our development strategies, alter our processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop our current and future product 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 derivation, interference or other proceedings in the United States Patent and Trademark Office ("USPTO") to determine derivation or priority of

invention. We may also have to participate in court proceedings or arbitration to defend and assert our rights. See "Item 1A. Risk Factors — Risks Related to Our Intellectual Property."

Our BET inhibitor patent portfolio is licensed in and/or is being developed by us and comprises or is derived from several PCT applications, various national applications and certain provisional applications.

As of December 31, 2024, our patent portfolio in relation to our repibresib program includes a granted patent in the United Kingdom, Indonesia, Israel, India, Mexico, and South Africa and pending compound and composition patent applications licensed by us from Tay. A PCT application covering the compound, which published as WO 2020/216779, was filed nationally in more than 15 jurisdictions, including the U.S., China, Europe, Eurasia, and Japan. Subject to being granted and payments of the appropriate maintenance fees, each patent will expire in 2040, without accounting for any potential patent term adjustment in the U.S. A PCT application covering methods of use, which published as WO 2023/081720, was filed nationally in ten jurisdictions, including the U.S., China, Europe, Eurasia, and Japan. Subject to being granted and payments of the appropriate maintenance fees, each patent will expire in 2042, without accounting for any potential patent term adjustment in the U.S. In addition, a PCT application, which published as WO 2024/220589, was filed nationally in ten jurisdictions, including the U.S., China, Europe, Eurasia, and Japan. Subject to being granted and payments of the appropriate maintenance fees, each patent will expire in 2042, without accounting for any potential patent term adjustment in the U.S. In addition, a PCT application, which published as WO 2024/220589, and a provisional application directed to various uses of repibresib have been filed. Subject to the PCT application being filed nationally, filing a non-provisional application, and these patent applications being granted and payments of the appropriate maintenance fees, each patent will expire in 2042 and 2044, respectively, without accounting for any potential patent term adjustment in the U.S.

As of December 31, 2024, our patent portfolio in relation to our VYN202 program includes a granted patent in the United Kingdom and pending compound and composition patent applications licensed by us from Tay. A PCT application covering the compound, which published as WO 2023/275542, was filed nationally in more than 15 jurisdictions, including the U.S., China, Europe, Eurasia and Japan. Subject to being granted and payments of the appropriate maintenance fees, each patent will expire in 2042, without accounting for any potential patent term adjustment in the United States. Two additional compound and composition PCT applications were also filed in relation to VYN202 and our oral BD2-selective BET inhibitor program exclusively licensed by us from Tay. Subject to these PCT applications being filed nationally, one of which published as WO 2024/018423, and the patent applications being granted and payments of the appropriate maintenance fees, the patents will expire in 2043, without accounting for any potential patent term adjustment in the United States. In addition, a provisional application directed to VYN202 method of use has been filed. Subject to filing a non-provisional and this patent application being granted and payments of the appropriate maintenance fees, this patent would expire in 2045, without accounting for any potential patent term adjustment in the United States.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. 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, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or by patent term extension, which compensates a patentee for delays at the FDA. The patent term of a European patent is 20 years from its filing date; however, unlike in the United States, the European patent does not grant patent term adjustments. The European Union does have a compensation program similar to patent term extension called supplementary patent certificate that would effectively extend the duration of protection of the product for up to five years. Obtaining a patent term extension in the United States or a supplementary patent certificate in the European Union is uncertain and will depend on eligibility and satisfying rigorous criteria in each jurisdiction.

Competition

Our drug development activities face, and will continue to face, intense competition from organizations such as pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies. Our drug development activities also face, and may continue to face, governmental actions designed to promote generic drug competition and lower prices. Any product candidate that we successfully develop and commercialize will compete with existing treatments, including those that may have achieved broad market acceptance, and any new treatment that may become available in the future.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, and preclinical and clinical development than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our development programs.

For vitiligo, our primary competitors include topical therapies such as generic and branded versions of calcineurin inhibitors, including ELIDEL, marketed by Bausch Health; OPZELURA, a topical JAK inhibitor marketed by Incyte Corporation; branded and generic versions of high potency steroids, including CLOBEX, marketed by Galderma Laboratories, LP; and other treatments including various lasers and ultraviolet light-based therapies. In addition, there are several prescription product candidates under development that could potentially be used to treat vitiligo and compete with repibresib gel, if approved, including but not limited to oral JAK inhibitors being developed by Incyte, Pfizer and AbbVie.

We intend to develop VYN202 for the treatment of various immune-mediated conditions. Our initial proof-of-concept indication is moderate-to-severe plaque psoriasis which is a competitive market. The psoriasis market includes several approved anti-IL-17 antibody therapies, including COSENTYX, marketed by Novartis; TALTZ, marketed by Eli Lilly; SILIQ, marketed by Bausch Health; and BIMZELX, marketed by UCB SA. Other classes of injectable biologics approved for use in indications for which IL-17 therapeutics are also approved include anti-IL-12/23 and anti TNFα monoclonal antibodies marketed by AbbVie, Sun Pharmaceutical Industries and Janssen Pharmaceuticals, among others. Furthermore, the oral PDE4 inhibitor, OTEZLA, marketed by Amgen, and oral TYK2 inhibitor, SOTYKTU, marketed by Bristol Myers Squibb, are approved for the treatment of psoriasis. In addition, we are aware of other oral therapeutic candidates including other TYK2 inhibitors, oral IL-17 inhibitors, and oral IL-23 inhibitors being developed by Takeda Pharmaceutical Company, Ventyx Biosciences, Eli Lilly, LEO Pharma, Janssen Pharmaceuticals, among others. We anticipate our second indication, subject to adequate levels of funding, will be rheumatoid arthritis which is also a competitive market. Medications for the treatment of rheumatoid arthritis include corticosteroids and disease-modifying anti-rheumatic drugs ("DMARDs"). DMARDs include (i) methotrexate, sulfasalazine, leflunomide and hydroxychloroquine, (ii) biologic DMARDs, and (iii) targeted synthetic DMARDs such as JAK inhibitors. These drugs are produced and sold, or are approved for marketing, by large pharmaceutical companies, including AbbVie, Amgen, Bristol Myers Squibb, Johnson & Johnson, UCB, Roche, Eli Lilly, and Pfizer. In addition, several other companies are developing drugs for the treatment of rheumatoid arthritis that, if approved, could compete with VYN202 if the indication is pursued and approved.

The commercial opportunity for our product candidates, if approved, could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drug we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than us, which could result in our competitors establishing a strong market position before our product candidates are able to enter the market.

Government Regulation

Our business is subject to extensive government regulation. Regulation by governmental authorities in the United States and other jurisdictions is a significant factor in our research and development activities.

Product approval process in the United States

Review and approval of drugs

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations. In general, new drug products require the submission of a New Drug Application ("NDA") and approval thereof by the FDA prior to being marketed in the United States. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions and enforcement actions brought by the FDA, the Department of Justice or other governmental entities. Possible sanctions may include the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

The process required by the FDA prior to marketing and distributing a new drug product in the United States generally involves the following:

- completion of laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice ("GLP") or other applicable regulations;
- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") requirements to establish the safety and efficacy of the proposed drug for its intended use;
- preparation and submission to the FDA of an NDA or supplemental NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product or components thereof are produced, to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites and the sponsor's clinical trial records to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and FDA review and approval of an NDA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and the potential requirement to conduct post-approval studies.

Preclinical studies

Preclinical studies include laboratory evaluation, as well as animal studies to assess the potential safety and efficacy of the product candidate. Preclinical safety tests must be conducted in compliance with the FDA's GLP regulations. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND which must become effective before clinical trials may be commenced.

Clinical trials in support of an NDA

Clinical trials involve the administration of an investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other

things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Clinical trials are typically conducted in three sequential phases, which, in some cases, may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- Phase 2: The drug is administered to a limited patient population to identify possible short-term adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Submission of an NDA to the FDA

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture, control and composition of the product, are submitted to the FDA as part of an NDA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act ("PDUFA") as amended, applicants are required to pay fees to the FDA for reviewing an NDA. These user fees, as well as the annual fees required for commercial manufacturing establishments and for approved products, can be substantial. Each NDA submitted to the FDA for approval is reviewed for administrative completeness and reviewability within 60 days following submission of the application. If found complete, the FDA will "file" the NDA, thus triggering a full review of the application. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within ten to twelve months; most NDAs for priority review drugs are reviewed in six to eight months. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process, and will not approve the product unless cGMP compliance is satisfactory at such facilities. The FDA may deny approval

of a NDA if applicable statutory or regulatory criteria are not satisfied, or it may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or may never be granted. If a product is approved, the approval will specify the indicated uses for which the product may be marketed in the United States pursuant to that NDA, may require that warning statements be included in the product labeling, may require that additional studies or trials be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or may impose other limitations. After evaluating the NDA and all related information, including any advisory committee recommendation, if applicable, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA will issue an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or non-clinical testing in a resubmission to the NDA in order for the FDA to reconsider the application. FDA has committed to reviewing such submissions in two or six months depending on the type of information included in the resubmission. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product.

Once a product is approved, marketing the product for other indicated uses or making certain manufacturing or other changes requires FDA review and approval of a supplemental NDA or a new NDA, which may require additional clinical data and review fees. In addition, further post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur at any time following approval. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including Fast Track designation, Breakthrough Therapy designation, Accelerated Approval, and Priority Review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Under the fast track program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a fast track drug concurrent with, or after, the filing of the IND for the product candidate. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. FDA may initiate review of sections of a fast track drug's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted.

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

products, are also eligible for rolling review of the NDA. Both fast track and breakthrough therapy products are also eligible for accelerated approval and/or priority review, if relevant criteria are met.

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions, or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated approval regulations are subject to prior review by FDA.

Once an NDA is submitted for a product intended to treat a serious condition, the FDA may assign a priority review designation if FDA determines that the product, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the current PDUFA agreement, for NDAs for new molecular entities, these six- and ten- month review periods are measured from the 60-day filing date rather than the receipt date, which typically adds approximately two months to the timeline for review from the date of submission. Most products that are eligible for fast track and/or breakthrough therapy designation are also likely to be considered appropriate to request and potentially receive a priority review. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, the manufacturer of an investigational drug for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on responding to requests for expanded access. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Post-approval requirements

Any drug products for which we receive FDA approval will be subject to continuing regulation by the FDA. Certain requirements include, inter alia, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information on an annual basis or more frequently for specific events, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among others, standards for direct-to-consumer advertising, prohibitions against promoting drugs for uses or patient populations that are not described in the drug's approved labeling, known as "off-label use," and other promotional activities, such as those considered to be false or misleading. Failure to comply with FDA requirements can have negative consequences, including the immediate discontinuation of noncomplying materials, adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies.

Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not encourage, market or promote such off-label uses. As a result, "off-label promotion" has formed the basis for litigation under the Federal False Claims Act ("FCA") violations of which are subject to significant civil fines and penalties. In addition, under the federal Physician Payments Sunshine Act, manufacturers of certain prescription products are required to disclose annually to the Centers for Medicare & Medicaid Services ("CMS") payments or transfers of value made to "covered recipients" and teaching hospitals, and ownership or investment interests held by covered recipients and their immediate family members. Reportable

payments and transfers of value may be direct or indirect, in cash or kind, for any reason, and are required to be disclosed even if the transfers are not related to an approved product. Failure to comply with the Physician Payments Sunshine Act could result in penalties up to $1.15 million per year.

The manufacturing of any of our product candidates, if approved, will be required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. The FDA's cGMP regulations require, among other things, quality control and quality assurance, as well as the corresponding maintenance of comprehensive records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments and list any products they make with the FDA and to comply with related requirements in certain states. These entities are further subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Discovery of problems with a product after approval may result in serious and extensive restrictions or other consequences for a product, manufacturer or holder of an approved NDA, as well as lead to potential market disruptions. These restrictions or consequences may include untitled or warning letters, recalls, suspension of a product until the FDA is assured that quality standards can be met, and continuing oversight of manufacturing by the FDA under a "consent decree," which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, or Phase IV testing, as well as REMS to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of approved products.

Pediatric trials and exclusivity

Even when not pursuing a pediatric indication, under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric trial plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric trials the applicant plans to conduct, including trial objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act.

Separately, in the event the FDA makes a written request for pediatric data relating to a drug product, an NDA sponsor who submits such data may be entitled to pediatric exclusivity. Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional 6 months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity.

Patent term restoration and extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, generally referred to as the "Hatch-Waxman Act," which permits an extension of the term of a patent for up to five years to compensate patent holders for marketing time lost while developing the product and awaiting government approval during

the FDA regulatory review. The basis for the patent extension is the regulatory review period, which is basically composed of two parts, a testing phase and an approval phase, less a reduction, if any, in either part for a period time where there was a finding of lack of due diligence. The restoration period granted can be up to one-half the time between the effective date of an IND and the submission date of an NDA (testing phase), plus the time between the submission date of an NDA and the ultimate approval date (approval phase). Patent term extension cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product may be extended, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 days of FDA approval. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals and the scope of the extended patent is limited to the approved drug. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA. The term of a patent which claims a human drug product, a method of using the product, or a method of manufacturing the product may potentially be extended if it satisfies the various conditions including that it is the first permitted commercial marketing or use of the drug.

Review and approval of drug products outside the United States

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval process varies from country to country and can be subject to uncertainties, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Regulation in the European Economic Area

In the European Economic Area ("EEA") which is composed of the Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA").

There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products that contain a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application ("MAA") is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Under the accelerated procedure the standard 210 days review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Prior to obtaining an MA in the EEA, applicants have to demonstrate compliance with all measures included in a Pediatric Investigation Plan ("PIP") approved by the EEA regulatory agency, covering all subsets of the pediatric population, unless the EEA regulatory agency has granted (1) a product-specific waiver, (2) a class waiver or (3) a deferral for one or more of the measures included in the PIP.

In the EEA, upon receiving a MA, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the EEA from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EEA regulatory agencies to be a new chemical entity, and products may not qualify for data exclusivity.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product and any product candidates for which we obtain regulatory approval. In the United States and other markets, sales of any product, and any product candidates for which we receive regulatory approval for commercial sale, will depend in part on the availability of coverage and adequate reimbursement from third party payors. Third party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication.

Third party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. A payor may not consider a product to be medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved, or that other payors will similarly provide similar coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

CMS administers the Medicaid drug rebate program, in which pharmaceutical manufacturers pay quarterly rebates to each state Medicaid agency. Generally, for branded prescription drugs marketed under NDAs, manufacturers are required to rebate the greater of 23.1% of the average manufacturer price or the difference between such price and the best price during a specified period (subject to inflation). An additional rebate for products marketed under NDAs is payable if the average manufacturer price increases at a rate higher than inflation, and other methodologies apply to new formulations of existing drugs. In addition, the Patient Protection and Affordable Care Act (the "ACA") revised certain definitions used for purposes of calculating the rebates, including the definition of "average manufacturer price." Various state Medicaid programs have implemented voluntary supplemental drug rebate programs that may provide states with additional manufacturer rebates in exchange for preferred status on a state's formulary or for patient populations that are not included in the traditional Medicaid drug benefit coverage.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies or trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, and particularly on prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced

markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Reform

In March 2010, the then President of the United States signed one of the most significant healthcare reform measures in decades, the ACA. The ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the pharmaceutical industry. This comprehensive legislative overhaul was expected to extend coverage to approximately 36 million previously uninsured Americans. The ACA also requires the pharmaceutical industry to share in the costs of reform by increasing Medicaid rebates and expanding Medicaid rebates to cover Medicaid managed care programs, among other things. The ACA also includes funding of pharmaceutical costs for Medicare patients in excess of the prescription drug coverage limit and below the catastrophic coverage threshold.

There have been executive, judicial, Congressional, and political challenges and amendments to certain aspects of the ACA. For example on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that there will be additional health reform measures. It is unclear how any such challenges, if any, and other efforts to modify, repeal and replace the ACA will impact the ACA.

Further, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices, including several recent U.S. Congressional inquiries and federal and state legislation designed to, among other things, increase drug pricing transparency, expedite generic competition, review relationships between pricing and manufacturer patient assistance programs, and reform government program drug reimbursement methodologies. For example, the IRA, among other things (i) directs the U.S. Department of Health and Human Services ("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 (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting 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 drugs covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced, allowing an agency to grant a compulsory license on a privately owned patent to third parties, if the invention was developed with federal funding and the agency finds that certain statutory criteria apply. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. We anticipate that these and other healthcare

reform efforts will continue to result in additional downward pressure on drug pricing, particularly in light of recent U.S. Presidential and Congressional elections. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Healthcare Laws

Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with healthcare providers, third party payors and other customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced price items and services. The intent standard under the federal Anti-Kickback Statute was amended by ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, under the ACA, 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 federal civil FCA. Additionally, many states have similar laws that apply to their state health care programs as well as private payors. Violations of the federal or state anti-kickback laws can result in exclusion from federal and state health care programs and substantial civil and criminal penalties;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment from Medicare, Medicaid or other federal healthcare programs, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Even where pharmaceutical companies do not submit claims directly to payors, they can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or paying a kickback that results in a claim for items or services. In addition, activities relating to the reporting of wholesaler or estimated retail prices for pharmaceutical products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for such products, and the sale and marketing of such products, are subject to scrutiny under this law. Private individuals or whistleblowers can bring FCA "qui tam" actions on behalf of the government and may share in amounts recovered. Proof of intent to deceive is not required to establish liability under the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program, including any third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false statements relating to healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, which imposes privacy, security, transmission and breach reporting obligations, including mandatory contractual terms, with respect to individually

identifiable health information including Protected Heath Information ("PHI"), upon "covered entities" subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates and covered subcontractors that perform services on their behalf that involve individually identifiable health information, including PHI. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Other federal and state laws, such as the Federal Trade Commission Act, also impose requirements with respect to individuals' personal information;

- the federal Physician Payments Sunshine Act requires certain manufacturers of prescription drugs, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value to physicians, dentists, optometrists, podiatrists, chiropractors, certain other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to physicians; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply more broadly than their U.S. federal analogues, such as to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state laws that require drug companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to drug pricing or payments and other transfers of value to healthcare providers or marketing expenditures and pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation ("GDPR") which became effective in May 2018); state 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; and state laws related to insurance fraud in the case of claims involving private insurers.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or consent decree, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

Environmental, Health and Safety Matters

We are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions governing, among other things, (i) the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; and (ii) chemical, air, water and ground contamination, air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If we fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third party claims, including those relating to personal injury (including

exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities which were previously permitted.

The operations of our subcontractors and suppliers are also subject to various laws and regulations relating to environmental, health and safety matters, and their failure to comply with such laws and regulations could have a material adverse effect on our business and reputation, result in an interruption or delay in the development or manufacture of our product candidates, or increase the costs for the development or manufacture of our product candidates.

Human Capital Resources

As of December 31, 2024, we had a total of 13 full-time employees. All of our employees are located in the United States. From time to time, we also retain independent contractors and consultants to support our organization. We believe our internal R&D capabilities coupled with our third-party R&D consultants are sufficient to execute our clinical development strategy in a cost-effective manner. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Attracting, retaining and developing employees from a wide range of backgrounds to support our research, development and clinical activities is an integral part of our human capital strategy and we believe we offer competitive compensation (including salary, incentive bonus, and equity) and benefits packages.

Corporate Information

We were incorporated in October 2011 as a Delaware corporation under the name Tigercat Pharma, Inc. We changed our name to VYNE Therapeutics Inc. in September 2020, following the merger between Foamix Pharmaceuticals Ltd. ("Foamix") and Menlo Therapeutics Inc. (our predecessor company) ("Menlo") in March 2020.

We are a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act. As such, we are eligible to take advantage of certain reduced or scaled disclosure requirements available to smaller reporting companies. See the risk factor captioned "We are eligible to report as a 'smaller reporting company,' and as a result of the reduced reporting requirements applicable to such companies, our securities may be less attractive to investors" for more information.

Our principal executive offices are located at 685 Route 202/206 N., Suite 301, Bridgewater, NJ 08807. Our website is www.vynetherapeutics.com. We may use our website to comply with disclosure obligations under Regulation FD. Therefore, investors should monitor our website in addition to following its press releases, filings with the SEC, public conference calls, and webcasts. The contents of our website are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

ITEM 1A — RISK FACTORS

In conducting our business, we face many risks that may interfere with our business objectives. Some of these risks could materially and adversely affect our business, financial condition and results of operations. In particular, we are subject to various risks resulting from changing economic, political, industry, business and financial conditions. The risks and uncertainties described below are not the only ones we face. You should carefully consider the following factors and other information in this Annual Report on Form 10-K. If any of the negative events referred to below occur, our business, financial condition and results of operations could suffer. In any such case, the trading price of our common stock could decline.

Risks Related to Development of Our Product Candidates

Our business is substantially dependent on the successful development of our BET inhibitor product candidates.

Our current development pipeline consists of our BET inhibitor product candidates, repibresib gel (VYN201) and VYN202, which we are developing for the treatment of immuno-inflammatory diseases. The success of our business is dependent on our successful development and/or our ability to pursue strategic initiatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize, these product candidates.

Our ability to successfully progress these candidates may be hampered for many reasons, including:

- a product candidate may in a preclinical study or clinical trial be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other proprietary rights;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third party payors, if applicable;
- creation of intellectual property rights, such as patents, which are necessary to protect our interests in a product candidate, can be challenging in relation to pharmaceutical formulations and their uses with known active pharmaceutical ingredients and generally used combinations of inactive ingredients approved by the FDA;
- intellectual property rights, such as patents, which are necessary to protect our interests in a product candidate, may be difficult to obtain or unobtainable or if obtained may be difficult to enforce or unenforceable; and
- intellectual property rights, such as patents, may fail to provide adequate protection, may be challenged and one or more claims may be revoked or the patent may be held to be invalid.

The development of these new chemical entities carries even greater risk and a higher probability of failure. Our failure to successfully develop our product candidates will have a material adverse effect on our business and financial condition.

Our product candidates are in clinical development and may fail in development or suffer delays that materially and adversely affect their viability. If we are unable to complete development of, or commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Each of our product candidates is in clinical development. We initiated a Phase 2b trial for repibresib gel in nonsegmental vitiligo in June 2024 and a Phase 1b trial for VYN202 in February 2025. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

We may not have the resources to advance the development of our product candidates if we experience issues that delay or prevent their regulatory approval, or our ability to commercialize them, including:

- preclinical study results, including toxicology data, may show the product candidate to be less effective than desired or to have harmful or problematic side effects;

- negative or inconclusive results from our clinical trials, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- our third-party manufacturers' inability to successfully manufacture our product candidates in sufficient quantities or at all;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials;
- delays in enrolling patients in our clinical trials;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated costs of our clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that no longer make a product candidate economically feasible;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology; and
- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

Our inability to advance or complete the development of our product candidates, or significant delays in doing so, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may encounter delays in enrolling patients and successfully completing clinical trials for our product candidates and may be delayed in, or prevented from, commencing such trials due to factors that are largely beyond our control.

We have in the past experienced and may in the future experience delays in completing clinical trials and in commencing future clinical trials. Clinical trials can be delayed or aborted for a variety of other reasons, including delay or failure to:

- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which may be subject to extensive negotiation and vary significantly among different CROs and trial sites;
- obtain approval from an institutional review board ("IRB") at each site;
- enlist an adequate number of suitable patients to participate in a trial;
- have patients complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of the product candidate for use in clinical trials.

Patient enrollment is also a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and

patients' perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including any new drugs or treatments that may be approved for the indications we are investigating.

We may be delayed in commencing our clinical trials if the FDA, or other applicable regulatory authority, finds deficiencies or requests additional information with respect to our INDs. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

For example, our Phase 1a trial for VYN202 was initially placed on a clinical hold. Following submission of additional nonclinical study data, the hold was lifted and we proceeded to conduct the trial, which was completed in the fourth quarter of 2024. We may also encounter delays if a clinical trial or a clinical trial site is suspended or terminated by us, the IRB of the institutions in which such trials are being conducted, by the trial's data safety monitoring board, or by the FDA. Such authorities may suspend or terminate one or more of our clinical trials due to a number of factors, including our failure to conduct the clinical trial in accordance with relevant regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in carrying out or completing any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Drug development is very expensive, time-consuming and uncertain. Our preclinical studies and clinical trials may fail to adequately demonstrate the safety and efficacy of our current or any future product candidates, or serious adverse side effects could be identified. Any of these outcomes could prevent or delay regulatory approval and commercialization or harm our ability to pursue strategic alternatives for our product candidates.

Drug development is very expensive, time-consuming and difficult to design and implement, and its outcome is inherently uncertain, particularly as it relates to new chemical entities. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through preclinical studies and clinical trials that a product candidate is both safe and effective for use in the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. The clinical trials for these product candidates may take significantly longer than expected to complete. In addition, we, any partner with which we may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may prevent, suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- lack of effectiveness of any product candidate during clinical trials or the failure of a product candidate to meet specified endpoints;
- discovery of serious or unexpected side effects experienced by trial participants, toxicities or other safety issues;
- slower than expected rates of subject recruitment and patient enrollment in clinical trials resulting from numerous factors, including the prevalence of clinical trials for our competitors for their product candidates treating the same indication;
- difficulty in retaining subjects who have initiated participation in a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;

- difficulty in obtaining IRB approval for studies to be conducted at each site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper dosing;
- failure of our CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; and
- insufficient data to support regulatory approval.

If we experience delays in the completion of, or if we terminate, any of our future clinical trials, our business, financial condition, operating results and prospects would be adversely affected.

In addition, product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate. For example, some systemic BET inhibitors have been linked to tolerability issues, particularly in the gastrointestinal tract and bone marrow suppressive effects like thrombocytopenia. If our product candidates are associated with side effects in preclinical studies and/or clinical trials or have characteristics that are unexpected, a number of potentially significant negative consequences could result, including:

- our development costs could increase;
- we may need to abandon development activities or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective;
- we may need to abandon the development or limit the further development of our product candidates, including in various populations and for certain indications;
- we could be sued and held liable for harm caused to patients;
- our reputation may suffer;
- regulatory authorities may require that we suspend, discontinue, or limit our clinical trials based on safety information;
- regulatory authorities may withdraw approval to market such product;
- regulatory authorities may require additional warnings on the product labeling;
- a medication guide outlining the risks of such side effects for distribution to patients may be required; and

- market acceptance of any products that do obtain regulatory approval could be inhibited.

Any of these events could prevent us from pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize the particular product candidate and could significantly harm our business, results of operations and prospects.

New chemical entities may require more time and resources for development, testing and regulatory approval.

Each of our BET inhibitor programs involves a novel therapeutic approach and new chemical entity, requires significant further research and development and regulatory approvals and is subject to the risks of failure inherent in the development of products based on innovative approaches. New chemical entities derived from our InhiBET platform are molecules that have not previously been approved and marketed as therapeutics. As a result, the product candidates from our InhiBET platform may face greater risk of unanticipated safety issues or other side-effects, or may not demonstrate efficacy. For example, systemic BET inhibitors have historically targeted both BD1 and BD2 less selectively, causing gastrointestinal toxicity and bone marrow suppressive effects like thrombocytopenia. While we believe VYN202's high selectivity for BD2 may alleviate the therapeutic limiting toxicities observed by other less BD2-selective BET inhibitors, we may need to spend more time and greater resources verifying any toxicity associated with VYN202. Accordingly, the regulatory pathway for our new chemical entities may be more demanding and take a longer period of time.

Results obtained in preclinical studies and completed clinical trials may not predict success in later clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and any future clinical trials that we may conduct may not demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates in any indication. Companies in the biopharmaceutical industry frequently suffer significant setbacks in later-stage clinical trials, even after achieving promising results in preclinical studies or earlier clinical trials. Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Any of these events could prevent us from pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize a particular product candidate and could significantly harm our business, results of operations and prospects.

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

We may publicly disclose top-line or preliminary data from our clinical trials based on a preliminary analysis of then-available data. In that case, the results and related findings and conclusions remain subject to change following a complete analysis of all data related to the trial. We also make certain assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Accordingly, top-line and preliminary data should not be considered complete and should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available. Adverse differences between interim, top-line or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could

impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular program, product candidate or our business.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We have a limited history as a clinical-stage biopharmaceutical company developing product candidates for immuno-inflammatory conditions, which may make it difficult to assess our future viability.

Our team has limited experience in developing drugs for the treatment of immuno-inflammatory conditions. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer history of being a clinical-stage biopharmaceutical company focused on developing drugs in this area. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

We may spend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have chosen to initially evaluate repibresib gel in the treatment of nonsegmental vitiligo, and we intend to initially evaluate VYN202 in the treatment of moderate-to-severe plaque psoriasis and, subject to adequate levels of funding, moderate-to-severe adult-onset rheumatoid arthritis. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through partnerships, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We face competition from entities that have developed or may develop product candidates for the diseases addressed by our product candidates, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs is extremely competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments, such as OPZELURA (ruxolitinib) cream, include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to

develop product candidates. There is intense and rapidly evolving competition in the biotechnology and biopharmaceutical fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on therapeutics for autoimmune diseases. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent. Our success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing therapeutics. Our commercial opportunity and success will be reduced or eliminated if competing therapeutics are safer, more effective, or less expensive than the therapeutics we develop.

We have not obtained regulatory approvals to market our product candidates, and we may be delayed in obtaining or fail to obtain such regulatory approvals and to commercialize these product candidates.

The process of developing, obtaining regulatory approval for and commercializing our other product candidates is long, complex, costly and uncertain, and delays or failure can occur at any stage. Furthermore, the research, testing, manufacturing, labeling, marketing, sale and distribution of drugs are subject to extensive and rigorous regulation by the FDA. We are not permitted to market any of our product candidates in the United States until we receive approval of the applicable NDA from the FDA. To gain approval of an NDA or other equivalent regulatory approval, we must provide the FDA with clinical data and other information that demonstrates the continued safety and efficacy of the product for the intended indication.

Even if we believe our clinical trials were successful, the FDA may require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may require us to expend more resources than we have available. It is also possible that additional studies we conduct may not be considered sufficient by the FDA to provide regulatory approval.

If any of these outcomes occur, we would not receive approval for our other product candidates and may need to discontinue the development of such product candidates.

Even if our product candidates receive marketing approval, we may continue to face future developmental and regulatory difficulties. In addition, we are subject to government regulations and we may experience delays in obtaining required regulatory approvals to market our proposed product candidates.

Even if we receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of additional costly post-approval clinical trials or REMS to monitor the safety or efficacy of the product, which could negatively impact us by reducing revenues or increasing expenses, and cause the product not to be commercially viable. Absence of long-term safety data may further limit the approved uses of products.

The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Furthermore, any such approved product will remain subject to extensive regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping.

If we fail to comply with the regulatory requirements of the FDA, or if we discover previously unknown problems with any approved commercial products, manufacturers or manufacturing processes, we could be subject to administrative or judicially imposed sanctions or other setbacks, which could require us to take corrective actions, including to:

- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- refuse to approve pending applications or supplements to applications;
- suspend any ongoing clinical trials;

- suspend or withdraw marketing approval;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- seize or detain products;
- ban or restrict imports and exports;
- issue warning letters or untitled letters;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- refuse to approve pending applications or supplements to applications.

In addition, various aspects of our operations are subject to federal, state or local laws, rules and regulations, any of which may change from time to time. Costs arising out of any regulatory developments could be time-consuming and expensive and could divert management resources and attention and, consequently, could adversely affect our business operations and financial performance.

We rely on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs, to assist us in conducting our clinical trials for our other product candidates. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's and other regulatory authorities' good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of clinical trial participants are protected. If we or our CROs fail to comply with applicable GCPs, or if our CROs do not adequately monitor the conduct of medical institutions, clinical investigators, contract laboratories or other third parties involved in our clinical trials, the clinical data generated in our clinical trials may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical trials before approving any marketing applications.

If the third parties or consultants that assist us in conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, or for any other reason, our clinical trial results may be negatively impacted and/or we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible. As a result, our clinical trials may be extended, delayed or terminated or may need to be repeated. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for the product candidates being tested in such trials, and will not be able to, or may be delayed in our efforts to, successfully commercialize these product candidates.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delays.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. For example, we are evaluating a gel formulation of repibresib in our Phase 2b trial rather than an ointment, which was used in our completed Phase 1b trial. Such modifications carry the risk that they will not achieve these intended objectives, and may also require additional testing, FDA notification or FDA approval. Any of these changes could cause our product candidates to perform differently and affect the results of planned

clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates.

Risks Related to Our Financial Position and Need for Capital

We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain marketing approval for and/or commercialize our product candidates or identify and consummate transactions with third-party partners to further develop our product candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates from discovery through preclinical and clinical development. In addition, we may not be able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates, and our product candidates, if approved, may not achieve commercial success. Furthermore, we incur and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. We also expect to add additional personnel to support our operational plans and strategic direction as needed.

As of December 31, 2024, we had $61.5 million in cash, cash equivalents and marketable securities. We believe these resources will enable us to fund our operating expenses and capital expenditure requirements for a period of at least 12 months from the date of this Annual Report on Form 10-K based on our current operating assumptions. These assumptions may prove to be wrong, however, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional products or product candidates, and changes in regulation.

Our future capital requirements depend on many factors, including:

- milestone payments associated with our development programs;
- the number and development requirements of the product candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our product candidates;
- costs associated with manufacturing and supplying our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we in-license or acquire additional product candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the impact on the timing of our preclinical studies, on the recruitment, enrollment, conduct and timing of our clinical trials, and on our business, due to external or macroeconomic factors;
- our headcount and associated costs as we expand our research and development infrastructure;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates, and earn revenue from such arrangements; and
- the ongoing costs of operating as a public company.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to revise our operating plan in order to:

- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates (including any planned clinical trials to pursue additional indications for other product candidates).

If we raise additional capital through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new debt securities or equity securities may have a preference over our common stock. In addition, if we issue warrants or preferred stock in connection with our financing activities, such securities may include terms that are unfavorable to our stockholders, including anti-dilution provisions and other preferences. In addition, any holders of preferred stock may receive preferential voting rights that are superior to the voting rights of holders of our common stock. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures or specified financial ratios, any of which could restrict our ability to operate our business.

We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future, which could harm our future business prospects.

We have historically incurred substantial net losses, including net losses of $39.8 million and $28.5 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $731.2 million. We expect our losses to continue as we continue to devote a substantial portion of our resources to our research and development efforts. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and shareholders' equity. Because of the numerous risks and uncertainties associated with our research and development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop product candidates and conduct preclinical studies and clinical trials;
- initiate and continue research and development, including preclinical, clinical and discovery efforts for any future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates that may successfully complete clinical development;
- add personnel to support our product candidate development;
- hire and retain additional personnel, such as clinical, quality control, scientific, and administrative personnel;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we currently expect.

SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3.

SEC regulations limit the amount that companies with a public float of less than $75 million may raise during any 12-month period pursuant to a shelf registration statement on Form S-3, referred to as the baby shelf rules. As of the filing of this Annual Report on Form 10-K, we are subject to such rules. Under these rules, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3, including our at-the-market equity offering program, will be limited to one-third of the aggregate market value of the shares of our common stock held by our non-affiliates. Therefore, we will be significantly limited in the amount of proceeds we are able to raise by selling shares of our common stock using our Form S-3 until such time as our public float exceeds $75 million. Furthermore, if we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by the SEC staff.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

We currently expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. On March 1, 2024, we entered into a sales agreement with Cowen and Company, LLC, as sales agent ("Cowen") under which we may offer and sell, from time to time at our sole discretion, shares of our common stock through Cowen in an at-the-market offering having an aggregate offering price up to $50.0 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation, anti-dilution protection or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, we may opportunistically seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are otherwise unable to raise additional funds through equity or debt financings when needed, we may be required to delay, reduce or terminate our product development or grant rights to third parties to develop product candidates that we would otherwise prefer to develop ourselves.

Other Risks Related to Our Business and Financial Operations

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

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or eventual commercialization of our product candidates in the future. We may enter into arrangements on a selective basis, depending on the merits of retaining certain rights ourselves compared to entering into selective collaboration arrangements with pharmaceutical or biotechnology companies internationally and possibly also in the United States. Any such collaboration arrangements may not be successful.

In addition, the success of future collaboration arrangements that we may enter into will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

When entering collaboration arrangements, we are subject to a number of risks, including:

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial or abandon products, repeat or conduct new clinical trials, require a new formulation of products for clinical testing, may decide not to pursue development and commercialization of a product or

product candidate or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- any safety issues or adverse side effects that result from trials conducted by a collaborator will adversely impact our ability to obtain regulatory approval for our product candidates;
- any failure by a collaborator to demonstrate efficacy of a product candidate in its clinical trials could decrease the perceived likelihood of success for our clinical trials;
- disagreements between parties to a collaboration arrangement regarding clinical development matters may lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement;
- collaboration arrangements are complex and time-consuming to negotiate, document and implement, and we may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements;
- collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party and any such termination or expiration would adversely affect us financially and could harm our business reputation;
- collaboration agreements may be terminated and, if terminated, may result in delays or the need for a new collaborator or additional capital to pursue further development of our product candidates in certain markets;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- terms of any collaborations or other arrangements that we may establish may not be favorable to us;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- we will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators;
- collaborators may not properly use, manage, maintain or defend our confidential information and intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop such intellectual property and they may be able to develop such products without us;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- adverse regulatory determinations or other legal action may interfere with the ability of a collaborator to conduct clinical trials or other development activity;
- one or more collaborators may be subject to regulatory or legal action resulting from the failure to meet healthcare industry compliance requirements in the conduct of clinical trials; and
- collaboration arrangements could be adversely impacted by changes in collaborators' key management personnel and other personnel that are administering collaboration agreements.

We are subject to various risks and uncertainties arising out of the completed divestiture of our commercial business, any of which could materially and adversely affect our business and operations, and our stock price.

We completed the sale of our prior commercial business in January 2022. Pursuant to the terms of the Asset Purchase Agreement entered into in connection with the purchase of that business by Journey Medical

Corporation ("Journey"), we are eligible to receive sales milestone payments of up to $450.0 million in the aggregate upon the achievement of specified levels of net sales on a product-by-product basis, beginning with annual net sales exceeding $100.0 million. In addition, we are entitled to receive certain payments from any licensing or sublicensing of the assets by Journey outside of the United States. Under the terms of the agreement, Journey does not have any diligence obligations to achieve any such net sales milestones, and we can provide no assurance that such milestones will ever be met. Furthermore, Journey may decide not to license or sublicense the assets in any territory outside of the United States, in which case we would not receive any additional related payments. If any of the foregoing events occur, we will not realize all of the benefits of the sale.

In addition, we are still subject to potential liabilities relating to our historical commercial business operations that were subject to the Asset Purchase Agreement. Under the terms of the Asset Purchase Agreement, we retained and are responsible for historical liabilities of the commercial business operations based on events occurring prior to the sale other than those liabilities expressly assumed by Journey. For example, we remain liable for payment of product sales provisions, such as distribution fees and trade discounts and allowances, rebates, chargebacks and other discounts and product returns. See "Part II — Item 8. Financial Statements — Note 2 — Significant Accounting Policies — Revenue Recognition — Product Sales Provisions." We are also obligated to indemnify Journey against certain potential liabilities and for breaches of certain representations, warranties and covenants under the agreement up to certain caps, and those liabilities may be set off against any future payments owed to us by Journey. In addition to direct expenditures for damages, settlement and defense costs, there is the possibility of adverse publicity as a result of any such claims, any of which could have a material adverse effect on our business and stock price. In addition, we remain subject to potential investigation or inquiry by regulatory authorities with respect to our legacy commercial business operations, which could result in additional distraction to our management and could ultimately result in further liabilities.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products could impair our ability to grow our business.

We may in-license, acquire and develop additional product candidates. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate is lengthy and complex. Other companies, including some with substantially greater financial and other resources may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party product candidates, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Additionally, we may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

We may engage in strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.

We may in-license and acquire product candidates or engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including out-licensing, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example,

these transactions entail numerous potential operational and financial risks, including:

- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects.

We may decide not to continue developing any of our product candidates at any time during development or of any of our products after approval, which would reduce or eliminate our potential return on investment for those product candidates or products.

We have in the past decided and may again in the future decide to discontinue the development of any of our product candidates in our pipeline or not to continue to commercialize any approved product. We may discontinue development of other product candidates for a variety of reasons, such as the appearance of new technologies that make our product less commercially viable, resource allocation management, an increase in competition from generic or other competing products, changes in or failure to comply with applicable regulatory requirements, the discovery of unforeseen side effects during clinical development or after the approved product has been marketed or the occurrence of adverse events at a rate or severity level that is greater than experienced in prior clinical trials. If we discontinue a program in which we have invested significant resources, we will receive a limited return on our investment and we will have missed the opportunity to have allocated those resources to other product candidates in our pipeline that may have had potentially more productive uses.

Supply interruptions may disrupt the availability of our product candidates and cause delays in conducting preclinical or clinical activities.

We depend on a limited number of manufacturing facilities to manufacture our product candidates. Numerous factors could cause interruptions in the supply or manufacture of our product candidates, including:

- timing, scheduling and prioritization of production by our contract manufacturers or a breach of our agreements by our contract manufacturers;
- labor interruptions;
- insufficient raw and intermediate materials necessary for production;
- changes in our sources for manufacturing;
- the timing and delivery of shipments;
- our failure to locate and obtain replacement suppliers and manufacturers as needed on a timely basis;
- conditions affecting the cost and availability of raw materials, including inflationary factors; and

- business interruptions resulting from geopolitical actions, including war, such as the current Russia-Ukraine war and Israel-Hamas war, and terrorism, outbreak of a contagious disease, or natural disasters including earthquakes, typhoons, floods and fires.

Furthermore, the primary manufacturer of the active pharmaceutical ingredient ("API") in our product candidates is located in China. Certain Chinese biotechnology companies and contract manufacturing organizations may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations. Therefore, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines.

Production of product is necessary to perform preclinical activities and clinical trials and successful registration batches are necessary to file for approval to commercially market and sell product candidates. Delays in obtaining clinical material or registration batches could adversely impact our clinical trials and delay regulatory approval for our product candidates.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2024, we had federal and state net operating loss carryforwards of $343.4 million and $53.6 million, respectively, of which $44.3 million will begin to expire in 2031 for federal and $53.6 million will begin to expire in 2040 for state purposes. As of December 31, 2024, we had federal research and development tax credit carryforwards of $7.2 million which will begin to expire in 2031. We have no state research and development tax credit carryforwards.

Portions of these net operating loss and tax credit carryforwards could expire unused and be unavailable if we do not generate sufficient taxable income prior to their expiration. U.S. federal net operating losses incurred in the taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the ability to utilize such federal net operating loss carryforwards to offset taxable income is limited to 80% of our current year taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change, by value, in its equity ownership by significant stockholders over a three-year period) the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or tax liability may be limited. We have not completed a 382 study through December 31, 2024, however, we may have experienced ownership changes in the past, including in connection with the 2020 merger between Menlo (our predecessor company) and Foamix. In addition, our private placement transaction in November 2023 likely resulted in an ownership change for purposes of Section 382. We may also experience ownership changes in the future as a result of the subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn taxable income, our ability to use our net operating loss and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

The Israeli Tax Authority may disagree with our conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

In December 2020, we initiated a voluntary liquidation of our Israeli subsidiary in order to consolidate the ownership of our intellectual property. In connection with the liquidation, the intellectual property and other assets owned by our Israeli subsidiary were assigned to us. Based on our analysis, we notified the Israeli Tax Authority that the gains realized by our Israeli subsidiary from the transfer of its assets to us were offset by net operating losses and that the liquidation did not result in tax in Israel under Israeli tax law. In the event that the Israeli Tax Authority does not agree with our analysis, we may be subject to a material tax

liability. In addition, we may incur additional costs associated with defending our position. Any such outcome may have a material adverse effect on our financial results.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully execute our strategy.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management. The loss of services of any of these individuals could delay or prevent the successful preclinical and clinical development of our product pipeline.

Competition for qualified personnel in the pharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We may need to hire additional personnel as we expand our clinical development activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

We may become subject to lawsuits or investigations that could have a material adverse impact on our business, results of operations and financial condition.

From time to time and in the ordinary course of our business, we may become involved in various lawsuits, in addition to product liability lawsuits and lawsuits to protect and enforce our intellectual property. These lawsuits may include claims initiated by our third-party collaborators, suppliers, manufacturers, former employees, contractors or vendors and claims related to the sale of securities and related disclosure. In addition, we may become involved in an investigation concerning, or indirectly related to, our business activities, including our previous commercial activities. All such lawsuits and investigations are inherently unpredictable and, regardless of the merits of the claims, litigation may be expensive, time-consuming and disruptive to our operations and distracting to management. If resolved against us, such lawsuits could result in excessive verdicts, injunctive relief or other equitable relief that may affect how we operate our business. Similarly, if we settle such lawsuits, it may affect how we operate our business. Future court decisions, alternative dispute resolution awards, business expansion or legislative activity may increase our exposure to litigation and regulatory investigations. In some cases, substantial non-economic remedies or punitive damages may be sought. Although we maintain liability insurance coverage, including director and officer insurance with liability coverage limits, such coverage may not cover any particular verdict, judgment or settlement that may be entered against us, or our officers and directors, and such coverage may not prove to be adequate or such coverage may not continue to remain available on acceptable terms or at all. If we incur liability that exceeds our insurance coverage or that is not within the scope of the coverage in lawsuits brought against us, it could have a material adverse effect on our business, results of operations and financial condition.

If our information technology systems or those of third parties upon which we rely or our data are, or were, compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequence.

In the ordinary course of our business, we and the third parties upon which we rely process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). Despite the implementation of security measures, our information technology systems and infrastructure, and those of our current and any future partners, contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or in non-encrypted portable media or storage devices.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information

technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. Remote work 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, including working at home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) 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. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could cause damage or destroy assets, compromise business systems, result in proprietary information, trade secrets and other sensitive information being altered, lost, stolen, or published and may result in loss of intellectual property and in employee or third-party information being compromised, or otherwise disrupt business operations. For example, the loss of manufacturing records or 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our current and any future product candidates could be delayed.

Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs, distributors, prescribers, pharmacies and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws

may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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 operating results.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption and ultimately delaying our development activities. For example, inflation rates, particularly in the United States and United Kingdom, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Additionally, global commerce has experienced periods of volatility and interruption following the invasion of Ukraine by Russia in February 2022 and the escalation of conflict in the Middle East in October 2023. In early 2025, the U.S. government also began imposing tariffs on certain foreign products, including products from China, which may lead to retaliatory tariff policies from other nations and result in increased costs of conducting our business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and geopolitical and financial market conditions could adversely impact our business.

Risks Related to Government Regulation

We are subject to various U.S. federal, state, local and foreign health care fraud and abuse laws, including anti-kickback, self-referral, false claims and fraud laws, health information privacy and security, and transparency laws, and any violations by us of such laws could result in substantial penalties or other consequences including criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal, state, local and foreign health care fraud and abuse laws pertaining to our business, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers, patients and third-party payors are subject to scrutiny under these laws. These laws may impact, among other things, our potential sales, marketing, patient assistance and education programs. We may also be subject to patient information privacy and security regulation by both the federal government, states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully offering, soliciting, receiving, or paying remuneration directly or indirectly, in cash or in kind to induce or reward either the referral of an individual for, or the purchase, order or recommendation of goods or services for which payment may be made in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services.

The intent standard under the federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it, in order to have committed a violation. In addition, the ACA provides 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 FCA. Additionally, many states have similar laws that apply to their state health care programs as well as private payors. Violations of the federal or state anti-kickback laws can result in exclusion from federal and state health care programs and substantial civil and criminal penalties;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the FCA, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment from Medicare, Medicaid or other federal healthcare programs, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. Even where pharmaceutical companies do not submit claims directly to payors, they can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, marketing products of sub-standard quality, or, as noted above, paying a kickback that results in a claim for items or services. In addition, activities relating to the reporting of wholesaler or estimated retail prices for pharmaceutical products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for such products, and the sale and marketing of such products, are subject to scrutiny under this law. For example, several pharmaceutical and other healthcare companies have faced enforcement actions under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Private individuals or "whistleblowers" can bring FCA "qui tam" actions on behalf of the government and may share in recovered amounts. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Proof of intent to deceive is not required to establish liability under the civil False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program, including any third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making false statements relating to healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information held by certain healthcare providers, health plans and healthcare clearinghouses, known as "covered entities," and "business associates." Among other things, HITECH made certain aspects of HIPAA's rules (notably the Security Rule) directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, and their covered subcontractors. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. The Department of Health and Human

Services Office for Civil Rights ("OCR") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes. The OCR has increased both its efforts to audit HIPAA compliance and its level of enforcement, with one penalty amounting to $16 million. In addition, according to the United States Federal Trade Commission ("FTC") failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act ("FTCA") 15 USC § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule;

- the federal Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of prescription drugs, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as nurse practitioners and physicians assistants) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, Section 6004 of the ACA requires annual reporting of information about drug samples that manufacturers and authorized distributors provide to physicians; and
- analogous state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, and other states' laws addressing the pharmaceutical and healthcare industries, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and in some cases that may apply regardless of payor, *i.e.*, even if reimbursement is not available; state laws that require drug companies to comply with the industry's voluntary compliance guidelines (the PhRMA Code) and the applicable compliance program guidance promulgated by the federal government (HHS-OIG) or otherwise prohibit or restrict gifts or payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require drug manufacturers to report information related to drug pricing or payments and other transfers of value to healthcare providers or marketing expenditures and pricing information; and state laws related to insurance fraud in the case of claims involving private insurers.

These and similar laws may be subject to amendment or reinterpretation, and implementing regulations may be revised or reinterpreted, in ways that may significantly affect our business. State and federal authorities have aggressively targeted pharmaceutical companies for alleged violations of these fraud and abuse laws based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws or regulations that apply to us, we may be subject to significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, debarment from contracting with the U.S. government, injunctions and private qui tam actions brought by individual whistleblowers in the name of the government. Companies targeted in such actions have, among other consequences, paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements that severely restrict the manner in which they conduct their business, including the requirement of additional reporting and oversight obligations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be

challenged under one or more of these laws. Responding to investigations, enforcement actions and litigation can be time-and resource-consuming and can divert management's attention from the business. Any such investigation, action, litigation or settlement could increase our costs or otherwise have an adverse effect on our business and reputation. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

We and third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

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, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information. The data processing activities related to our work subject us and the third parties with whom we work to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services.

Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA"), (collectively, "CCPA") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law, and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

When our employees and personnel use generative artificial intelligence ("AI") technologies to perform their work, the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Healthcare reforms by governmental authorities and related reductions in pharmaceutical pricing, reimbursement and coverage by third party payors may adversely affect our business.

We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third party coverage of any future products and how much or under what circumstances healthcare providers will prescribe or administer our products, if approved.

In both the United States and other countries, sales of our products, if approved, will depend in part upon the coverage and adequate reimbursement from third party payors, which include governmental authorities, managed care organizations and other private health insurers. Third party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. A payor may not consider a product to be medically necessary or cost-effective. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved, or that other payors will similarly provide similar coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs.

Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. Any reduction in reimbursement that results from federal legislation or regulation may also result in a similar reduction in payments from private payors, as private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

Significant developments that may adversely affect pricing in the United States include the enactment of federal healthcare reform laws and regulations. Changes in the healthcare system enacted as part of healthcare reform in the United States, as well as the increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, may result in increased pricing pressure by influencing, for instance, the reimbursement policies of third party payors. While healthcare reform legislation, such as the ACA, may have increased the number of patients who are expected to have insurance coverage for our product candidates, provisions such as the assessment of a branded pharmaceutical manufacturer fee and an increase in the amount of rebates that manufacturers pay for coverage of their drugs by Medicaid programs may have an adverse effect on us. It is uncertain how current and future reforms in these areas will influence the future of our business operations and financial condition.

Since its enactment, there have been judicial, Congressional and political challenges and amendments to certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, if any, and additional reform measures of the second Trump administration will impact the ACA.

Although we cannot predict the full effect on our business of the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, any future products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer any products we market in the future. This could materially and adversely affect our business by reducing our ability to generate revenues, raise capital, obtain additional licensees, and market our products, if approved. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of certain products under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. For example, the IRA, among other things (i) directs the U.S. Department of Health and Human Services ("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 (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates under Medicare Part B and 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 drugs covered under Part D for price negotiation in 2025. Each year thereafter, more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for

Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, individual states in the United States are also increasingly passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

It is likely that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for a pharmaceutical manufacturer's products or additional pricing pressure.

Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of our product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any of our product candidates. For example, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, inter alia, require:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could adversely affect our business and our financial results.

We and our contract manufacturers are subject to significant regulation with respect to manufacturing of our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

We and the contract manufacturers for our product candidates are subject to extensive regulation. Some components of a finished drug product used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product and product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of regulatory applications on a timely basis and where required, must adhere to the FDA's or other regulator's good laboratory practices and cGMP regulations enforced by the FDA or other regulator through facilities inspection programs. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product and potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates

or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA or other marketing approval of the products may not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other regulators can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in supply. The number of manufacturers with the necessary manufacturing capabilities is limited. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical timelines.

These factors could cause the delay of clinical studies, regulatory submissions, or required approvals of any future products, and cause us to incur higher costs. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure, validate and obtain approval of one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenues.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, and such delays could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We are subject to various U.S. and foreign anti-bribery and anti-corruption laws, and any violations by us of such laws could result in substantial penalties.

The U.S. Foreign Corrupt Practices Act ("FCPA"), and similar worldwide anti-bribery and anti-corruption laws, generally prohibit companies and their intermediaries from directly or indirectly offering, making or authorizing improper payments or the provision of anything of value to government officials for the purpose of obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books

and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Our business involves the use of hazardous materials and we and our third party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third party subcontractors' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including key components of our product candidates, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials are stored at our and our subcontractors' facilities pending their use and disposal.

Despite our efforts, we cannot eliminate the risk of contamination. This could cause an interruption of our development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our subcontractors and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case and there may be risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations.

Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Sanctions and other trade control laws create the potential for significant liabilities, penalties and reputational harm.

We may be subject to national laws as well as international treaties and conventions controlling imports, exports, re-export and diversion of goods, services and technology. These include import and customs laws, export controls, trade embargoes and economic sanctions, denied party watch lists and anti-boycott measures (collectively "Customs and Trade Controls"). Applicable Customs and Trade Controls are administered by the U.S. Treasury's Office of Foreign Assets Control (OFAC), other U.S. agencies, Israel's Ministry of Finance, and other agencies of other jurisdictions where we do business. Customs and Trade Controls relate to a number of aspects of our business, including most notably the sales of API as well as the licensing of intellectual property. Customs and Trade Controls has been the subject of increasing focus and activity by regulatory authorities, both in the United States and elsewhere, in recent years. Compliance with Customs and Trade Controls may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, Customs and Trade Controls may prohibit the provision of certain products and services to countries, governments, and persons targeted by sanctions. Although we have policies and procedures designed to address compliance with Customs and Trade Controls, actions by our employees, by third-party intermediaries or others acting on our behalf in violation of relevant laws and regulations may expose us to liability and penalties for violations of Customs and Trade Controls and accordingly may have a material adverse effect on our reputation and our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If our efforts to obtain, protect or enforce our patents and other intellectual property rights related to any of our product candidates are not adequate, we may not be able to compete effectively and we otherwise may be harmed.

Our success depends in part on our ability to obtain and maintain patent protection and other intellectual property rights and to utilize trade secret protection for our intellectual property and proprietary

technologies, our product candidates and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection, trademarks, domain names, trade dress, copyright, confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to our programs. Limitations on the scope of our intellectual property rights may limit our ability to defend our product candidates and to prevent third parties from designing around such rights and competing against us. Other parties may compete with us, for example, by independently developing or obtaining competing compounds and formulations and methods of manufacture that design around our various patent claims, or by using formulations from expired patents, but which may contain the same active ingredients, and or by opposing our applications or seeking to invalidate our patents. In addition, other parties may seek to impede us or limit our ability to operate, and or seek to compete with us, for example, by filing patent applications directed to methods of manufacture of our compounds, directed to methods of use of our compounds, and or directed to formulations for use with our compounds.

The pending patent applications in relation to repibresib gel and VYN202 are primarily licensed in from Tay and are subject to the terms and conditions of the respective licenses. If we were unable to comply with the license terms, we could be at risk of potentially forfeiting the licenses and rights to these pending patent applications, which could revert back to the licensors, and we would then no longer be able to pursue these programs.

Our ability to file, prosecute and obtain issued patents in the US and in key foreign jurisdictions and the expiration dates of such patents, if granted, will limit our ability to profit from the commercialization of our product candidates, if approved, as may challenges to our patent applications and claims. Furthermore, any disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, there may be an invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a party were to prevail on a legal assertion of invalidity and/or unenforceability against our intellectual property related to one or more of our product candidates, we would lose at least part, and perhaps all, of the patent protection on such products or product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Our pending patent applications may not issue, or the scope of the claims of patent applications that do issue may be too narrow or inadequate to provide or protect a competitive advantage. Even if these patents do successfully issue, third parties may challenge the validity, enforceability or scope of such granted patents or any other granted patents we own or license, which may result in such patents being narrowed, invalidated, or held unenforceable.

We have in-licensed intellectual property necessary to develop our BET inhibitor product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights.

We have in-licensed our BET inhibitor compounds from Tay. Our arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if our counterparts fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell BET inhibitor products that are covered by such intellectual property.

Since 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 licensor were the first to (i) file any patent application related to our product candidates or (ii) conceive and invent any of the inventions claimed in our patents or patent applications or in our licensed in patents or patent applications.

The United States utilizes a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third

party that files a patent application in the USPTO under the first-to-file system before us could be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party.

Other patent laws limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. The USPTO Patent Trial and Appeal Board (PTAB) applies the same claim construction standard applied by civil courts under 35 USC §282(b) in *IPR*, post-grant review, and the transitional program for covered business method patents proceedings. The impact this may have in practice on the use and outcome of USPTO proceedings is uncertain. PTAB proceedings continue to be a developing and uncertain area of practice and law. Because of lower costs and the fact that USPTO statistics indicate that a high rate of challenged claims are being invalidated in these USPTO procedures, they may continue to be a popular and effective means of challenging patents.

Even where patent, trade secret and other intellectual property laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke actions or counterclaims against us, and our competitors have intellectual property of their own, some of which include substantial patent portfolios. An unfavorable outcome could have a material adverse effect on our business and could result in the challenged patent(s) or one or more of claims being interpreted narrowly or invalidated, or held not to be infringed, or one or more of our patent applications may not be granted.

We also rely on trade secret protection and confidentiality agreements to protect our know-how, data and information e.g., prior to filing patent applications and during the period before they are published. We additionally rely on trade secret protection and confidentiality agreements to protect proprietary know-how that we consider may be maintained as a trade secret rather than the subject of a patent application. We further rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. We additionally rely on trade secret protection and confidentiality agreements to protect proprietary inventions and related know-how before patent applications are filed and published. We also enter into and rely on, where appropriate, common interest agreements to protect privileged confidential information.

In an effort to protect our trade secrets and other confidential information, we incorporate confidentiality provisions in all our employees' agreements and require our consultants, contractors and licensees to which we disclose such information to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that confidential information, as defined in the agreement and disclosed to the individual by us during the course of the individual's relationship with us, be kept confidential and not disclosed to third parties for an agreed term. These agreements, however, may not provide us with adequate protection against accidental or improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could significantly affect our competitive position and we could lose our trade secrets, or they could become otherwise known, or be independently discovered by our competitors. Although we make efforts to protect our trade secrets and other confidential information we cannot be certain that all parties that gain access to our proprietary information, or who may be involved in the development of our intellectual property have entered into written confidentiality agreements, or that such agreements will be sufficiently protective, or that they will not be breached. Also, to the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Additionally, others may independently develop the same or substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information. Any of the foregoing could deteriorate our competitive advantages, undermine the trade secret and contractual protections afforded to our confidential information and have material adverse effects on our business. We rely on information technology and access to the internet. Loss of material on servers or the cloud, disruptions and or breaches of cybersecurity could deteriorate our competitive advantages, undermine the trade secret and contractual protections afforded to our confidential information and have material adverse effects on our business.

Changes in U.S. or foreign patent law and practice could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other companies in the markets in which we participate, our success is heavily dependent on intellectual property, particularly patents. The strength of patents in the pharmaceutical field involves complex legal and scientific questions and moreover in the United States and in many foreign jurisdictions patent policy, practice and case law continues to evolve and change and the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. This uncertainty includes changes to the patent laws through one or more of legislative action to change statutory patent law, rule changes and practice directions issued by National Patent Offices, or court action that may reinterpret, limit or expand on existing law in ways affecting the scope or validity of granted patents and what may be claimed in pending applications. Particularly in recent years in the United States, there have been several major legislative developments and court decisions that have affected patent laws and how they are applied in significant ways and there may be more developments in the future that may weaken or undermine our ability to obtain patents or to enforce our existing and future patents. Additionally, new guidelines are issued by the USPTO and by the FDA from time to time which can impact patent practice in the pharmaceutical industry in significant ways. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

If we infringe or are alleged to infringe or otherwise violate intellectual property rights of third parties, our business could be harmed.

Our research and development activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of topical and oral drugs have developed and may continue to develop large portfolios of patents and patent applications relating to our business. In particular, there are patents and pending patent applications held by third parties that relate to new compounds that act as pan-BD BET inhibitors and also those that relate to BD2-selective BET inhibitors, as well as to methods of manufacture and methods of use for indications we are pursuing, or are considering to pursue with our repibresib and VYN202 product candidates. There may be granted patents with claims that could be asserted against us in relation to such products or product candidates. There may also be granted patents held by third parties that may be infringed or otherwise violated by our other product candidates and activities, and we do not know whether or to what extent we may be infringing or otherwise violating third party patents. There may also be third party patent applications, some of which may not yet have been published, which if approved and granted as patents may be asserted against us in relation to our product candidates or activities. Patent applications can take years to issue and there may be applications that are pending and in the course of prosecution claims may change or be added and there may be patents and claims of which we are unaware that may later issue with claims that might be infringed by commercializing a product or product candidate. We may fail to identify applications and granted patents that may be asserted against us in relation to our product candidates or activities. Searches and analyses undertaken may miss or not uncover all potential and future threats. It should be noted in this regard that no search is completely exhaustive. For example, a relevant patent or published application could escape detection because of unusual terminology or use of terminology that is still evolving in developing technological fields. Also, databases used in the searches may not be entirely complete. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages and legal fees. These third parties could include non-practicing entities that have no relevant products or revenue. Further, if a patent infringement suit were brought against us, we could be temporarily or permanently enjoined or otherwise forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both and may limit us in other ways, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a

product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been and there currently is substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. Such litigation can be very expensive, and the cost burden of intellectual property litigation may impact on our other activities. In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, review, re-examination or other post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or any future products. In some jurisdictions, third party observations or pre-grant oppositions may be filed, for example in Europe, India and Israel. A third party may initially sometimes choose to submit exploratory observations or oppositions in one or more foreign jurisdictions prior to commencing proceedings in the United States, where the costs could be higher. The cost and burden to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings and their outcome could impair our ability to compete in the marketplace and impose a substantial financial burden on us, and may further have an adverse effect on our ability to raise funds to pursue research and development activities and clinical trials. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, several of our employees were previously employed at universities or other pharmaceutical companies, including potential competitors. While we take steps to prevent our employees from using the proprietary information or know-how of others that is not in the public domain or that has not already been independently developed by us earlier, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed, confidential information, intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we do not succeed with respect to any such claims, in addition to paying monetary damages and possible ongoing royalties, we may lose valuable intellectual property rights or personnel.

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

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance or late compliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. Similarly, compliance with relevant provisions is required to maintain trademark applications and registrations, while non-compliance can, likewise, result in loss of rights. In some circumstances, however, we may allow intellectual property rights to become abandoned, such as, where they are no longer considered of interest.

We instruct foreign agents including translation agencies to prepare and file applications in multiple jurisdictions. If an agent omitted to file the patent application and where appropriate the translation timely in accordance with the national provisions or failed to translate the application accurately and or introduced errors into the translation we may suffer loss of rights and we may not discover this until after the filing deadline has passed.

If we are unable to secure trademark registrations, secure appropriate domain names and protect our trademarks or trade dress from infringement, our business prospects may be harmed.

We own trademarks that identify "VYNE" and "VYNE Therapeutics" and have submitted applications to register these trademarks in the United States and in various other jurisdictions. Similarly, we own

trademarks that represent our leaf logo which can be and is used with the "VYNE" and "VYNE Therapeutics" trademarks and our VYNE identity and have submitted applications to register these leaf trademarks in the United States and in some other jurisdictions. We have selected the trademark InhiBET for use in relation to our BET inhibitor programs and we have applied to register the trademark in Israel and the United States. We have not yet selected or submitted trademark applications for a proposed commercial trade name for any of our product candidates or activities in the United States or elsewhere and failure to do so and secure registrations could adversely affect our business.

Applications for trademarks may be rejected during prosecution and we may be unable to overcome such proceedings or we may have to narrow or limit the scope of the applications or rely on a lower level of protection provided by common law unregistered trademark rights, if any. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings or we may have to narrow or limit their scope.

In the United States, the FDA evaluates and must approve any trademark we propose to use with products for which we seek regulatory approval regardless of whether we have registered it, or applied to register it, as a trademark. The FDA review will include an evaluation of potential for confusion with other product names. Selecting a product trademark can be an expensive process. If the FDA objects to proposed trademarks this could delay regulatory approval and we may be required to expend significant resources in an effort to identify suitable substitutes that would qualify as a registerable trademark, not infringe any existing third party trademark rights and be acceptable to the FDA.

Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third party infringers or violators may be unduly expensive and time-consuming, and the outcome may be an inadequate remedy.

Additionally, we have rights in certain domain names associated with our business. If others seek to use domain names closely similar and we are not successful in asserting and protecting our rights it could adversely affect our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third party infringement or unauthorized use. This can be expensive and burdensome, particularly for a company of our size, as well as time-consuming. In addition, in an infringement proceeding, a court may decide that a patent or certain patent claims of ours are not valid, or are unenforceable, or may refuse to stop the other party or parties from using the technology or method at issue on the grounds that our patent claims do not cover its or their technology or method or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation review, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or licensees. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful in any proceedings (domestic or foreign, litigation or USPTO or foreign patent office or other proceedings) they may result in substantial costs and distraction to our management. Moreover, proceedings may be appealed and obtaining a final resolution can take a long time and substantial resources. We may not be able, alone or with our licensors or licensees, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount and extent of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or

proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed and this may be so even if the results are not considered material.

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

Filing, prosecuting and defending patents on product candidates in all or most countries throughout the world would be prohibitively expensive. We primarily file patent applications in the United States and may file in some other selected jurisdictions on a case-by-case basis. In general, we may on a case-by-case basis file national applications more narrowly in respect of patent applications directed to compositions of matter and methods of treatment than for those concerning new chemical entities. As a result, our intellectual property rights in countries outside the United States are generally significantly less extensive than those in the United States. In addition, the laws of some foreign countries and jurisdictions, particularly of certain developing countries and jurisdictions, do not protect intellectual property rights to the same extent as federal and state laws in the United States, and these countries and jurisdictions may limit the scope of what can be claimed, and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may seek to exploit our technologies in jurisdictions where we have a patent application filed, for example, as it has not been allowed or if allowed where they intend to challenge one or more granted claims. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but protection and enforcement is not as strong or effective as that in the United States. These products may compete with our product candidates, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Moreover, competitors or others may raise legal challenges to our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. In some foreign jurisdictions the patent system, for example, may not allow certain types of claims that are acceptable in the United States or may only accept claims of a narrower scope. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and methods of treatment, which could make it difficult for us to stop the infringement of our patents or of other intellectual property protection, misappropriation of intellectual property rights, or marketing of competing products in violation of our proprietary rights generally. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In such countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims or issue proceedings against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Further, third parties may prevail in their claims against us, which could potentially result in the award of injunctions or substantial damages against us. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws and practice.

We may not be able to enforce covenants not to compete under applicable employment laws.

We generally enter into non-competition agreements as part of our employment agreements with our employees. These agreements generally prohibit our employees, if they cease working for us, from competing

directly with us or working for our competitors or clients for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefiting from the expertise our former employees or consultants developed while working for us.

Risks Related to the Ownership of Our Common Stock

The trading price of the shares of our common stock is volatile, and stockholders could incur substantial losses.

Our stock price is volatile. The stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, our stock price, and the stock price of many other public companies, experienced a period of high volatility in recent years. Such volatility resulted in rapid and substantial increases and decreases in our stock price that may or may not be related to our operating performance or prospects. As a result of this volatility, stockholders may not be able to sell their common stock at or above the price paid for the shares. In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies, including us, following periods of volatility in the market prices of these companies' common stock. If we are subject to future lawsuits we would be subject to additional risks as described in "We may become subject to lawsuits or investigations that could have a material adverse impact on our business, results of operations and financial condition" above. The market price for our common stock may be influenced by many factors, including:

- our ability to successfully develop our product candidates;
- announcement of technological innovations or new products by us;
- development of technological innovations or new competitive products by others;
- announcement of clinical trial results or any other clinical data results we announce;
- the commencement or enrollment of our ongoing clinical trials or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- announcements of clinical trials results by competitors;
- adverse results from, delays in or termination of clinical trials;
- any delay in our regulatory filings and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse regulatory decisions, including failure to receive regulatory approval of product candidates;
- failure to achieve a publicly announced milestone;
- unanticipated serious safety concerns;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- future capital raising transactions;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;

- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- the loss of or failure to obtain material intellectual property rights;
- our sale or proposed sale, or the sale by our significant stockholders, of our common stock or other securities in the future;
- general political and economic conditions;
- the sentiment of the retail investor community; and
- other events or factors, many of which are beyond our control.

Consequently, the current market price of our common stock may not be indicative of future market prices, and we may be unable to sustain or increase the value of an investment in our common stock.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of at least 66⅔% of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chief executive officer or the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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 directors and executive officers may be subject to litigation for a variety of claims or disputes. 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 Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We 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.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain directors' and officers' liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and could harm our business, results of operations, and financial condition. Further, a stockholder's investment may be harmed to the extent that we pay the costs of settlement and damage awards against our directors and executive officers as required by these indemnification provisions.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain exclusive forum selection clauses, which could limit our stockholders' ability 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 the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, our amended and restated bylaws

provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, against us, our officers, directors, employees or underwriters. These choice of forum 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, which may discourage such lawsuits against us and our directors, officers and other employees.

Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We are eligible to report as a "smaller reporting company," and as a result of the reduced reporting requirements applicable to such companies, our securities may be less attractive to investors.

We are eligible to report as a smaller reporting company. For as long as we continue to be eligible to report as a "smaller reporting company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting, as well as reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements.

We may take advantage of these reporting exemptions until we are no longer a smaller reporting company. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of common stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed fiscal year and the market value of our shares of common stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our securities less attractive because we rely on any of these exemptions, there may be a less active trading market for our securities and the price of our securities may be more volatile.

General Risk Factors

An active public market for our common stock may not be sustained.

Although our common stock is quoted on the Nasdaq Capital Market, an active trading market for our common stock may not be sustained. The lack of an active market may impair the ability of holders of our common stock to sell their shares at the time they wish to sell them or at a price that they consider reasonable. The lack of an active market may also reduce the fair market value of our common stock, and may cause the trading price of our common stock to be more volatile. The lack of an active market may contribute to volatility of our stock price and impair our ability to raise capital.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the analysts, or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline. If our operating results fail to meet the forecast of analysts, our stock price will likely decline.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our directors, officers or holders of a large number of

shares intend to sell shares, could reduce the market price of our common stock. Moreover, certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered and intend to continue to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We do not currently intend to pay dividends on our common stock, and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, stockholders are not likely to receive any dividends on their common stock for the foreseeable future. Since we do not intend to pay dividends, stockholders' ability to receive a return on their investment will depend on any future appreciation in the market value of our common stock. Our common stock may not appreciate or even maintain the price at which our holders have purchased it.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market ("Nasdaq"). The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing each year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that we incur substantial additional professional fees and internal costs within our accounting and finance functions and that we expend significant management efforts.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant additional legal, accounting and other costs, as compared to the costs we incurred as a private company. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We may experience significantly increased general and administrative expenses and a diversion of management's time and attention from our primary business operations if we are required to invest significant resources to comply with new and evolving laws, regulations and standards. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

We are subject to risks related to climate change in the long term.

We are subject to transitional and physical risks related to climate change. Transitional risks include, for example, a disorderly global transition away from fossil fuels that may result in increased energy prices; customer preference for low or no-carbon products; stakeholder pressure to decarbonize assets; or new legal or regulatory requirements that result in new or expanded carbon pricing, taxes, restrictions on greenhouse gas emissions, and increased greenhouse gas disclosure and transparency. These risks could increase operating costs, including the cost of our electricity and energy use, or other compliance costs. Physical risks to our operations include water stress and drought; flooding and storm surge; wildfires; extreme temperatures and storms, which could impact trials, increase costs, or disrupt supply chains. Our supply chain is likely subject to these same transitional and physical risks and would likely pass along any increased costs to us. We do not anticipate that these risks will have a material financial impact to the company in the near term.

Governmental authorities, non-governmental organizations, customers, investors, employees, and other stakeholders are increasingly sensitive to environmental, social and governance (ESG) matters, such as equitable access to medicines and vaccines, product quality and safety, diversity, equity and inclusion, environmental stewardship, support for local communities, value chain environmental and social due diligence, corporate governance and transparency, and addressing human capital factors in our operations. In addition, governments and the public expect companies to report on our business practices with respect to human rights, responsible sourcing and environmental impact, as well as the actions of our third-party contractors and suppliers around the world. This focus on ESG matters may lead to new expectations or requirements that could result in increased costs associated with research and development of our products. Our ability to compete could also be affected by changing customer preferences and requirements, such as growing demand for companies to establish validated Net Zero emissions targets or offer more sustainable products. If we do not meet, or are perceived not to meet, stakeholder expectations in key ESG areas, we risk negative stakeholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, or other negative impacts on our business and operations. While we monitor ESG matters, we cannot be certain that we will manage such matters successfully, or that we will successfully meet the expectations of investors, employees, consumers, governments and other stakeholders.

ITEM 1B — UNRESOLVED STAFF COMMENTS

None.

ITEM 1C — 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 and confidential information that is proprietary, strategic or competitive in nature ("Information Systems and Data").

We retain a chief information consultant and a third-party security management vendor to help identify, assess and manage our cybersecurity threats and risks. These partners identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods, including, for example, automated tools, cybersecurity threat subscription services, threat report analysis, internal and external audits, and threat and vulnerability assessments.

Depending on the 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 policy, route risk assessments, data encryption, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring, penetration testing, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, our security management partners work with our Chief Financial Officer to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. In addition, our Chief Financial Officer evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, professional services firms, cybersecurity software providers and penetration testing firms. These third-parties also provide application and hosting services. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes risk assessments and audits for each vendor and a review of each such vendor's written security program.

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

Governance

Our Board addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats. Our cybersecurity risk assessment and management processes are implemented and maintained by our Chief Financial Officer who oversees the work performed by our information security consultant and third-party managed service provider. Our information security consultant has over 40 years of experience in pharmaceutical information technology, including many years as a chief information officer.

Our Chief Financial Officer is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. Our Chief Financial Officer, with support from our information security partners, is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the Chief Financial Officer and legal department. Our Chief Financial Officer works with our incident response team to help mitigate and remediate cybersecurity incidents of which they are notified. In addition, our incident response policy includes reporting to the Audit Committee for certain cybersecurity incidents.

The Audit Committee receives periodic reports from our Chief Financial Officer concerning our significant cybersecurity threats and risk and the processes we have implemented to address them. The Audit Committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

ITEM 2 — PROPERTIES

Our executive offices in the United States are located in Bridgewater, New Jersey. We currently lease approximately 5,755 square feet of office space under lease agreements that expire on September 30, 2025.

We believe that our current facilities are adequate to meet our current needs, and that suitable additional alternative space will be available in the future on commercially reasonable terms for our potential growth.

ITEM 3 — LEGAL PROCEEDINGS

From time to time, we may become involved in litigation or other legal proceedings relating to claims that we consider to be arising from the ordinary course of our business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business.

ITEM 4 — MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5 — MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is listed on the Nasdaq Capital Market under the symbol "VYNE."

On February 8, 2023, our board of directors approved, and on February 10, 2023 we effected, a 1-for-18 reverse stock split of our outstanding shares of common stock. No fractional shares were issued in connection with the reverse stock split, and in lieu thereof, each stockholder holding fractional shares was entitled to receive a cash payment (without interest or deduction) in an amount equal to such stockholder's respective pro rata share of the total net proceeds from our transfer agent's sale of all fractional shares at the then-prevailing prices on the open market. The par value of each share of common stock remained unchanged. A proportionate adjustment was also made to the maximum number of shares issuable under our equity incentive plans.

Unless noted, all references to shares of common stock and per share amounts contained in this Annual Report on Form 10-K have been retroactively adjusted to reflect the 1-for-18 reverse stock split.

Holders of Common Stock

As of February 4, 2025, there were 8 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered 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 in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in the section entitled "Item 1A. Risk Factors".

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing differentiated therapies to treat chronic inflammatory and immune-mediated conditions with high unmet need.

We have exclusive worldwide rights to research, develop and commercialize products containing small molecule bromodomain and extra-terminal domain ("BET") inhibitors for the treatment of any disease, disorder or condition in humans, which we licensed from Tay Therapeutics Ltd., formerly known as In4Derm Ltd ("Tay"). BET proteins are epigenetic enablers of transcription that regulate the expression of specific

genes. Each BET protein consists of two bromodomains ("BD1" and "BD2") and one end terminal ("ET") domain. Through our transaction with Tay, we obtained access to a library of new small molecule BET inhibitor compounds including those that inhibit both BD1 and BD2 ("pan-BD" BET inhibitor) and that selectively inhibit BD2 ("BD2-selective" BET inhibitor). Through our access to this library of new BET inhibitors, which comprise our InhiBET™ portfolio, we plan to develop product candidates for a diverse set of therapeutic indications. We have chosen to initially focus our development efforts with these molecules on immune-mediated inflammatory diseases, which are not being targeted by current BET inhibitors in development.

Our lead program is repibresib gel (also known as VYN201), a topically administered, small molecule pan-BD BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. In preclinical testing, repibresib produced consistent reductions in pro-inflammatory and disease-related biomarkers and improvements in disease severity across a variety of inflammatory and fibrotic preclinical models. In November 2022, we initiated a Phase 1 clinical trial evaluating a topical formulation of repibresib first in healthy volunteers (Phase 1a) and then in subjects (Phase 1b) with nonsegmental vitiligo (NSV), an immune-mediated condition that has a high unmet need and only one approved therapy. In the first quarter of 2023, we announced positive preliminary safety and tolerability, including hematology data, and predicted pharmacokinetic results (minimal systemic exposures) from the Phase 1a portion of the trial. We initiated the Phase 1b portion of the trial in NSV subjects in January 2023 and announced positive data from the Phase 1b trial in October 2023. We showed significant clinical improvements in vitiligo involving the face, which has the greatest psychosocial impact on patients, after 16 weeks of treatment which was assessed using the Facial-Vitiligo Area Scoring Index ("F-VASI"), a measure of severity of the condition on the face. We initiated a Phase 2b trial with repibresib gel in NSV subjects in June 2024. The Phase 2b trial is a randomized, double-blind, vehicle-controlled trial evaluating the efficacy, safety and pharmacokinetics of once-daily repibresib gel in NSV subjects in three dose cohorts (1%, 2% or 3% concentrations) compared to vehicle over 24 weeks, followed by a 28-week active treatment extension with subjects on vehicle crossing over to active doses. We enrolled approximately 45 patients in each arm and expect to report top-line results from the 24-week double-blind portion of the trial in mid-2025.

Our second program is VYN202, an oral, small molecule BD2-selective BET inhibitor. Prior studies have shown that while BD1 modulates cell-cycling and homeostatic functions, BD2 regulates gene expression of pro-inflammatory mediators in cells. VYN202 has been designed to achieve potential class-leading potency and selectivity for BD2 vs. BD1. By maximizing BD2 selectivity, we believe VYN202 has the potential to be a potent oral immunomodulator option for both acute control and chronic management of immune-mediated inflammatory conditions, without the hematologic and gastrointestinal adverse effects associated with earlier generation systemic pan-BD BET inhibitors that were being developed in oncologic settings. We have completed a Phase 1a single ascending dose/multiple ascending dose ("SAD/MAD") trial of VYN202 in healthy volunteers and announced positive data from this trial in December 2024. We observed that VYN202 had a favorable safety and tolerability profile with no drug-related adverse events historically associated with earlier generation, less BD2-selective BET inhibitors. VYN202 also demonstrated robust pharmacodynamic activity including evidence of target engagement and inhibition of several inflammatory biomarkers relevant to immune-mediated disorders in ex vivo stimulation assays. We initiated a Phase 1b trial in February 2025 in adult subjects with moderate-to-severe plaque psoriasis. The Phase 1b trial is a randomized, double-blind, placebo-controlled trial of once daily treatment with VYN202 capsules dosed for 12 weeks, to primarily evaluate the safety of VYN202 across four cohorts (0.25 mg, 0.5 mg, 1 mg doses and placebo), with secondary objectives that include pharmacokinetics and preliminary evidence of efficacy via endpoints evaluating improvements from baseline in PASI scores. The trial will also include a 4-week safety follow-up visit after completion of the 12-week dosing period. We expect to enroll approximately 80 subjects with moderate-to-severe plaque psoriasis and to report top-line results from the placebo-controlled trial by the end of 2025. Additionally, we anticipate that the data from the Phase 1b trial in plaque psoriasis subjects will provide key insights into VYN202's potential activity across a range of immune-mediated diseases.

We intend to advance our product candidates through further phases of clinical development toward regulatory approval. As part of our strategy to maximize the value of our pipeline, we may partner with larger pharmaceutical companies to expand and accelerate the development of our programs and explore other indications and therapeutic areas outside of our core focus in immune-mediated diseases.

Sale of Legacy Commercial Business

In January 2022, we entered into an Asset Purchase Agreement with Journey Medical Corporation ("Journey") pursuant to which we sold our Molecule Stabilizing Technology franchise, including our former products AMZEEQ, ZILXI, and FCD105, referred to collectively as the MST Franchise, to Journey. The assets included certain contracts, including license agreements, inventory and intellectual property related to the MST Franchise. We have classified the results of the MST Franchise as discontinued operations in our consolidated statements of operations and comprehensive loss and cash flows for all periods presented in this Annual Report on Form 10-K.

We received an upfront payment of $20.0 million at the closing of the sale of the MST franchise and an additional $5.0 million deferred payment in January 2023. We are also eligible to receive sales milestone payments of up to $450.0 million in the aggregate upon the achievement of specified levels of net sales on a product-by-product basis, beginning with annual net sales exceeding $100.0 million, as well as certain payments from any licensing or sublicensing of the purchased assets by Journey outside of the United States.

Known Trends, Events and Uncertainties

Business and Macroeconomic Conditions

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including inflation, interest rates, financial market volatility and uncertainty, the impact of war or military conflict, including the wars in Ukraine and the Middle East, rising tensions between China and Taiwan and the response thereto, public health pandemics, and supply chain disruptions. Adverse effects of these large macroeconomic conditions have been prevalent in many of the areas where we, our CROs, suppliers or third-party business partners conduct business and as a result, we have experienced disruptions and may continue to experience more pronounced disruptions in our operations. In addition, financial markets have experienced a period of high volatility due to these macroeconomic factors. The persistence of this volatility may impact our ability to engage in capital market activities and adequately fund our operations. As of the filing date of this Annual Report on Form 10-K, the extent to which these macroeconomic events and conditions may impact our financial condition, results of operations or liquidity is uncertain. The effect of these macroeconomic events and conditions may not be fully reflected in our results of operations and overall financial performance until future periods. See "Part I — Item 1A. Risk Factors" for further discussion of the possible impact of these macroeconomic conditions on our business.

Development and License Agreements

Agreements with Tay Therapeutics

Evaluation and Option Agreement

In April 2021, we entered into an Evaluation and Option Agreement (the "Option Agreement") with Tay. Pursuant to the Option Agreement, Tay granted us an exclusive option to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's BET inhibitor compounds for the treatment of any disease, disorder or condition in humans. Pursuant to the Option Agreement, we agreed to use commercially reasonable efforts to develop and manufacture a product with a pan-BD BET inhibitor as its active ingredient, and Tay agreed to provide a mutually agreed data package and select a new chemical entity development candidate from its Oral BETi Compounds. We paid a $1.0 million non-refundable cash payment to Tay upon execution of the Option Agreement.

Under the terms of the Option Agreement, our option (the "Oral Option") with respect to the Oral BETi Compounds was to expire on June 30, 2022, but in June 2022, we and Tay entered into a letter agreement to extend the option term to February 28, 2023. In February 2023, we and Tay entered into an additional letter agreement pursuant to which the option term was further extended to April 30, 2023. We exercised the Oral Option for VYN202 on April 28, 2023.

License for Locally Administered Pan-BD BET Inhibitor Program (Repibresib)

In August 2021, we exercised our option with respect to the repibresib program and entered into a License Agreement (the "Repibresib License Agreement") granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion. We are required to use commercially reasonable efforts to develop and, if approved, commercialize such products. Pursuant to the Repibresib License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products. Pursuant to the Repibresib License Agreement, we may develop a product that contains or incorporates a specific BET inhibitor, whether alone or in combination with other active ingredients, in any form, formulation, presentation, or dosage, and for any mode of administration.

We made a $0.5 million cash payment to Tay in 2021 in connection with entering into the Repibresib License Agreement. Pursuant to the Repibresib License Agreement, we agreed to make cash payments to Tay upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed topical product in the United States of up to $15.75 million for all indications, of which $1.8 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products we commercialize under the Repibresib License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales of licensed products under the Repibresib License Agreement and the VYN202 License Agreement, subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Pursuant to the Repibresib License Agreement, we were granted a sublicense under certain intellectual property which was licensed to Tay by the University of Dundee ("Dundee") pursuant to a certain license agreement between Tay and Dundee effective as of July 24, 2020 and amended and restated on October 8, 2021 (the "Head License"). On February 13, 2025, Tay and Dundee entered into an agreement for the termination of the Head License and assignment of such intellectual property from Dundee to Tay. Upon termination of the Head License, the Repibresib License Agreement was accordingly amended to reflect the assignment of the intellectual property to Tay upon its payment in full to Dundee. The amendment does not change any of Tay's or VYNE's rights or obligations under the Repibresib License Agreement, except that any obligations owed by VYNE to Dundee with respect to repibresib are now owed to Tay.

License for Selective BET Inhibitor Program (VYN202)

On April 28, 2023, we exercised the Oral Option and entered into a license agreement (the "VYN202 License Agreement") with Tay granting us a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's Oral BETi Compounds in all fields. We have the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at our sole cost and discretion, and shall use commercially reasonable efforts to develop and, if approved, commercialize such products. We may sublicense our rights to a third party without Tay's consent. Pursuant to the VYN202 License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products.

We made a cash payment of $3.75 million to Tay in connection with entering into the VYN202 License Agreement. Pursuant to the terms of the VYN202 License Agreement, we agreed to make cash payments to Tay of up to $43.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed oral product in the United States for all indications, of which $1.3 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products we commercialize under the VYN202 License Agreement, we will pay tiered royalties to Tay on net sales of such licensed products by us, our affiliates, or sublicensees, of 5%, 7.5% and 10%

based on tiered annual net sales of licensed products under the VYN202 License Agreement and the Repibresib License Agreement, subject to specified reductions. We are obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Components of Results of Operations

Segment Results

As of December 31, 2024, we adopted ASU 2023-07, *Segment Reporting (Topic 280)* to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The Company has identified and reports as one operating segment. See "Note 15 — Segment Information" for further details.

Revenues

Historically, we have generated revenues under development and license agreements, including royalty payments from sales of Finacea foam. We previously licensed the rights to Finacea to LEO Pharma A/S ("LEO Pharma"). This license was not part of the sale of our commercial business to Journey. Royalty revenues for the years ended December 31, 2024 and 2023 were $0.5 million and $0.4 million, respectively, from LEO Pharma in connection with sales of Finacea.

Operating Expenses

Research and development expenses

Our research and development expenses relate primarily to the development of repibresib and VYN202. We charge all research and development expenses to operations as they are incurred.

Our total research and development expenses for the years ended December 31, 2024 and 2023 were $30.9 million and $16.3 million, respectively.

Research and development expenses consist primarily of:

- employee-related expenses, including salaries, benefits and related expenses, including share-based compensation expenses, for research and development personnel;
- expenses incurred under agreements with third parties, including CROs, subcontractors, suppliers and consultants that conduct regulatory activities, clinical trials and preclinical studies;
- expenses incurred to acquire, develop and manufacture clinical trial materials;
- expenses and milestone payments incurred under licensing agreements;
- costs associated with the creation, development and protection of intellectual property; and
- other costs associated with preclinical and clinical activities and regulatory operations.

General and administrative expenses

Our general and administrative expenses for the years ended December 31, 2024 and 2023 were $13.2 million and $13.4 million, respectively.

Our general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and related expenses, including share-based compensation expenses;
- professional fees for legal, auditing, tax and other consulting expenses; and
- facility, insurance, information technology, travel, and depreciation expenses.

Other Income, net

Other income, net primarily consists of interest earned on our cash, cash equivalents and marketable securities.

Income Taxes and Net Operating Loss Carryforwards

We have incurred significant net operating losses ("NOLs") since our inception. We expect to continue to incur NOLs until such a time when we generate adequate revenues for us to reach profitability. As of December 31, 2024, we had federal and state net operating loss carryforwards of $343.4 million and $53.6 million, respectively, of which $44.3 million will begin to expire in 2031 for federal and $53.6 million will begin to expire in 2040 for state purposes. As of December 31, 2024, we had federal research and development tax credit carryforwards of $7.2 million which will begin to expire in 2031. We have no state research and development tax credit carryforwards. As of December 31, 2024, we had $299.1 million in federal and state NOLs with no limited period of use.

NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of our company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. State NOLs and tax credit carryforwards may be subject to similar limitations under state laws. We have not completed a 382 study through December 31, 2024, however, we may have experienced ownership changes in the past, including in connection with the 2020 merger between Menlo (our predecessor company) and Foamix. Our private placement transaction in November 2023 also likely resulted in an ownership change for purposes of Section 382. We may experience ownership changes in the future as a result of the subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, even if we earn net taxable income, our ability to use the NOL and tax credit carryforwards may be materially limited, which could harm our future operating results by effectively increasing our future tax obligations.

Results of Operations for the Years Ended December 31, 2024 and December 31, 2023

(in thousands, except %)	Year Ended December 31, 2024	Year Ended December 31, 2023	Increase/ (Decrease) $	Increase/ (Decrease) %
Revenues				
Royalty revenues	$ 501	$ 424	$ 77	18.2%
Total revenues	501	424	77	18.2%
Operating expenses				
Research and development	30,946	16,307	14,639	89.8%
General and administrative	13,192	13,375	(183)	(1.4)%
Total operating expenses	44,138	29,682	14,456	48.7%
Operating loss	(43,637)	(29,258)	14,379	49.1%
Other income, net	3,834	1,386	2,448	176.6%
Loss from continuing operations before income taxes	(39,803)	(27,872)	11,931	42.8%
Income tax expense	4	—	4	*
Loss from continuing operations	(39,807)	(27,872)	11,935	42.8%
Loss from discontinued operations, net of income taxes	(27)	(580)	(553)	(95.3)%
Net loss	$(39,834)	$(28,452)	$11,382	40.0%

* percentage not meaningful

Revenues

Revenues totaled $0.5 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively, consisting of royalty revenue from our royalty agreement with LEO Pharma.

Research and development expenses

Our research and development expenses for the year ended December 31, 2024 were $30.9 million, representing an increase of $14.6 million, or 89.8%, compared to $16.3 million for the year ended December 31, 2023. The increase was primarily due to an increase of $11.7 million in expenses for repibresib, an increase of $2.5 million in expenses for VYN202 and an increase of $0.8 million of employee-related expenses following the hiring of additional research and development personnel. The $11.7 million increase in expenses for repibresib primarily relates to preparatory activity and clinical trial costs incurred for our ongoing Phase 2b trial of repibresib in subjects with NSV. The $2.5 million increase in expenses for VYN202 is primarily associated with costs incurred for our Phase 1a SAD/MAD trial which was completed in the fourth quarter of 2024. Both trials were initiated in June 2024. These increases were partially offset by lower consulting expenses of $0.4 million.

General and administrative expenses

Our general and administrative expenses for the year ended December 31, 2024 were $13.2 million, representing a decrease of approximately $0.2 million, or 1.4%, compared to $13.4 million for the year ended December 31, 2023. The decrease was primarily driven by $0.9 million of employee related expenses, partially offset by increased consulting and professional fees of $0.8 million.

Other Income, net

Other income, net for the years ended December 31, 2024 and 2023 was $3.8 million and $1.4 million, respectively, primarily related to interest income earned on cash, cash equivalents and marketable securities.

Loss from discontinued operations, net of income taxes

Due to the sale of the MST Franchise during the first quarter of 2022, in accordance with ASC 205, Discontinued Operations, we have classified the results of the MST Franchise as discontinued operations in our consolidated statements of operations and comprehensive loss for all periods presented. See "Note 4 — Discontinued Operations" in the consolidated financial statements.

Liquidity and Capital Resources

Sources of Liquidity

Since the sale of the MST Franchise in January 2022, we have not generated any revenue from product sales. In addition, we have incurred losses and experienced negative operating cash flows since our inception and anticipate that we will continue to incur losses until such a time when our product candidates, if approved, are commercially successful, if at all. We will not generate any revenue from any current or future product candidates unless and until we obtain regulatory approval and commercialize such products. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See Item 1A "Risk Factors" for additional risks associated with our substantial capital requirements.

As of December 31, 2024, we had cash, cash equivalents, and marketable securities of $61.5 million and an accumulated deficit of $731.2 million. We had no outstanding debt as of December 31, 2024. For the year ended December 31, 2024, we incurred a net loss of $39.8 million and used $34.0 million of cash in operations. Based on our current operating plan, we believe our existing cash, cash equivalents, and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period of at least 12 months from the date of issuance of the audited consolidated financial statements included in this Annual Report on Form 10-K.

If our available cash, cash equivalents, and marketable securities are insufficient to satisfy our liquidity requirements, we may need to raise additional capital to fund our operations. No assurance can be given as to whether additional needed financing will be available on terms acceptable to us, if at all. If sufficient funds on acceptable terms are not available when needed, we may be required to suspend or forego certain planned activities. Failure to manage discretionary spending or raise additional financing, as needed, would adversely impact our ability to achieve our intended business objectives and have an adverse effect on our results of operations and future prospects.

Our sources of funding for the years ended December 31, 2024 and 2023 are further evaluated in the cash flow section below. Other than our obligations pursuant to the Tay License Agreements, we have no ongoing material financial commitments that may affect our liquidity over the next five years. See the section titled "Development and License Agreements — Agreements with Tay" for additional discussion of our financial obligations under the Tay License Agreements.

Future Funding Requirements

We do not expect to generate any product revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if, that will occur. Until we can generate significant revenue from product sales, if ever, we will continue to require substantial additional capital to develop our current and future product candidates and fund operations for the foreseeable future. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and studies and initiate clinical trials. We are subject to all the risks incident in the development of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm our business.

In order to complete the development of repibresib and VYN202 (including making milestone payments pursuant to the repibresib License Agreement and VYN202 License Agreement), or any future product candidates, we will require substantial additional capital. Accordingly, we expect to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that we raise additional capital through equity financings or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation, voting or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional capital from these sources on favorable terms, or at all.

In addition, the amount of proceeds we may be able to raise pursuant to our shelf registration statement on Form S-3 is limited. As of the filing of this Annual Report on Form 10-K, we are subject to the general instructions of Form S-3 known as the "baby shelf rules." Under these rules, the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of our common stock held by our non-affiliates. Therefore, we will be limited in the amount of proceeds we are able to raise by selling shares of common stock using our Form S-3 until such time as our public float exceeds $75.0 million.

Our ability to raise additional capital may also be adversely impacted by global economic conditions and disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from bank failures, other general macroeconomic conditions and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research or product development efforts. We cannot provide assurance that we will ever generate positive cash flow from operating activities.

Our present and future funding requirements will depend on a number of factors, including the following:

- the scope, timing, progress, results, and costs of researching and developing repibresib and VYN202 and conducting clinical trials, including larger and later-stage trials;
- the scope, timing, progress, results, and costs of preclinical studies and clinical trials for any other current and future programs;
- the time and costs involved in obtaining regulatory approval for our other pipeline product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these product candidates;
- terms and timing of any acquisitions, collaborations or other arrangements;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations;
- the number of potential new products we identify and decide to develop;
- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights; and
- the costs associated with operating as a public company.

Our operating plan may change as a result of many factors currently unknown to us, and any such change may affect our funding requirements. We may therefore need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations or additional license arrangements. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business.

For more information as to the risks associated with our future funding needs, see "Part I — Item 1A. Risk Factors" included herein.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash (used in) / provided by:		
Operating activities	$(33,972)	$(25,341)
Investing activities	23,365	(57,354)
Financing activities	(141)	82,394

Net cash used in operating activities

During the year ended December 31, 2024, net cash used in operating activities was $34.0 million and primarily reflected our net loss of $39.8 million adjusted for non-cash share-based compensation expense of $3.3 million, partially offset by the amortization of premium on marketable securities of $2.4 million. The remainder of the cash used in operations was due to net changes in assets and liabilities, which was largely driven by a $6.0 million increase in trade payables, accrued expenses, employee related obligations and other long-term liabilities. This increase was primarily comprised of accruals related to fees for contract research organizations, investigative sites, and other service providers that assist in conducting preclinical research studies and clinical trials.

During the year ended December 31, 2023, net cash used in operating activities was $25.3 million and primarily reflected our net loss of $28.5 million adjusted for non-cash items of $3.1 million primarily related

to share-based compensation expense. The remainder of the cash used in operations was driven by net changes in assets and liabilities.

Net cash provided by (used in) investing activities

During the year ended December 31, 2024, net cash provided by investing activities was $23.4 million and consisted of $84.0 million of proceeds received from the sale and maturity of marketable securities, partially offset by $60.5 million paid for the purchase of marketable securities and $0.1 million paid for the purchase of property and equipment.

During the year ended December 31, 2023, net cash used in investing activities was driven by the purchase of marketable securities of $62.4 million, partially offset by the receipt of the deferred payment from Journey in January 2023 of $5.0 million in connection with the sale of the MST Franchise.

Net cash (used in) provided by financing activities

During the year ended December 31, 2024, net cash used in financing activities related to $0.1 million of withholdings from the exercise of options and issuance of shares for share-based compensation arrangements.

During the year ended December 31, 2023, net cash provided by financing activities was $82.4 million and consisted primarily of net proceeds of $82.7 million from our issuance and sale of common stock and pre-funded warrants and $0.2 million of proceeds received from the sales of common stock under our at-the-market equity offering program, partially offset by $0.4 million paid for the redemption of previously outstanding convertible preferred stock.

Cash and Funding Sources

Our sources of funding in the year ended December 31, 2024 consisted primarily of $84.0 million of proceeds received from the sale and maturity of marketable securities.

Our sources of funding in the year ended December 31, 2023 totaled $87.8 million and consisted primarily of net proceeds of $82.7 million from our issuance and sale of common stock and pre-funded warrants, $5.0 million in proceeds from the deferred payment from the sale of the MST Franchise and $0.2 million in net proceeds from the issuance of common stock pursuant to our at-the-market offering program.

Contractual Obligations

Lease Commitments

In November 2022, we transitioned to a smaller corporate headquarters and signed a Sublease Agreement (the "Sublease") to sublease approximately 5,755 square feet of office space (the "Leased Premises") in Bridgewater, New Jersey through September 30, 2023. We signed a Lease Agreement (the "Master Lease") to lease the Leased Premises following the termination of the Sublease through September 30, 2025. We have aggregate operating lease obligations of $0.1 million at December 31, 2024.

R&D Commitments

We enter into contracts in the normal course of business with CROs, contract manufacturing organizations and other service providers for clinical trials, preclinical studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

As of December 31, 2024, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Significant Judgments and Estimates

We prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are more fully described in "Note 2 — Significant Accounting Policies," to the consolidated financial statements included in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to assist stockholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operations. These policies relate to significant areas involving management's judgments and estimates and that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

Research and Development Expenses

We make estimates of our accrued research and development expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. There may also be instances in which payments made to our vendors will exceed the level of service provided and result in a prepayment of the expense. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of the prepaid expense 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 may result in reporting higher or lower amounts in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Recently Issued Accounting Pronouncements

Certain recently issued accounting pronouncements are discussed in "Note 2 — Significant Accounting Policies," to the consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company," as defined by Item 10 of Regulation S-K, we are not required to provide quantitative or qualitative disclosures about market risk.

ITEM 8 — FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

VYNE THERAPEUTICS INC.

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2024

INDEX

Report of Independent Registered Public Accounting Firm

To the shareholders and the board of directors of VYNE Therapeutics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of VYNE Therapeutics Inc. (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in mezzanine equity and shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, 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 as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Baker Tilly US, LLP

We have served as the Company's auditor since 2022.

Tewksbury, Massachusetts
March 6, 2025

VYNE THERAPEUTICS INC.

CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2024	**2023**
Assets		
Current Assets:		
Cash and cash equivalents	$ 19,926	$ 30,620
Restricted cash	—	54
Investment in marketable securities (Note 6)	41,590	62,633
Prepaid and other current assets	2,921	2,656
Total Current Assets	64,437	95,963
Non-current Assets:		
Property and equipment, net (Note 7)	113	—
Operating lease right of use assets (Note 9)	93	207
Non-current prepaid expenses and other assets	2,262	1,515
Total Non-current Assets	2,468	1,722
Total Assets	$ 66,905	$ 97,685
Liabilities and Shareholders' Equity		
Current Liabilities:		
Trade payables	$ 2,707	$ 1,659
Accrued expenses (Note 8)	9,272	4,119
Employee-related obligations	1,428	1,645
Operating lease liabilities (Note 9)	99	115
Other current liabilities	1,313	—
Total Current Liabilities	14,819	7,538
Long-term Liabilities:		
Non-current operating lease liabilities (Note 9)	—	99
Other liabilities	—	1,313
Total Long-term Liabilities	—	1,412
Total Liabilities	14,819	8,950
Commitments and Contingencies (Note 11)		
Shareholders' Equity:		
Preferred stock: $0.0001 par value; 20,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock: $0.0001 par value; 150,000,000 shares authorized at December 31, 2024 and December 31, 2023; 14,830,013 and 14,098,888 shares issued and outstanding at December 31, 2024 and 2023, respectively	1	1
Additional paid-in capital	783,235	780,044
Accumulated other comprehensive income	20	26
Accumulated deficit	(731,170)	(691,336)
Total Shareholders' Equity	52,086	88,735
Total Liabilities and Shareholders' Equity	$ 66,905	$ 97,685

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

VYNE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(U.S. dollars in thousands, except per share data)

	Year ended December 31,	
	2024	2023
Revenues		
Royalty revenues	$ 501	$ 424
Total revenues	501	424
Operating expenses		
Research and development	30,946	16,307
General and administrative	13,192	13,375
Total operating expenses	44,138	29,682
Operating loss	(43,637)	(29,258)
Other income, net	3,834	1,386
Loss from continuing operations before income taxes	(39,803)	(27,872)
Income tax expense	4	—
Loss from continuing operations	(39,807)	(27,872)
Loss from discontinued operations, net of income taxes	(27)	(580)
Net loss	$(39,834)	$(28,452)
Loss per share from continuing operations, basic and diluted	$ (0.93)	$ (2.72)
Loss per share from discontinued operations, basic and diluted	$ —	$ (0.06)
Loss per share, basic and diluted	$ (0.93)	$ (2.78)
Weighted average shares outstanding – basic and diluted	42,589	10,273
Other comprehensive (loss) income:		
Unrealized (losses) gains on marketable securities, net of tax of $0	(6)	26
Total other comprehensive (loss) income	(6)	26
Comprehensive loss	$(39,840)	$(28,426)

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

VYNE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY
(U.S. dollars in thousands)

	Mezzanine Equity (Convertible Preferred Stock)		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total Shareholders' Equity
	Number of shares	Amounts	Number of shares	Amounts	Amounts			
BALANCE AT DECEMBER 31, 2022	**3,000**	**$ 211**	**3,229,704**	**$ —**	**$693,937**	**$ —**	**$(662,735)**	**$ 31,202**
CHANGES DURING 2023:								
Vesting of restricted stock units, net of withholding for tax, and shares issued under employee share purchase plan	—	—	50,214	—	(18)	—	—	(18)
Share-based compensation	—	—	—	—	3,305	—	—	3,305
Redemption of convertible preferred stock	(3,000)	(211)	—	—	—	—	(149)	(149)
Issuance of common stock in at-the-market offering, net of $5 in issuance costs	—	—	34,589	—	156	—	—	156
Issuance of common stock and pre-funded warrants in Private Placement, net of $5,486 in issuance costs	—	—	10,652,543	1	82,664	—	—	82,665
Cashless exercise of pre-funded warrants	—	—	131,838	—	—	—	—	—
Unrealized gains from marketable securities	—	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	—	(28,452)	(28,452)
BALANCE AT DECEMBER 31, 2023	**—**	**$ —**	**14,098,888**	**$ 1**	**$780,044**	**$ 26**	**$(691,336)**	**$ 88,735**
CHANGES DURING 2024:								
Vesting of restricted stock units, net of withholding for tax, and shares issued under employee share purchase plan	—	—	91,302	—	(112)	—	—	(112)
Share-based compensation	—	—	—	—	3,303	—	—	3,303
Cashless exercise of pre-funded warrants	—	—	639,823	—	—	—	—	—
Unrealized losses from marketable securities	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—		(39,834)	(39,834)
BALANCE AT DECEMBER 31, 2024	**—**	**$ —**	**14,830,013**	**$ 1**	**$783,235**	**$ 20**	**$(731,170)**	**$ 52,086**

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

VYNE THERAPEUTICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net loss	$(39,834)	$(28,452)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	4	—
Share-based compensation	3,303	3,305
Amortization of premium or discount on marketable securities	(2,443)	(255)
Unrealized (losses) gains on cash equivalents	(1)	1
Changes in operating assets and liabilities:		
Trade receivables, prepaid expenses and other current assets and operating lease right of use assets	(899)	405
Trade payables, accrued expenses, employee related obligations and other long-term liabilities	6,012	(559)
Operating lease liabilities	(114)	214
Net cash used in operating activities	(33,972)	(25,341)
Cash Flows From Investing Activities:		
Purchase of property and equipment	(117)	—
Proceeds from the sale of the MST Franchise	—	5,000
Proceeds from the sale and maturity of marketable securities	84,000	—
Purchases of marketable securities	(60,518)	(62,354)
Net cash provided by (used in) investing activities	23,365	(57,354)
Cash Flows From Financing Activities:		
Proceeds related to the issuance of common shares and pre-funded warrants through private placement, net of issuance costs	—	82,665
Proceeds related to the issuance of common shares through at-the-market offerings, net of issuance costs	—	156
Redemption of convertible preferred stock	—	(360)
Withholdings from exercise of options and issuance of shares for share-based compensation arrangements, net	(141)	(67)
Net cash (used in) provided by financing activities	(141)	82,394
Decrease in cash, cash equivalents and restricted cash	(10,748)	(301)
Cash, cash equivalents and restricted cash at beginning of the year	30,674	30,975
Cash, cash equivalents and restricted cash at end of the year	$ 19,926	$ 30,674
Cash and cash equivalents	19,926	30,620
Restricted cash	—	54
Total cash, cash equivalents and restricted cash	$ 19,926	$ 30,674
Supplementary information on investing and financing activities not involving cash flows:		
Accretion of preferred stock	$ —	$ 149
Issuance of vested shares under employee share purchase plan	$ 30	$ 48
Additions to operating lease right of use assets	$ —	$ 207
Additions to operating lease liabilities	$ —	$ 214

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

NOTE 1 — NATURE OF OPERATIONS

Company Overview

VYNE Therapeutics Inc. (the "Company") is a clinical-stage biopharmaceutical company focused on developing differentiated therapies to treat chronic inflammatory and immune-mediated conditions with high unmet need.

The Company has exclusive worldwide rights to research, develop and commercialize products containing small molecule bromodomain and extra-terminal domain ("BET") inhibitors for the treatment of any disease, disorder or condition in humans, which the Company licensed from Tay Therapeutics Ltd., formerly known as In4Derm Ltd ("Tay"). Through the Company's access to this library of new small molecule BET inhibitors, which comprise the Company's InhiBET™ portfolio, the Company plans to develop product candidates for a diverse set of therapeutic indications. The Company has chosen to initially focus its development efforts with these molecules on immune-mediated inflammatory diseases, which are not being targeted by current BET inhibitors in development.

The Company's lead program is repibresib gel (also known as VYN201), a topically administered, small molecule pan-BD BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. In preclinical testing, repibresib produced consistent reductions in pro-inflammatory and disease-related biomarkers and improvements in disease severity across a variety of inflammatory and fibrotic preclinical models. The Company is currently evaluating repibresib gel in a Phase 2b trial for the treatment of NSV.

The Company's second program is VYN202, an oral, small molecule BD2-selective BET inhibitor. VYN202 has been designed to achieve potential class-leading potency and selectivity for BD2 vs. BD1. By maximizing BD2 selectivity, the Company believes VYN202 has the potential to be a potent oral immunomodulator option for both acute control and chronic management of immune-mediated inflammatory conditions, without the hematologic and gastrointestinal adverse effects associated with earlier generation systemic pan-BD BET inhibitors that were being developed in oncologic settings. The Company has completed a Phase 1a single ascending dose/multiple ascending dose ("SAD/MAD") trial of VYN202 in healthy volunteers and announced positive data from this trial in December 2024. The Company initiated a Phase 1b trial in February 2025 in adult subjects with moderate-to-severe plaque psoriasis.

The Company intends to advance its product candidates through further phases of clinical development toward regulatory approval. As part of the strategy to maximize the value of the pipeline, the Company may partner with larger pharmaceutical companies to expand and accelerate the development of programs and explore other indications and therapeutic areas outside of the core focus in immune-mediated diseases.

For additional information regarding the sale of the Company's legacy commercial business (the "MST Franchise") to Journey Medical Corporation ("Journey") in January 2022 and the Company's licensing arrangements with Tay, see "Note 3 — Strategic Agreements."

The Company is a Delaware corporation, has its principal executive offices in Bridgewater, New Jersey and operates as one business segment.

Reverse stock split and recasting of per-share amounts

On February 8, 2023, the Company's board of directors approved a 1-for-18 reverse stock split of its outstanding shares of common stock. The reverse stock split was effected on February 10, 2023 at 5:01 p.m. Eastern time. At the effective time, every 18 issued and outstanding shares of the Company's common stock were converted into one share of common stock. No fractional shares were issued in connection with the reverse stock split, and in lieu thereof, each holder of fractional shares was entitled to receive a cash payment (without interest or deduction) from the Company's transfer agent in an amount equal to such

holder's respective pro rata share of the total net proceeds from the Company's transfer agent's sale of all fractional shares at the then-prevailing prices on the open market. A proportionate adjustment was also made to the maximum number of shares issuable under the Company's 2019 Equity Incentive Plan, 2018 Omnibus Incentive Plan and 2019 Employee Share Purchase Plan. The number of authorized shares of the Company's common stock and the par value of each share of common stock remained unchanged.

Unless noted, all common shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect the 1-for-18 reverse stock split.

Securities Purchase Agreement

On October 27, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional and other accredited investors (collectively, the "Purchasers"), pursuant to which the Company agreed to sell and issue to the Purchasers in a private placement transaction (the "Private Placement") (i) 10,652,543 shares of the Company's common stock and (ii) with respect to certain Purchasers, pre-funded warrants to purchase 28,614,437 shares of common stock in lieu of shares (the "Pre-Funded Warrants"). The purchase price per share of common stock was $2.245 per share (the "Stock Purchase Price") and the purchase price for the Pre-Funded Warrants was the Stock Purchase Price minus $0.0001 per Pre-Funded Warrant. On November 1, 2023, the Company received gross proceeds of $88.2 million from the Private Placement, before deducting fees to the placement agent and offering expenses payable by the Company. This transaction resulted in $5.5 million of issuance costs and net proceeds of $82.7 million as of December 31, 2023.

Liquidity and Capital Resources

As of December 31, 2024, the Company had cash, cash equivalents and marketable securities of $61.5 million and an accumulated deficit of $731.2 million. The Company had no outstanding debt as of December 31, 2024. For the year ended December 31, 2024, the Company incurred a net loss of $39.8 million and used $34.0 million of cash in operations. Other than in connection with its legacy commercial business that was sold in January 2022, the Company has funded its operations primarily through private and public placements of its equity, debt and warrants and through fees, cost reimbursements and payments received from its licensees. The Company has incurred losses and experienced negative operating cash flows since its inception and anticipates that it will continue to incur losses until such a time when its product candidates, if approved, are commercially successful, if at all. The Company will not generate any revenue from any current or future product candidates unless and until it obtains regulatory approval and commercializes such products.

If the Company's available cash, cash equivalents and marketable securities are insufficient to satisfy its liquidity requirements, the Company may need to raise additional capital to fund its operations. No assurance can be given as to whether additional needed financing will be available on terms acceptable to the Company, if at all. If sufficient funds on acceptable terms are not available when needed, the Company may be required to suspend or forego certain planned activities. Failure to manage discretionary spending or raise additional financing, as needed, would adversely impact the Company's ability to achieve its intended business objectives and have an adverse effect on its results of operations and future prospects. In addition, the amount of proceeds the Company may be able to raise pursuant to its shelf registration statement on Form S-3 is limited. As of the filing of this Annual Report on Form 10-K, the Company is subject to the general instructions of Form S-3 known as the "baby shelf rules." Under these rules, the amount of funds the Company can raise through primary public offerings of securities in any 12-month period using its registration statement on Form S-3 is limited to one-third of the aggregate market value of the shares of the Company's common stock held by its non-affiliates. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of common stock using its Form S-3 until such time as the Company's public float exceeds $75.0 million.

In accordance with Accounting Standards Codification ("ASC") Subtopic 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its audited consolidated financial statements are issued. As of the report date, the Company believes its existing cash, cash equivalents

and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period of at least 12 months from the date of issuance of these audited consolidated financial statements.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

b. Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany balances and transactions have been eliminated upon consolidation.

c. Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Significant items subject to such estimates and assumptions include research and development accruals. Actual results could differ from the Company's estimates.

d. Cash and cash equivalents

The Company considers cash equivalents to be all short-term, highly liquid investments, which include short-term bank deposits, treasury bills and money market funds with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

e. Restricted Cash

As of December 31, 2024 and 2023, the Company had no and less than $0.1 million of restricted cash, respectively, representing bank guarantees.

f. Marketable securities

Marketable securities with original maturities of greater than three months and remaining maturities of less than one year from the balance sheet date are classified as short-term. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term.

The Company classifies all marketable securities as available-for-sale debt securities. The Company's marketable securities are measured and reported at fair value using either quoted prices in active markets for identical securities or quoted prices in markets that are not active for identical or similar securities. Unrealized gains and losses are reported as a separate component of shareholders' equity. The cost of securities sold is determined on a specific identification basis, and realized gains and losses, if any, are included in other income, net within the consolidated statement of operations and comprehensive loss.

g. Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation. The Company's property and equipment are depreciated by the straight-line method on the basis of their estimated useful life.

Estimated useful lives are as follows:

	Estimated Useful Life
Office equipment	5 years

h. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the assets is less than the carrying amount of such assets, an impairment loss would be recognized. The assets would be written down to their estimated fair values, calculated based on the present value of expected future cash flows (discounted cash flows), or some other fair value measure.

i. Credit losses

An allowance is maintained for potential credit losses in accordance with accounting standards update ("ASU") No. 2016-13. The Company evaluates its allowance based on expected losses rather than incurred losses, which is known as the current expected credit loss ("CECL") model. The allowance is determined using the loss rate approach and is measured on a collective (pool) basis when similar risk characteristics exist. Where financial instruments do not share risk characteristics, they are evaluated on an individual basis. The allowance is based on relevant available information, from internal and external sources, relating to past events, current conditions, and reasonable and supportable forecasts. Trade receivable balances are written off against the allowance when it is deemed probable that the receivable will not be collected. Trade receivables, net are stated net of reserves for certain sales allowances and credit losses. Credit losses were not material for the years ended December 31, 2024 and 2023.

j. Leases

The Company's lease portfolio mainly consists of office space. Leases are classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. Operating lease assets represent the Company's right to use an underlying asset for the lease term whereas lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet. Operating lease expense is recognized on a straight-line basis over the expected lease term.

k. Contingencies

Certain conditions may exist as of the date of the consolidated financial statements, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company's management evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought.

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability is recorded as accrued expenses in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material are disclosed.

Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantees are disclosed.

l. Share-based compensation

The Company accounts for employees' and directors' share-based payment awards classified as equity awards using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period using the straight-line method. Forfeitures are recognized as they occur.

Share-based payments related to the employee share purchase plan ("ESPP") are recognized based on the fair value of each award estimated on the first day of the offering period and recognized as an expense over the offering period using the straight-line method.

The Company elected to recognize compensation costs for awards conditioned only on continued service that have a graded vesting schedule using the straight-line method.

m. Revenue recognition

The Company accounts for its revenue transactions under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*. In accordance with ASC Topic 606, the Company recognizes revenues when its customers obtain control of its product for an amount that reflects the consideration it expects to receive from its customers in exchange for that product. To determine revenue recognition for contracts that are determined to be in scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. Once the contract is determined to be within the scope of ASC Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when such performance obligation is satisfied.

Following the disposition of the MST Franchise in January 2022, the Company does not have any revenue generating products; however, the Company may receive royalty revenues from the sale of specified products (see "Note 4 — Discontinued Operations").

Royalty Revenues and Collaboration Agreements

The Company is entitled to royalty payments with respect to sales of Finacea foam. The Company previously licensed the rights to Finacea foam to LEO Pharma A/S ("LEO Pharma"). Finacea foam was not part of the MST Franchise that was sold in January 2022. Royalties are recognized as revenue when the product is sold by LEO Pharma. For the year ended December 31, 2024 and 2023, royalty revenues were $0.5 million and $0.4 million, respectively.

For collaboration agreements under ASC 606, the Company identifies the contract, identifies the performance obligations, determines the transaction price, allocates the contract transaction price to the performance obligations, and recognizes the revenue when (or as) the performance obligation is satisfied.

The Company identifies the performance obligations included within the agreement and evaluate which performance obligations are distinct. Upfront payments for licenses are evaluated to determine if the license is capable of being distinct from the obligations to participate on certain development and/or commercialization committees with the collaboration partners and supply manufactured drug product for clinical trials. For performance obligations that are satisfied over time, the Company utilizes the input method and revenue is recognized by consistently applying a method of measuring progress toward complete satisfaction of that performance obligation. The Company periodically reviews estimated periods of performance based on the progress under each arrangement and accounts for the impact of any changes in estimated periods of performance on a prospective basis.

Milestone payments are a form of variable consideration as the payments are contingent upon achievement of a substantive event. Milestone payments are estimated and are included in the transaction price when the Company determines that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods.

Product Sales Provisions

The Company's net product revenues were generated through sales of AMZEEQ, which was approved by the FDA in October 2019 and was commercially launched in the United States in January 2020, and

ZILXI, which was approved by the FDA in May 2020 and was commercially launched in the United States in October 2020. The Company sold the MST Franchise on January 12, 2022 and, as such, the Company no longer generates revenue from the sale of these products.

Provisions for distribution fees, trade discounts and chargebacks related to the sales of AMZEEQ and ZILXI are reflected as a reduction to trade receivables, net on the consolidated balance sheet. All other provisions, including rebates, other discounts and return provisions are reflected as a liability within accrued expenses on the consolidated balance sheet. The revenue reserve liability was $2.1 million and $2.3 million as of December 31, 2024 and 2023, respectively. Under the terms of the Asset Purchase Agreement, the Company retained and is responsible for historical liabilities of the commercial business operations based on events occurring prior to the sale other than those liabilities expressly assumed by Journey.

Contract Assets and Contract Liabilities

The Company did not have any contract assets (unbilled receivables) related to product sales as of December 31, 2024 or 2023, as customer invoicing generally occurred before or at the time of revenue recognition. Similarly, the Company did not have any contract assets (unbilled receivables) related to its royalty revenues as of December 31, 2024 or 2023.

The Company did not have any contract liabilities as of December 31, 2024 or 2023, as the Company did not receive payments in advance of fulfilling its performance obligations to its customers.

n. Collaboration arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. To the extent the arrangement is within the scope of ASC 808, the Company will assess whether aspects of the arrangement between it and their collaboration partner are within the scope of other accounting literature.

o. Research and development expenses

All expenses associated with research and development are expensed as incurred. Research and development expenses include expenses directly attributable to conducting the Company's research and development programs, including expenses incurred under arrangements with third parties, such as contract research organizations, contract development and manufacturing organizations and consultants as well as the cost of clinical trials, clinical trial supplies, salaries, share-based compensation expenses, payroll taxes and other employee benefits.

Expenses are considered incurred based on the evaluation of the progress to completion of specific tasks under each contract using information and data provided by the service providers and vendors or the Company's estimate of the level of service that has been performed at each reporting date, whereas payments are dictated by the terms of each agreement, such as the successful enrollment of a certain number of patients, site initiation, and the completion of clinical trial milestones. As such, depending on the timing of the payment relative to the receipt of goods or services, management may record prepaid expenses, accrued expenses, or other assets.

p. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

q. Income taxes

Deferred taxes

Income taxes are computed using the asset and liability method. Under the asset and liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the currently enacted tax rates and laws. A valuation allowance is recognized to the extent that it is more likely than not that the deferred taxes will not be realized in the foreseeable future. Given the Company's losses, the Company has provided a full valuation allowance with respect to its deferred tax assets.

Uncertainty in income tax

The Company follows a two-step approach in recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the available evidence indicates that it is more likely than not that the position will be sustained based on technical merits. If this threshold is met, the second step is to measure the tax position as the largest amount that has more than a 50% likelihood of being realized upon ultimate settlement.

r. Net loss per share

Net loss per share, basic and diluted, is computed on the basis of the net loss from continuing operations for the period divided by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is based upon the weighted average number of shares of common stock and of common stock equivalents outstanding when dilutive.

The Company has issued the Pre-Funded Warrants, which do not expire until they are exercised in full (see "Note 12 — Mezzanine Equity and Shareholder's Equity"). Pursuant to the guidance of ASC 260-10, the Company concluded that because the equity-classified Pre-Funded Warrants were immediately exercisable for little or no cash consideration, due to the non-substantive exercise price, all of the necessary conditions for issuance of the underlying shares of common stock had been met when the Pre-Funded Warrants were issued. Therefore, the underlying shares of common stock should be included in the denominator for both the calculation of basic and diluted net loss per share of common stock for the year ended December 31, 2024.

The following stock options, restricted stock units ("RSUs") and warrants were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	Year ended December 31,	
(in numbers of shares)	**2024**	**2023**
Outstanding stock options and RSUs	2,335,019	1,205,516
Warrants	27,509	27,509

s. Concentration of credit risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash and cash equivalents, restricted cash, marketable securities and accounts receivables. The Company deposits cash and cash equivalents with highly rated financial institutions and, as a matter of

policy, limits the amounts of credit exposure to any single financial institution. In addition, all marketable securities carry a high credit rating or are government insured. The Company has not experienced any material credit losses in these accounts and does not believe it is exposed to significant credit risk on these instruments.

Existing royalty receivables relate to one customer, but do not present a credit risk due to their immaterial nature. There was no restricted cash as of December 31, 2024, thereby presenting no credit risk.

t. Employee Retention Tax Credit

In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law, providing numerous tax provisions and other stimulus measures, including employee retention tax credits ("ERTC"). The ERTC was a refundable tax credit against certain employment taxes for qualifying businesses retaining employees on their payroll during the COVID-19 pandemic and allowed eligible employers to claim a refundable tax credit against the employer share of Social Security tax equal to 70% of the qualified wages they paid to employees, initially from March 27, 2020 until June 30, 2021, and extended through September 30, 2021. During 2022, the Company filed returns with the Internal Revenue Service (IRS) and claimed credits totaling $1.3 million. During the first quarter of 2023, the Company received the full $1.3 million. As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company has accounted for the ERTC by analogy to International Accounting Standard, Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20"). The ERTC filings remain open to examination by the IRS until April 2025, and as such the Company has recorded the $1.3 million received within other current liabilities on the consolidated balance sheet as of December 31, 2024 until such a time that the Company has reasonable assurance that the conditions associated with the grants have been met.

u. Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815, 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 reporting period end date while the warrants are outstanding. For issued warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded 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 as a non-cash gain or loss on the statements of operations. Liability-classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded as a component of other income, net in the statements of operations. As of December 31, 2024 and 2023, all of the Company's outstanding warrants were equity-classified warrants.

v. Newly issued and recently adopted accounting pronouncements:

Recent Accounting Guidance Issued

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments — *Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*" (ASU 2016-13), which requires companies to measure credit losses of financial instruments, including customer accounts receivable and marketable securities, utilizing a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. As a smaller reporting

company, the Company adopted ASU 2016-13 effective January 1, 2023, and there was no material impact on the consolidated financial statements upon adoption.

In December 2022, the FASB issued ASU No. 2022-06, "*Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848"* (ASU 2022-06), which provides extension of the sunset date of Topic 848 from December 31, 2022 to December 31, 2024. The Company is currently evaluating the impact of ASU 2020-04 and ASU 2022-06 on its consolidated financial statements. Currently, the Company does not expect the adoption of the new standard to have a material impact to the consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *"Segment Reporting (Topic 280) — Improvements to Reportable Segment Disclosures"* (ASU 2023-07), to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 31, 2024. The Company adopted the standard as of December 31, 2024. See Note 15 in the accompanying notes to the consolidated financial statement for further information.

In December 2023, the FASB issued ASU No. 2023-09, "*Income Taxes (Topic 740) — Improvements to Income Tax Disclosures*" ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. Public business entities are required to adopt this standard for annual fiscal periods beginning after December 31, 2024 and early adoption is permitted. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *"Comprehensive Income (Topic 220) — Disaggregation of Income Statement Expenses"* ("ASU 2024-03"), to improve financial reporting by requiring disclosures in the notes to financial statements about specific types of expenses included in the expense captions presented on the face of the statement of operations. The requirements of the ASU, as clarified by ASU 2025-01 issued in January 2025, are effective for annual reporting periods beginning after December 15, 2026 and for interim reporting periods beginning after December 15, 2027, with early adoption permitted. The requirements will be applied prospectively with the option for retrospective application. The Company is evaluating the impact the adoption of this guidance will have on its consolidated financial statements and related disclosures.

NOTE 3 — STRATEGIC AGREEMENTS

Agreements with Tay Therapeutics

Evaluation and Option Agreement

In April 2021, the Company entered into an Evaluation and Option Agreement (the "Option Agreement") with Tay. Pursuant to the Option Agreement, Tay granted the Company an exclusive option to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's BET inhibitor compounds for the treatment of any disease, disorder or condition in humans. Pursuant to the Option Agreement, the Company agreed to use commercially reasonable efforts to stabilize, develop and manufacture a product with a pan-BD BET inhibitor as its active ingredient and Tay agreed to provide a mutually agreed data package and select new chemical entity development candidate from its highly selective BET inhibitor compounds (the "Oral BETi Compounds"). The Company paid a $1.0 million non-refundable cash payment to Tay upon execution of the Option Agreement, 50% of which was to be used by Tay in the development of the Oral BETi Compounds.

Under the terms of the Option Agreement, the Company's option (the "Oral Option") with respect to the Oral BETi Compounds was to expire on June 30, 2022 (the "Option Term"), but in June 2022, the Company and Tay entered into a Letter Agreement (the "Letter Agreement") to extend the Option Term to February 28, 2023. Pursuant to the terms of the Letter Agreement, the Company paid Tay $386,366 (£300,000) on June 28, 2022 to extend the Option Term. In addition, on August 29, 2022, the Company made a second payment to Tay of $997,407 (£850,000) pursuant to the terms of the Letter Agreement following the discovery of potential Oral BETi Compounds for further development. Both payments were recorded as research and development expense. On February 27, 2023, the parties entered into an additional

Letter Agreement (the "Second Letter Agreement") pursuant to which the Option Term was extended to April 30, 2023. As consideration for the extension of the Option Term, the Company paid Tay $250,000 upon the execution of the Second Letter Agreement. Per the terms of the Second Letter Agreement, this fee was deducted from the upfront fee paid by the Company to Tay following the Company's exercise of the Oral Option, as described below.

License for Locally Administered Pan-BD BET Inhibitor Program (Repibresib)

On August 6, 2021, the Company exercised its option with respect to the repibresib program and, on August 9, 2021, the parties entered into a License Agreement (the "Repibresib License Agreement") granting the Company a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds in all fields. The Company has the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at its sole cost and discretion. The Company is required to use commercially reasonable efforts to develop and, if approved, commercialize such products. Pursuant to the Repibresib License Agreement, a joint development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products. Pursuant to the Repibresib License Agreement, the Company may develop a product that contains or incorporates a specific BET inhibitor, whether alone or in combination with other active ingredients, in any form, formulation, presentation, or dosage, and for any mode of administration.

The Company made a $0.5 million cash payment to Tay in connection with entering into the Repibresib License Agreement. Pursuant to the Repibresib License Agreement, the Company has agreed to make cash payments to Tay of up to $15.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed topical product in the United States for all indications, of which $1.8 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products the Company commercializes under the Repibresib License Agreement, the Company will pay tiered royalties to Tay on net sales of such licensed products by the Company, its affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Pursuant to the Repibresib License Agreement, VYNE was granted a sublicense under certain intellectual property which was licensed to Tay by the University of Dundee ("Dundee") pursuant to a certain license agreement between Tay and Dundee effective as of July 24, 2020 and amended and restated on October 8, 2021 (the "Head License"). On February 13, 2025, Tay and Dundee entered into an agreement for the termination of the Head License and assignment of such intellectual property from Dundee to Tay. Upon termination of the Head License, the Repibresib License Agreement was accordingly amended to reflect the assignment of the intellectual property to Tay upon its payment in full to Dundee. The amendment does not change any of Tay's or VYNE's rights or obligations under the Repibresib License Agreement, except that any references to the Head License were removed and any obligations owed by VYNE to Dundee with respect to repibresib are now owed to Tay.

License for Selective BET Inhibitor Program (VYN202)

On April 28, 2023, the Company exercised the Oral Option and entered into a license agreement (the "VYN202 License Agreement") with Tay granting the Company a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's Oral BETi Compounds in all fields. The Company has the sole responsibility for development, regulatory, marketing and commercialization activities to be conducted for the licensed products at the sole cost and discretion of the Company, and shall use commercially reasonable efforts to develop and, if approved, commercialize such products. VYNE may sublicense its rights to a third party without Tay's consent. Pursuant to the License Agreement, a joint

development committee consisting of one representative from each party reviews the progress of the development plan for the licensed products.

The Company made a cash payment of $3.75 million, after deducting the $250,000 paid in February 2023, to Tay in connection with entering into the VYN202 License Agreement. This payment was recorded as a research and development expense in the period paid. Pursuant to the terms of the VYN202 License Agreement, the Company agreed to make cash payments to Tay of up to $43.75 million upon the achievement of specified clinical development and regulatory approval milestones with respect to each licensed oral product in the United States for all indications, of which $1.3 million has been paid or accrued through December 31, 2024. Tay is entitled to additional milestone payments upon the achievement of regulatory approvals in certain non-U.S. jurisdictions. In addition, with respect to any products the Company commercializes under the VYN202 License Agreement, the Company will pay tiered royalties to Tay on net sales of such licensed products by the Company, its affiliates, or sublicensees, of 5%, 7.5% and 10% based on tiered annual net sales bands subject to specified reductions. The Company is obligated to pay royalties until the latest of (1) the tenth anniversary of the first commercial sale of the relevant licensed product, (2) the expiration of the last valid claim of the licensed patent rights covering such licensed product in such country and (3) the expiration of regulatory exclusivity for the relevant licensed product in the relevant country, on a licensed product-by-licensed product and country-by-country basis.

Sale of the MST Franchise

On January 12, 2022, VYNE entered into an Asset Purchase Agreement (the "Purchase Agreement") with Journey pursuant to which the Company sold its MST Franchise to Journey. The assets included certain contracts, including the license agreement with Cutia Therapeutics (HK) Limited ("Cutia"), inventory and intellectual property related to the MST Franchise (together, the "Assets"). Pursuant to the Agreement, Journey assumed certain liabilities of the MST Franchise. There were no current or long-term liabilities recorded by the Company which were transferred to Journey.

Pursuant to the Purchase Agreement, the Company received an upfront payment of $20.0 million at the closing of the sale of the MST franchise and received an additional $5.0 million deferred payment in January 2023. The Company is also eligible to receive sales milestone payments of up to $450.0 million in the aggregate upon the achievement of specified levels of net sales on a product-by-product basis, beginning with annual net sales exceeding $100.0 million (with products covered in three categories (1) AMZEEQ (and certain modifications), (2) ZILXI (and certain modifications), and (3) FCD105 and other products covered by the patents being transferred, including certain modifications). In addition, the Company is entitled to receive certain payments from any licensing or sublicensing of the assets by Journey outside of the United States.

NOTE 4 — DISCONTINUED OPERATIONS

The Company determined that the sale of the MST Franchise represented a strategic shift that had a major effect on the business and therefore the MST Franchise met the criteria for classification as discontinued operations. Accordingly the MST Franchise is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. As such, the general and administrative expenses in discontinued operations include corporate costs incurred directly to solely support the MST Franchise. The negative product sales for the year ended December 31, 2023 was primarily attributable to a change in the product returns provision following the sale of the MST Franchise.

The following table presents the combined results of discontinued operations of the MST Franchise:

	Year ended December 31,	
(in thousands)	2024	2023
Product sales, net	$ —	$(525)
Operating expenses:		
General and administrative	27	55
Total operating expenses	27	55
Loss from discontinued operations, before taxes	(27)	(580)
Income tax expense	—	—
Net loss from discontinued operations	$(27)	$(580)

There were no non-cash items related to discontinued operations for the years ended December 31, 2024 and 2023.

The milestone payments for sales of ZILXI, AMZEEQ and FCD105 represent contingent consideration. Contingent consideration has been accounted for as a gain contingency in accordance with ASC 450, *Contingencies*, and will be recognized in earnings in the period when realizable.

NOTE 5 — FAIR VALUE MEASUREMENTS

The Company's financial assets that are measured at fair value as of December 31, 2024 and 2023 are classified in the tables below in one of the three categories described in "Note 2(p) — Fair value measurement" above:

	December 31, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$19,926	$ —	$ —	$19,926
Marketable securities	—	41,590	—	41,590
Total assets	$19,926	$41,590	$ —	$61,516

	December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$20,353	$10,267	$ —	$30,620
Marketable securities	—	62,633	—	62,633
Total assets	$20,353	$72,900	$ —	$93,253

Other financial instruments consist of trade receivables, trade payables and accrued expenses. The fair value of these financial instruments approximates their carrying values due to their short-term nature. In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities.

NOTE 6 — MARKETABLE SECURITIES

As of December 31, 2024 and 2023, marketable securities consisted of U.S. Government and agency debt securities as well as U.S. Treasury bills.

The following tables sets forth the Company's marketable securities:

	December 31,	
(in thousands)	2024	2023
U.S. Government and agency debt securities	$10,572	$31,886
U.S. Treasury bills	31,018	30,747
Total	$41,590	$62,633

As of December 31, 2024 and 2023, the amortized cost, gross unrealized gains, gross unrealized losses and fair value were as follows:

	December 31, 2024			
(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
U.S. Government and agency debt securities	$10,568	$ 4	$ —	$10,572
U.S. Treasury bills	31,002	16	—	31,018
Total	$41,570	$20	$ —	$41,590

	December 31, 2023			
(in thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
U.S. Government and agency debt securities	$31,866	$30	$(10)	$31,886
U.S. Treasury bills	30,742	5	—	30,747
Total	$62,608	$35	$(10)	$62,633

As of December 31, 2024 and 2023, $41.6 million and $62.6 million, respectively, of the marketable securities were in an unrealized gain position. The Company determined that unrealized gains and losses on marketable securities were primarily due to interest rate changes. No allowance for credit losses related to any of these securities was recorded for the years ended December 31, 2024 and 2023. All maturities are less than 12 months.

NOTE 7 — PROPERTY AND EQUIPMENT

The following table sets forth the Company's property and equipment, net as of December 31, 2024:

(in thousands)	December 31, 2024
Office equipment	$117
Property and equipment	117
Less: Accumulated depreciation	(4)
Property and equipment, net	$113

The Company had no property and equipment as of December 31, 2023.

Depreciation expense totaled $4 thousand and $0 for the years ended December 31, 2024 and 2023, respectively, which is included within general and administrative expenses on the consolidated statements of operations and comprehensive loss.

NOTE 8 — ACCRUED EXPENSES

Accrued expenses consisted of the following:

(in thousands)	December 31, 2024	2023
Product sales provisions[1]	$2,107	$2,250
Research and development[2]	6,622	990
Professional services	491	648
Other	52	231
Total accrued expenses	$9,272	$4,119

(1) Comprised primarily of liabilities related to product returns associated with the MST Franchise.

(2) Comprised primarily of accruals related to fees for contract research organizations, investigative sites, and other service providers that assist in conducting preclinical research studies and clinical trials.

NOTE 9 — OPERATING LEASE

As of December 31, 2024, the Company had an operating lease for its principal executive office in Bridgewater, New Jersey.

In November 2022, the Company transitioned to a smaller corporate headquarters and signed a Sublease Agreement (the "Sublease") to sublease approximately 5,755 square feet of office space (the "Leased Premises") in Bridgewater, New Jersey through September 30, 2023. Following the termination of the Sublease, the Company signed a Lease Agreement (the "Master Lease") to lease the Leased Premises through September 30, 2025. The Company recorded a right of use asset of $0.2 million and liability of $0.3 million at the commencement date of the Master Lease on October 1, 2023.

The components of lease expense are as follows:

(in thousands)	Year ended December 31, 2024	2023
Operating lease expense	$126	$ 32
Short-term lease expense	—	86
Variable lease expense	10	(16)
Total lease expense	$136	$102

Variable lease expense primarily consists of utility and other common area maintenance ("CAM") charges. For the year ended December 31, 2023 the variable lease expenses included a reversal of immaterial expense related to CAM charges. Lease expense is included within general and administrative expenses on the consolidated statements of operations and comprehensive loss.

Supplemental operating cash flows information is as follows:

(in thousands)	Year ended December 31, 2024	2023
Operating leases	$126	$25

Supplemental consolidated balance sheet information related to leases is as follows:

(in thousands)	December 31, 2024	December 31, 2023
Operating lease right-of-use assets	$ 93	$ 207
Operating lease liabilities	$ 99	$ 214
Weighted average remaining lease term	0.75	1.75
Weighted average discount rate	8.00%	8.00%

Maturities of lease liabilities as of December 31, 2024 are as follows:

(in thousands)	Year ended December 31, 2024
2025	$101
Total lease payments	101
Less imputed interest	(2)
Total lease liability	99
Total current operating lease liabilities	$ 99

NOTE 10 — EMPLOYEE SAVINGS PLAN

The Company makes retirement savings plans available to all of its employees and those of its subsidiary, which are intended to qualify as deferred compensation plans under Section 401(k) of the Internal Revenue Code (the "401(k) Plans"). The Company made contributions to these 401(k) Plans during the years ended December 31, 2024 and 2023 of $0.1 million in each period.

NOTE 11 — COMMITMENTS AND CONTINGENCIES

Litigation and contingencies

The Company may periodically become subject to legal proceedings and claims arising in connection with its business. As of December 31, 2024, there were no claims or actions pending against the Company that, in the opinion of management, are likely to have a material adverse effect on the Company.

NOTE 12 — MEZZANINE AND SHAREHOLDERS' EQUITY

Preferred stock

As of December 31, 2024, the Company's Amended and Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") authorized the Company to issue 20,000,000 shares of preferred stock, par value $0.0001 per share. There were no shares of preferred stock issued and outstanding as of December 31, 2024 and 2023.

Shares of preferred stock may be issued from time to time in one or more series. The voting powers (if any), preferences and relative, participating, optional or other special rights, and the qualifications, limitations and restrictions of any series of preferred stock will be set forth in a Certificate of Designation filed pursuant to the Delaware General Corporation Law, as determined by the Company's Board of Directors.

On November 11, 2022, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Mutual Fund Series Trust, on behalf of AlphaCentric LifeSci Healthcare Fund ("AlphaCentric"), pursuant to which the Company issued on November 14, 2022, in a private placement transaction, an aggregate of 3,000 shares of Series A Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred"), for an aggregate subscription amount equal to $300,000. This transaction resulted in $89,000 of issuance costs and net proceeds of $211,000.

The Company determined that the Series A Preferred should be classified as Mezzanine Equity (temporary equity outside of permanent equity), because the Series A Preferred more closely aligned with debt as the intent was for redemption by either the holder or the Company due to the favorable redemption terms.

The Purchase Agreement required that the Company convene a meeting of stockholders for the purpose of presenting a proposal (the "Proposal") authorizing the Company's board of directors to approve a reverse stock split of its outstanding common stock, with the recommendation of the board of directors that the Proposal be approved, and that the Company use reasonable best efforts to obtain approval of the Proposal. The meeting was convened on January 12, 2023, and the Proposal was approved.

Additionally, the Purchase Agreement contained customary representations, warranties and agreements of the Company and AlphaCentric, and customary indemnification rights and obligations of the parties.

Pursuant to the Purchase Agreement, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of Delaware on November 14, 2022 designating 3,000 shares out of the authorized but unissued shares of its preferred stock as Series A Preferred with a par value of $0.0001 per share and establishing the rights, preferences and limitations of the Series A Preferred. The Certificate of Designation provided, among other things, that except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series A Preferred would have no voting rights (other than the right to vote as a class on certain matters as provided in the Certificate of Designation). However, pursuant to the Certificate of Designation, each share of Series A Preferred entitled the holder thereof (i) to vote on the Proposal and any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Proposal, and (ii) to 1,000,000 votes per share of Series A Preferred on the Proposal and any such adjournment proposal. The Series A Preferred should, except as required by law, vote together with the common stock (and other issued and outstanding shares of preferred stock entitled to vote), as a single class; provided, however, that such shares of Series A Preferred should, to the extent cast on the Proposal or any such adjournment proposal, be automatically and without further action of the holders thereof voted in the same proportion as the shares of common stock (excluding abstentions and any shares of common stock that are not voted) and any other issued and outstanding shares of preferred stock of the Company entitled to vote (other than the Series A Preferred or shares of such other preferred stock, if any, not voted) are voted on the Proposal. In addition, the Series A Preferred were entitled to customary dividends and distributions when and if paid on shares of the common stock and were entitled to the voting rights discussed above. The Series A Preferred had preference over the common stock with respect to distribution of assets or available proceeds, as applicable, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or any other deemed liquidation event.

The shares of Series A Preferred were convertible at the option of the holder, at a conversion price of $4.68 per share (as adjusted for the reverse stock split), into shares of the Company's common stock, at any time and from time to time from and after 15 business days following the earlier of (i) the date of the approval of the Proposal or (ii) the date the Company otherwise satisfied the Nasdaq listing requirements.

The Company had the right to redeem the Series A Preferred at any time during the 15 business days following the approval of the Proposal (the "Company Redemption Period") at 120% of the stated value. Each holder of Series A Preferred had the right to require the Company to redeem all or a portion of the Series A Preferred held by such holder following the expiration of the Company Redemption Period at 130% of the stated value. In addition, the Company would automatically redeem all of the Series A Preferred within five business days following a delisting event as specified in the Certificate of Designation at 130% of the stated value.

On January 17, 2023, the Company redeemed all outstanding shares of its Series A Preferred, for an aggregate of $360,000 paid to AlphaCentric. The redemption payment represented 120% of the stated value of the Series A Preferred Stock pursuant to the Certificate of Designation.

On January 17, 2023, the Company filed a Certificate of Elimination (the "Certificate") with the Secretary of State of the State of Delaware with respect to the Series A Preferred Stock. The Certificate (i) eliminated the previous designation of 3,000 shares of Series A Preferred Stock from the Company's

Amended and Restated Certificate of Incorporation, none of which were outstanding at the time of filing, and (ii) caused such shares of Series A Preferred Stock to resume their status as authorized but unissued and non-designated shares of preferred stock.

Common stock

Pursuant to the Certificate of Incorporation, the Company is authorized to issue 150,000,000 shares of common stock, par value $0.0001 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 all classes of preferred stock outstanding. The Company has never declared any dividends on common stock.

On February 8, 2023, the Company's Board of Directors approved a 1-for-18 reverse stock split of the Company's outstanding shares of common stock. The reverse stock split was effected on February 10, 2023. At the effective time, every 18 issued and outstanding shares of the Company's common stock were converted into one share of common stock. No fractional shares were issued in connection with the reverse stock split, and in lieu thereof, each holder of fractional shares was entitled to receive a cash payment (without interest or deduction) in an amount equal to such holder's respective pro rata share of the total net proceeds from the Company's transfer agent's sale of all fractional shares at the then-prevailing prices on the open market. The number of authorized shares of the Company's common stock and the par value of each share of common stock remained unchanged.

Unless noted, all common stock and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect the 1-for-18 reverse stock split.

As of December 31, 2024, the Company had reserved shares of common stock for future issuance as follows:

(in numbers of shares)	December 31, 2024
Shares underlying outstanding Pre-Funded Warrants	27,842,740
Common stock options outstanding (Note 13)	1,584,304
Shares available for future grant under 2023 Plan (Note 13)	1,574,557
Outstanding restricted stock units (Note 13)	750,715
Shares available for grant under the Employee Stock Purchase Plan (Note 13)	87,122
Shares underlying other outstanding warrants	27,509
Shares available for future grant under 2024 Inducement Plan (Note 13)	1
	31,866,948

Issuances of common stock and warrants

At-the-Market Equity Offering Program

On August 12, 2021, the Company entered into a sales agreement (the "Cantor Sales Agreement") with Cantor Fitzgerald to sell shares of the Company's common stock, from time to time, with aggregate gross sales proceeds of up to $50.0 million through an at-the-market equity offering program under which Cantor Fitzgerald would act as the Company's sales agent. Cantor Fitzgerald was entitled to compensation for its services equal to up to 3.0% of the gross proceeds of any shares of common stock sold under the Cantor Sales Agreement. During the year ended December 31, 2023, the Company issued and sold 34,589 shares of common stock at a weighted average per share price of $4.66 pursuant to the Cantor Sales Agreement for $0.2 million in net proceeds. On February 27, 2024, the Company delivered notice to Cantor Fitzgerald to terminate the Cantor Sales Agreement. The Company cannot make any future sales of its common stock pursuant to the Cantor Sales Agreement.

On March 1, 2024, the Company entered into a Sales Agreement (the "Cowen Sales Agreement") with Cowen and Company, LLC, as sales agent ("Cowen") under which the Company may offer and sell, from

time to time at its sole discretion, shares of the Company's common stock through Cowen in an at-the-market offering having an aggregate offering price up to $50.0 million. Cowen is entitled to compensation for its services equal to 3.0% of the gross proceeds of any shares of common stock sold under the Cowen Sales Agreement. The Company did not sell any shares of common stock under the Cowen Sales Agreement during the year ended December 31, 2024.

Private Placement

On October 27, 2023, the Company entered into the Securities Purchase Agreement, pursuant to which the Company agreed to sell and issue to the Purchasers in the Private Placement (i) 10,652,543 shares of the Company's common stock and (ii) with respect to certain Purchasers, Pre-Funded Warrants to purchase 28,614,437 shares of common stock in lieu of shares. The Stock Purchase Price was $2.245 per share and the purchase price for the Pre-Funded Warrants was the Stock Purchase Price minus $0.0001 per Pre-Funded Warrant. On November 1, 2023, the Company received gross proceeds of $88.2 million from the Private Placement. This transaction resulted in $5.5 million of issuance costs and net proceeds of $82.7 million.

Pre-Funded Warrants

The Pre-Funded Warrants issued in the Private Placement will not expire until exercised in full. The Pre-Funded Warrants may not be exercised if the aggregate number of shares of common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation; provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 60 days' notice to the Company, but not to exceed any percentage in excess of 19.99%.

As of December 31, 2023, 131,843 of Pre-Funded Warrants were exercised pursuant to a net exercise mechanism. During the year ended December 31, 2024, 639,854 of Pre-Funded Warrants were exercised pursuant to a net exercise mechanism. As of December 31, 2024, 27,842,740 Pre-Funded Warrants remained outstanding.

Other Warrants

As of December 31, 2024 and 2023, the Company had warrants to purchase an aggregate of 27,509 shares of the Company's common stock outstanding, with exercise prices of $8.40, and an expiration date of July 29, 2026. These warrants were issued by Foamix (as defined below) in connection with a financing in July 2019 and were subsequently assumed by the Company in connection with the Merger (as defined below). Pursuant to the warrant certificate, the exercise price of the warrant will be proportionally adjusted in the event that the Company issues common stock at a price per share less than the exercise price (the "Down Round Feature"). During the year ended December 31, 2023, the Down Round Feature was triggered due to the price per share received from the issuances of common stock. The Company calculated the value of the effect of Down Round Feature measured as the difference between the warrants' fair value, using the Black-Scholes-Merton option-pricing model, before and after the Down Round Feature was triggered using the original exercise price and the new exercise price. The difference in fair value of the effect of the Down Round Feature was immaterial and had an immaterial impact on net loss per share in the period presented. The exercise price will continue to be adjusted in the event the Company issues additional shares of common stock below the then-current exercise price, in accordance with the terms of the warrants.

The Pre-Funded Warrants and warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants and warrants do not provide any guarantee of value or return.

NOTE 13 — SHARE-BASED COMPENSATION

2023 Equity Incentive Plan

The Company maintains the 2023 Equity Incentive Plan (the "2023 Plan") and previously maintained the 2019 Equity Incentive Plan (the "2019 Plan") and 2018 Omnibus Incentive Plan (the "2018 Plan").

Following stockholder approval during the year ended December 31, 2023, any shares then available for future grant under the 2019 Plan and 2018 Plan were allocated to the 2023 Plan and no further grants could be made under the 2018 Plan and the 2019 Plan. In December 2024, stockholders approved a proposal to amend the 2023 Plan to further increase shares available for grant under the 2023 Plan by 1,520,000 shares. As of December 31, 2024, 1,574,557 shares remained issuable under the 2023 Plan.

2024 Inducement Plan

On February 28, 2024, the Board approved the Company's 2024 Inducement Plan (the "Inducement Plan"). Pursuant to the Inducement Plan and Nasdaq Listing Rule 5635(c)(4), the Company is permitted to grant equity awards as an inducement material to an individual's entering into employment with the Company, subject to certain conditions ("Inducement Grants"). In November 2024, the Board reduced the number of shares available to be issued under the Inducement Plan to one share. As of December 31, 2024, there was one share available for future Inducement Grants.

2019 Employee Share Purchase Plan

The Company has adopted an Employee Share Purchase Plan ("ESPP") pursuant to which qualified employees (as defined in the ESPP) may elect to purchase designated shares of the Company's common stock at a price equal to 85% of the lesser of the fair market value of the common stock at the beginning or end of each semi-annual share purchase period ("Purchase Period"). Employees are permitted to purchase the number of shares purchasable with up to 15% of the earnings paid (as such term is defined in the ESPP) to each of the participating employees during the Purchase Period, subject to certain limitations under Section 423 of the U.S. Internal Revenue Code.

As of December 31, 2024, 87,122 shares remained available for grant under the ESPP.

During the years ended December 31, 2024 and 2023, 14,080 and 15,261 shares were purchased by employees pursuant to the ESPP, respectively.

Options and Restricted Stock Units ("RSUs") granted to employees and directors

For the years ended December 31, 2024 and 2023, the Company granted options and RSUs to employees and directors as follows:

	Year ended December 31, 2024			
	Award amount	Exercise price range	Vesting period	Expiration
Options	870,000	$1.96 – $2.40	1 year – 4 years	10 years
RSUs	435,000	—	4 years	—

	Year ended December 31, 2023			
	Award amount	Exercise price range	Vesting period	Expiration
Options	535,000	$2.70	1 year – 4 years	10 years
RSUs	435,000	—	4 years	—

During the years ended December 31, 2024 and 2023, the fair value of options and RSUs granted to employees and directors was $2.6 million and $2.4 million, respectively. The fair value of RSUs granted is based on the share price on grant date. One share of common stock will be issued upon settlement of each RSU that vests.

The fair value of each option granted is estimated using the Black-Scholes option pricing method. The volatility is based on a combination of historical volatilities of companies in comparable stages as well as companies in the industry, by statistical analysis of daily share pricing model. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the options granted in dollar terms. The Company's management uses the expected term of each option as its expected life. The expected term of the options granted represents the period of time that granted options are expected to

remain outstanding and is based on the simplified method. Under the simplified method, the expected life of an option is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company used the simplified method due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the stock options.

The underlying data used for computing the fair value of the options are as follows:

	Year ended December 31,	
	2024	2023
Exercise price	$1.96 – $2.40	$2.70
Dividend yield	—%	—%
Expected volatility	104.00% – 105.73%	104.42% – 105.64%
Risk-free interest rate	3.95% – 4.32%	4.04%
Expected term	6 years	6 years

Modification of share-based compensation

On November 10, 2019, Menlo Therapeutics Inc. ("Menlo") entered into a merger agreement (the "Merger Agreement") with Foamix Pharmaceuticals Ltd. ("Foamix") and Giants Merger Subsidiary Ltd., a wholly-owned subsidiary of Menlo ("Merger Sub"). On March 9, 2020, Merger Sub merged with and into Foamix, with Foamix surviving as a wholly-owned subsidiary of Menlo (the "Merger"). The combined company changed its name to VYNE in September 2020. Pursuant to the Merger, all outstanding options and RSUs granted by Foamix were exchanged for stock options and RSUs of Menlo's common stock according to the exchange ratio set forth in the Merger Agreement. In addition, for each option and RSU the holder received a contingent stock right ("CSR"). This transaction was considered to be a modification under ASC 718, Compensation — Stock Compensation. The modification did not affect the remaining requisite service period. As a result of the modification, for outstanding options and RSUs granted to Foamix employees and consultants, the Company recorded immaterial incremental compensation expense. On April 6, 2020, pursuant to the terms of the agreement governing the CSRs, each CSR was converted into 1.2082 shares of Menlo common stock, resulting in an effective exchange ratio in the Merger of 1.8006 shares of Menlo common stock for each Foamix ordinary share. As a result of the modification, for outstanding options and RSUs granted to Foamix employees and consultants, the Company recorded incremental compensation expense of $7 thousand and $46 thousand for the years ended December 31, 2024 and 2023, respectively.

Summary of outstanding and exercisable options and RSUs

The following table summarizes stock option activity for the year ended December 31, 2024:

	Number of options	Weighted Average Exercise Price
Outstanding at December 31, 2023	744,537	$ 40.65
Granted	870,000	2.27
Forfeited	(25,572)	2.94
Expired	(4,661)	222.61
Outstanding at December 31, 2024	1,584,304	$ 19.65
Exercisable at December 31, 2024	397,143	$ 70.32

The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was $1.6 million and $1.2 million, respectively. The weighted average remaining contractual term of outstanding and exercisable options as of December 31, 2024 was 8.62 years and 7.06 years, respectively. Total unrecognized share-based compensation for options at December 31, 2024 was $1.9 million, which is expected to be recognized over a weighted average period of 2.76 years.

The intrinsic value of outstanding and exercisable options was $1.3 million and $134 thousand, respectively, as of December 31, 2024.

The following table summarizes RSU activity for the year ended December 31, 2024:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	460,979	$4.99
Awarded	435,000	2.33
Vested	(119,724)	9.76
Forfeited	(25,540)	2.79
Outstanding at December 31, 2024	750,715	$2.77

The weighted average remaining contractual term of outstanding RSUs as of December 31, 2024 was 1.52 years. Total unrecognized compensation expense related to the unvested portion of the RSUs at December 31, 2024 was $1.8 million, which is expected to be recognized over a weighted average period of 3.11 years.

Share-based compensation expenses

The following table illustrates the allocation of share-based compensation expense on the line items on the statements of operations and comprehensive loss:

	Year ended December 31,	
(in thousands)	**2024**	**2023**
Research and development	$ 548	$ 534
General and administrative	2,755	2,771
Total	$3,303	$3,305

NOTE 14 — INCOME TAX

The loss before income taxes and the related tax (benefit) expense is as follows:

	Year ended December 31,	
(in thousands)	**2024**	**2023**
Income (loss) before income taxes:		
Domestic	$(39,830)	$(28,459)
Foreign	—	7
Total loss before taxes	$(39,830)	$(28,452)
Current taxes:		
Federal	$ —	$ (123)
State	4	2
Foreign	—	121
Total current taxes	$ 4	$ —

A reconciliation of income taxes at the U.S. federal statutory rate to the provision for income taxes is as follows:

	Year ended December 31,	
	2024	2023
Federal income tax provision at statutory rate	21.00%	21.00%
State income tax provision, net of federal benefit	(0.01)%	(0.01)%
Permanent differences	(0.06)%	(0.57)%
Change in valuation allowances	(20.94)%	(20.42)%
Effective income tax rate	(0.01)%	—%

The income tax expense for the years ended December 31, 2024 and 2023 differed from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before tax expense as a result of nondeductible expenses, changes in state effective tax rates, foreign taxes, tax credits generated, true up of net operating loss carryforwards, and increase in the Company's valuation allowance. The Company applies the elements of ASC 740-10 regarding accounting for uncertainty in income taxes. This clarifies the accounting for uncertainty in income taxes recognized in financial statements and required impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. Included in other liabilities on the consolidated balance sheets are the total amount of unrecognized tax benefits of approximately $2.6 million and $2.5 million as of December 31, 2024 and 2023, respectively, net of the federal benefit, which is offset by a valuation allowance. The Company's policy is to recognize interest and penalties related to tax matters within the income tax provision. Tax years beginning in 2020 are generally subject to examination by taxing authorities, although net operating losses from all years are subject to examinations and adjustments for at least three years following the year in which the attributes are used.

The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
(in thousands)	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 75,922	$ 72,508
Tax credit carryforwards	7,171	6,851
Section 174 expenses	14,720	7,775
Share-based compensation	2,217	1,988
Accrued expenses and other	649	651
Total gross deferred tax assets	100,679	89,773
Less: valuation allowance	(100,679)	(89,773)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is contingent upon sufficient future taxable income during the period that deductible temporary differences and carry forward losses are expected to be available to reduce taxable income. As the achievement of required future taxable income is not likely, the Company recorded a full valuation allowance.

At December 31, 2024 and 2023, the Company recorded a valuation allowance against its net deferred tax assets of $100.7 million and $89.8 million, respectively. The change in the valuation allowance during the years ended December 31, 2024 and 2023 was an increase of $10.9 million and $2.9 million, respectively. A valuation allowance has been recorded since, in the judgment of management, these assets are not more likely than not to be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences and carryforwards become deductible or are utilized. As of December 31, 2024, the Company had federal and state net operating loss carryforwards of $343.4 million and $53.6 million, respectively, of which $44.3 million will begin to expire in

2031 for federal and $53.6 million will begin to expire in 2040 for state purposes. As of December 31, 2024, the Company had federal research and development tax credit carryforwards of $7.2 million which will begin to expire in 2031. The Company has no state research and development tax credit carryforwards. As a result of U.S. tax reform legislation, federal net operating losses generated beginning in 2018 and subsequent years carryforward indefinitely, however, the Company has federal net operating losses that pre-date U.S. tax reform legislation which begin to expire in 2031 and federal credit carryforwards that begin to expire in 2031. State net operating loss carryforwards begin to expire in 2031, and the state credit carryforwards began to expire in 2031. Sections 382 and 383 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses and certain other tax attributes, such as research and development tax credits, to an annual limitation in the event of certain ownership changes, as defined. The Company has not completed a 382 study through December 31, 2024, however, it may have experienced ownership changes in the past, including in connection with the Merger. In addition, the Private Placement likely resulted in an ownership change for purposes of Section 382 and therefore the Company may be materially limited in the amount of NOL and R&D tax credit available for utilization in the future.

The Company generated research and development tax credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, a partial reserve has been presented as an uncertain tax position which is offset against the gross research and development deferred tax asset. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

Uncertain tax positions:

ASC No. 740, Income Taxes, requires significant judgment in determining what constitutes an individual tax position as well as assessing the outcome of each tax position. Changes in judgment as to recognition or measurement of tax positions can materially affect the estimate of the effective tax rate and consequently, affect the operating results of the Company.

The following table summarizes the activity of the Company's unrecognized tax benefits (in thousands):

Balance at January 1, 2023	$2,854
Additions for prior year positions	19
Additions for current year positions	105
Reductions related to expiration of statute of limitations	(520)
Balance at December 31, 2023	$2,458
Reductions for prior year positions	(3)
Additions for current year positions	111
Balance at December 31, 2024	$2,566

NOTE 15 — SEGMENT INFORMATION

The Company operates in one operating segment, and therefore one reportable segment, focused on the development of differentiated therapies to treat chronic inflammatory and immune-mediated conditions of high unmet need. This determination, that the Company operates as a single operating segment, is consistent with the financial information regularly reviewed by the Chief Operating Decision Maker ("CODM") for purposes of evaluating performance, allocating resources, and planning and forecasting for future periods. The Company's Chief Executive Officer ("CEO") is the CODM.

The accounting policies for the single operating segment are the same as those described in "Note 2 — Significant Accounting Policies." The CODM uses net loss based on net loss that is reported on the consolidated statement of operations and comprehensive loss to allocate resources (including employees, property, and financial resources), predominantly during the annual budget and forecasting process. The Company's CODM views specific program spend within research and development expenses as well as overall

general and administrative expenses as significant segment expenses. As a pre-product revenue company, the CODM also considers budget versus actual results for expenses that are deemed significant and cash forecast models for assessing performance and to decide the level of investment in the Company's operating and capital allocation activities. Further, the measure of segment assets is reported on the consolidated balance sheet as total consolidated assets. All long-lived assets are held in the United States. All revenues are generated in the US.

The following table presents segment revenue and significant expenses regularly reviewed by the CODM for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	2023
Royalty revenues	$ 501	$ 424
Operating expenses		
Research and development:		
Repibresib (VYN201)	16,271	4,593
VYN202	11,262	8,770
Other segment items*	3,413	2,944
General and administrative	13,192	13,375
Total operating expenses	44,138	29,682
Operating loss	(43,637)	(29,258)
Other income, net	3,834	1,386
Loss from continuing operations before income taxes	(39,803)	(27,872)
Income tax expense	4	—
Loss from continuing operations	(39,807)	(27,872)
Loss from discontinued operations, net of income taxes	(27)	(580)
Net loss	$(39,834)	$(28,452)

* Other segment items relate to research and development expenses that cannot be directly allocated to one specific product candidate, such as employee-related expenses, consulting, quality control, regulatory, and general IP legal expenses.

Accordingly, the Company manages its operations as a single operating and reportable segment, and the consolidated financial statements and notes thereto are presented as a single reportable segment.

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 maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the company's management, including its chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of December 31, 2024. Based on such evaluation, those officers have concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes and includes those policies and procedures that (a) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting, as of December 31, 2024. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on these criteria.

ITEM 9B — OTHER INFORMATION

None.

ITEM 9C — DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10 — DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

The following table sets forth information regarding our executive officers and members of our Board of Directors (the "Board") as of the date of this Annual Report on Form 10-K.

Name	Age	Position(s)
Executive Officers and Employee Director		
David Domzalski	58	President, Chief Executive Officer and Director
Tyler Zeronda	39	Chief Financial Officer and Treasurer
Iain Stuart, Ph.D.	52	Chief Scientific Officer
Mutya Harsch	50	Chief Legal Officer, General Counsel and Secretary
Non-Employee Directors		
Sharon Barbari	70	Director
Steven Basta	59	Director
Christine Borowski, Ph.D.	47	Director
Anthony Bruno	68	Director
Patrick LePore	69	Lead Independent Director
Elisabeth Sandoval Little	63	Director

Executive Officers

David Domzalski has served as our President and Chief Executive Officer and as a director since March 2020. From July 2017 until the March 2020 closing of the Merger between Menlo and Foamix, Mr. Domzalski served as the Chief Executive Officer of Foamix. He also served as a director of Foamix from 2018 to the closing of the Merger. Mr. Domzalski's tenure with Foamix began in 2014 when he served as President of its U.S. subsidiary. Prior to that, Mr. Domzalski was the Vice President of Sales and Marketing at LEO Pharma, Inc. from 2009 to 2013. Mr. Domzalski holds a B.A. in economics and political science from Muhlenberg College in Allentown, Pennsylvania. We believe Mr. Domzalski is qualified to serve on our Board given his leadership position with our company and Foamix, and his extensive experience in operating and leadership roles in the pharmaceutical industry.

Tyler Zeronda was appointed as our Chief Financial Officer and Treasurer in March 2022 and previously served as our Interim Chief Financial Officer and Treasurer beginning in June 2021. Mr. Zeronda has been responsible for all finance activities related to our commercial operations, financial planning, treasury, risk management and supply chain matters. Mr. Zeronda joined Foamix in April 2019, and from the closing of the Merger in 2020 until June 2021, Mr. Zeronda served as our Vice President of Finance. From 2013 to April 2019, Mr. Zeronda held positions of increasing responsibility in finance at the publicly held company Aerie Pharmaceuticals Inc., culminating in his role as Director of Finance. Prior to joining Aerie, Mr. Zeronda was employed at the accounting firm Ernst & Young LLP where he focused on assurance services for companies in the healthcare industry. Mr. Zeronda received his M.S. in accounting from the

University of Virginia. He holds a B.A. in economics and business from Lafayette College and is licensed as a Certified Public Accountant in the state of New York.

Iain Stuart, Ph.D. has served as our Chief Scientific Officer since the closing of the Merger. From January 2019 until the closing of the Merger in 2020, Dr. Stuart served as Foamix's Chief Scientific Officer, Senior Vice President of Research & Development from 2017 to January 2019 and Vice President of Clinical Development from 2016 to 2017. Prior to joining Foamix, Dr. Stuart held several positions, including Vice President of Medical Strategy and Scientific Affairs, at LEO Pharma Inc. from 2008 to 2016. Dr. Stuart holds a Ph.D. from Glasgow Caledonian University in Scotland.

Mutya Harsch has served as our Chief Legal Officer, General Counsel and Secretary since the closing of the Merger, having previously served with Foamix since 2018, most recently as General Counsel and Chief Legal Officer. Ms. Harsch previously held positions as Special Counsel, Mergers & Acquisitions at Cooley LLP from 2015 to 2017 and as a corporate lawyer at Davis Polk & Wardwell from 2005 to 2015. From October 2021 to June 2023, she served on the board of directors of the publicly held company Satsuma Pharmaceuticals Inc. Ms. Harsch received her J.D. and B.A. from the University of California at Berkeley.

Non-Employee Directors

Sharon Barbari has served on our Board since the closing of the Merger, having previously served as a director of Foamix from January 2019 to the closing of the Merger in 2020. From 2004 to 2017, Ms. Barbari served as Chief Financial Officer at Cytokinetics. From 2002 to 2004, she served as Chief Financial Officer and Senior Vice President of Finance and Administration at InterMune. From 1998 to 2002, she served in senior financial roles at Gilead Sciences, including as Chief Financial Officer. Ms. Barbari was also employed as Vice President of Strategic Planning at Foote, Cone & Belding Healthcare. She began her career at Syntex Corporation/Roche Pharmaceuticals, where she held various roles of increasing responsibility from 1972 to 1996. Ms. Barbari served on the board of directors of the publicly held company Agile Therapeutics from June 2020 until its merger with Exeltis Project, Inc., a U.S. subsidiary of Insud Pharma, S.L., in August 2024. She previously was a board member for the Association of Bioscience Finance Officers Northern California Chapter, Phytogen Life Sciences and Sonoma Pharmaceuticals. In 2017, Ms. Barbari was a recipient of the YWCA Silicon Valley Tribute to Women Awards. She received her B.S. in accounting from San Jose State University. We believe Ms. Barbari is qualified to serve on our Board because of her financial executive and leadership roles in various biotechnology and pharmaceutical companies.

Steven Basta has served on our Board since 2015. Mr. Basta served with Menlo as our President and Chief Executive Officer from 2015 until the closing of the Merger. Mr. Basta has served as the Chief Executive Officer of SaNOtize Research and Development Corp. since September 2023. From December 2020 until October 2022, Mr. Basta served as the Chief Executive Officer of Mahana Therapeutics, a privately held digital therapeutics company. From 2011 to 2015, Mr. Basta served as Chief Executive Officer of AlterG, a privately held medical device company. From 2002 to 2010, Mr. Basta served as Chief Executive Officer of BioForm Medical, a publicly held medical aesthetics company acquired by Merz, and from 2010 to 2011 served as Chief Executive Officer of its successor Merz Aesthetics. He has served on the board of DermBiont, Inc., a privately held pharmaceutical company, since 2020, and has served as chairman of the board of directors of Illumisonics, a privately held company, since November 2023. Mr. Basta served as a director of the publicly held company Viveve Medical from 2018 until March 2023, including as Chairman of the Board beginning in January 2019. Mr. Basta received a B.A. from The Johns Hopkins University and an M.B.A. from the Kellogg Graduate School of Management at Northwestern University. We believe Mr. Basta is qualified to serve on our Board because of his extensive experience in leadership and management roles at various life sciences companies.

Christine Borowski, Ph.D. has served on our Board since January 2024. Dr. Borowski has served as Principal at Access Biotechnology since January 2024, and previously served as Vice President (from January 2022) and Senior Associate (from July 2019) at Access Biotechnology. Prior to that, Dr. Borowski worked on therapeutics company creation at Apple Tree Partners from 2017 to May 2019. Before joining Apple Tree Partners, Dr. Borowski worked as an editor at several scientific journals, most recently as Chief Editor of Nature Medicine from 2014 to 2017. She earned a B.S. in Biology from the University of Kentucky, a Ph.D. in Immunology from Harvard University, and completed her postdoctoral work on natural killer T cell development at the University of Chicago. Dr. Borowski was appointed to the Board in

connection with Access Biotechnology's equity investment in the Company in November 2023. We believe Dr. Borowski is qualified to serve on our Board because of her expertise in immunology and extensive experience in the biopharmaceutical industry.

Anthony Bruno has served on our Board since the closing of the Merger, having previously served as a director of Foamix from 2018 to the closing of the Merger in 2020. Prior to his retirement in 2018, Mr. Bruno served as a strategic consultant to Foamix from 2014 to 2018 and to a number of healthcare-focused investment funds between 2011 and 2018. He was employed at Warner Chilcott from 2000 to 2011, most recently as Executive Vice President, with responsibility for all business development activities including product acquisitions and divestitures as well as licensing agreements. Mr. Bruno also spent 16 years at Warner Lambert, holding several positions of increasing strategic responsibility. Mr. Bruno began his career as an associate with the law firm of Shearman & Sterling. Mr. Bruno holds a B.A. in Political Science from Syracuse University and a J.D. from The George Washington University Law School. We believe Mr. Bruno is qualified to serve on our Board given his experience as an accomplished pharmaceutical executive with broad expertise in the legal, business development, and corporate development functions, as well as his significant experience in product licensing and M&A transactions.

Patrick LePore has served on our Board since September 2020 and was appointed as our lead independent director in February 2021. Mr. LePore served as Chairman, Chief Executive Officer and President of the publicly held company Par Pharmaceutical Companies, Inc. from 2006 until its acquisition by private equity investor TPG Capital in 2012. He remained as chairman of the new company where he led the sale of the company to Endo Pharmaceuticals in 2015. Mr. LePore began his career with Hoffmann-LaRoche. He later founded Boron, LePore & Associates, a medical communications company, which he took public in 1997 and which was eventually sold to Cardinal Health. Within the past five years, Mr. LePore served as Chairman of the Board of the publicly held pharmaceutical company Lannett Company, Inc and as a director of the publicly held companies Matinas BioPharma Holdings, Inc., PharMerica Corporation and Innoviva, Inc. He also previously served as a trustee of Villanova University, from which he holds a bachelor's degree. He holds a Master of Business Administration from Farleigh Dickinson University. We believe Mr. LePore is qualified to serve on our Board given his extensive experience as a senior level executive and board member for several companies in the pharmaceutical sector.

Elisabeth Sandoval Little has served on our Board since March 2019. Ms. Sandoval Little currently serves as a consultant to the pharmaceutical industry. From 2016 to 2019, she served as the Chief Commercial Officer and Executive Vice President of Corporate Strategy for Alder Biopharmaceuticals, a publicly held biopharmaceutical company. From 2012 to 2015, Ms. Sandoval Little was Chief Commercial Officer for KYTHERA Biopharmaceuticals until KYTHERA's acquisition by Allergan. Ms. Sandoval Little previously served as Vice President of Marketing for Bausch and Lomb Surgical and Vice President of Global Marketing at Allergan with responsibility for the Medical Aesthetics division. She spent over 20 years at Allergan in sales and marketing leadership roles in the specialties of dermatology, neurology, and aesthetics. Ms. Sandoval Little began her career in research and development at Johnson & Johnson's Ethicon division. Ms. Sandoval Little currently serves on the board of directors of the publicly held company PROCEPT BioRobotics Corporation and the privately held company Feldan Therapeutics, and previously served on the board of directors of the publicly held company Satsuma Pharmaceuticals from May 2019 until June 2023 and the publicly held company Intersect ENT, Inc. from April 2021 until its acquisition by Medtronic plc in May 2022. She holds an M.B.A. from Pepperdine University and a B.S. in biology from the University of California, Irvine. We believe that Ms. Sandoval Little is qualified to serve on our Board because of her extensive background working in the dermatology industry and her experience in strategic planning, business transactions, sales operations and executive leadership.

Corporate Governance Guidelines

The Board has documented our governance practices in our corporate governance guidelines to assure that the Board will have the necessary authority and practices in place to review and evaluate our business operations as needed and to make decisions that are independent of our management. The guidelines are also intended to align the interests of directors and management with those of our stockholders. The corporate governance guidelines set forth certain practices the Board will follow with respect to Board composition, Board committees, Board nomination, director qualifications and evaluation of the Board and committees.

The corporate governance guidelines and the charter for each committee of the Board described below may be viewed on the "Corporate Governance" section of our "Investors & Media" page on our corporate website located at vynetherapeutics.com.

Leadership Structure of the Board

Our amended and restated bylaws and corporate governance guidelines provide our Board with flexibility to designate the position of Chairman of the Board, and if so, to combine or separate the positions of Chairman of the Board and Chief Executive Officer, or to appoint a lead director in accordance with its determination that utilizing a particular structure would be in the best interests of the Company.

Upon the recommendation of our Nominating and Corporate Governance Committee, our Board has appointed Patrick LePore to serve as our lead independent director. The Board determined that the appointment of a lead independent director was in our best interests and those of our stockholders as it strengthens the Board's independence and commitment to strong governance practices.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our Board encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the Board at regular Board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Committees of the Board of Directors

The Board has a standing Audit Committee, Compensation Committee and a Nominating and Corporate Governance Committee. The Board may establish other committees to facilitate the management of our business. The current composition and functions of each committee are described below.

Name	Audit	Compensation	Nominating and Corporate Governance
David Domzalski	—	—	—
Sharon Barbari	X*	X	—
Steven Basta	X	—	—
Christine Borowski, Ph.D.	—	—	X
Anthony Bruno	—	X	X*
Patrick LePore	—	—	X
Elisabeth Sandoval Little	X	X*	—

* Committee Chairperson

Below is a description of each committee of the Board.

Audit Committee

Our Audit Committee oversees our corporate accounting and financial reporting process. Among other matters, the Audit Committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;

- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- monitors the rotation of partners of the independent registered public accounting firm on our engagement team in accordance with requirements established by the SEC;
- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates; and
- reviews the Audit Committee charter and the committee's performance at least annually.

The current members of our Audit Committee are Mses. Barbari and Sandoval Little and Mr. Basta, with Ms. Barbari serving as chairperson of the committee. All members of our Audit Committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our Board has determined that each of Ms. Barbari and Mr. Basta qualifies as an audit committee financial expert under the applicable rules of the SEC and has the requisite financial sophistication as defined under the applicable rules and regulations of Nasdaq. Under the rules of the SEC, members of the Audit Committee must also meet heightened independence standards. Our Board has determined that Mses. Barbari and Sandoval Little and Mr. Basta are independent under the applicable rules of the SEC and Nasdaq.

The Audit Committee operates under a written charter, available on our corporate website, that satisfies the applicable standards of the rules of the SEC and Nasdaq.

Compensation Committee

Our Compensation Committee oversees policies and makes determinations relating to compensation and benefits of our current and prospective officers, directors and employees. The Compensation Committee periodically evaluates the performance of our Company, and where appropriate, our officers, in light of the goals and objectives it has established, and determines and approves, or may recommend to the Board to approve, the bonus award, if any, payable to these officers. The Compensation Committee may establish compensation and make bonus awards to our chief executive officer directly or may make recommendations to the Board regarding compensation and bonus awards payable to our chief executive officer. Our Compensation Committee also reviews director compensation and makes recommendations to the Board regarding director compensation. The Compensation Committee also reviews and approves or makes recommendations to our Board regarding the issuance of stock options and other awards under our stock plans. The Compensation Committee will periodically review and evaluate the performance of the Compensation Committee and its members, including compliance by the Compensation Committee with its charter.

The current members of our Compensation Committee are Mses. Barbari and Sandoval Little and Mr. Bruno, with Ms. Sandoval Little serving as the chairperson of the committee. Our Board has determined that each of Mses. Barbari and Sandoval and Mr. Bruno is independent under the applicable rules and regulations of Nasdaq and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Our executive officers submit proposals to the Board and the Compensation Committee regarding our executive compensation. Our Chief Executive Officer also annually reviews the performance of each executive officer and makes recommendations regarding their compensation. The Compensation Committee considers those recommendations in determining base salaries, adjustments to base salaries, annual cash bonus program targets and awards and equity awards, if any, for the executive officers and other members of senior management.

The Compensation Committee has evaluated the independence of its compensation consultant, considering the independence factors specified in the listing requirements of Nasdaq and concluded that their work for the Compensation Committee does not raise any conflicts of interest.

The Compensation Committee operates under a written charter, available on our corporate website, that satisfies the applicable standards of the rules of the SEC and Nasdaq.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is responsible for making recommendations to our Board regarding candidates for directorships and the size and composition of our Board. In addition, the Nominating and Corporate Governance Committee is responsible for overseeing our corporate governance policies and reporting and making recommendations to our Board concerning governance matters.

The current members of our Nominating and Corporate Governance Committee are Dr. Borowski and Messrs. Bruno and LePore, with Mr. Bruno serving as the chairperson of the committee. Our Board has determined that each of Dr. Borowski and Messrs. Bruno and LePore is an independent director under the applicable rules and regulations of Nasdaq relating to nominating and corporate governance committee independence.

The Nominating and Corporate Governance Committee operates under a written charter, available on our corporate website, that satisfies the applicable standards of the SEC and Nasdaq.

Our Nominating and Corporate Governance Committee is responsible for reviewing with the Board, on an annual basis, the appropriate characteristics, skills and experience required for the Board as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the Nominating and Corporate Governance Committee, in recommending candidates for election, and the Board, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including:

- the candidate's experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- the candidate's experience as a board member of another publicly held company;
- the candidate's professional and academic experience relevant to our industry;
- the strength of the candidate's leadership skills;
- the candidate's experience in finance and accounting and/or executive compensation practices; and
- whether the candidate has the time required for preparation, participation and attendance at Board meetings and committee meetings, if applicable.

Currently, our Nominating and Corporate Governance Committee and Board evaluate each individual in the context of the Board as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these areas. The Nominating and Corporate Governance Committee will consider individuals who are properly proposed by stockholders to serve on the Board in accordance with laws and regulations established by the SEC and the Nasdaq listing requirements, our bylaws and applicable corporate law, and make recommendations to the Board regarding such individuals based on the established criteria for members of our Board. The Nominating and Corporate Governance Committee may consider in the future whether we should adopt a more formal policy regarding stockholder nominations.

Stockholder Communications with the Board of Directors

The Board will consider any written or electronic communication from our stockholders to the Board, a committee of the Board or any individual director. Any stockholder who wishes to communicate to the Board, a committee of the Board or any individual director should submit written or electronic communications to our corporate secretary at our principal executive offices, which shall include contact

information for such stockholder. All communications from stockholders received shall be forwarded by our secretary to the Board, a committee of the Board or an individual director, as appropriate, on a periodic basis, but in any event no later than the Board's next scheduled meeting. The Board, a committee of the Board, or individual directors, as appropriate, will consider and review carefully any communications from stockholders forwarded by our secretary.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on the "Corporate Governance" section of our "Investors & Media" page on our corporate website located at vynetherapeutics.com. Any amendments to the code, or any waivers of its requirements, will be disclosed on our website. The reference to our web address does not constitute incorporation by reference of the information contained at or available through our website.

Insider Trading Policy and Prohibition on Margin Accounts and Hedging and Similar Transactions

Our employees and directors are subject to an insider trading policy. This policy governs the purchase, sale, and/or other dispositions of the Company's securities by directors, officers and employees that is designed to promote compliance with insider trading laws, rules and regulations, as well as procedures designed to further the foregoing purposes. In addition, it is the Company's intent to comply with applicable laws and regulations relating to insider trading. This policy also prohibits directors, officers and employees from holding our securities in a margin account or pledging our securities as collateral for a loan. In addition, our insider trading policy prohibits employees and directors from engaging in put or call options, short selling, or similar hedging activities involving our stock. We prohibit these transactions because they may reduce the individual's incentive to improve our performance, focus the individual on short-term performance at the expense of long-term objectives, and misalign the individual's interests with those of our stockholders generally. The policy is filed as an exhibit to this Annual Report on Form 10-K.

ITEM 11 — EXECUTIVE COMPENSATION

The following is a discussion of compensation arrangements of our named executive officers ("NEOs"). As a "smaller reporting company" as defined under SEC rules, we have elected to comply with the scaled disclosure requirements applicable to such companies.

Our NEOs for the year ended December 31, 2024 were:

- David Domzalski, President and Chief Executive Officer;
- Iain Stuart, Chief Scientific Officer; and
- Mutya Harsch, Chief Legal Officer, General Counsel and Secretary.

Summary Compensation Table

The following table sets forth the compensation information for our NEOs for the years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Non-equity Incentive Compensation ($)[1]	Stock Awards ($)[2]	Option Awards ($)[2]	All Other Compensation ($)[3]	Total Compensation ($)
David Domzalski	2024	637,560	—	361,497	524,250	436,500	13,800	1,973,607
President and Chief Executive Officer	2023	637,560	382,536	573,804	607,500	501,750	13,200	2,716,350
Iain Stuart	2024	455,555	—	172,200	145,625	121,250	13,800	908,430
Chief Scientific Officer	2023	421,811	168,724	253,086	168,750	139,375	13,200	1,164,946
Mutya Harsch	2024	443,280	—	167,560	145,625	121,250	13,800	891,515
Chief Legal Officer, General Counsel and Secretary	2023	382,594[5]	168,869	253,302	168,750	139,375	13,200	1,126,090

(1) The amounts reported in this column reflect cash bonuses earned pursuant to the achievement of our corporate objectives for the applicable year. See "Narrative Disclosure to Summary Compensation Table — Non-Equity Incentive Plan Compensation" for additional discussion regarding the 2024 cash bonuses.

(2) Represents the grant date fair value of the restricted stock units and stock options granted in accordance with ASC 718. The assumptions used in calculating the grant date fair values are set forth in Note 13 to the consolidated financial statements included in this Annual Report on Form 10-K.

(3) Reflects employer matching contributions to each individual's 401(k) plan.

Narrative Disclosure to Summary Compensation Table

We periodically review compensation for our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

Our Compensation Committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the Compensation Committee then recommends the compensation for each executive officer. Our Compensation Committee, without members of management present, discusses and ultimately approves the compensation of our executive officers. In 2023 the Compensation Committee retained F.W. Cook & Co. ("F.W. Cook"), a compensation consulting firm, to evaluate and make recommendations with respect to our executive compensation program and retention incentives. F.W. Cook's engagement included assisting the Compensation Committee with developing retention incentives for our employees, the selection of a peer group of companies for benchmarking purposes, an analysis of our existing executive compensation, including our equity incentive plan and equity award granting practices, and an analysis of our director compensation policy. In 2023, F.W. Cook presented the Compensation Committee with data about the compensation paid by our peer group of companies and other employers, who we believe compete with us for executives, updated the Compensation Committee on new developments in areas that fall within the Compensation Committee's jurisdiction and advised the Compensation Committee regarding all of its responsibilities. F.W. Cook served at the pleasure of the Compensation Committee rather than us, and the consultant's fees were approved by the Compensation Committee.

Annual Base Salary

The base salary for Mr. Domzalski, our CEO, remained unchanged from 2023 through 2024 and 2025. Mr. Domzalski's annual base salary for 2025 remains $637,560. For 2024, Dr. Stuart's annual base salary increased from $421,811 in 2023 to $455,555 in 2024. For 2024, Ms. Harsch's annual base salary increased from $422,172 in 2023 to $443,280 through 2024. Ms. Harsch was on a reduced schedule from July 2023 through August 2023. During such time, Ms. Harsch maintained her responsibilities as Chief Legal Officer, General Counsel and Secretary of the Company and was paid 25% of her base salary for the period. Dr. Stuart's and Ms. Harsch's annual base salaries for 2025 are $471,499 and $458,795, respectively.

Non-Equity Incentive Plan Compensation

Mr. Domzalski's eligibility to receive his target annual bonus, which is currently 60% of his base salary, is based solely on the achievement of corporate performance objectives. For Ms. Harsch's and Dr. Stuart's target bonus, which is currently 40% of their respective base salaries, the bonus amounts earned are based 75% on the achievement of corporate performance objectives and 25% on the achievement of individual performance objectives. Each of our NEOs has a maximum bonus opportunity equal to 200% of their target bonus.

For the 2024 bonuses, the corporate performance objectives included the advancement of our biotech strategy through organic development of existing products and opportunistic transactions and partnerships. The corporate objectives also included the achievement of certain research and development and financial objectives. In February 2025, our Compensation Committee assessed the level of achievement of corporate and individual performance objectives and considered, among other things, the increase in our share price and the improved strength of our management team and board through the hiring of additional research and development colleagues and the addition of Ms. Borowski to our Board of Directors. In addition, the Compensation Committee considered the level of achievement of certain milestones related to repibresib gel including the initiation of the Phase 2b trial and the completion of enrollment of subjects with NSV in the trial. The Compensation Committee also considered the advancement of VYN202 including the clearance of our IND and successful completion of the Phase 1a SAD/MAD trial in healthy volunteers. The Compensation Committee also determined that Dr. Stuart and Ms. Harsch had fully achieved all individual objectives. After applying such levels of achievement to the applicable weightings, the Compensation Committee, in consultation with F.W. Cook, awarded each of Mr. Domzalski, Dr. Stuart and Ms. Harsch 94.5% of their respective target bonus. The actual bonus amounts paid for 2024 are reflected in the "Non-Equity Incentive Compensation" column of the Summary Compensation Table above.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees, including our NEOs, with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Internal Revenue Code (the "Code") limits. Currently, we match each eligible employee's contributions up to 4% of total eligible compensation. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Employee Benefits and Perquisites

All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans, including medical, dental and vision benefits, medical and dependent care flexible spending accounts, short-term and long-term disability insurance and life insurance. In addition, all of our employees are eligible to participate in our Employee Share Purchase Plan, which allows them to purchase shares of our common stock at a 15% discount to prevailing market prices, subject to certain terms and conditions. We do not provide our NEOs with perquisites or other personal benefits, other than the retirement, health and welfare benefits that apply uniformly to all of our employees.

Equity-Based Awards

Since December 2023, equity-based awards to our NEOs have been made under our 2023 Plan. The equity-based incentive awards granted to our NEOs are designed to align the interests of our NEOs with those of our stockholders. Generally, the vesting of equity awards is tied to each officer's continuous service with us and serves as an additional retention measure. Our executives generally are awarded an initial new hire grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

On December 11, 2023, the Compensation Committee approved the grant of restricted stock units and options to our employees under our 2023 Plan, including members of management, for both 2023 and 2024. The Compensation Committee determined that such grants were appropriate to provide long-term incentives that align the interests of the Company's employees with the interests of stockholders. In making its decision, the Compensation Committee considered: (i) that our employees were not previously awarded equity compensation in the first quarter of 2023, consistent with past practice; (ii) that the ownership percentage in the Company for our Chief Executive Officer, the Chief Financial Officer and other NEOs based on total shares outstanding (inclusive of shares underlying pre-funded warrants) was significantly lower than ownership percentages for such officers at peer companies; (iii) given the small size of our workforce, the impact of the loss of any employee, especially members of management, on our ability to execute our corporate objectives for 2024 and beyond; and (iv) our recent financing activities and the increased total number of shares outstanding, inclusive of shares underlying the pre-funded warrants that were issued to shareholders in the private placement.

For Mr. Domzalski, the Compensation Committee approved the grant of 225,000 restricted stock units and options to purchase 225,000 shares with a grant date of December 13, 2023, and a grant of 225,000 restricted stock units and options to purchase 225,000 shares with a grant date of January 1, 2024. For each of Ms. Harsch and Dr. Stuart, the Compensation Committee approved the grant of 62,500 restricted stock units and options to purchase 62,500 shares with a grant date of December 13, 2023, and a grant of 62,500 restricted stock units and options to purchase 62,500 shares with a grant date of January 1, 2024. These equity awards vest over a four-year period, with 25% vesting on the first anniversary of the last day of the quarter in which the grant was made, and 6.25% vesting every quarter thereafter, in each case, subject to the executive's continued service to the Company through the vesting date. The exercise price for each option is the closing price of our common stock on the applicable grant date.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth all outstanding equity awards held by each of our NEOs as of December 31, 2024.

		Option Awards				Share Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Shares That Have Not Vested (#)	Market Value of Shares or Units of Shares That Have Not Vested(5)($)
David Domzalski	11/10/2015	5,922	—	285.84	11/10/2025	—	—
	3/1/2016	1,500	—	241.92	3/1/2026	—	—
	2/21/2017	1,784	—	408.96	2/21/2027	—	—
	8/8/2017	8,195	—	230.40	8/8/2027	—	—
	5/8/2018	1,755	—	203.04	5/8/2028	—	—
	1/1/2019	4,276	—	151.20	1/1/2029	—	—
	2/24/2020	6,024	—	161.28	2/24/2030	—	—
	5/6/2020	9,443	—	140.40	5/6/2030	—	—
	2/22/2021	18,686	1,243(1)	149.94	2/22/2031	533(1)	1,786
	9/2/2021	17,795	—	30.24	9/2/2031	—	—
	3/17/2022	11,931	5,418(2)	10.98	3/17/2032	5,420(2)	18,157
	12/13/2023	56,250	168,750(3)	2.70	12/13/2033	168,750(3)	565,313
	1/1/2024	—	225,000(4)	2.33	1/1/2034	225,000(4)	753,750
Iain Stuart	11/15/2016	1,000	—	342.00	11/15/2026	—	—
	8/8/2017	325	—	216.00	8/8/2027	—	—
	2/27/2018	750	—	254.16	2/27/2028	—	—
	1/1/2019	1,900	—	151.20	1/1/2029	—	—
	2/24/2020	2,409	—	161.28	2/24/2030	—	—
	5/6/2020	1,561	—	140.40	5/6/2030	—	—
	2/22/2021	3,549	236(1)	149.94	2/22/2031	101(1)	338
	9/2/2021	3,380	—	30.24	9/2/2031	—	—
	3/17/2022	2,866	1,300(2)	10.98	3/17/2032	1,300(2)	4,355
	12/13/2023	15,625	46,875(3)	2.70	12/13/2033	46,875(3)	157,031
	1/1/2024	—	62,500(4)	2.33	1/1/2034	62,500(4)	209,375
Mutya Harsch	2/27/2018	1,250	—	254.16	2/27/2028	—	—
	1/1/2019	1,758	—	151.20	1/1/2029	—	—
	2/24/2020	2,409	—	161.28	2/24/2030	—	—
	5/6/2020	2,082	—	140.40	5/6/2030	—	—
	2/22/2021	3,549	236(1)	149.94	2/22/2031	101(1)	338
	9/2/2021	3,380	—	30.24	9/2/2031	—	—
	3/17/2022	2,865	1,300(2)	10.98	3/17/2032	1,300(2)	4,355
	12/13/2023	15,625	46,875(3)	2.70	12/13/2033	46,875(3)	157,031
	1/1/2024	—	62,500(4)	2.33	1/1/2034	62,500(4)	209,375

(1) This award vested 25% on March 31, 2022, with 6.25% vesting every quarter thereafter through March 31, 2025, subject to the executive's continuous service through each applicable vesting date.

(2) This award vested 25% on March 31, 2023, with 6.25% vesting every quarter thereafter through March 31, 2026, subject to the executive's continuous service through each applicable vesting date.

(3) This award vested 25% on December 31, 2024, with 6.25% vesting every quarter thereafter through December 31, 2027, subject to the executive's continuous service through each applicable vesting date.

(4) This award vests 25% on March 31, 2025, with 6.25% vesting every quarter thereafter through March 31, 2028, subject to the executive's continuous service through each applicable vesting date.

(5) The market value is based on the closing price of our common stock on December 31, 2024.

Compensation Arrangements with Named Executive Officers

We have entered into agreements with each of our named executive officers in connection with his or her employment with us. These agreements set forth the terms and conditions of employment of each NEO, including base salary, target bonus and standard employee benefit plan participation. Our Board or the Compensation Committee reviews each NEO's base salary and other compensation from time to time to ensure compensation adequately reflects the NEO's qualifications, experience, role and responsibilities. The following summaries of the compensation arrangements do not purport to be complete and are qualified in their entirety by reference to each agreement.

David Domzalski, President and Chief Executive Officer

The terms of Mr. Domzalski's employment are governed by his Offer Letter, dated as of March 25, 2020. Mr. Domzalski's annual base salary is currently $637,560. Mr. Domzalski is also eligible to receive an annual cash target bonus of 60% of his base salary, up to the maximum bonus opportunity allowable under the applicable annual bonus plan or program in effect from time to time (such maximum bonus opportunity currently being 200% of the target bonus), subject to the achievement of Company performance criteria determined by the Board or the Compensation Committee.

Mr. Domzalski's Offer Letter provides that if Mr. Domzalski's employment is terminated by us without Cause or he resigns for Good Reason (each as defined below), then, subject to his execution and non-revocation of a release of claims, Mr. Domzalski will be entitled to receive (i) a severance payment equal to 100% of his annual base salary then in effect, (ii) payment of COBRA premiums for healthcare plan continuation at active employee rates for 12 months following the date of termination and (iii) full accelerated vesting of all of outstanding and unvested stock options and restricted stock units on the date of termination, with such stock options remaining exercisable for 90 days following the date of termination.

If Mr. Domzalski's employment is terminated by us without Cause or he resigns for Good Reason, in each case, within 12 months following a Change in Control (as defined in the 2019 Plan), then, subject to his execution and non-revocation of a release of claims, Mr. Domzalski will be entitled to receive (i) a severance payment equal to 1.5 times the sum of his base salary and target bonus for the year of termination, (ii) a prorated target annual bonus payment for the year of termination, (iii) payment of COBRA premiums for healthcare plan continuation at active employee rates for 18 months following the date of termination and (iv) full accelerated vesting of all of outstanding and unvested stock options and restricted stock units on the date of termination, with such stock options remaining exercisable for 90 days following the date of termination.

For purposes of Mr. Domzalski's Offer Letter:

"Cause" means (1) the executive's commission of an act of fraud or dishonesty in the course of his employment; (2) his indictment, conviction or entering of a plea of nolo contendere for a crime constituting a felony; (3) his gross negligence or willful misconduct in connection with his employment; (4) his willful and continued failure to substantially perform his duties; (5) his breach of any of the restrictive covenants; or (6) a material breach of this agreement or any other agreement, plan or arrangement by and between Mr. Domzalski and us or any of our subsidiaries and affiliates or any of our policies or those of our subsidiaries and affiliates by Mr. Domzalski.

"Good Reason" means (i) a material diminution in his base salary or target bonus (provided that failure to earn a bonus equal to or in excess of the target bonus by reason of failure to achieve applicable performance goals shall not be deemed Good Reason); (ii) a material diminution of his position, responsibilities, duties or authorities from those in effect as of the effective date; (iii) any change in reporting structure such that he is required to report to someone other than the Board; (iv) any material breach by us of our obligations under the Offer Letter; or (v) a change in his primary work location that increases his commute by more than 50 miles, in each case subject to certain notice and cure periods.

We must provide Mr. Domzalski with 30 days' notice prior to a termination without Cause, and he must provide us with 30 days' notice prior to any resignation for Good Reason.

Iain Stuart, Chief Scientific Officer

The terms of Dr. Stuart's employment are governed by his Offer Letter, dated as of March 7, 2022. Dr. Stuart's annual base salary is currently $471,499. Dr. Stuart is also eligible to receive an annual target bonus of 40% of his annual base salary, up to the maximum bonus opportunity allowable under the applicable annual bonus plan or program in effect from time to time (such maximum bonus opportunity currently being 200% of the target bonus). His eligibility for such annual target bonus, and the amount of such annual target bonus, is subject to the achievement of corporate performance goals and his achievement of individual performance targets and milestone criteria, as determined by the Chief Executive Officer, in accordance with our bonus plan.

In the event of a termination of his employment without Cause (as defined in the 2019 Plan) or if he resigns for Good Reason, subject to Dr. Stuart's execution of a release of claims, Dr. Stuart will receive (i) a lump sum severance payment equal to 75% of his base salary then in effect and (ii) payment of COBRA premiums for healthcare plan continuation at active employee rates for nine months following the date of termination, provided that our obligation under clause (ii) shall terminate on the earlier of (x) the date on which he enrolls in a group health plan offered by another employer and (y) the date on which he is no longer eligible for continuation coverage under COBRA.

In addition, if Dr. Stuart's employment is terminated by us without Cause or if he terminates his employment with Good Reason within the twelve month period after a Change of Control, he will be entitled to receive a change of control payment equal to (i) one times the sum of his then current base salary plus his target bonus, (ii) his pro rata target bonus for the year of termination, and (iii) payment of COBRA premiums for healthcare plan continuation at active employee rates for 12 months following the date of termination, provided that our obligation under clause (iii) shall terminate on the earlier of (x) the date on which he enrolls in a group health plan offered by another employer and (y) the date on which he is no longer eligible for continuation coverage under COBRA. In addition, in the event of such a termination, all of Dr. Stuart's unvested stock options and restricted stock units will become fully vested.

For purposes of Dr. Stuart's Offer Letter, "Good Reason" means: (i) a material reduction in his base salary; (ii) a material reduction in his target annual bonus opportunity; (iii) a relocation of his principal place of employment by more than 25 miles provided that such relocation increases his daily commute; or (iv) an adverse change in his position, including title, reporting relationship(s), authority, duties or responsibilities, in each case subject to certain notice and cure periods.

We must provide Dr. Stuart with 30 days' notice prior to a termination without Cause, and he must provide us with 30 days' notice prior to any resignation for Good Reason.

Dr. Stuart's Offer Letter also contains customary confidentiality, non-competition and non-solicitation covenants.

Mutya Harsch, Chief Legal Officer, General Counsel and Secretary

The terms of Ms. Harsch's employment are governed by her Offer Letter, dated as of April 7, 2021. Ms. Harsch's annual base salary is currently $458,795. Ms. Harsch is also eligible to receive an annual target bonus of 40% of her annual base salary, up to the maximum bonus opportunity allowable under the applicable annual bonus plan or program in effect from time to time (such maximum bonus opportunity currently being 200% of the target bonus). Her eligibility for such annual target bonus, and the amount of such annual target bonus, is subject to the achievement of corporate performance goals and her achievement of individual performance targets and milestone criteria, as determined by the Chief Executive Officer, in accordance with our bonus plan.

The Offer Letter provides that, in the event of a termination of her employment without Cause (as defined in the 2019 Plan), subject to Ms. Harsch's execution of a release of claims, Ms. Harsch will receive (i) a lump sum severance payment equal to 75% of her base salary then in effect and (ii) payment of COBRA premiums for healthcare plan continuation at active employee rates for nine months following the date of

termination, provided that our obligation under clause (ii) shall terminate on the earlier of (x) the date on which she enrolls in a group health plan offered by another employer and (y) the date on which she is no longer eligible for continuation coverage under COBRA.

In addition, if Ms. Harsch's employment is terminated by us without Cause or she terminates her employment with Good Reason within the twelve month period after a Change of Control (as defined in the 2019 Plan), she will be entitled to receive a change of control payment equal to (i) one times the sum of her then current base salary plus her target bonus, (ii) her pro rata target bonus for the year of termination, and (iii) payment of COBRA premiums for healthcare plan continuation at active employee rates for 12 months following the date of termination, provided that our obligation under clause (iii) shall terminate on the earlier of (x) the date on which she enrolls in a group health plan offered by another employer and (y) the date on which she is no longer eligible for continuation coverage under COBRA. In addition, in the event of such a termination, all of Ms. Harsch's unvested stock options and restricted stock units will become fully vested.

For purposes of Ms. Harsch's Offer Letter, "Good Reason" means: (i) a material reduction in her base salary; (ii) a material reduction in her target annual bonus opportunity; (iii) a relocation of her principal place of employment by more than 25 miles provided that such relocation increases her daily commute; or (iv) an adverse change in her position, including title, reporting relationship(s), authority, duties or responsibilities, in each case subject to certain notice and cure periods.

We must provide Ms. Harsch with 30 days' notice prior to a termination without Cause, and she must provide us with 30 days' notice prior to any resignation for Good Reason.

Ms. Harsch's Offer Letter also contains customary confidentiality, non-competition and non-solicitation covenants.

Clawback Policies

In May 2021, the Board adopted a compensation clawback policy with respect to compensation paid to our executive officers. Under the terms of the policy, compensation can be recovered for a financial restatement or materially inaccurate performance calculation. In this case, we may seek recoupment of short and long-term cash or equity incentive compensation (including time- and performance-based awards) awarded after the effective date of the policy. In addition, compensation may be recovered for willful misconduct or gross negligence that results in material adverse reputational or economic impact on us. In this case, we may seek recoupment of 100% of incentive compensation for "Cause" and if no "Cause," recoupment is based on the impact of the triggering event, if quantifiable at the Compensation Committee's discretion. In addition, in November 2023 we adopted an additional clawback policy as required by the Dodd-Frank Wall Street Reform and Consumer Protection Act and related stock exchange listing standards. The policy adopted in November 2023 is filed as an exhibit to this Annual Report on Form 10-K.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

From time to time, we grant equity awards, including stock options, to our employees, including our named executive officers. Historically, we have typically granted new-hire option awards on, or within the calendar quarter of, a new hire's employment start date and annual refresh employee option grants in the first quarter of each fiscal year, which refresh grants are typically approved at a regularly scheduled meeting of the Compensation Committee occurring in such quarter. Also, non-employee directors receive automatic grants of initial and annual stock option awards, at the time of a director's initial appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, pursuant to our non-employee director compensation policy, as further described under the heading, "Director Compensation — Non-Employee Director Compensation Policy" below. We do not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. The Compensation Committee considers whether there is any material nonpublic information ("MNPI") about our company when determining the timing of stock option grants and does not seek to time the award of stock options in relation to our public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation.

The following table is being provided pursuant to Item 402(x)(2) of Regulation S-K.

Name (a)	Grant date (b)	Number of securities underlying the award (c)	Exercise price of the award ($/Sh) (d)	Grant date fair value of the award (e)	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information (f)[1]
David Domzalski . . .	January 1, 2024	225,000	$2.33	$436,500	1.3%
Iain Stuart	January 1, 2024	62,500	$2.33	$121,500	1.3%
Mutya Harsch	January 1, 2024	62,500	$2.33	$121,500	1.3%

(1) The option grants reported in this table were made two business days before the Company filed a Form 8-K under Item 5.02 reporting the previously disclosed appointment of Dr. Christine Borowski as a non-employee director of the Company.

Director Compensation

Non-Employee Director Compensation Policy

Our Board adopted a non-employee director compensation policy effective as of December 11, 2023. Set forth below is a summary of the compensation paid to the non-executive members of the Board during 2024 pursuant to the policy.

Initial Equity Grants. Each non-employee director who joins the Board will receive, upon appointment, options to purchase shares of our common stock representing two times the annual grant described below. The options will vest and become exercisable as to one-third of the shares on each of the first three anniversaries of the date of grant, subject to the director's continued service through each applicable vesting date.

Annual Grant. Each non-executive director who has served as a director on our Board for at least six months will be granted options to purchase an amount of shares of our common stock representing 0.047% of the shares outstanding (inclusive of pre-funded warrants) on the date of our annual meeting of stockholders. The options vest on the one-year anniversary of the date of grant.

The exercise price per share of each option granted as described above will be equal to the per share fair market value of our stock on the date of grant. Each such option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the non-employee director's service with us. In the event of a change of control transaction, any unvested portion of an equity award granted under this policy will fully vest and become exercisable immediately prior to the effective date of such transaction, subject to the non-employee director's continuous service with us on the effective date of such transaction.

Annual Cash Retainers. Each of our non-employee directors receives an annual cash retainer of $40,000, payable quarterly in arrears, prorated based on the days served in the applicable fiscal quarter. In addition to the annual cash retainer, each of our non-employee directors receives fees for their service as a member or chair of a committee of our Board as set forth in the table below:

	Member	Chair
Additional annual retainer fees for service as a member or chair of the following committees (with chair fees inclusive of fees for service as a member):		
Audit Committee	$10,000	$20,000
Compensation Committee	$ 7,500	$15,000
Nominating and Corporate Governance Committee	$ 5,000	$10,000

In addition, if a non-employee director is appointed to serve in a leadership position on the Board, such non-employee director will be entitled to receive additional annual cash compensation of $40,000 for service as non-employee chair of the Board or $25,000 for service as lead independent director.

We also reimburse all of our non-employee directors for their reasonable and customary business expenses incurred in connection with their service as a director.

None of our non-employee directors may receive cash and equity-based compensation (calculated based on grant date fair value) exceeding, in the aggregate, $750,000 in any calendar year or $1,000,000 in the calendar year a director is first appointed or elected to the Board.

One-Time Option Grant

On January 1, 2024, our Compensation Committee granted each non-executive director (except for Ms. Borowski) a one-time option grant for 20,000 shares of our common stock, which will vest on January 1, 2025, subject to each director's continuous service through such date. The Compensation Committee granted these one-time awards following consultation with the Company's independent compensation consultant, taking into consideration that all equity awards for directors were significantly underwater and that in light of the Company's recent financing (among other things), director stock ownership levels, based on the total shares outstanding inclusive of shares underlying pre-funded warrants, were well below the target levels for the Company's peer companies.

Director Compensation Table

The following table sets forth information for the fiscal year ended December 31, 2024 regarding the compensation awarded to, earned by or paid to our non-executive directors.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	Total Compensation ($)
Sharon Barbari	67,788	76,200	143,988
Steven Basta	49,425	76,200	125,625
Christine Borowski[3]	44,712	115,400	160,112
Anthony Bruno	57,500	76,200	133,700
Patrick LePore	70,575	76,200	146,775
Elisabeth Sandoval Little	65,000	76,200	141,200

(1) Represent the grant date fair value of stock options granted as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value are set forth in Note 13 to the financial statements included in this Annual Report on Form 10-K.

(2) Each of our non-employee directors was granted an option to purchase 20,000 shares of our common stock on December 12, 2024 at an exercise price of $2.40.

(3) Dr. Borowski was appointed as a director, effective January 1, 2024. The amount reported in the Option Awards column includes the grant date fair value of the initial grant made to Dr. Borowski when she joined the Board.

As of December 31, 2024, our non-employee directors held the following equity awards:

Name	Shares Underlying Outstanding Options
Sharon Barbari	63,407
Steven Basta	74,285
Christine Borowski	60,000
Anthony Bruno	63,213
Patrick LePore	62,901
Elisabeth Sandoval Little	63,837

ITEM 12 — SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information relating to the beneficial ownership of our common stock as of February 14, 2025, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after February 14, 2025 through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 15,209,862 shares of our common stock outstanding as of February 14, 2025. Shares of our common stock that a person has the right to acquire within 60 days after February 14, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o VYNE Therapeutics Inc., 685 Route 202/206 N., Suite 301, Bridgewater, NJ 08807.

Name of Beneficial Owner	Number of Shares Owned and Nature of Beneficial Ownership	Percent of Class
5% and Greater Stockholders:		
AI Biotechnology LLC[(1)]	1,519,465	9.99%
Cormorant Global Healthcare Master Fund, LP[(2)]	1,519,465	9.99%
Eventide Healthcare Innovation Fund I LP[(3)]	1,519,465	9.99%
Citadel CEMF Investments Ltd.[(4)]	1,181,088	7.77%

Name of Beneficial Owner	Number of Shares Owned and Nature of Beneficial Ownership	Percent of Class
Named Executive Officers and Directors:		
David Domzalski[5]	370,498	2.39%
Mutya Harsch[6]	106,508	*
Iain Stuart[7]	92,501	*
Steven Basta[8]	61,735	*
Sharon Barbari[9]	44,448	*
Anthony Bruno[10]	45,088	*
Patrick LePore[11]	94,373	*
Elisabeth Sandoval Little[12]	43,837	*
Christine Borowski[13]	13,334	*
All current directors and executive officers as a group (10 persons)[14]	933,842	5.86%

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) This information has been obtained from a Schedule 13D filed on November 13, 2023 by AI Biotechnology LLC, Access Industries Holdings LLC ("AIH"), Access Industries Management, LLC ("AIM") and Mr. Len Blavatnik. Consists of (i) 1,116,585 shares of common stock and (ii) 402,880 shares of common stock issuable upon exercise of Pre-Funded Warrants. Such amount does not include 7,389,568 shares of common stock issuable upon exercise of Pre-Funded Warrants because they are subject to limitations on exercisability if such exercise would result in entities affiliated with AI Biotechnology LLC beneficially owning more than 9.99% of our common stock then issued and outstanding after giving effect to such exercise. AIH directly controls all of the outstanding voting interest in AI Biotechnology LLC. AIM controls AIH. Len Blavatnik controls AIM and holds a majority of the outstanding voting interests in AIH. By virtue of the foregoing, each of Len Blavatnik, AIM and AIH may be deemed to have voting and investment power over the Shares held by AI Biotechnology LLC. The business address of each of AI Biotechnology LLC, AIM, AIH and Len Blavatnik is c/o Access Industries, Inc. 40 West 57th Street, 28th Floor, New York, NY 10019.

(2) This information has been obtained from a Schedule 13G filed on November 13, 2023 by Cormorant Global Healthcare Master Fund, LP ("Cormorant LP"), Cormorant Global Healthcare GP, LLC ("Cormorant GP"), Cormorant Asset Management, LP ("Cormorant AM LP") and Bihua Chen. Consists of 1,394,336 shares of common stock held by Cormorant LP and 125,129 shares of common stock issuable upon exercise of Pre-Funded Warrants. Such amount does not include 2,935,014 shares of common stock issuable upon exercise of Pre-Funded Warrants because they are subject to limitations on exercisability if such exercise would result in entities affiliated with Cormorant LP beneficially owning more than 9.99% of our common stock then issued and outstanding after giving effect to such exercise. Cormorant GP serves as the General Partner of Cormorant LP. Cormorant AM LP serves as the investment manager to Cormorant LP. Bihua Chen serves as the Managing Member of Cormorant GP and the General Partner of Cormorant AM LP (together with Cormorant LP, the "Cormorant Entities"). By virtue of the foregoing, each of Bihua Chen and the Cormorant Entities may be deemed to have voting and investment power over the shares held by Cormorant LP. The business address of each of Bihua Chen and the Cormorant Entities is 200 Clarendon St., 52nd Floor, Boston, Massachusetts 02116.

(3) This information has been obtained from a Schedule 13G filed on November 13, 2023 by Eventide Asset Management, LLC ("EAM"), Finny Kuruvilla and Robin John. Consists of 1,394,336 shares of common stock held by Eventide Healthcare Innovation Fund I LP ("Eventide LP") and 125,129 shares of common stock issuable upon exercise of Pre-Funded Warrants. Such amount does not include 5,162,284 shares of common stock issuable upon exercise of Pre-Funded Warrants because they are subject to limitations on exercisability if such exercise would result in entities affiliated with Eventide LP beneficially owning more than 9.99% of our common stock then issued and outstanding after giving

effect to such exercise. Eventide Healthcare Innovation GP LLC ("Eventide GP") is the General Partner of Eventide LP. EAM is the Managing Member of Eventide GP. Robin John is the chief executive officer of EAM. Finny Kuruvilla and Kyle Rasbach are members of Eventide LP's investment committee. By virtue of the foregoing, each of Mr. John, EAM and Eventide GP may be deemed to have, and Mr. Kuruvilla and Mr. Rasbach may be deemed to share, voting and investment power over the Shares held by Eventide LP. The business address of each of Eventide LP, Eventide GP, EAM, Mr. John, Mr. Kuruvilla and Mr. Rasbach is Eventide Healthcare Innovation Fund I LP c/o Eventide Asset Management, LLC, 1 International Place, Suite 4210, Boston, MA 02110.

(4) This information has been obtained from a Schedule 13G/A filed on February 14, 2024 by Citadel Advisors LLC ("Citadel Advisors"), Citadel Advisors Holdings LP ("CAH"), Citadel GP LLC ("CGP"), Citadel Securities LLC ("Citadel Securities"), Citadel Securities Group LP, Citadel Securities GP LLC and Mr. Kenneth Griffin. Consists of 1,181,088 shares of common stock held by Citadel CEMF Investments Ltd. ("CCIL") and Citadel Securities. Citadel Advisors is the portfolio manager of CCIL. CAH is the sole member of Citadel Advisors. CGP is the General Partner of CAH. Kenneth Griffin owns a controlling interest in CGP. Mr. Griffin, as the owner of a controlling interest in CGP, may be deemed to have shared power to vote and/or shared power to dispose of the securities held by CCIL. This disclosure shall not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities of the Company other than the securities actually owned by such person (if any). The business address of CCIL is c/o Citadel Enterprise Americas LLC, Southeast Financial Center, 200 S. Biscayne Blvd., Suite 3300, Miami, FL 33131.

(5) Includes 82,370 shares of common stock, 216,199 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025, and 71,929 shares of common stock underlying restricted stock units that are scheduled to vest within 60 days of February 14, 2025.

(6) Includes 33,553 shares of common stock, 52,945 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025, and 20,010 shares of common stock underlying restricted stock units that are scheduled to vest within 60 days of February 14, 2025.

(7) Includes 19,217 shares of common stock, 53,392 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025, and 19,892 shares of common stock underlying restricted stock units that are scheduled to vest within 60 days of February 14, 2025.

(8) Consists of (i) 2,842 shares of common stock, (ii) 3,601 shares of common stock held by The Shelter Trust under the Basta Revocable Trust (the "Shelter Trust"), (iii) 1,007 shares of common stock held by the Basta Revocable Trust dated August 4, 2017 (the "Basta Trust"), and (iv) 54,285 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025. As the trustee of each of the Shelter Trust and the Basta Trust, Mr. Basta has voting and investment power over the shares of common stock held by each of the Shelter Trust and the Basta Trust.

(9) Includes 1,041 shares of common stock and 43,407 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025.

(10) Includes 1,875 shares of common stock and 43,213 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025.

(11) Includes 51,472 shares of common stock and 42,901 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025.

(12) Includes 43,837 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025.

(13) Includes 13,334 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025.

(14) Includes 607,734 shares of common stock underlying options that are exercisable within 60 days of February 14, 2025 and 111,831 shares of common stock underlying restricted stock units that are scheduled to vest within 60 days of February 14, 2025.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2024.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights and vesting of RSUs	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	2,205,019[(1)]	$12.96	1,661,679[(3)]
Equity compensation plans not approved by security holders	130,000[(2)]	$ 1.96	1[(4)]
Total	2,335,019	$14.92	1,661,680

(1) Includes all awards outstanding under the 2023 Plan, the 2019 Plan, the 2018 Plan, the Foamix Pharmaceuticals Ltd. 2015 Israeli Share Incentive Plan, the Tigercat Pharma, Inc. 2011 Stock Incentive Plan or the Foamix Pharmaceuticals Ltd. 2009 Israeli Share Option Plan (collectively, the "Prior Plans"). We may no longer issue awards pursuant to any of the Prior Plans. Weighted average exercise price gives effect to outstanding restricted stock units, which have no exercise price. Excluding the restricted stock units, the weighted average exercise price would be $19.65 per share. For a description of the material terms of our equity plan, see "Item 8 — Notes to Consolidated Financial Statements — Note 13 — Share-Based Compensation."

(2) Includes stock options outstanding under our Inducement Plan. For a description of the material terms of our equity plans, see "Item 8 — Notes to Consolidated Financial Statements — Note 13 — Share-Based Compensation."

(3) Includes 1,574,557 shares available for future issuance under the 2023 Plan and 87,122 shares available for future purchase under the ESPP, and one share available for future grant under the Inducement Plan.

(4) Includes 1 share available for future issuance under our Inducement Plan.

ITEM 13 — CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Policies and Procedures for Related Party Transactions

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including without limitation purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee considers all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction.

Certain Related Party Transactions

The following is a description of transactions since January 1, 2023 to which we have been a party, in which the amount involved exceeds $120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

Director and Executive Officer Compensation

Please see "Director Compensation" and "Executive Compensation" for information regarding the compensation of our directors and executive officers.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding these agreements, see "Item 11. Executive Compensation."

Indemnification Agreements and Directors' and Officers' Liability Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements require us to, among other things, indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer. We have obtained an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws.

Independence of Board of Directors and its Committees

Under Nasdaq listing standards, independent directors must comprise a majority of a listed company's board of directors within a specified period of the closing of our initial public offering. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. We currently satisfy the audit committee independence requirements of Rule 10A-3. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our Board has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our Board determined that each of our directors, except for Mr. Domzalski as our chief executive officer, is an independent director as defined under the applicable rules and regulations of the SEC and the listing requirements and rules of Nasdaq.

ITEM 14 — PRINCIPAL ACCOUNTANT FEES AND SERVICES

Baker Tilly US, LLP served as our principal independent registered public accounting firm for the years ended December 31, 2024 and 2023. The following table provides information regarding fees paid by us to Baker Tilly US, LLP for the years ended December 31, 2024 and 2023:

	Year ended December 31,	
	2024	2023
	(U.S. dollars in thousands)	
Audit fees[1]	$359	$379
Tax fees[2]	4	16
Total Fees	$363	$395

(1) Includes professional services rendered in connection with the audit of our annual financial statements, the review of our interim financial statements and fees for registration statements, comfort letters and statutory audits.

(2) Includes professional services rendered for tax compliance services.

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of our accounting, auditing and reporting practices include the approval of audit and non-audit services to be provided by the external auditor. The audit committee pre-approves all non-audit services provided to us by our independent registered public accounting firm.

PART IV

ITEM 15 — EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents Filed as Part of This Report

1. ***Financial statements***.

See Index to Financial Statements under Item 8 of Part II of this Annual Report on Form 10-K, which is incorporated herein by reference.

2. ***Financial statement schedules***.

No schedules are applicable or required, or the information is included in the consolidated financial statements or notes thereto.

3. ***Exhibits***. See Item 15(b) below.

(b) Exhibits

Exhibit Number	Description Of Document	Incorporation by Reference				Filed Herewith
		Form	SEC File No.	Exhibit	Filing Date	
3.1(a)	Amended and Restated Certificate of Incorporation.	10-K	001-38356	3.1	March 17, 2022	
3.1(b)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation.	8-K	001-38356	3.1	February 10, 2023	
3.2	Amended and Restated Bylaws.	10-Q	001-38356	3.2	November 14, 2022	
4.1	Description of Securities Registered Under Section 12 of the Securities Exchange Act of 1934.	10-K	001-38356	4.1	March 14, 2023	
4.2	Second Amended and Restated Warrant, by and among VYNE Therapeutics Inc. and Perceptive Credit Holdings II, LP.	10-Q	001-38356	4.1	May 11, 2020	
4.3	Second Amended and Restated Warrant, by and among VYNE Therapeutics Inc. and Orbimed Royalty & Credit Opportunities III, LP.	10-Q	001-38356	4.2	May 11, 2020	
4.4	Form of Pre-Funded Warrant to Purchase Common Stock.	8-K	001-38356	4.1	October 30, 2023	
10.1†*	License Agreement (Topical), dated as of August 9, 2021, by and between In4Derm Limited and VYNE Therapeutics Inc.	10-Q	001-38356	10.1	November, 10, 2021	
10.2†*	License Agreement (Oral), dated as of April 28, 2023, by and between Tay Therapeutics and VYNE Therapeutics Inc.	10-Q	001-38356	10.1	August 14, 2023	
10.3	Sales Agreement, dated as of March 1, 2024, by and between VYNE Therapeutics Inc. and Cowen and Company, LLC.	10-K	001-38356	10.3	March 1, 2024	

Exhibit Number	Description Of Document	Incorporation by Reference				Filed Herewith
		Form	SEC File No.	Exhibit	Filing Date	
10.4#	2009 Israeli Share Option Plan.	F-1/A	001-36621	10.1	September 3, 2014	
10.5(a)#	2011 Stock Incentive Plan, as amended.	S-1	001-38356	10.4(a)	December 28, 2017	
10.5(b)#	Amendment to 2011 Stock Incentive Plan.	S-1	001-38356	10.4(b)	December 28, 2017	
10.5(c)#	Form of Stock Option Agreement under 2011 Stock Incentive Plan.	S-1	001-38356	10.4(c)	December 28, 2017	
10.5(d)#	Form of Immediately Exercisable Stock Option Agreement under 2011 Stock Incentive Plan.	S-1	001-38356	10.4(d)	December 28, 2017	
10.6#	2015 Israeli Share Incentive Plan.	F-3	001-36621	10.2	October 21, 2015	
10.7(a)#	2018 Omnibus Incentive Plan.	S-1/A	001-38356	10.5(a)	January 12, 2018	
10.7(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan.	S-1/A	001-38356	10.5(b)	January 12, 2018	
10.7(c)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.	10-K	001-38356	10.11(c)	March 4, 2021	
10.8(a)#	2019 Equity Incentive Plan.	10-Q	001-38356	10.5	May 11, 2020	
10.8(b)#	Form of Share Option Grant Notice and Option Agreement under the 2019 Equity Incentive Plan for U.S. and Israeli Employees.	10-Q	001-38356	10.8	May 11, 2020	
10.8(c)#	Form of Restricted Share Unit Grant Notice and Restricted Share Unit Award Agreement under the 2019 Equity Incentive Plan for U.S. and Israeli Employees.	10-Q	001-38356	10.9	May 11, 2020	
10.9#	2019 Employee Share Purchase Plan.	10-Q	001-38356	10.10	May 11, 2020	
10.10#	Offer Letter, dated as of March 25, 2020, by and between VYNE Pharmaceuticals Inc. and David Domzalski.	10-Q	001-38356	10.13	May 11, 2020	
10.11#	Offer Letter, dated as of April 7, 2021, by and between VYNE Pharmaceuticals Inc. and Mutya Harsch.	10-Q	001-38356	10.2	May 6, 2021	
10.12#	Offer Letter, dated as of March 7, 2022, by and between VYNE Pharmaceuticals Inc. and Iain Stuart.	10-K	001-38356	10.12	March 17, 2022	
10.13#	Offer Letter, dated as of March 15, 2022, by and between VYNE Pharmaceuticals Inc. and Tyler Zeronda.	10-K	001-38356	10.13	March 17, 2022	

Exhibit Number	Description Of Document	Incorporation by Reference				Filed Herewith
		Form	SEC File No.	Exhibit	Filing Date	
10.14	Form of Securities Purchase Agreement, dated as of October 27, 2023, by and among VYNE Therapeutics Inc. and the Purchasers.	8-K	001-38356	10.1	October 30, 2023	
10.15	Form of Registration Rights Agreement, dated as of October 27, 2023, by and among VYNE Therapeutics Inc. and the Purchasers.	8-K	001-38356	10.2	October 30, 2023	
10.16(a)#	VYNE Therapeutics Inc. 2023 Equity Incentive Plan.	8-K	001-38356	10.1	December 13, 2023	
10.16(b)#	Form of Director Option Grant Notice and Option Agreement under the 2023 Equity Incentive Plan	8-K	001-38356	10.2	December 13, 2023	
10.16(c)#	Form of Employee Option Grant Notice and Option Agreement under the 2023 Equity Incentive Plan.	8-K	001-38356	10.3	December 13, 2023	
10.16(d)#	Form of Employee Restricted Share Unit Grant Notice and Restricted Share Unit Award Agreement under the 2023 Equity Incentive Plan.	8-K	001-38356	10.4	December 13, 2023	
10.17#	Non-Employee Director Compensation Policy.	10-K	001-38356	10.17	March 1, 2024	
10.18	First amendment to VYNE Therapeutics Inc. 2023 Equity Incentive Plan	8-K	001-38356	10.1	December 12, 2024	
10.19†*	Amendment to License Agreement (Topical) dated as February 12, 2025, by and between Tay Therapeutics Inc. and VYNE Therapeutics Inc.					X
19	Insider Trading Policy.					X
21.1	List of Subsidiaries of VYNE Therapeutics Inc.					X
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney (included on signature page).					X
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

Exhibit Number	Description Of Document	Incorporation by Reference				Filed Herewith
		Form	SEC File No.	Exhibit	Filing Date	
32.1**	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2**	Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
97.1#	VYNE Therapeutics Inc. Incentive Compensation Recoupment Policy, dated November 8, 2023.	10-K	001-38356	97.1	March 1, 2024	
101.INS	XBRL Instance Document — the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Document					X
101.LAB	XBRL Taxonomy Extension Label Document					X
101.PRE	XBRL Taxonomy Presentation Linkbase Document					X
104	Cover Page Interactive Data Filed (embedded within the XBRL document)					

* Exhibits and schedules omitted pursuant to Item 601(a)(5) of Regulation S-K.

† Portions of this exhibit have been omitted in accordance with Item 601(b)(10)(iv) of Regulation S-K because the identified confidential portions are not material and are of the type that the registrant treats as private or confidential.

# Indicates management contract or compensatory plan.

** These certifications are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

The agreements and other documents filed as exhibits to this Annual Report on Form 10-K are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 6, 2025

VYNE Therapeutics Inc.

By: /s/ David Domzalski
David Domzalski
Chief Executive Officer

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Domzalski, Tyler Zeronda and Mutya Harsch, and each of them, his or her attorney-in-fact and agent, each with the power of substitution, for him or her 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 exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, or his or her or their substitute or substitutes, may do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ David Domzalski David Domzalski	Director and Chief Executive Officer (*Principal Executive Officer*)	March 6, 2025
/s/ Tyler Zeronda Tyler Zeronda	Chief Financial Officer (*Principal Financial Officer* and *Principal Accounting Officer*)	March 6, 2025
/s/ Sharon Barbari Sharon Barbari	Director	March 6, 2025
/s/ Steven Basta Steven Basta	Director	March 6, 2025
/s/ Christine Borowski Christine Borowski	Director	March 6, 2025
/s/ Anthony Bruno Anthony Bruno	Director	March 6, 2025
/s/ Patrick LePore Patrick LePore	Director	March 6, 2025
/s/ Elisabeth Sandoval Little Elisabeth Sandoval Little	Director	March 6, 2025