# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2022**

**or**

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

**FOR THE TRANSITION PERIOD FROM TO .**

**Commission File Number 001-38356**

# 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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $22.3 million, computed by reference to the last sales price reported by the Nasdaq Global Select Market as of June 30, 2022. Shares of common stock held by each executive officer, director, and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 1, 2023, there were 3,264,272 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 raise substantial additional financing to fund our operations and continue as a going concern;
- 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;
- our ability to select a lead candidate and exercise our option with respect to oral BET inhibitor compounds under the terms of the Evaluation and Option Agreement with Tay Therapeutics Limited (formerly known as In4Derm Limited);
- our ability to enroll patients and successfully complete, and receive favorable results in, clinical trials for our product candidates;
- the timing of commencement of future preclinical studies and clinical trials;
- 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;
- risks and uncertainties arising out of the completed divestiture of our commercial business;
- disruptions related to COVID-19 and other 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 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;
- the regulatory approval process for our product candidates, including any delay or failure in obtaining requisite approvals;
- developments and projections relating to our competitors and the markets in which we compete, including competing drugs and therapies;
- our ability to comply with various regulations applicable to our business, including continued listing rules imposed by Nasdaq;
- 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;

- 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 the section entitled "Risk Factors" in Part I, Item IA and elsewhere in this Annual Report on Form 10-K as well as our other filings made with the 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.

## SPECIAL NOTE REGARDING 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.

## SPECIAL NOTE REGARDING 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 product and company names mentioned herein may be the trademarks of their respective owners.

## PART I

### ITEM 1 — BUSINESS

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing proprietary, innovative and differentiated therapies for the treatment of immuno-inflammatory conditions.

In August 2021, we entered into a transaction with Tay Therapeutics Ltd. (formerly known as In4Derm Ltd., "Tay") providing us with exclusive worldwide rights to research, develop and commercialize products containing bromodomain and extra-terminal ("BET") inhibitors for the treatment of any disease, disorder or condition in humans. Through our access to this library of new chemical BET inhibitor compounds, we plan to develop product candidates for a diverse set of indications. Based on preclinical data generated to date, we have chosen to focus our initial efforts for this platform on select therapeutic areas in immuno-inflammatory disease.

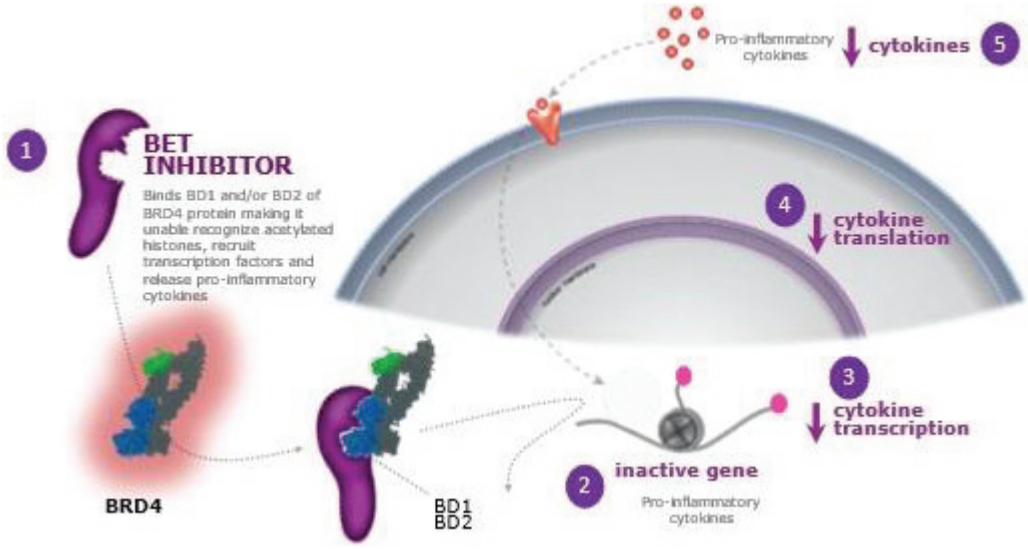
Our lead program is VYN201, a locally administered pan-BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. To date, VYN201 has produced consistent reductions in pro-inflammatory and disease-related biomarkers, improvements in disease severity and a demonstrated local activity through several preclinical models. We believe that these data suggest potential broad utility for VYN201 across multiple routes of administration. In November 2022, we initiated a Phase 1a/b clinical trial evaluating a topical formulation of VYN201 for the treatment of nonsegmental vitiligo. In February 2023, we announced positive preliminary safety data from the Phase 1a portion of the trial. The first nonsegmental vitiligo patient was dosed in the Phase 1b portion of the trial in January 2023 and we expect topline results from this trial in mid-2023.

Our second program is VYN202, a BD2-selective oral small molecule BET inhibitor. VYN202 is in preclinical development for the treatment of immuno-inflammatory indications, and is being designed to achieve class-leading selectivity (BD2 vs. BD1), maximum potency versus BD2 and optimal oral bioavailability. By maximizing BD2 selectivity, we believe VYN202 has the potential to be a more conveniently-administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, where the damaging effects of unrestricted inflammatory signaling activity is common.

We intend to actively evaluate and enter into strategic partnerships to advance our product candidates through the clinic toward commercialization, and may also partner with leading pharmaceutical companies to advance our molecules in therapeutic areas outside of our core focus in immunology. We believe selectively entering into collaborations has the potential to expand and accelerate the development of our programs and maximize the value of our pipeline.

#### *BET Inhibition and Immuno-Inflammatory Disease*

BET proteins are epigenetic enablers of transcription and regulate the expression of specific genes. Each BET protein consists of two bromodomains (BD1 and BD2) and one end terminal domain. BD1 and BD2 enable chromatin remodeling and recruit transcription factors to facilitate gene transcriptions. In certain cases, BET proteins activate oncogenes leading to increased cell proliferation and survival and an increase in 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 pharmaceutical companies, including large pharmaceutical companies. In addition to impacting oncogenetics, BET proteins regulate the expression of many immunity-associated genes and pathways by directing the transcription of a wide range of pro-inflammatory and immunoregulatory genes, leading to increased cytokine expression that activate B cells and T cells and subsequent inflammatory processes. Inhibiting BET proteins prevents the formation of complexes required to facilitate transcription, thereby inhibiting the subsequent translation of the corresponding protein. As such, BET inhibitors could present as an attractive, non-steroidal, therapeutic option for the treatment of immuno-inflammatory diseases.




**Our Portfolio of 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 pro-inflammatory cytokines. Based on this evaluation, we are targeting indications whose pathogenesis is linked to the proliferation of these specific cytokines, and we are developing formulations designed to maximize the anti-inflammatory effect of the drug 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 immuno-inflammatory conditions.

*VYN201 — Locally Administered Pan-BD BET Inhibitor*

Our lead BET inhibitor candidate in development is VYN201. VYN201 was developed using the InhiBET platform and is a locally administered pan-BD 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 VYN201 program is to develop a therapy that delivers a potent, localized anti-inflammatory effect and is rapidly cleared through metabolic processes so as to avoid systemic absorption.

To date, we have conducted several preclinical studies which have demonstrated VYN201's anti-fibrotic and anti-inflammatory activity and the ability to significantly reduce the expression of certain cytokines relevant to certain autoimmune diseases. Based on such data, we believe VYN201 has the potential to be highly versatile by serving as a locally acting therapy with low systemic exposure.

*Phase 1a/b Clinical Trial in Nonsegmental Vitiligo*

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% of the world population. It is estimated that there are at least 1.9 million patients diagnosed with vitiligo in the United States, with the majority of patients (approximately 90%) suffering from nonsegmental vitiligo. There is currently only one FDA-approved product for the treatment of nonsegmental vitiligo which includes a black box safety warning. Based on preclinical data generated to date, we believe that VYN201 has the potential to offer a targeted, safe and more efficacious treatment option that lowers the disease recurrence rate and is effective for all skin tones and scar types.

In November 2022, we announced the commencement of a Phase 1a/b clinical trial evaluating VYN201 for the treatment of nonsegmental vitiligo. The Phase 1a/b clinical trial is being conducted in U.S.-based clinical centers. In the Phase 1a portion of the clinical trial, single ascending and multiple ascending doses of VYN201 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 VYN201. Evaluated doses included VYN201 0.025%, 0.1%, 0.5%, 1.0% and 2.0% ointment strengths. 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. No healthy volunteers withdrew from the trial for any reason. Based on these results, we selected 0.5%, 1.0% and 2.0% ointment strengths for evaluation in the ongoing Phase 1b trial evaluating VYN201 in nonsegmental vitiligo patients.

In January 2023, we dosed the first vitiligo patient in the Phase 1b portion of the Phase 1 trial. In the Phase 1b portion, up to 30 patients with a clinical diagnosis of nonsegmental vitiligo will receive VYN201 once daily for up to 16 weeks in three dose cohorts. Exploratory efficacy of VYN201 in nonsegmental vitiligo patients will be assessed, including pharmacodynamic biomarkers and photography. We expect topline results for the Phase 1b portion of the trial in mid-2023.

*Vitiligo Preclinical Model*

In March 2022, we announced positive preclinical data in an ex vivo skin model of vitiligo. The objectives of this study were to evaluate the potential of VYN201 to (i) reduce Matrix Metalloproteinase-9 ("MMP-9") secretion (reducing the secretion of MMP-9 allows for melanocyte stabilization and limits loss of melanocytes/depigmentation in vitiligo); (ii) reduce soluble adhesion molecule, E-cadherin (soluble E-cadherin is a biomarker of melanocyte loss due to degradation of matrix-bound E-cadherin by MMP-9); (iii) minimize the loss of melanocytes by assessing melanin pigment content and (iv) affect the expression of genes commonly associated with melanogenesis (melanin synthesis, melanosome maturation and transport). In the preclinical model, VYN201 reduced the expression of key pro-inflammatory biomarkers relevant to the pathogenesis of vitiligo, and demonstrated marked reduction in melanocyte loss. Specifically, VYN201 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% concentrations. In addition, VYN201 significantly upregulated WNT16, a member of the WNT family of genes. The WNT signaling pathway is known to be dysregulated in vitiligo and is believed to play a key role in melanocyte regeneration.

*Th17 Inflammation Preclinical Model*

Data suggests that T helper 17 (Th17) cells play an important role in the pathogenesis of a diverse group of immune-mediated diseases, including psoriasis, rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease, and asthma, among others. In October 2021, we evaluated the impact of VYN201 on Th17 mediated inflammation in a well-established preclinical animal model and an ex vivo human tissue study. In the animal model, depilated mice were topically dosed with imiquimod cream to induce a Th17 inflammation pathology over a 7-day induction phase. A further 7-day treatment phase evaluated three doses of VYN201 (0.001%, 0.01% and 0.1% concentrations) compared to a class 1 super-potent glucocorticosteroid product positive control (clobetasol propionate 0.05% cream) and vehicle control. Further, an imiquimod-naive control group (healthy control group) was included for VYN201 vehicle treatment. VYN201 significantly reduced the expression of several key pro-inflammatory cytokines relevant to Th17-mediated autoimmune diseases in the animal model and the ex vivo human tissue study. A dose-dependent improvement in the signs and symptoms of inflammation was observed for VYN201 treatment groups and treatment with VYN201 at all concentrations was well-tolerated.

*Fibrotic Tissue Preclinical Model*

In November 2021, we announced results from a preclinical animal model in which we evaluated VYN201's ability to reduce fibrosis. In the preclinical study, duplicate identical skin incisions were induced on the flanks of hairless mice under anesthesia. The animals were topically dosed once daily with either 100mg VYN201 vehicle, VYN201 1%, or a hydroalcoholic gel (a negative control known to delay healing) until each lesion had completely healed. VYN201 demonstrated improvements in reducing fibrotic tissue mass

and overall skin repair outcomes with no negative impact on healing time. Animals treated with VYN201 1% had a statistically significant decrease (improvement) in global external lesion severity score, a comprehensive evaluation of length, width, swelling and visibility of lesions, compared to those treated with hydroalcoholic gel, consistent with the vehicle control. In addition, animals treated with VYN201 1% had a significantly lower global internal lesion severity score than those treated with VYN201 vehicle or hydroalcoholic gel, indicative of an improved internal lesion outcome and a positive effect on reducing the formation of fibrotic tissue mass in the lesion bed.

*Rheumatoid Arthritis Preclinical Model*

In March 2022, we announced preclinical data showing that intra-articular injections of VYN201 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 by systemically injecting a mixture of four arthritogenic monoclonal antibodies against collagen II at day 1. In addition, the mice received a lipopolysaccharide injection systemically at day 4 to stimulate an acute systemic inflammatory response. Each treatment group (n=7 per group) was injected with either (i) an intra-articular dose of VYN201 vehicle, (ii) an intra-articular dose of VYN201, (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. For the VYN201 treatment groups, four doses of VYN201 were evaluated (at concentrations ranging from 0.01 to 10 mg/kg). 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). VYN201 demonstrated 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 VYN201 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 — Selective BET Inhibitor*

We are currently evaluating several BD2-selective oral small molecule BET inhibitors for our VYN202 program. Systemic BET inhibitors have historically targeted both BD1 and BD2 less selectively, causing gastrointestinal and hematologic toxicities, such as thrombocytopenia. The compounds that we are currently evaluating for our VYN202 program are being designed to potentially reduce the therapeutic limiting toxicities of BRD4 BET inhibitors currently in development by optimizing BD2 versus BD1 selectivity. By maximizing BD2 selectivity, we believe VYN202 has the potential to present a more conveniently-administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, where the damaging effects of unrestricted inflammatory signaling activity is common. Following the receipt of positive results from our preclinical activities evaluating these compounds, we intend to exercise our option with respect to the oral molecules. See "— Development and License Agreements — Agreements with Tay Therapeutics" for additional information.

***FMX114***

FMX114 is our proprietary investigational combination gel formulation of tofacitinib and fingolimod that is designed to address both the source and cause of inflammation in atopic dermatitis ("AD"). On August 10, 2022, we announced that our Phase 2a clinical trial evaluating the safety and efficacy of FMX114 for mild-to-moderate AD did not meet its primary endpoint, which was based on assessments of the absolute and percent change relative to baseline in the atopic dermatitis severity index ("ADSI") scoring assessment at week 4. In the weeks that followed, we performed additional analyses which showed that while efficacy results for FMX114 were not statistically significant at week 4, FMX114 was statistically superior to vehicle at weeks 1, 2 and 3 in the Phase 2a trial. Additionally, data received from the two-week open label extension during which both AD lesions of participating patients were treated with FMX114 showed that

efficacy results continued to develop beyond week 4 of the trial and that the separation of treatment effect for lesions treated with FMX114 as compared to lesions treated with vehicle increased for lesions that had a higher ADSI score at baseline. Accordingly, we believe that FMX114 may have an improved overall treatment effect on patients with more severe disease at baseline and that FMX114 may have increased potential to effectively treat patients with more moderate-to-severe AD. We are evaluating partnering opportunities for this program and intend to focus our resources on the BET inhibitor development programs.

**Divestiture of Minocycline Business**

On January 12, 2022, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Journey Medical Corporation ("Journey") pursuant to which we divested our Molecule Stabilizing Technology franchise ("MST Franchise"), including AMZEEQ, ZILXI, and FCD105, to Journey (the "Sale"). Pursuant to the Purchase Agreement, we received an upfront payment of $20.0 million and an additional $5.0 million on January 12, 2023, the one-year anniversary of the closing of the transaction. 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 $100,000,000 (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, we are entitled to receive certain payments from any licensing or sublicensing of the assets by Journey outside of the United States. The Purchase Agreement includes customary representations and warranties, as well as indemnification rights for breaches of representations, warranties, and covenants, as well as certain other matters, subject to customary deductibles, caps, and other limitations.

***Manufacturing***

We currently contract with third party manufacturers for all of our required raw materials, active ingredients and finished products for our preclinical research 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.

We, together with our contract manufacturing organizations ("CMOs") have developed the validation processes, methods, tests and/or controls 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 cGMP.

**Development and License Agreements**

***Agreements with Tay Therapeutics***

On April 30, 2021, we entered into an Evaluation and Option Agreement (the "Option Agreement") with Tay. Tay is a spin-out of the University of Dundee's School of Life Sciences and has discovered and is developing proprietary BET inhibitors for the treatment of immunology and oncology conditions. 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 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 an NCE development candidate from its highly selective BET inhibitor compounds (the "Oral BETi Compounds"). We 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.

*Locally Administered Pan-BD BET Inhibitor Program (VYN201)*

On August 6, 2021, we exercised our option with respect to the VYN201 program and, on August 9, 2021, the parties entered into a License Agreement (the "VYN201 License Agreement") granting VYNE a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds. 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 VYN201 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 VYN201 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 connection with entering into the VYN201 License Agreement. Pursuant to the VYN201 License Agreement, we have 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. Tay is entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. In addition, with respect to any products we commercialize under the VYN201 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 bands subject to specified reductions. We are obligated to pay royalties until the later 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.

*Selective BET Inhibitor Program (VYN202)*

Under the Option Agreement, we have an exclusive option (the "Option") to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's Oral BETi Compounds. Under the original terms of the Option Agreement, the Option was to expire upon the earlier of (i) 14 days following the delivery of an agreed data package and selection of a lead candidate by In4Derm and (ii) June 30, 2022 (the "Option Term"). On June 15, 2022, the parties entered into a letter agreement to extend the Option Term to February 28, 2023. We recently informed Tay that we require additional preclinical data in order to complete our assessment of the Oral BETi Compounds. In consideration of the significant progress made by the parties and our desire to maintain optionality with respect to our right to exercise the Option for the Oral BETi Compounds, the parties entered into a Letter Agreement on February 27, 2023 (the "Letter Agreement") to extend the Option Term to April 30, 2023. Pursuant to the terms of the Letter Agreement, we agreed to pay Tay a non-refundable fee in the amount of $250,000 to extend the Option Term. This fee will be deducted from the $4.0 million payable to Tay in the event that we exercise the Option pursuant to the Option Agreement.

In the event that we exercise the Option, the parties will sign a license agreement (the "Oral License Agreement") and we will pay Tay a $4.0 million upfront cash payment, less the amount paid pursuant to the Letter Agreement. The Oral License Agreement will include cash payments of up to $43.75 million payable to Tay 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. Tay will be entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. In addition, with respect to any products we commercialize under the Oral 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 bands subject to specified reductions.

***LEO Pharma A/S for Finacea® Foam***

In September 2015, Bayer HealthCare AG ("Bayer") began selling in the United States a product branded Finacea® Foam, based on our legacy foam technology. Finacea is a prescription topical drug which was developed through a collaboration between Foamix (our predecessor) and Bayer. Bayer sold the

product to LEO Pharma A/S ("LEO") in 2018. Pursuant to the license agreement with LEO for Finacea, we are entitled to receive royalties on net sales of Finacea. In 2022, we received (or became entitled to receive) a total of $0.5 million in royalties from sales of Finacea from LEO.

**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. Such agreements and rights may however be breached, and we may not have adequate remedies for any 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 patent portfolio in relation to our VYN201 BET inhibitor program includes a granted patent in the UK and pending compound and composition patent applications in various jurisdictions worldwide that are licensed by us. In addition, we have filed a PCT application directed to various uses thereof. We have various non-provisional and nationally filed PCT patent applications pending in relation to FMX114 including applications filed in Australia, Brazil, Canada, Europe, Japan and the US. Subject to filing a non-provisional, the PCT's being filed nationally, and the pending patent applications being granted (without terminal disclaimers) and payments of the appropriate maintenance fees, the patent applications in relation to VYN201 will expire in 2040 and 2042 and the patent applications related to FMX114 will expire in 2040, 2041 and 2043.

In addition, in connection with our legacy business, we have various granted patents worldwide owned or licensed by us related to pharmaceutical compositions and their uses, including various foam-based platforms, various gel-based platforms, and other technology.

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 US 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, 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 VYN201, including but not limited to: topical cerdulatinib, under development by Dermavant Sciences, Inc., and both oral PF-06651600 and oral PF-06700841 under development by Pfizer Inc.

While we have not yet identified an initial indication for VYN202, there is intense competition for the treatment of immuno-inflammatory conditions. VYN202, if approved, will compete with existing treatments and new treatments that may become available in the future.

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 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 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 a 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 the 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 I: 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 II: 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 III: 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 a 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 a 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 a 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 risk evaluation and mitigation strategies ("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 a 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. With enactment of the Food and Drug Administration Safety and Innovation Act (the "FDASIA") in 2012, 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 FDASIA.

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. In other words, the total maximum patent life for the product with the patent extension cannot exceed 14 years from the products approval date, which amounts to 14 years of potential marketing time. 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. 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 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 to certain aspects of the ACA. For example, the ACA's individual mandate was repealed by Congress in The Tax Cuts and Jobs Act of 2017 (the "Tax Act"), which was signed into law in December 2017 and became effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Ultimately, on June 17, 2021, the U.S. Supreme Court held that state and individual plaintiffs did not have standing to challenge the individual mandate provision of the ACA; in so holding, the Supreme Court did not consider larger constitutional questions about the validity of this provision or the validity of the ACA in its entirety. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and 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. At the federal level, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries.

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. We anticipate that these and other healthcare reform efforts will continue to result in additional downward pressure on drug pricing. 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 PHI, upon "covered entities" subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates 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 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**

As of December 31, 2022, we had a total of 12 full-time employees. 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 well positioned to execute our pipeline 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 diverse 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 (the "Merger") between Foamix Pharmaceuticals Ltd. ("Foamix") and Menlo Therapeutics Inc. ("Menlo") in March 2020.

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act") and as modified by the JOBS Act and a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements, such as the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, and certain reduced or scaled disclosure requirements available to smaller reporting companies.

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. 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.*

**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:

- We will need substantial additional funding to fund our operations, and there is substantial doubt about our ability to continue as a going concern. If we cannot obtain substantial additional funding, we could be forced to delay, reduce or terminate our research and development activities which would have a material adverse effect on our financial condition;
- Our business is substantially dependent on the successful development of our BET inhibitor product candidates;
- We may be unable to develop a lead molecule for the VYN202 program and exercise our option to license the applicable BET inhibitor compounds from Tay;

- We may encounter delays in enrolling patients and successfully completing clinical trials for our product candidates, and may even be 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 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;
- New chemical entities may require more time and resources for development, testing and regulatory approval;
- Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could result in the abandonment or limitation of the development of our product candidates or prevent or delay our ability to pursue strategic alternatives for our product candidates;
- Results obtained in non-clinical studies and completed clinical trials may not predict success in later clinical trials;
- Topline 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 are subject to various risks and uncertainties arising out of the completed divestiture of our commercial business;
- 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 intend to 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;
- The COVID-19 pandemic could adversely affect our operations, including at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business;
- 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; and

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

**Risks Related to our Financial Position and Need for Capital**

***We will need substantial additional funding to fund our operations, and there is substantial doubt about our ability to continue as a going concern. If we cannot obtain substantial additional funding, we could be forced to delay, reduce or terminate our research and development activities which would have a material adverse effect on our financial condition.***

Developing and commercializing biopharmaceutical products and conducting preclinical studies and clinical trials is an expensive and highly uncertain process that takes years to complete. As of December 31, 2022, we had approximately $31.0 million in cash, cash equivalents and restricted cash. We received an additional $5.0 million deferred payment in January 2023 from the sale of our MST Franchise. Based on our current operating plan, we do not have sufficient cash and cash equivalents to fund our anticipated level of operations as they become due during the twelve months following the date of the issuance of the financial statements included herein. Our estimates may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. The aforementioned factors raise substantial doubt about our ability to continue as a going concern, as reflected in the audit report included with the audited financial statements included elsewhere in this report. In addition, see "Part II. Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity" for further discussion regarding our liquidity. We may not be able to raise any proceeds from financing transactions. Accordingly, additional funds may not be obtained for our ongoing operations and we may not succeed in our future operations. Unless we are able to raise additional capital to finance our operations, our long-term business plan may not be accomplished, and we may be forced to cease, reduce, or delay operations, including our product candidate programs.

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;
- 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 the COVID-19 pandemic or any other 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.

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 shareholders 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 $23.2 million and $73.3 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $662.7 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 operational, financial and management information systems and personnel, including personnel to support our product candidate development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration (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 instructions, 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 under which Cantor Fitzgerald is acting as our sales agent, 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 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.

In addition, on March 15, 2022, we entered into a purchase agreement (the "Equity Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, we have the right, but not the obligation, to sell to Lincoln Park up to $30.0 million of shares of our common stock over the 36-month term of the Equity Purchase Agreement. Upon execution of the Equity Purchase Agreement, we issued 92,644 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Equity Purchase Agreement. We may be limited in the amount of shares we can sell pursuant to the terms of the Equity Purchase Agreement. For example, we are prohibited from directing Lincoln Park to purchase shares under the Equity Purchase Agreement if such purchase would result in Lincoln Park beneficially owning more than 9.99% of our total outstanding shares. In addition, under applicable rules of Nasdaq, in no event may we issue or sell to Lincoln Park under the Equity Purchase Agreement shares of our common stock, including the commitment shares, in excess of 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Equity Purchase Agreement (the "Exchange Cap") unless (i) we obtain stockholder approval to issue shares of our common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Equity Purchase Agreement equals or exceeds the minimum price per share as mandated by Nasdaq rules. If any of the foregoing occur, we will be limited in the amount of proceeds we will be able to raise under the Equity Purchase Agreement which could have a material adverse effect on our financial condition and liquidity.

***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. 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 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.

**Risks Related to Development of Our Product Candidates**

***We may be unable to develop a lead molecule for the VYN202 program and exercise our Option to license the applicable Oral BETi Compounds from Tay.***

As discussed in "Item 1. Business — Development and License Agreements — Agreements with Tay Therapeutics," under the terms of the Option Agreement, as amended, our Option to exercise our rights with respect to Tay's highly selective BET inhibitor compounds expires on April 30, 2023. We are currently

working with Tay to complete our assessment of several compounds that may be suitable for the program. However, we may be unable to select a viable lead molecule in a timely manner or at all. If we are unable to exercise the Option, we may be forced to terminate the program and would have a material adverse effect on our ability to execute our strategy of enhancing our pipeline.

***Our product candidates are in early stages of development and may fail in development or suffer delays that materially and adversely affect their commercial 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.***

All of our product candidates are in early stages of development. We only recently commenced a Phase 1a/b clinical trial evaluating our lead candidate, VYN201, for the treatment of nonsegmental vitiligo in November 2022. In addition, our VYN202 program is in preclinical development and may never advance to clinical-stage development. 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 therapeutics candidates if we experience issues that delay or prevent the regulatory approval of, or our ability to commercialize, our product candidates, including:

- 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;
- 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;
- 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 therapeutics 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 in particular or as a result of the impacts of the COVID-19 pandemic; 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.

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

In January 2022, we divested our commercial business, the MST Franchise, in order to focus our efforts and resources on drug development. Our current development pipeline primarily consists of our BET inhibitor product candidates, 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 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.

Furthermore, VYN201 and VYN202 are very early stage programs. 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.

***We may encounter delays in enrolling patients and successfully completing clinical trials for our product candidates and may even be 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, including due to reasons associated with COVID-19. For example, in 2022, we experienced delays in enrolling patients in our Phase 2a clinical trial evaluating FMX114 for the treatment of atopic dermatitis ("AD"), a program for which we are not currently making any additional investment in, due to COVID-19 related issues. We rely on contract research organizations ("CROs") and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. 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 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 also encounter delays if a clinical trial 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.

***Clinical drug development is very expensive, time-consuming and uncertain. Our 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.***

Clinical 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 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 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 COVID-19 or 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.

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

Our BET inhibitor program is in the early stages of development, involves a novel therapeutic approach and new chemical entities, 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. Further, the regulatory pathway for our new chemical entities may be more demanding.

***Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could result in the abandonment or limitation of the development of our product candidates or prevent or delay our ability to pursue strategic alternatives for our product candidates.***

If our product candidates are associated with side effects in preclinical studies and/or clinical trials or have characteristics that are unexpected, our development costs could increase or 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. The FDA or an IRB may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could result in regulatory authorities failing to provide marketing authorization

for our product candidates. Many 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.

Before any potential third-party partners can obtain marketing approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Additionally, if we or others identify undesirable side effects caused by our drugs, a number of potentially significant negative consequences could result, including:

- 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 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
- 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 would be harmed.

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.

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

Success in preclinical testing, such as testing for VYN201, and early clinical trials does not ensure that later clinical trials will be successful, and any other 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. We and other companies in the biopharmaceutical industry have frequently suffered significant setbacks in later clinical trials, even after achieving promising results in earlier non-clinical studies or clinical trials. For example, in August 2022, our Phase 2a clinical trial for FMX114 did not meet its primary endpoint of improving symptoms and severity of AD after four weeks of treatment. In addition, 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.

***Topline 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 topline or preliminary data from our clinical trials which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a 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 topline 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. Topline 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, topline 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, topline or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim, topline 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, topline 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.

***Our current and future clinical trials or those of any future collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.***

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to such trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, certain BET inhibitors have been linked to tolerability issues, particularly in the gastrointestinal tract. We, the FDA or other applicable regulatory authorities, or an IRB may suspend any clinical trials of any product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved therapeutic due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

***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 evaluate VYN201 in the treatment of nonsegmental vitiligo. 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. For example, during 2022, we decided not to pursue further development of FMX114 for the treatment of AD and instead to focus our research and development efforts

on VYN201 and VYN202. 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 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, fibrosis and cancer, as well as numerous small companies. 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.

***The COVID-19 pandemic could adversely affect our operations, including at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business.***

Our business has been adversely affected by the effects of the COVID-19 pandemic, which has resulted in a variety of restrictions in order to reduce the spread of the disease, which, among other things, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. For example, enrollment and other operations related to our Phase 1b/2a clinical trial for FMX114 in Australia were negatively impacted by the COVID-19 pandemic and restrictions imposed by Australian authorities in 2022. In addition, some of our third-party preclinical science partners and manufacturers which we use for the supply of materials for our product candidates or other materials necessary to manufacture drug product to conduct preclinical studies and clinical trials are located in countries affected by COVID-19, particularly in China, and should they experience disruptions, such as lockdowns, temporary closures or suspension of services, we would likely experience delays in advancing these studies and trials. Any delay in the development of our product candidates could have a material adverse effect on our business and results of operations.

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

We also 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 studies 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 studies 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, the clinical data generated in our future clinical studies may be deemed unreliable and the FDA and other regulatory authorities may require us to perform additional clinical studies 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, we may need to conduct additional clinical trials or enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and 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 delay.***

As product candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered in an effort to optimize processes and results. 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.

**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 commercial business on January 12, 2022. Pursuant to the terms of the Asset Purchase Agreement, 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. Per the terms of the agreement, Journey does not have any diligence obligations to achieve any such net sales milestones and no assurance can be given that such milestones will be met. Furthermore, Journey may decide not to license or sublicense the assets in any territory outside of the United States and therefore we may 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 distractions and 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 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 a possibility of adverse publicity as a result of 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 with respect to our legacy commercial business operations, which may result in potential 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 have no current plan, commitment or obligation to enter into any transaction described above.

***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;
- 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 terrorism, COVID-19 or another outbreak of a contagious disease, or natural disasters including earthquakes, typhoons, floods and fires.

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, 2022, we had federal and state net operating loss carryforwards of $318.3 million and $90.4 million, respectively, of which $44.3 million and $89.0 million of these carryforwards will begin to expire in 2031 for federal and state purposes, respectively. As of December 31, 2022, we had federal and state research and development tax credit carryforwards of $6.6 million and $1.2 million, respectively. The federal credits begin to expire in 2031 and the state research credits have no expiration dates. 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. 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 determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Sections 382 or 383. We may have experienced ownership changes in the past, including in connection with our initial public offering and the Merger, and we may experience ownership changes in the future as a result of 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 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 therewith, the intellectual property and other assets owned by our Israeli subsidiary was 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 amount and/or fail to realize the expected benefits of the transaction. In addition, we may incur additional costs associated with defending our position. Such tax liability and increase in costs 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 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.

***Our business and operations could suffer in the event of failure, invasion, corruption, destruction or interruption of our or our partners' critical information technology systems or infrastructure.***

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, 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, particularly during the COVID-19 pandemic. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, 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, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate 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. 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 recently 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;
- 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;

- 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. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The recent implementation of the GDPR has increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business; and
- 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, and may apply more broadly than HIPAA, thus complicating compliance efforts — for example, the California Consumer Privacy Act ("CCPA") which became effective on January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The California Attorney General has issued clarifying regulations, and in November 2020, California voters approved the California Privacy Rights Act of 2020 which modified and expanded the CCPA and created the California Privacy Protection Agency to implement and enforce the CCPA. Although the law includes limited exceptions, including for certain information collected as part of clinical trials as specified in the law, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted.

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 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.

***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 are increasingly challenging the price and examining the cost effectiveness of medical products and services.

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, including the ACA and the Medicare Prescription Drug Improvement and Modernization Act of 2003. 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 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 to certain aspects of the ACA. For example, while in office, then-President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, in December 2017, Congress repealed the tax penalty for an individual's failure to maintain ACA-mandated health insurance, commonly known as the "individual mandate", as part

of legislation enacted in 2017, the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and inseverable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA were invalid as well. Ultimately, on June 17, 2021, the U.S. Supreme Court held that state and individual plaintiffs did not have standing to challenge the individual mandate provision of the ACA; in so holding, the Supreme Court did not consider larger constitutional questions about the validity of this provision or the validity of the ACA in its entirety. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, if any, and other efforts to modify, repeal and replace the ACA will impact the ACA.

Although we cannot predict the form of any such replacement of the ACA may take, if any, or 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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, 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. 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, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical 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 offering, making or authorizing improper payments 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 for international operations. 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 Israel's Ministry of Finance, the U.S. Treasury's Office of Foreign Assets Control (OFAC), other U.S. agencies 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 API as well as the licensing of intellectual property, as provided above. Compliance with 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. 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. Where we have product candidates which are new chemical entities (compounds) or drugs like VYN201, 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 VYN201 are primarily licensed in from the University of Dundee and 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. Moreover, if we are unable to develop a lead candidate for the VYN202 program, we may not exercise our Option, which could cause us to terminate the program and this would have a material adverse effect on our ability to execute our strategy of enhancing our pipeline.

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.***

For applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be invoked by a third party, or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. An interference is a contest between an application and either another application or a patent in determining priority, that is, which party first invented the commonly claimed invention. A panel of Board members enters final judgment on questions of priority and patentability arising in an interference. As of March 16, 2013, the United States transitioned to 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 new first-to-file system before we did, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party.

The change to "first-to-file" from "first-to-invent" is one of the changes to the patent laws of the U.S. resulting from the Leahy-Smith America Invents Act ("AIA") signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. Until a few years ago, a lower evidentiary standard was applied in certain USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim. Under the new final rule, effective for petitions filed on or after November 13, 2018, the USPTO Patent Trial and Appeal Board (PTAB) is to apply 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. The PTAB proceedings continues 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. For example, a bill has been introduced in the United States that is intended to facilitate patent challenges at the PTO's Patent Trial and Appeal Board and if enacted may lead to lower drug prices. This in turn may have a negative impact reducing both the value of patents and the commercial revenues that may be obtained from the development of new drugs and new compositions comprising known drugs. 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.

***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 VYN201 product candidate and in relation to other product candidates and activities that we are considering. 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 VYN201 or any of our other 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 VYN201 or any of our other 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 BETi 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 US 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 U.S. 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 benefitting from the expertise our former employees or consultants developed while working for us.

For example, Israeli labor courts place emphasis on freedom of employment and have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the protection of a company's trade secrets or other intellectual property.

**Risks Related to the Securities Markets and 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 2021 and 2022. 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 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, including the impact of COVID-19 or of another pandemic or epidemic on our business and the broader economy as a whole;
- 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 66 2/3% 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 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.

***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 an "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Decreased disclosures in our SEC filings due to our status as an emerging growth company may make it harder for investors to analyze our results of operations and financial prospects. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until December 31, 2023.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

**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, impair our ability to raise capital and may impair our ability to acquire other businesses, applications or technologies using our shares as consideration.

***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.

## ITEM 1B — UNRESOLVED STAFF COMMENTS

None.

## 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 new lease agreements signed in November 2022 that expire on September 30, 2025. The leases relating to office and warehouse space in Israel expired on December 31, 2022 and were not renewed.

We believe that our current office space in the United States is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms for our future 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. See "Item 8. Financial Statements and Supplementary Data — Note 9. Commitments and Contingencies."

## ITEM 4 — MINE SAFETY DISCLOSURES

Not applicable.

# PART II

## ITEM 5 — MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER 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 a 1-for-18 reverse stock split of our 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 our 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 stockholder holding fractional shares was entitled to receive a cash payment (without interest or deduction) from our transfer agent in an amount equal to such stockholder's respective pro rata shares of the total net proceeds from our transfer agent 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 2019 Equity Incentive Plan, 2018 Omnibus Incentive Plan and 2019 Employee Share Purchase Plan.

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 a 1-for-18 reverse stock split.

**Holders of Common Stock**

As of March 1, 2023, there were 9 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.

**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 report. 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 report, particularly in the section entitled "Item 1A. Risk Factors".

### Company Overview

We are a clinical-stage biopharmaceutical company focused on developing proprietary, innovative and differentiated therapies for the treatment of immuno-inflammatory conditions.

In August 2021, we entered into a transaction with Tay providing us with exclusive worldwide rights to research, develop and commercialize products containing BET inhibitors for the treatment of any disease, disorder or condition in humans. Through our access to this library of new chemical BET inhibitor compounds, we plan to develop product candidates for a diverse set of indications. Based on preclinical data generated to date, we have chosen to focus our initial efforts for this platform on select therapeutic areas in immuno-inflammatory disease.

Our lead program is VYN201, a locally administered pan-BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. To date, VYN201 has produced consistent reductions in pro-inflammatory and disease-related biomarkers, improvements in disease severity and a demonstrated local activity through several preclinical models. We believe that these data suggest potential broad utility for VYN201 across multiple routes of administration. In November 2022, we initiated a Phase 1a/b clinical trial evaluating a topical formulation of VYN201 for the treatment of nonsegmental vitiligo. In February 2023, we announced positive preliminary safety data from the Phase 1a portion of the trial. The first nonsegmental vitiligo patient was dosed in the Phase 1b portion of the trial in January 2023 and we expect topline results from this trial in mid-2023.

Our second program is VYN202, a BD2-selective oral small molecule BET inhibitor. VYN202 is in preclinical development for the treatment of immuno-inflammatory indications, and is being designed to achieve class-leading selectivity (BD2 vs. BD1), maximum potency versus BD2 and optimal oral bioavailability. By maximizing BD2 selectivity, we believe VYN202 has the potential to be a more conveniently-administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, where the damaging effects of unrestricted inflammatory signaling activity is common.

We intend to actively evaluate and enter into strategic partnerships to advance our product candidates through the clinic toward commercialization, and may also partner with leading pharmaceutical companies to advance our molecules in therapeutic areas outside of our core focus in immunology. We believe selectively entering into collaborations has the potential to expand and accelerate the development of our programs and maximize the value of our pipeline.

### Known Trends, Events and Uncertainties

#### *Business and Macroeconomic Conditions*

The extent of the impact of macroeconomic events and conditions, including inflation, increasing interest rates, adverse developments affecting financial institutions, increasing financial market volatility and uncertainty, the impact of war or military conflict, including the war in Ukraine, and public health pandemics on our operational and financial performance will continue to depend on certain developments, including the impact on our financing activities, clinical studies, employee or industry events, and effect on our suppliers and manufacturers, all of which are uncertain and cannot be predicted. 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. For example, we have experienced delays in enrollment in our clinical trials, and we may continue to experience such delays for a variety of reasons, including COVID-19, labor shortages and supply chain disruptions in distribution of clinical trial materials, study monitoring and data analysis, any of which could materially adversely impact our business, results of operations and overall financial performance in future periods. 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, 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.

**Collaboration Arrangements**

***Agreements with Tay Therapeutics***

On April 30, 2021, we entered into 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 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 for its Oral BETi Compounds. We 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.

*Locally Administered Pan-BD BET Inhibitor Program (VYN201)*

On August 6, 2021, we exercised our option with respect to the VYN201 program and, on August 9, 2021, the parties entered into the VYN201 License Agreement granting VYNE a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's pan-BD BET inhibitor compounds. 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 VYN201 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 VYN201 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 connection with entering into the VYN201 License Agreement. Pursuant to the VYN201 License Agreement, we have 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. Tay is entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. Tay is entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. In addition, with respect to any products we commercialize under the VYN201 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 bands subject to specified reductions. We are obligated to pay royalties until the later 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.

*Selective BET Inhibitor Program (VYN202)*

Under the Option Agreement, we have an exclusive option (the "Option") to obtain certain exclusive worldwide rights to research, develop and commercialize products containing Tay's Oral BETi Compounds. Under the original terms of the Option Agreement, the Option was to expire upon the earlier of (i) 14 days following the delivery of an agreed data package and selection of a lead candidate by In4Derm and (ii) June 30, 2022 (the "Option Term"). On June 15, 2022, the parties entered into a letter agreement to extend the Option Term to February 28, 2023. We recently informed Tay that we would like additional time to complete our assessment of the Oral BETi Compounds. In consideration of the significant progress made by the parties and our desire to maintain optionality with respect to our right to exercise the Option for the Oral BETi Compounds, the parties entered into a Letter Agreement on February 27, 2023 (the "Letter Agreement") to extend the Option Term to April 30, 2023. Pursuant to the terms of the Letter Agreement, we agreed to pay Tay $250,000 to extend the Option Term. This fee will be deducted from the $4.0 million payable to Tay in the event that we exercise the Option pursuant to the Option Agreement.

Upon exercise of the Option, the parties will sign a license agreement (the "Oral License Agreement") and we will pay Tay a $4.0 million cash payment, less the amount paid pursuant to the Letter Agreement. The Oral License Agreement will include cash payments of up to $43.75 million payable to Tay 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. Tay will be entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. In addition, with respect to any products we commercialize under the Oral 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 bands subject to specified reductions.

**Components of Results of Operations**

***Revenues***

Our revenue reported for the periods presented is comprised of AMZEEQ and ZILXI product sales and royalty revenue.

AMZEEQ and ZILXI were commercially launched in January and October of 2020, respectively. We have not generated revenue from the sales of these products following January 12, 2022, the date we sold the MST Franchise to Journey. As a result of the disposition of these assets, product sales have been reclassified to discontinued operations for all periods presented. We will not commercially launch our other product candidates in the United States or generate any revenues from sales of any of our product candidates unless and until we obtain marketing approval.

Historically, we have generated revenues under development and license agreements including royalty payments in relation to Finacea, the prescription foam product that we developed in collaboration with Bayer, which later assigned it to Leo Pharma A/S ("LEO"). In the year ended December 31, 2022 and 2021 we received royalties of $0.5 million and $0.9 million, respectively. Our rights to royalty payments from the sale of Finacea were not transferred in the sale of the MST Franchise.

***Cost of Goods Sold***

Cost of goods sold expenses consist of direct and indirect costs to procure and manufacture AMZEEQ and ZILXI and primarily consist of:

- third party expenses incurred in manufacturing product for sale;
- transportation costs incurred in shipping manufacturing materials between third parties; and
- other costs associated with delivery and manufacturing of product.

Prior to receiving FDA approval, these costs for AMZEEQ and ZILXI were expensed as research and development expenses. We began capitalizing inventory costs for AMZEEQ and ZILXI after receipt of FDA approval. As a result of the sale of the MST Franchise, cost of goods sold has been reclassified to discontinued operations for all periods presented.

***Operating Expenses***

*Research and development expenses*

Our research and development expenses have related primarily to the development of FMX114, VYN201 and VYN202. We charge all research and development expenses to operations as they are incurred. Following the sale of the MST Franchise in January 2022, our research and development has been focused on our immuno-inflammatory pipeline, including VYN201, VYN202 and FMX114. As a result of the sale of the MST Franchise in January 2022, research and development expenses related to the MST Franchise have been reclassified to discontinued operations for all periods presented.

Our total research and development expenses for the years ended December 31, 2022 and 2021 were $18.4 million and $19.5 million, respectively.

Research and development expenses consist primarily of:

- employee-related expenses, including salaries, benefits and related expenses, including share based compensation expenses, for researched and development personnel;
- expenses incurred under agreements with third parties, including subcontractors, suppliers and consultants that conduct regulatory activities, clinical trials and preclinical studies;
- expenses incurred to acquire, develop and manufacture clinical trial materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs;
- costs associated with the creation, development and protection of intellectual property;
- other costs associated with preclinical and clinical activities and regulatory operations; and
- materials and manufacturing costs related to commercial production prior to FDA approval.

*Selling, general and administrative expenses*

Our selling, general and administrative expenses for the year ended December 31, 2022 and 2021 were $16.4 million and $20.3 million, respectively.

Our selling, general and administrative expenses consist principally of:

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

As a result of the sale of the MST Franchise in January 2022, selling, general and administrative expenses related to the MST Franchise have been reclassified to discontinued operations for all periods presented.

***Interest Expense***

During 2021, interest expense primarily consisted of interest expense on our long-term debt of $2.6 million. During the year ended December 31, 2021, interest expense also included prepayment penalties of $1.4 million and the write off of deferred financing costs of $1.6 million. We prepaid our indebtedness outstanding under the Amended and Restated Credit Agreement in August 2021. Accordingly, we did not incur interest expenses in 2022.

***Other Income (Expense), net***

Other income (expense), net primarily consists of interest earned on our cash and cash equivalents and foreign exchange rate gains and losses.

*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, 2022, we had federal and state net operating loss carryforwards of $318.3 million and $90.4 million, respectively, of which $44.3 million and $89.0 million of these carryforwards will begin to expire starting in 2031 through 2040 for federal and state purposes, respectively. As of December 31, 2022, we had federal and state research and development tax credit carryforwards of $6.6 million and $1.2 million, respectively. The federal credits begin to expire in 2031 and the California research credits have no expiration dates. As of December 31, 2022,we had $274.0 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 determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Sections 382 or 383. We may have experienced ownership changes in the past, including in connection to our initial public offering ("IPO"), and as a result of the Merger and/or 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, 2022 and December 31, 2021**

*Summary of Operations*

| | Year Ended December 31, | | Increase/ (Decrease) | Increase/ (Decrease) |
|---|---|---|---|---|
| **(in thousands, except %)** | **2022** | **2021** | **$** | **%** |
| **Revenues** | | | | |
| Royalty revenues | $ 477 | $ 931 | $ (454) | (48.8)% |
| **Total revenues** | 477 | $ 931 | (454) | (48.8)% |
| **Operating Expenses** | | | | |
| Research and development | 18,385 | 19,543 | (1,158) | (5.9)% |
| Selling, general and administrative | 16,387 | 20,299 | (3,912) | (19.3)% |
| **Total operating expenses** | 34,772 | 39,842 | (5,070) | (12.7)% |
| **Operating loss** | (34,295) | (38,911) | (4,616) | (11.9)% |
| Interest expense | — | (5,610) | (5,610) | (100.0)% |
| Other income (expense), net | 363 | (135) | 498 | 368.9% |
| **Loss from continuing operations before income taxes** | (33,932) | (44,656) | (10,724) | (24.0)% |
| Income tax expense (benefit) | 13 | (448) | (461) | (102.9)% |
| **Loss from continuing operations** | (33,945) | (44,208) | (10,263) | (23.2)% |
| **Income (loss) from discontinued operations, net of income taxes** | 10,735 | (29,121) | 39,856 | 136.9% |
| **Net loss** | (23,210) | (73,329) | (50,119) | (68.3)% |

***Revenues***

Revenues totaled $0.5 million and $0.9 million for the years ended December 31, 2022 and 2021, respectively, consisting of royalty revenue.

We divested our MST Franchise on January 12, 2022. As a result of the sale, we will not generate revenue from the sales of AMZEEQ or ZILXI following such date. Product revenues have been reclassified to discontinued operations for all periods presented.

***Research and development expenses***

Our research and development expenses for the year ended December 31, 2022 were $18.4 million, representing a decrease of $1.2 million, or 5.9%, compared to $19.5 million for the year ended December 31, 2021. The decrease was primarily due to lower employee-related expenses of $2.1 million, a decrease of $2.4 million in expenses for FMX114 and a decrease of $0.9 million in expenses for other R&D related activities. These decreases described above were partially offset by an increase of $2.8 million in expenses for VYN201 and the option extension fee for the VYN202 program totaling $1.4 million.

***Selling, general and administrative expenses***

Our selling, general and administrative expenses for the year ended December 31, 2022 were $16.4 million, representing a decrease of $3.9 million, or 19.3%, compared to $20.3 million for the year ended December 31, 2021. The decrease was primarily due to lower employee-related expenses of $2.1 million and a decrease of $1.8 million in expenses for consulting and professional fees.

***Interest Expense***

As a result of the prepayment of our indebtedness outstanding under the Amended and Restated Credit Agreement in August 2021, we did not incur interest expense for the year ended December 31, 2022. During the year ended December 31, 2021, interest expense totaled $5.6 million and primarily consisted of $2.6 million of interest expense associated with our indebtedness outstanding under the Amended and Restated Credit Agreement and also included prepayment penalties of $1.4 million and write off of deferred financing costs of $1.6 million.

***Other Income (Expense), net***

Other income for the year ended December 31, 2022 was $0.4 million, representing an increase of $0.5 million, or 368.9%, compared to $0.1 million of other expense for the year ended December 31, 2021.

**Liquidity**

Since inception, we have funded operations primarily through private and public placements of our equity, debt and warrants and through fees, cost reimbursements and payments received from our licensees. We commenced generating product revenues related to sales of AMZEEQ and ZILXI in January 2020 and October 2020, respectively. AMZEEQ and ZILXI were sold as part of the sale of the MST Franchise on January 12, 2022 and, as such, we no longer generate revenue from the sale of these products. 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. For the year ended December 31, 2022, we incurred a net loss of $23.2 million and used $29.2 million of cash in operations. The net loss was comprised of $10.7 million of income from discontinued operations and $33.9 million loss from continuing operations.

As of December 31, 2022, we had cash and cash equivalents, and restricted cash of $31.0 million and an accumulated deficit of $662.7 million. We received the $5.0 million deferred payment from Journey on January 12, 2023, the one-year anniversary of the sale of the MST Franchise. We had no outstanding debt as of December 31, 2022. In addition, in March 2022, we entered into the Equity Purchase Agreement with Lincoln Park Capital which provides that, upon the terms and subject to the conditions and limitations set

forth therein, we may sell to Lincoln Park up to $30.0 million of shares of our common stock over the 36-month term of the Equity Purchase Agreement. As of December 31, 2022, no shares have been sold under the Equity Purchase Agreement.

As described above, following the sale of the MST Franchise, we refocused our limited resources on our immuno-inflammatory pipeline. Continued research and development activities for these programs, including preclinical and clinical testing of our product candidates, will require significant additional financing. Our future viability and our ability to continue as a going concern is dependent on our ability to raise sufficient working capital through either debt or equity financings to fund our operations and successfully develop commercially viable product candidates. There is no assurance that we will be able to achieve these objectives under acceptable terms or at all.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40), we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that our consolidated financial statements are issued. The accompanying audited consolidated financial statements have been prepared assuming we will continue as a going concern and contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Our ability to continue as a going concern is expected to be impacted by the outcome of the plans outlined above, including our ability to raise additional capital to fund our operations and the development and results from clinical trials for the BET inhibitor programs. Based on our current plans and assumptions, we believe that absent sufficient proceeds received from equity transactions, financing transactions or business development transactions, we will not have sufficient cash and cash equivalents to fund our operations beyond one year from the issuance of the accompanying audited consolidated financial statements. This assumption does not include proceeds that can be drawn from Lincoln Park under the Equity Purchase Agreement. Accordingly, we will, over the course of the next twelve months, require significant additional financing to continue our operations and meaningfully advance the development of our product candidates, including potentially selling a significant amount of shares pursuant to the Equity Purchase Agreement. We may also employ strategies to further extend our ability to fund our operations including: (1) identification of third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates, which may generate revenue and/or milestone payments and/or (2) refocusing our resources on research and development programs we choose to prioritize and reducing spending on other programs by delaying or discontinuing development. In addition, the amount of proceeds we may be able to raise pursuant to our existing shelf registration statement on Form S-3 may be 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 instructions, 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 our common stock using our Form S-3 until such time as our public float exceeds $75 million. These factors raise substantial doubt about our ability to continue as a going concern. Failure to successfully receive additional financing will require us to delay, scale back or otherwise modify our business and our research and development activities and other operations. See "Item1A. Risk Factors — Risks Related to our Financial Position and Need for Capital — We will need substantial additional funding to fund our operations, and there is substantial doubt about our ability to continue as a going concern. We could also be forced to delay, reduce or terminate our research and development activities which would have a material adverse effect on our financial condition." The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should we be unable to continue as a going concern.

**Capital Resources**

***Overview***

To date, we have financed our operations primarily through private and public placements of our common stock, debt and warrants and through the sale of our products, fees, cost reimbursements and

payments received from our licensees. In January 2022, we sold our MST Franchise, which resulted in an upfront payment of $20.0 million at the close of the sale and deferred payment of $5.0 million in January 2023.

***Cash Flows***

The following table summarizes our statement of cash flows for the years ended December 31, 2022 and 2021:

| | Year Ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands) | |
| Net cash (used in) / provided by: | | |
| Operating activities | $(29,200) | $(56,367) |
| Investing activities | 15,667 | 1,027 |
| Financing activities | 1,653 | 39,777 |

*Net cash used in operating activities*

During the year ended December 31, 2022, net cash used in operating activities was $29.2 million and primarily reflected our net loss of $23.2 million adjusted for the gain on the sale of the MST Franchise of $12.9 million and non-cash items of $4.7 million related to stock-based compensation expense, depreciation and amortization, and loss from sale and disposal of property and fixed assets. The remainder of the cash used in operations is driven by net change in assets and liabilities.

During the year ended December 31, 2021, net cash used in operating activities was $56.4 million and primarily reflected our net loss of $73.3 million, partially offset by non-cash charges and non-cash finance expense of $10.8 million related to stock-based compensation expense, depreciation and amortization and $1.4 million in debt prepayment premium. The remainder of the cash used in operations is driven by net decrease in assets and liabilities.

*Net cash provided by investing activities*

During the year ended December 31, 2022, net cash provided by investing activities was $15.7 million and was the result of net proceeds from the disposition of the MST Franchise.

During the year ended December 31, 2021, net cash provided by investing activities was $1.0 million and was primarily comprised of proceeds from the sale and maturity of marketable securities and bank deposits.

*Net cash provided by financing activities*

During the year ended December 31, 2022, net cash provided by financing activities was $1.7 million and was primarily attributable to the issuance of common stock and convertible preferred stock.

During the year ended December 31, 2021, net cash provided by financing activities was $39.8 million and was primarily attributable to $76.0 million of cash from the issuance of common stock offset by $36.4 million from the prepayment of debt.

***Cash and Funding Sources***

Our sources of funding in the year ended December 31, 2022 totaled $17.3 million and consisted primarily of $15.7 million net proceeds from the sale of the MST Franchise and $1.5 million net proceeds from the issuance of common stock pursuant to our at-the-market offering facility.

Our sources of funding in the year ended December 31, 2021 totaled $76.0 million and consisted primarily of $29.2 million net proceeds from our at-the-market program and $46.8 million net proceeds from our registered direct public offering completed in January 2021.

We have no ongoing material financial commitments (such as lines of credit) that may affect our liquidity over the next five years.

***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. In addition, we signed a Lease Agreement (the "Master Lease") to lease the Leased Premises following the termination of the Sublease through September 30, 2025. We expect to incur $0.1 million of rent expense in 2023 relating to the sublease. The future minimum lease payments for the Master Lease total approximately $0.3 million through September 30, 2025.

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.

***Funding Requirements***

Our present and future funding requirements will depend on many factors, including the following:

- costs associated with the research and development of product candidates;
- 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 number of potential new products we identify and decide to develop; and
- 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.

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 "Item 1A — Risk Factors" included herein.

**Off-Balance Sheet Arrangements**

As of December 31, 2022, 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 "Financial Statements and Supplementary Data" of this Annual Report, we believe that the following accounting policies are the most critical to assist shareholders 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.

***Revenue Recognition***

We record revenue based on a five-step model in accordance with Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"). For collaboration agreements under ASC 606 we identify the contract, we identify the performance obligations, determine the transaction price, allocate the contract transaction price to the performance obligations, and recognize the revenue when (or as) the performance obligation is satisfied.

*Royalty Revenues and Collaboration Agreements*

We identify 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, we utilize the input method and revenue is recognized by consistently applying a method of measuring progress toward complete satisfaction of that performance obligation. We periodically review our estimated periods of performance based on the progress under each arrangement and account 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 included in the transaction price when we determine that it is probable that there will not be a significant reversal of cumulative revenue recognized in future periods.

*Product sales, Product Sales Provisions and Product Returns*

As a result of the disposition of the MST Franchise in January 2022, we no longer have any revenue generating products. See Note 4, "Discontinued Operations." Our 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.

Our customers were a limited number of national and select regional wholesalers (the "distributors") and certain independent and specialty pharmacies (together, the "customers"). Net product revenue was typically recognized when customers obtained control our products, which occurred at a point in time, typically upon delivery of product to the customers. Product revenue is recorded net of distribution fees, trade discounts, allowances, rebates, copay program coupons, chargebacks, estimated returns and other incentives. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these revenue deductions on gross sales for a reporting period. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment. Consistent with industry practice, customers are generally allowed to return products within a specified period of time before and after its expiration date. We estimate the amount of product that will be returned and deducts these estimated amounts from its gross revenue at the time the revenue is

recognized. The information utilized to estimate the returns provision includes: (i) actual return history (ii) historical return industry information regarding rates for comparable pharmaceutical products and product portfolios, (iii) external data with respect to inventory levels in the wholesale distribution channel, (iv) external data with respect to prescription demand for products and (v) remaining shelf lives of products at the date of sale.

***Discontinued Operations***

We accounted for the sale of the MST Franchise in accordance with Accounting Standards Codification, ASC, 205 *Discontinued Operations* and Accounting Standards Update, ASU, No. 2014-08, *Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity*. We followed the held-for-sale criteria as defined in ASC 360 and ASC 205. ASC 205 requires that a component of an entity that has been disposed of or is classified as held for sale and has operations and cash flows that can be clearly distinguished from the rest of the entity be reported as assets held for sale and discontinued operations. In the period a component of an entity has been disposed of or classified as held for sale, the results of operations for the periods presented are reclassified into separate line items in the consolidated statements of operations. Assets and liabilities are also reclassified into separate line items on the related consolidated balance sheets for the periods presented. ASU 2014-08 requires that only a disposal of a component of an entity, or a group of components of an entity, that represents a strategic shift that has, or will have, a major effect on the reporting entity's operations and financial results be reported in the financial statements as discontinued operations. ASU 2014-08 also provides guidance on the financial statement presentations and disclosures of discontinued operations.

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 oncology business as discontinued operations in our consolidated statements of operations and cash flows for all periods presented, see Note 4, Discontinued Operations in the consolidated financial statements. All disposed assets and liabilities associated with our MST Franchise were therefore classified as assets and liabilities of discontinued operations in our consolidated balance sheets for the periods presented. All amounts included in the notes to the consolidated financial statements relate to continuing operations unless otherwise noted.

**Recently Issued Accounting Pronouncements**

Certain recently issued accounting pronouncements are discussed in Note 2, "Significant Accounting Policies," to the consolidated financial statements included in "Financial Statements and Supplementary Data" of this Annual Report.

## 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

**Financial Statements**

**VYNE THERAPEUTICS INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2022**

**INDEX**

Item 8. Financial Statements and Supplementary Data

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of VYNE Therapeutics Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheet of VYNE Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2022, and the related consolidated statements of operations, changes in mezzanine equity and shareholders' equity, and cash flows for the year ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

***Going Concern Uncertainty***

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

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Baker Tilly US, LLP
Tewksbury, Massachusetts
March 14, 2023
We have served as the Company's auditor since 2022.

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of VYNE Therapeutics Inc.

***Opinion on the Financial Statements***

We have audited the consolidated balance sheet of VYNE Therapeutics Inc. and its subsidiaries (the "Company") as of December 31, 2021, and the related consolidated statements of operations, of changes in mezzanine equity and shareholders' equity and of cash flows for the year then ended, including 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, 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

*Substantial Doubt About the Company's Ability to Continue as a Going Concern*

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

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit 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 audit 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 audit provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Florham Park, New Jersey
March 17, 2022, except for the effects of the reverse stock split discussed in Note 1 and the effects of discontinued operations discussed in Note 4 to the consolidated financial statements, as to which the date is March 14, 2023

We served as the Company's auditor from 2020 to 2022.

**VYNE THERAPEUTICS INC.**

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

| | December 31 | |
|---|---|---|
| | **2022** | **2021** |
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 30,908 | $ 42,250 |
| Restricted cash | 67 | 605 |
| Trade receivable, net of allowances | 173 | 7,583 |
| Amount due from sale of MST Franchise | 5,000 | — |
| Prepaid and other expenses | 2,127 | 4,565 |
| Operating lease right of use assets (Note 7) | — | 338 |
| Discontinued operations – current assets (Note 4) | — | 7,845 |
| Total Current Assets | 38,275 | 63,186 |
| Property and equipment, net (Note 5) | — | 354 |
| Non-current prepaid expenses and other assets | 2,483 | 3,506 |
| **Total Assets** | $ 40,758 | $ 67,046 |
| **Liabilities, Mezzanine Equity and Shareholders' Equity** | | |
| Current Liabilities: | | |
| Trade payables | $ 2,386 | $ 6,510 |
| Accrued expenses (Note 6) | 4,381 | 8,593 |
| Employee-related obligations | 2,372 | 2,752 |
| Liability for employee severance benefits | 206 | 206 |
| Operating lease liabilities (Note 7) | — | 349 |
| **Total Liabilities** | 9,345 | 18,410 |
| **Commitments and Contingencies** (Note 9) | | |
| **Mezzanine Equity:** | | |
| Convertible Preferred Stock: $0.0001 par value; 20,000,000 and 0 shares authorized at December 31, 2022 and December 31, 2021, respectively; Series A Preferred Stock: 3,000 and 0 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively (Note 11) | 211 | — |
| **Shareholders' Equity:** | | |
| Common stock: $0.0001 par value; 150,000,000 shares and 150,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 3,229,704 and 2,976,541 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively | — | 5 |
| Additional paid-in capital | 693,937 | 688,156 |
| Accumulated deficit | (662,735) | (639,525) |
| **Total Shareholders' Equity** | 31,202 | 48,636 |
| **Total Liabilities, Mezzanine Equity and Shareholders' Equity** | $ 40,758 | $ 67,046 |

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

**VYNE THERAPEUTICS INC.**

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

| | Year ended December 31, | |
|---|---|---|
| | **2022** | **2021** |
| **Revenues** | | |
| Royalty revenues | $ 477 | $ 931 |
| **Total Revenues** | 477 | 931 |
| **Operating Expenses:** | | |
| Research and development | 18,385 | 19,543 |
| Selling, general and administrative | 16,387 | 20,299 |
| **Total Operating Expenses** | 34,772 | 39,842 |
| **Operating Loss** | (34,295) | (38,911) |
| Interest expense | — | (5,610) |
| Other income (expense), net | 363 | (135) |
| **Loss from continuing operations before income taxes** | (33,932) | (44,656) |
| Income tax expense (benefit) | 13 | (448) |
| **Loss from continuing operations** | (33,945) | (44,208) |
| Income (loss) from discontinued operations, net of income taxes | 10,735 | (29,121) |
| **Net Loss** | $(23,210) | $(73,329) |
| **Loss per share from continuing operations, basic and diluted** | $ (10.65) | $ (15.46) |
| **Income (loss) per share from discontinued operations, basic and diluted** | $ 3.37 | $ (10.18) |
| **Loss per share basic and diluted** | $ (7.28) | $ (25.64) |
| **Weighted average shares outstanding – basic and diluted** | 3,186 | 2,859 |

**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, except share data)

| | Mezzanine Equity (Convertible Preferred Stock) | | Common stock | | Additional paid-in capital | Accumulated deficit Amounts | Total Shareholders' Equity |
|---|---|---|---|---|---|---|---|
| | Number of shares | Amounts | Number of shares | Amounts | | | |
| **BALANCE AT DECEMBER 31, 2020** | **—** | **$ —** | **2,400,290** | **$ 4** | **$603,685** | **$(566,196)** | **$ 37,493** |
| **CHANGES DURING 2021:** | | | | | | | |
| Net loss | — | — | — | — | — | (73,329) | (73,329) |
| Exercise of options, vesting of restricted stock units and shares issued under employee stock purchase plan | — | — | 20,274 | — | 410 | — | 410 |
| Stock-based compensation | — | — | — | — | 8,080 | — | 8,080 |
| Deemed dividend to warrants holders due to warrant modification | | | — | — | — | — | — |
| Issuance of common stock under at-the-market offering, net of $1,038 issuance costs | — | — | 262,962 | — | 29,158 | — | 29,158 |
| Issuance of common stock through a registered direct offering, net of $3,177 issuance costs | — | — | 293,015 | 1 | 46,823 | — | 46,824 |
| **BALANCE AT DECEMBER 31, 2021** | **—** | **$ —** | **2,976,541** | **$ 5** | **$688,156** | **$(639,525)** | **$ 48,636** |
| **CHANGES DURING 2022:** | | | | | | | |
| Net loss | — | — | — | — | — | (23,210) | (23,210) |
| Reclassification due to reverse stock split | — | — | — | (5) | 5 | — | — |
| Vesting of restricted stock units and shares issued under employee share purchase plan | — | — | 16,749 | — | 9 | — | 9 |
| Stock-based compensation | — | — | — | — | 4,297 | — | 4,297 |
| Issuance of commitment shares in March 2022 | — | — | 92,644 | — | — | — | — |
| Issuance of common stock, under at-the-market offering, net of $135 in issuance costs | — | — | 143,770 | — | 1,470 | — | 1,470 |
| Issuance of convertible preferred stock, net of $89 in issuance costs | 3,000 | 211 | — | — | — | — | — |
| **BALANCE AT DECEMBER 31, 2022** | **3,000** | **$211** | **3,229,704** | **$—** | **$693,937** | **$(662,735)** | **$ 31,202** |

**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, | |
|---|---|---|
| | 2022 | 2021 |
| **Cash Flows From Operating Activities:** | | |
| Net Loss | $(23,210) | $(73,329) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 72 | 109 |
| Stock-based compensation | 4,297 | 8,080 |
| Non-cash finance expense, net | — | 2,472 |
| Loss from sale and disposal of fixed assets | 282 | 93 |
| Debt prepayment premium | — | 1,432 |
| Gain on the sale of the MST Franchise | (12,918) | — |
| Changes in operating asset and liabilities: | | |
| Decrease in trade receivables, prepaid and other assets | 11,210 | 7,709 |
| Decrease in inventory | 97 | 113 |
| Decrease in other non-current assets | — | 841 |
| Decrease in trade payables, accrued expenses and employee related obligations and severance benefits | (8,681) | (2,675) |
| Decrease in operating lease liabilities | (349) | (1,212) |
| Net cash used in operating activities | (29,200) | (56,367) |
| **Cash Flows From Investing Activities:** | | |
| Proceeds from the sale of the MST Franchise | 15,667 | — |
| Proceeds from sale and maturity of marketable securities and bank deposits | — | 1,027 |
| Net cash provided by investing activities | 15,667 | 1,027 |
| **Cash Flows From Financing Activities:** | | |
| Proceeds related to the issuance of common shares through offerings, net of issuance costs | 1,470 | 75,981 |
| Debt repayment | — | (36,432) |
| (Withholdings) proceeds from exercise of options and issuance of shares for stock-based compensation arrangements, net | (28) | 522 |
| Withholding tax from net exercise of restricted share units | — | (294) |
| Proceeds related to issuance of convertible preferred stock, net of issuance costs | 211 | — |
| Net cash provided by financing activities | 1,653 | 39,777 |
| **Decrease in cash, cash equivalents and restricted cash** | (11,880) | (15,563) |
| **Cash, cash equivalents and restricted cash at beginning of the year** | 42,855 | 58,418 |
| **Cash, cash equivalents and restricted cash at end of the year** | $ 30,975 | $ 42,855 |
| Cash and cash equivalents | 30,908 | 42,250 |
| Restricted cash | 67 | 605 |
| **Total cash, cash equivalents and restricted cash shown in statement of cash flows** | $ 30,975 | $ 42,855 |
| **Supplementary information on investing and financing activities not involving cash flows:** | | |
| Issuance of shares under employee share purchase plan | $ 37 | $ 169 |
| Amount due from sale of MST Franchise | $ 5,000 | $ — |
| **Supplemental disclosure of cash flow information:** | | |
| Interest received | $ 446 | $ 17 |
| Interest paid | $ — | $ 2,385 |

**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 proprietary, innovative and differentiated therapies for the treatment of immuno-inflammatory conditions.

In August 2021, the Company entered into a transaction with Tay Therapeutics Ltd. (formerly known as In4Derm Limited, "Tay") providing the Company with exclusive worldwide rights to research, develop and commercialize products containing bromodomain and extra-terminal ("BET") inhibitors for the treatment of any disease, disorder or condition in humans. Through our access to this library of new chemical BET inhibitor compounds, the Company plans to develop product candidates for a diverse set of indications. Based on preclinical data generated to date, the Company has chosen to focus its initial efforts for this platform on select therapeutic areas in immuno-inflammatory disease.

The Company's lead program is VYN201, a locally administered pan-BET inhibitor designed as a "soft" drug to address diseases involving multiple, diverse inflammatory cell signaling pathways while providing low systemic exposure. To date, VYN201 has produced consistent reductions in pro-inflammatory and disease-related biomarkers, improvements in disease severity and a demonstrated local activity through several preclinical models. The Company believes that these data suggest potential broad utility for VYN201 across multiple routes of administration. In November 2022, the Company initiated a Phase 1a/b clinical trial evaluating a topical formulation of VYN201 for the treatment of nonsegmental vitiligo. In February 2023, the Company announced positive preliminary safety data from the Phase 1a portion of the trial. The first nonsegmental vitiligo patient was dosed in the Phase 1b portion of the trial in January 2023 and the Company expects topline results from this trial in mid-2023.

The Company's second program is VYN202, a BD2-selective oral small molecule BET inhibitor. VYN202 is in preclinical development for the treatment of immuno-inflammatory indications, and is being designed to achieve class-leading selectivity (BD2 vs. BD1), maximum potency versus BD2 and optimal oral bioavailability. By maximizing BD2 selectivity, the Company believes VYN202 has the potential to be a more conveniently-administered non-biologic treatment option for both acute control and chronic management of immuno-inflammatory indications, where the damaging effects of unrestricted inflammatory signaling activity is common.

The Company intends to actively evaluate and enter into strategic partnerships to advance its product candidates through the clinic toward commercialization, and may also partner with leading pharmaceutical companies to advance the Company's molecules in therapeutic areas outside of its core focus in immunology. The Company believes selectively entering into collaborations has the potential to expand and accelerate the development of its programs and maximize the value of its pipeline.

In August 2021, the Company determined to dispose of its legacy commercial business and focus its strategy on the development of BET inhibitor product candidates through its licensing arrangements with Tay. For additional information regarding the sale of the commercial business to Journey Medical Corporation 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 10, 2021, the Company's board of directors approved a one-for-four reverse stock split of its outstanding shares of common stock. The reverse stock split was effected on February 12, 2021 at 5:00 p.m.

Eastern time. At the effective time, every four 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 stockholder holding 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 stockholder's respective pro rata shares of the total net proceeds from the Company's transfer agent sale of all fractional shares at the then-prevailing prices on the open market. In connection with the reverse stock split, the number of authorized shares of the Company's common stock was also reduced on a one-for-four basis, from 300 million shares to 75 million shares. 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 the Company's 2019 Equity Incentive Plan, 2018 Omnibus Incentive Plan and 2019 Employee Share Purchase Plan. None of the authorized shares were impacted by the reverse stock split.

On July 19, 2021, the Company held its meeting of Stockholders (the "Annual Meeting"). Following the approval by the holders of a majority of the outstanding shares of common stock at the Annual Meeting, the Company filed a Certificate of Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 75,000,000 to 150,000,000 shares of common stock, par value $0.0001 per share.

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 stockholder holding 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 stockholder's respective pro rata shares of the total net proceeds from the Company's transfer agent 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 a 1-for-18 reverse stock split.

*Liquidity and Capital Resources*

Since inception, the Company has funded 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 commenced generating product revenues related to sales of AMZEEQ and ZILXI in January 2020 and October 2020, respectively. AMZEEQ and ZILXI were sold as part of the sale of the MST Franchise on January 12, 2022 and, as such, the Company no longer generates revenue from the sale of these products. 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. For the year ended December 31, 2022, the Company incurred a net loss of $23.2 million and used $29.2 million of cash in operations. The net loss was comprised of $10.7 million of income from discontinued operations and $33.9 million loss from continuing operations.

As of December 31, 2022, the Company had cash and cash equivalents, and restricted cash of $31.0 million and an accumulated deficit of $662.7 million. The Company received the $5.0 million deferred payment from Journey on January 12, 2023, the one-year anniversary of the sale of the MST Franchise. The Company had no outstanding debt as of December 31, 2022.

The Company has taken a number of actions to support its operations and meet its liquidity needs. Beginning in the second quarter of 2021, the Company conducted a review of its commercial and research and development portfolio to determine how to optimally deploy capital and drive shareholder value. Following its review, the Company initiated a process to explore a possible sale or license of its MST Franchise, including AMZEEQ, ZILXI, FCD105 and the underlying MST platform and refocus its resources

on its immuno-inflammatory development programs. As a result of this decision, the Company restructured its operations and reduced its workforce, which lowered operating costs. In January 2022, the Company sold its MST Franchise.

In March 2022, the Company entered into an equity purchase agreement (the "Equity Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $30.0 million of shares of its common stock over the 36-month term of the Equity Purchase Agreement. The Company has not made any sales pursuant to the Equity Purchase Agreement to date.

As described above, the Company refocused its limited resources on its immuno-inflammatory pipeline. Continued research and development activities for these programs, including preclinical and clinical testing of the Company's product candidates, will require significant additional financing. The future viability of the Company and its ability to continue as a going concern is dependent on its ability to raise sufficient working capital through either debt or equity financings to fund its operations and successfully develop commercially viable product candidates. There is no assurance the Company will be able to achieve these objectives under acceptable terms or at all.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year after the date that its consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company's ability to continue as a going concern is expected to be impacted by the outcome of the plans outlined above, including the Company's ability to raise additional capital to fund its operations and the development and results from clinical trials for the BET inhibitor programs. Based on its current plans and assumptions, the Company believes that absent sufficient proceeds received from financing transactions or business development transactions, the Company will not have sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these consolidated financial statements. This assumption does not include proceeds that can be drawn from Lincoln Park. Accordingly, the Company will, over the course of the next twelve months, require significant additional financing to continue its operations and meaningfully advance the development of its product candidates, including potentially selling a significant amount of shares pursuant to the Equity Purchase Agreement. The Company may also employ strategies to further extend its ability to fund its operations including: (1) identification of third-party partners to further develop, obtain marketing approval for and/or commercialize its product candidates, which may generate revenue and/or milestone payments and/or (2) refocusing its resources on research and development programs it chooses to prioritize and reducing spending on other programs by delaying or discontinuing development. In addition, the amount of proceeds the Company may be able to raise pursuant to its existing shelf registration statement on Form S-3 may be 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 instructions, 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 its common stock held by non-affiliates of the Company. Therefore, the Company will be limited in the amount of proceeds it is able to raise by selling shares of its common stock using its Form S-3 until such time as its public float exceeds $75.0 million. These factors raise substantial doubt about the Company's ability to continue as a going concern. Failure to successfully receive additional financing will require the Company to delay, scale back or otherwise modify its business and its research and development activities and other operations. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

## 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 revenue recognition and product returns accrual. Actual results could differ from the Company's estimates.

The COVID-19 pandemic and government measures taken in response to the pandemic have had a negative impact on the Company's operations in 2021. Access to healthcare providers was limited, which has negatively impacted sales and the Company's ability to execute its commercial strategy with respect to AMZEEQ and ZILXI prior to the sale of the assets to Journey in January 2022. In addition, the Company further assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts of COVID-19 as of December 31, 2022 and through the date of this report.

### d. Foreign Currency Translation

Transactions and balances originally denominated in dollars are presented at their original amounts. Balances in non-dollar currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. For non-dollar transactions and other items in the statements of operations (indicated below), the following exchange rates are used: (i) for transactions — exchange rates at transaction dates or average rates; and (ii) for other items (derived from non-monetary balance sheet items such as depreciation and amortization, etc.) — historical exchange rates. Currency transaction gains and losses are presented in financial income or expenses, as appropriate.

### e. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits 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. As of December 31, 2022 and December 31, 2021, the Company had approximately $28.0 million and $29.5 million, respectively, of cash equivalents classified as Level 1 financial instruments.

### f. Restricted Cash

As of December 31, 2022, the Company had restricted cash of $0.1 million. This amount represents bank guarantees for the Company's Israeli branch.

### g. Marketable securities

The Company's marketable equity securities are recorded at fair value, with unrealized gains and losses included in other income, net in the consolidated statement of operations.

### h. Inventory

As of December 31, 2021 and January 12, 2022, the date the inventory was sold as part of the sale of the MST Franchise, inventories were stated at the lower of cost and net realizable value with cost determined on a first-in, first-out basis by product. The Company capitalized inventory costs associated with products

following regulatory approval when future commercialization was considered probable and the future economic benefit was expected to be realized. The Company periodically reviewed its inventory levels and, if necessary, wrote down inventory that was expected to expire prior to being sold, inventory in excess of expected sales requirements and inventory that failed to meet commercial sale specifications, with a corresponding charge to cost of goods sold. There were no material write-downs for the year ended December 31, 2021 and for the period from December 31, 2021 to January 12, 2022. As a result of the sale of the MST Franchise there were no inventory balances at December 31, 2022.

**i. Property and equipment**

1) Property and equipment are stated at cost, net of accumulated depreciation and amortization.

2) The Company's property and equipment are depreciated by the straight-line method on the basis of their estimated useful life.

Annual rates of depreciation are as follows:

| | Estimated Useful Life |
|---|---|
| Computers | 3 – 7 years |
| Laboratory equipment | 5 – 14 years |
| Office furniture and equipment | 7 – 14 years |

Leasehold improvements are amortized by the straight-line method over the expected lease term, which is shorter than the estimated useful life of the improvements.

**j. 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.

**k. Allowance for doubtful accounts**

An allowance for doubtful accounts is maintained for potential credit losses based on the aging of trade receivables, historical bad debts experience and changes in customer payment patterns. 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 provisions for doubtful accounts. Provisions for doubtful accounts were not material for the years ended December 31, 2022 and 2021.

**l. Debt**

Debt discounts created as a result of the allocation of proceeds received from a debt issuance to warrants issued are amortized to interest expense under the effective interest method over the life of the recognized debt liability.

Debt issuance costs include the costs of debt financings undertaken by the Company, including legal fees and other direct costs of the financing. Debt issuance costs related to a recognized debt liability are presented on the consolidated balance sheet as a direct deduction from the carrying amount of the debt liability and are amortized to interest expense over the term of the related debt, using the effective interest method.

**m. 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.

**n. 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.

**o. 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.

**p. 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.

As a result of the disposition of the MST Franchise in January 2022, the Company no longer has any revenue generating products; however, it still receives certain royalty revenues (see Note 4 Discontinued Operations).

***Royalty Revenues and Collaboration Agreements***

The Company is entitled to royalty payments with respect to sales of a product developed by a customer in collaboration with the Company. Royalties are recognized as the products are sold by the customer. Revenues in the amount of $0.5 million and $0.9 million were recorded during the year ended December 31, 2022 and 2021, 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 review our estimated periods of performance based on the progress under each arrangement and account 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 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 Revenues, net***

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. The following is a description of the Company's accounting policies related to the sales of AMZEEQ and ZILXI.

*Product sales*

The Company's customers were a limited number of national and select regional wholesalers (the "distributors") and certain independent and specialty pharmacies (together, the "customers"). These distributors would subsequently resell the product, primarily to retail pharmacies that dispense the product to patients. Net product revenue was typically recognized when customers obtained control of the Company's products, which occurred at a point in time, typically upon delivery of product to the customers. The Company evaluated the creditworthiness of its customers to determine whether it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur. The Company did not assess whether a contract had a significant financing component if the expectation was such that the period between the transfer of the promised goods to the customer and the receipt of payment would be less than one year. Standard credit terms did not exceed 75 days. The Company expensed incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that would have been recognized is one year or less or the amount is immaterial. Shipping and handling costs related to the Company's product sales were included in selling, general and administrative expenses.

Product revenue is recorded net of distribution fees, trade discounts, allowances, rebates, copay program coupons, chargebacks, estimated returns and other incentives. These reserves are classified as either reductions of accounts receivable or as current liabilities. The estimates of reserves established for variable consideration reflect contractual and statutory requirements, known market events and trends, industry data and forecasted customer mix. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net product revenues only to the extent that it is probable that a significant reversal of the amount of the

cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment.

*Product Sales Provisions*

Provisions for distribution fees, trade discounts and chargebacks 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. Provisions for revenue reserves reduced product revenues by $62.9 million for the year ended December 31, 2021. The revenue reserve accrual was $2.7 million and $5.5 million as of December 31, 2022 and December 31, 2021, respectively and was reflected in accrued expenses in the consolidated balance sheet. Actual amounts may ultimately differ from these estimates. If actual results vary, estimates may be adjusted in the period such change in estimate becomes known, which could have an impact on earnings in the period of adjustment.

*Distribution Fees and Trade Discounts and Allowances*

The Company paid fees for distribution services and for certain data that distributors provide to the Company and generally provided discounts on sales to its distributors for prompt payment. These fees and discounts are contractual in nature and the Company expects its distributors to earn these fees and discounts, and accordingly deducts the full amount of these fees and discounts from its gross product revenues at the time such revenues are recognized.

*Rebates, Chargebacks and Other Discounts*

Product sales made under managed-care and governmental pricing programs in the U.S. are subject to rebates. Managed Care rebates relate to contractual agreements to sell products to managed care organizations and pharmacy benefit managers at contractual rebate percentages in exchange for volume and/or market share. Chargebacks relate to contractual agreements to sell products to government agencies and other indirect customers at contractual prices that are lower than the list prices the Company charges wholesalers. When these government agencies or other indirect customers purchase products through wholesalers at these reduced prices, the wholesaler charges the Company for the difference between the prices they paid the Company and the prices at which they sold the products to the indirect customers. The Company estimates the rebates and chargebacks it expects to be obligated to provide and deducts these estimated amounts from its gross product revenue at the time the revenue is recognized. The Company estimates the rebates and chargebacks that it expects to be obligated to provide based upon (i) the Company's current contracts and negotiations, (ii) estimates regarding the payer mix based on third-party data and utilization, (iii) inventory held by distributors and (iv) estimates of inventory held at the retail channel. Other discounts include the Company's co-pay assistance coupon programs for commercially-insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to pay associated with product that has been recognized as revenue.

*Product Returns*

Consistent with industry practice, customers are generally allowed to return products within a specified period of time before and after its expiration date. The Company estimates the amount of product that will be returned and deducts these estimated amounts from its gross revenue at the time the revenue is recognized. The information utilized to estimate the returns provision includes: (i) actual return history (ii) historical return industry information regarding rates for comparable pharmaceutical products and product portfolios, (iii) external data with respect to inventory levels in the wholesale distribution channel, (iv) external data with respect to prescription demand for products and (v) remaining shelf lives of products at the date of sale.

*Contract Assets and Contract Liabilities*

The Company did not have any contract assets (unbilled receivables) related to product sales or as of December 31, 2022, as customer invoicing generally occurs before or at the time of revenue recognition. The

Company did not have any contract assets (unbilled receivables) related to its license revenues as of December 31, 2022 or 2021.

The Company did not have any contract liabilities as of December 31, 2022 or 2021, as the Company did not receive payments in advance of fulfilling its performance obligations to its customers.

*Sales Commissions*

Sales commissions are generally attributed to periods shorter than one year and therefore are expensed when incurred. Sales commissions are included in discontinued operations.

**q. 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.

**r. Research and development costs**

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of clinical trials, clinical trial supplies, salaries, share-based compensation expenses, payroll taxes and other employee benefits, lab expenses, consumable equipment and consulting fees. All costs associated with research and developments are expensed as incurred.

**s. 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.

**t. 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 common shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of common stock and of common stock equivalents outstanding when dilutive. Common stock equivalents include outstanding stock options and warrants which are included under the treasury share method when dilutive.

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 (share data):

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Outstanding share options and RSUs | 313,403 | 294,797 |
| Warrants | 27,509 | 27,509 |

**u. 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.

**v. Discontinued Operations**

The Company accounted for the sale of the MST Franchise in accordance with ASC 205, *Discontinued Operations,* and ASU No. 2014-08, *Reporting of Discontinued Operations and Disclosures of Disposals of Components of an Entity*. The Company followed the held-for-sale criteria as defined in ASC 360 *Property, Plant and Equipment* and ASC 205. ASC 205 requires that a component of an entity that has been disposed of or is classified as held for sale and has operations and cash flows that can be clearly distinguished from the rest of the entity be reported as assets held for sale and discontinued operations. In the period a component of an entity has been disposed of or classified as held for sale, the results of operations for the periods presented are reclassified into separate line items in the consolidated statements of operations. Assets and liabilities are also reclassified into separate line items on the related consolidated balance sheets for the periods presented. Non-cash items presented in the statement of cash flows and related to discontinued operations are presented in Note 4 — Discontinued Operations. ASU 2014-08 requires that only a disposal of a component of an entity, or a group of components of an entity, that represents a strategic shift that has, or will have, a major effect on the reporting entity's operations and financial results be reported in the consolidated financial statements as discontinued operations. ASU 2014-08 also provides guidance on the financial statement presentations and disclosures of discontinued operations.

Due to the sale of the MST Franchise during the first quarter of 2022, in accordance with ASC 205, the Company has classified the results of the MST Franchise as discontinued operations in its consolidated statements of operations and cash flows for all periods presented, see Note 4, Discontinued Operations. All disposed assets and liabilities associated with the MST Franchise were therefore classified as assets and liabilities of discontinued operations in the Company's consolidated balance sheets for the periods presented. All amounts included in the notes to the consolidated financial statements relate to continuing operations unless otherwise noted.

**w. 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 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.

For the year ended December 31, 2022, the Company had other receivables of $5.2 million primarily relating to the deferred payment from the sale of the MST Franchise and royalty receivables. The Company

received the $5.0 million deferred payment in January 2023. Existing royalty receivables relate to one customer, but do not present a credit risk due to immaterial nature. Restricted cash as of December 31, 2022 was $0.1 million which does not present a credit risk due to immaterial nature. All marketable securities were sold as of December 31, 2021.

For the year ended December 31, 2021, the Company's three largest customers represented 17%, 15% and 9%, of product revenue and collectively 58% of accounts receivable.

**x. Comprehensive loss**

For the years ended December 31, 2022 and 2021, comprehensive loss was equal to the net loss as presented in the accompanying consolidated statements of operations.

**y. Newly issued and recently adopted accounting pronouncements**:

*Recent Accounting Guidance Issued:*

In June 2016, the FASB issued Accounting Standards Update 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, 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 Accounting Standard Updates to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. As a smaller reporting company, the Company will adopt ASU 2016-13 effective January 1, 2023. Currently, the Company does not expect the adoption of the new standard to have a material impact to the consolidated financial statements.

In December 2019, the FASB issued Accounting Standards Update No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which clarifies and simplifies certain aspects of the accounting for income taxes. The standard is effective for years beginning after December 15, 2020, and interim periods beginning after December 15, 2020. This guidance became effective during the first quarter of 2021. The adoption of the new standard did not have a material impact to the Company's consolidated financial statements.

In March 2020, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2020-04, "*Reference Rate Reform* (Topic 848): *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*" (ASU 2020-04), which provides guidance to alleviate the burden in accounting for reference rate reform by allowing certain expedients and exceptions in applying generally accepted accounting principles to contracts, hedging relationships, and other transactions impacted by reference rate reform. The provisions of ASU 2020-04 apply only to those transactions that reference LIBOR or another reference rate expected to be discontinued due to reference rate reform. Adoption of the provisions of ASU 2020-04 are optional and are effective from March 12, 2020 through December 31, 2022.

In December 2022, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 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 August 2020, the FASB issued ASU No. 2020-06, "*Debt — Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging — Contracts in Entity's Own Equity* (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*" ("ASU 2020-06"), which simplifies the accounting for convertible instruments by eliminating the requirement to separately account for embedded conversion features as an equity component in certain circumstances. A convertible debt instrument will be reported as a single liability instrument with no separate accounting for an embedded conversion feature unless separate accounting is required for an embedded conversion feature as a derivative or under the substantial premium model. The ASU simplifies the diluted earnings per share calculation by

requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. Further, the ASU requires enhanced disclosures about convertible instruments. The Company adopted ASU 2020-06 as of January 1, 2022 and there was no material impact on the consolidated financial statements upon adoption.

**NOTE 3 — STRATEGIC AGREEMENTS**

*Sale of the MST Franchise*

Beginning in the second quarter of 2021, the Company conducted a review of its commercial and research and development portfolio to determine how to optimally deploy capital and drive shareholder value. During the course of this review, the Company carefully considered the revenues received from the commercialization of AMZEEQ and ZILXI and the associated costs to drive those revenues, the protracted negative impact of the COVID-19 pandemic during the commercial launches of both AMZEEQ and ZILXI, the payor landscape, as well as the costs to develop each of its pipeline products. During this process, the Company evaluated several strategic options including the acquisition of marketed assets, out-licensing its approved products outside of the United States, and possible partnering or co-development relationships with interested parties. Following its review, the Company determined to initiate a process to explore a possible sale or license of its topical minocycline franchise, including AMZEEQ, ZILXI, FCD105 (the Company's former Phase 3 proprietary novel topical combination foam formulation of minocycline and adapalene for the treatment of moderate-to-severe acne vulgaris) and the underlying Molecule Stabilizing Technology platform.

On January 12, 2022, VYNE entered into an Asset Purchase Agreement (the "Purchase Agreement") with Journey Medical Corporation ("Journey") pursuant to which the Company sold its Molecule Stabilizing Technology franchise, including AMZEEQ, ZILXI, and FCD105 (the "MST Franchise"), to Journey. The assets include 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 including, among others, those arising from VYNE's patent infringement suit initiated against Padagis Israel Pharmaceuticals Ltd. 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.

As the Company transitioned from a commercial organization to one focused on research and development, the Company streamlined operations by eliminating the vast majority of planned expenditures supporting its commercial operations. Furthermore, following its decision to divest the MST Franchise, the Company reduced its workforce by terminating approximately 70 employees. The Company incurred a one-time charge of $1.6 million in the year ended December 31, 2021 in connection with this restructuring plan, consisting of $1.4 million of employee termination costs, including severance and other benefits, and retention payments of $0.2 million. The Company did not incur any material expenses in 2022 as a result of the restructuring plan.

*BET Inhibitor License Agreements*

On August 12, 2021, the Company announced a transaction with Tay Therapeutics Limited (formerly known as In4Derm Limited), a company incorporated and registered in Scotland ("Tay"). Tay is a spin-out of the University of Dundee's School of Life Sciences which has discovered and is developing proprietary Bromodomain and Extra-Terminal Domain ("BET") inhibitors for the treatment of immunology and oncology conditions. On April 30, 2021, the parties entered into an Evaluation and Option Agreement (the

"Option Agreement") pursuant to which Tay granted the Company an exclusive option to obtain exclusive worldwide rights to research, develop and commercialize products containing Tay's BET inhibitor compounds, which are new chemical entities for treatments in all fields for any disease, disorder or condition in humans. Under the terms of the Option Agreement, the Company's option with respect to selective BET inhibitor compounds ("Oral Option") was to expire upon the earlier of (i) 14 days following the delivery of an agreed data package and selection of a lead new chemical entity candidate by Tay or (ii) June 30, 2022 (the "Option Term"). On June 15, 2022, the parties 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 $386,366 (£300,000) on June 28, 2022 to Tay to extend the Option Term. In addition, a second payment of $997,407 (£850,000) was paid to Tay pursuant to the terms of the Letter Agreement on August 29, 2022 following the discovery of potential preclinical candidates. Both payments were recorded as research and development expense. On February 27, 2023, the parties entered into a Letter Agreement (the "Second Letter Agreement") pursuant to which the Option Term has been 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 will be deducted from the upfront fee payable by the Company to Tay in the event that the Company exercises the Oral Option.

On August 6, 2021, the Company exercised its option with respect to certain of Tay's pan-BD Inhibitor Compounds ("Topical Option"). On August 9, 2021, the parties entered into a License Agreement (the "VYN201 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 paid a $1.0 million cash payment to Tay upon the execution of the Option Agreement and $0.5 million in connection with entering into the VYN201 License Agreement. These payments were recorded as a research and development expense in the period paid. Pursuant to the VYN201 License Agreement, the Company has 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. Tay is entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. The VYN201 License Agreement provides for tiered royalty payments of up to 10% of annual net sales on the licensed product.

In the event that the Company exercises the Oral Option, the parties will enter into a license agreement (the "VYN202 License Agreement") granting the Company a worldwide, exclusive license that is sublicensable through multiple tiers to exploit certain of Tay's selective BET inhibitor compounds in all fields. The Company will owe a $4.0 million cash payment, less the extension fee paid in connection with Second Letter Agreement, to Tay in connection with entering into the VYN202 License Agreement. If the parties enter into the VYN202 License Agreement, the Company will 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. Tay will also be entitled to additional milestones upon the achievement of regulatory approvals in certain jurisdictions outside the U.S. The VYN202 License Agreement will provide for tiered royalty payments of up to 10% of annual net sales on the licensed product.

**NOTE 4 — DISCONTINUED OPERATIONS**

On January 12, 2022, the Company entered into the Purchase Agreement with Journey pursuant to which the Company sold its MST Franchise to Journey. The Company has determined that the sale of the MST Franchise represents a strategic shift that had a major effect on the business and therefore the MST Franchise met the criteria for classification as discontinued operations at March 31, 2022. Accordingly the MST Franchise is reported as discontinued operations in accordance with ASC 205-20, *Discontinued Operations*. Amounts applicable to prior years have been recast to conform to the discontinued operations presentation. The Company recognized a gain on the sale of the MST Franchise upon closing. The negative product sales for the year ended December 31, 2022 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:

| (in thousands) | Year ended December 31, 2022 | 2021 |
|---|---|---|
| Product sales, net | $ (1,844) | $ 13,824 |
| Cost of goods sold | 80 | 3,348 |
| Operating expenses: | | |
| Research and development | — | 5,415 |
| Selling, general and administrative | 259 | 34,182 |
| Total operating expenses | 259 | 39,597 |
| Loss from discontinued operations | (2,183) | (29,121) |
| Gain on the sale of the MST Franchise | 12,918 | — |
| Income (loss) from discontinued operations, before income taxes | 10,735 | (29,121) |
| Income tax expense | — | — |
| Net income (loss) from discontinued operations | $10,735 | $(29,121) |

The following table presents the carrying amounts of the classes of assets related to the discontinued operations of the MST Franchise as of December 31, 2021:

| (in thousands) | December 31, 2021 |
|---|---|
| Current assets: | |
| Inventory | $7,291 |
| Prepaid expenses and other assets | 554 |
| Total current assets of discontinued operations | $7,845 |

Inventory was primarily comprised of $3.3 million of raw materials and $4.0 million of finished goods.

The following table presents non-cash items related to discontinued operations, which are included in the Company's consolidated statement of cash flows for the years ended December 31, 2022 and 2021:

| (in thousands) | Year ended December 31, 2022 | 2021 |
|---|---|---|
| **Cash Flows From Operating Activities:** | | |
| Stock-based compensation (income) expense* | $ (352) | $1,123 |
| Gain on the sale of the MST Franchise | (12,918) | — |
| Total non-cash items of discontinued operations | $(13,270) | $1,123 |
| **Supplemental disclosure of cash flow information:** | | |
| Amount due from sale of MST Franchise | $ 5,000 | $ — |

* Income from stock-based compensation is related to forfeitures.

The following table presents the gain on the sale of the MST Franchise:

| (in thousands) | Year ended December 31, 2022 |
|---|---|
| Cash proceeds | 20,000 |
| Proceeds paid in January 2023 | 5,000 |
| | 25,000 |
| Less transaction costs | (4,334) |
| Less carrying value of assets sold | (7,748) |

| (in thousands) | Year ended December 31, 2022 |
|---|---|
| Gain on sale, before income taxes | 12,918 |
| Income tax expense | — |
| Gain on sale net of tax | $12,918 |

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 research and development, marketing, selling and general and administrative expenses in discontinued operations include corporate costs incurred directly to solely support the MST Franchise.

The milestone payment 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 — PROPERTY AND EQUIPMENT

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cost: | | |
| Leasehold improvements | $ — | $ 59 |
| Computers and software | — | 374 |
| Laboratory equipment | — | 53 |
| Furniture | — | 419 |
| | — | 905 |
| Less: | | |
| Accumulated depreciation and amortization | — | 551 |
| Property and Equipment, net | $ — | $354 |

Depreciation and amortization expense totaled $0.1 million and $0.1 million for the years ended December 31, 2022 and 2021, respectively.

During the years ended December 31, 2022 and December 31, 2021, the Company disposed of fixed assets in the net amount of $0.3 million and $0.1 million, respectively. Loss on disposal of fixed assets during the year ended December 31, 2022 relates to the write-off of laboratory and leasehold improvements due to a reduction in office space in Israel and the US and is reflected in operating expenses in the Consolidated Statements of Operations.

## NOTE 6 — ACCRUED EXPENSES

Accrued expenses consisted of the following:

| | December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Product sales provisions | $2,695 | $5,489 |
| Professional services | 519 | 1,213 |
| Research and development | 987 | 969 |
| Commercialized product accruals | — | 596 |
| Other | 180 | 326 |
| Total Accrued Expenses | $4,381 | $8,593 |

## NOTE 7 — OPERATING LEASE

As of December 31, 2022, the Company had operating leases for its principal executive office in Bridgewater, New Jersey. As of December 31, 2021, the Company previously had operating leases for its vehicles. In connection with the strategic business review and sale of the MST Franchise certain vehicle leases were transferred to members of the commercial workforce resulting in the elimination of the operating lease amounts related to fleet vehicles.

On March 13, 2019, the Company signed an amendment to the original lease agreement for its principal executive office in Bridgewater, New Jersey (the "Lease Amendment"). The Lease Amendment included an extension of the lease period of the 10,000 square feet previously leased under the original agreement (the "Original Space") and an addition of 4,639 square feet (the "Additional Space"). The Company entered the Additional Space following a period of preparation by the lessor completed during September 2019 (the "Commencement Date"). The term included in the Lease Amendment expired on September 30, 2022.

Pursuant to the Lease Amendment, the Company recognized an additional right of use asset and liability in the amount of $0.7 million. The Additional Space was considered a new lease agreement and was recognized as a right of use asset and liability, in the amount of $0.3 million, on the Commencement Date. The lease liability matured on September 30, 2022.

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. In addition, the Company signed a Lease Agreement (the "Master Lease") to lease the Leased Premises following the termination of the Sublease through September 30, 2025. The Company will record a right of use asset and liability at the commencement date of the Master Lease. The Master Lease is expected to result in total lease payments of approximately $0.3 million.

The lease agreement for the office space in Israel was a one year lease that expired in December 2022. Given the short-term nature of the lease term, the Company did not recognize a right-of-use asset and liability.

Operating lease costs for the year ended December 31, 2022 are as follows:

| (in thousands) | Year Ended December 31 2022 | Year Ended December 31 2021 |
|---|---|---|
| Office lease expenses | $297 | $357 |

The operating lease costs include an immaterial amount of variable lease payments for the years ended December 31, 2022 and 2021, respectively. Lease expense is included within selling, general and administrative expenses on the Consolidated Statements of Operations.

As of December 31, 2021, the lease liabilities reflect a weighted average discount rate of 13.10% and a remaining weighted average lease term of 0.75 as of December 31, 2021. There were no lease liabilities as of December 31, 2022.

As of December 31, 2021, the Company had a lien in the amount of $0.6 million related to a letter of credit on the Company's cash in respect of bank guarantees granted in order to secure the lease agreements. In April 2022, the lien was released and the Company reclassed the $0.6 million from restricted cash to cash and cash equivalents due to the lien release. This amount was presented as restricted cash in the Company's consolidated balance sheet as of December 31, 2021.

## NOTE 8 — EMPLOYEE SAVINGS PLAN

Beginning September 2017, the Company has made retirement savings plans available to all employees of the 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, 2022, and 2021 of approximately $0.1 million and $0.4 million, respectively.

## NOTE 9 — 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, 2022, there are 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 10 — LONG-TERM DEBT

On July 29, 2019, Foamix entered into a Credit Agreement (the "Credit Agreement") to secure up to $50.0 million from two lenders, one of which is a significant stockholder of the Company and is considered a related party, and a Securities Purchase Agreement with one of the lenders for gross proceeds of approximately $14.0 million, before deducting offering expenses (see "Note 12 — Share Capital" for more information). On March 9, 2020, the Company entered into an Amended and Restated Credit Agreement and Guaranty (as further amended on August 5, 2020, the "Amended and Restated Credit Agreement"), whereby the Company guaranteed the indebtedness obligations of the borrower and granted a first priority security interest in substantially all of the Company's assets for the benefit of the lenders.

The term loans drawn under the Amended and Restated Credit Agreement were comprised as follows: (a) $15.0 million that was funded on July 29, 2019 (the "Tranche 1 Loan") and (b) $20.0 million that was funded on December 17, 2019 (the "Tranche 2 Loan"). The Tranche 2 Loan was borrowed following the FDA's approval of the Company's NDA for AMZEEQ and listing of AMZEEQ in the FDA's "Orange Book," in addition to maintaining its arrangements with a third party for the commercial supply and manufacture of AMZEEQ. Subject to any acceleration as provided in the Amended and Restated Credit Agreement, including upon an event of default (as defined in the Amended and Restated Credit Agreement), the loans will mature on July 29, 2024 and bear interest equal to the sum of (A) 8.25% (subject to increase in accordance with the terms of the Amended and Restated Credit Agreement) plus (B) the greater of (x) the one-month LIBOR as of the second business day immediately preceding the first day of the calendar month or the date of borrowing (if such loan is not outstanding as of the first day of the calendar month), as applicable, and (y) 2.75%. A fee in an amount equal to 1.0% of the aggregate principal amount of all loans made on any given borrowing date shall be payable to the lenders.

The loans were scheduled to mature on July 29, 2024. However, following discussions with the Company's lenders regarding the revenue targets included in the Amended and Restated Credit Agreement, the revenue expected to be generated for the trailing twelve month period ended June 30, 2021 and the Company's strategic business review discussed in Note 1, the Company determined to prepay its outstanding indebtedness in addition to a 4% prepayment fee and accrued but unpaid interest in the total amount of approximately $36.5 million on August 11, 2021. Following the prepayment, the Amended and Restated Credit Agreement and the security interests thereunder were terminated. As of December 31, 2022 there was no debt outstanding.

Perceptive Credit Holdings II, LP ("Perceptive") was one of the lenders and the administrative agent under the Amended and Restated Credit Agreement. As of August 11, 2021, the date of the prepayment, affiliates of Perceptive were holders of more than 5% of the Company's outstanding common stock. In connection with the prepayment of the Company's indebtedness, Perceptive received $18.3 million, representing their portion of the principal amount, interest and prepayment premium. As of December 31, 2021, Perceptive was no longer a related party.

In addition, on July 29, 2019, the lenders under the Credit Agreement were issued warrants to purchase up to an aggregate of 61,111 of Foamix ordinary shares, at an exercise price of $37.62 per share (the "Warrants"), which represented the five-day volume weighted average price of the Foamix ordinary shares as of the trading day immediately prior to the issuance of the Warrants. In connection with the completion of the Merger on March 9, 2020, the applicable exchange ratio (the "Exchange Ratio") was applied to the

Warrants such that they became exercisable for 36,202 shares of the Company's common stock, and the exercise price was adjusted to $63.54. On April 6, 2020, following the Phase 3 PN Trial results, the Warrants were further adjusted for the conversion of the contingent stock rights and reverse stock split. As of December 31, 2022, the Warrants were exercisable for 27,509 shares of the Company's common stock with an exercise price of $76.78 per share. Payment of the exercise price will be made, at the option of the holder, either in cash or as a reduction of common stock issuable upon exercise of the Warrant, with an aggregate fair value equal to the aggregate exercise price ("cashless exercise"), or any combination of the foregoing. The Warrants are exercisable pursuant to the terms, and subject to the conditions, thereof and expire on July 29, 2026. Any Warrants left outstanding will be cashless exercised on the Warrants' expiration date, if in the money. The Warrants issued were classified as equity in accordance with ASC 815-40. Proceeds received under the Tranche 1 Loan were allocated to the Warrants and the Tranche 1 Loan on a relative fair value basis. The exercise price of the Warrants will be adjusted in the event of issuances of common stock at a price lower than the exercise price of the warrants then in effect (the "Down Round Feature"). During the years ended December 31, 2022 and 2021, the Down Round Feature was triggered due to the price per share received from the issuance of common stock. Refer to Note 11 — Mezzanine and Shareholders' Equity for further information on the impact of the Down Round Feature. The Warrants expire on July 29, 2026.

During the year ended December 31, 2021 the Company recorded interest expense of $5.6 million comprised of interest on debt of $3.8 million and discount cost of $1.8 million. The interest expense includes a debt prepayment fee of $1.4 million and the write-off of discount costs of $1.6 million associated with the Company's prepayment of outstanding indebtedness resulting in a total extinguishment loss of $3.0 million.

## NOTE 11 — MEZZANINE AND SHAREHOLDERS' EQUITY

***Preferred stock***

As of December 31, 2022, the Company's Certificate of Incorporation, as amended, authorized the Company to issue 20,000,000 shares of preferred stock, par value $0.0001 per share. There were 3,000 and 0 shares of Series A Convertible Preferred Stock issued and outstanding as of December 31, 2022 and December 31, 2021, respectively.

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 (the "Purchaser"), pursuant to which the Company issued on November 14, 2022 (the "Closing Date"), in a private placement transaction (the "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 a net subscription of $211,000 as of December 31, 2022.

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

The Purchase Agreement required that the Company convene, no later than January 31, 2023 (excluding adjournments and assuming no review of the Company's proxy statement by the Securities and Exchange Commission), an annual meeting or special meeting of stockholders for the purpose of presenting to the Company's stockholders a proposal (the "Proposal") to approve a reverse stock split of its outstanding Common Stock (the "Reverse Stock Split"), 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.

Additionally, the Purchase Agreement contained customary representations, warranties and agreements of the Company and the Purchaser, 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 designating 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.

On November 14, 2022, the Company filed the Certificate of Designation with the Secretary of State of the State of Delaware designating 3,000 shares out of the authorized but unissued shares of its preferred stock as Series A Preferred with a stated par value of $0.0001 per share. 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 satisfies 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 the sole holder of the Series A Preferred Stock. The redemption payment represents 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***

The number of shares of common stock authorized under the Company's Amended and Restated Certificate of Incorporation was proportionately reduced in connection with the Company's 1-for-4 reverse stock split in February 2021. On July 19, 2021, the Company held its meeting of Stockholders (the "Annual Meeting"). Following the approval by the holders of a majority of the outstanding shares of common stock at the Annual Meeting, the Company filed a Certificate of Amended and Restated Certificate of

Incorporation to increase the number of authorized shares of common stock from 75,000,000 to 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 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 stockholder holding 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 stockholder's respective pro rata shares of the total net proceeds from the Company's transfer agent 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 shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect a 1-for-18 reverse stock split.

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

| | Year ended December 31, 2022 |
|---|---|
| Common stock options outstanding (Note 12) | 229,787 |
| Shares available for grant under the Employee Stock Purchase Plan (Note 12) | 116,463 |
| Outstanding restricted stock units (Note 12) | 83,616 |
| Shares available for future grant under 2018 and 2019 Plans (Note 12) | 72,148 |
| Shares reserved for conversion of Series A Convertible Preferred Stock* | 64,102 |
| Shares underlying outstanding warrants | 27,509 |
| | 593,625 |

* The Series A Convertible Preferred Stock was fully redeemed on January 17, 2023.

***Warrants***

As of December 31, 2022 and December 31, 2021, the Company had equity-classified warrants to purchase an aggregate of 27,509 shares of the Company's common stock outstanding, with an exercise price of $76.78 as of December 31, 2022 and an expiration date of July 29, 2026. The exercise price will be adjusted in the event the Down Round Feature is triggered. During the year ended December 31, 2022 and 2021, the Down Round Feature was triggered due to the price per share received from the issuance 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 no impact on net loss per share in the periods presented. The exercise price will continue to be adjusted in the event the Company issues additional shares of common stock below the current exercise price, in accordance with the terms of the warrants.

***Issuance of stock***

On February 1, 2019, the Company entered into a Sales Agreement (the "2019 Sales Agreement") with Cantor Fitzgerald & Co. ("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 acted 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 2019 Sales Agreement. From January 1, 2021 through January 25, 2021 the Company issued and sold 154,334 shares of common stock at a weighted average price per share of $175.68 pursuant to the 2019 Sales Agreement for $26.3 million in net proceeds. Effective as of January 25, 2021, the Company terminated the 2019 Sales Agreement.

On January 26, 2021, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors for the sale of an aggregate of 293,015 shares of common stock of the Company, at a purchase price of $170.64 per share in a registered direct offering. The offering was completed on January 28, 2021 and the Company received approximately $46.8 million in net proceeds, after deducting placement agent fees and other offering expenses.

On August 12, 2021, the Company entered into a new sales agreement (the "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 will act as the Company's sales agent. Cantor Fitzgerald is 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 Sales Agreement. During the year ended December 31, 2021, the Company issued and sold 108,629 shares of common stock at a weighted average per share price of $28.26 pursuant to the Sales Agreement for $2.9 million in net proceeds. During the year ended December 31, 2022, the Company issued and sold 143,770 shares of common stock at a weighted average per share price of $11.16 pursuant to the 2021 Sales Agreement for $1.5 million in net proceeds. This agreement was in effect as of December 31, 2022.

On March 15, 2022, the Company entered into the Equity Purchase Agreement, with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park, at the Company's discretion, up to $30.0 million of shares of its common stock over the 36-month term of the Equity Purchase Agreement. Upon execution of the Equity Purchase Agreement, the Company issued 92,644 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Equity Purchase Agreement. The issuance of these shares were specific incremental costs directly attributable to the proposed offering. The commitment shares were valued at $0.9 million and recorded as an addition to equity for the issuance of common stock and treated as a reduction to equity as a cost of capital to be raised under the Equity Purchase Agreement. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of the Company's common stock. The Equity Purchase Agreement may be terminated by the Company at any time, at its sole discretion, without any additional cost or penalty. As of December 31, 2022, the Company had not sold any shares of its common stock to Lincoln Park under the Equity Purchase Agreement.

## NOTE 12 — SHARE BASED COMPENSATION

Equity incentive plans:

The Company maintains the 2019 Equity Incentive Plan (the "2019 Plan") and 2018 Omnibus Incentive Plan (the "2018 Plan"). As of December 31, 2022, 57,338 shares remain issuable under the 2019 Plan and 14,810 shares remain issuable under the 2018 Plan. In January 2022, the number of shares reserved under the 2018 Plan automatically increased by 41,666 shares of common stock pursuant to the terms of the 2018 Plan.

Employee Share Purchase Plan:

The Company adopted Foamix's 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, 2022, 116,463 shares remain available for grant under the ESPP.

During the year ended December 31, 2022 and 2021, 7,549 and 3,994 shares were issued to employees pursuant to the ESPP, respectively.

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

In the years ended December 31, 2022 and 2021, the Company granted options and RSUs as follows:

| | Year ended December 31, 2022 | | | |
|---|---|---|---|---|
| | Award amount | Exercise price range | Vesting period | Expiration |
| Employees and Directors: | | | | |
| Options | 48,861 | $5.62 – $10.98 | 1 year – 4 years | 10 years |
| RSU | 40,339 | — | 4 years | — |

| | Year ended December 31, 2021 | | | |
|---|---|---|---|---|
| | Award amount | Exercise price range | Vesting period | Expiration |
| Employees and Directors: | | | | |
| Options | 93,689 | $30.24 – $199.44 | 1 year – 4 years | 10 years |
| RSU | 53,934 | — | 2 years – 4 years | — |

The fair value of options and RSUs granted to employees and directors during 2022 and 2021 was $0.8 million and $9.4 million, respectively. One share of Common Stock will be issued for each RSU that vests.

The fair value of RSUs granted to employees and directors is based on the share price on grant date.

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.

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

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Fair value of stock option | $3.55 – $7.49 | $18.36 – $121.50 |
| Dividend yield | 0% | 0% |
| Expected volatility | 73.70% – 74.40% | 68.38% – 69.38% |
| Risk – free interest rate | 2.20% – 2.92% | 0.50% – 1.29% |
| 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 by the Company 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. The conversion was considered by the company to be a modification under ASC 718. As a result of the modification, for outstanding options and RSUs granted to Foamix employees and consultants, the Company recorded incremental compensation of $0.2 million and $1.8 million for the years ended December 31, 2022 and December 31, 2021, respectively. As of December 31, 2022 there is $0.1 million of unrecognized incremental compensation expense related to the modification which will be amortized using a graded vesting method over the next 1 year.

*Summary of outstanding and exercisable options and RSUs:*

The following table summarizes the number of options outstanding for the year ended December 31, 2022, and related information:

| | Number of options | Weighted Average Exercise Price |
|---|---|---|
| Outstanding at December 31, 2021 | 224,664 | $165.12 |
| Granted | 48,861 | 10.35 |
| Forfeited | (26,234) | 102.28 |
| Expired | (17,504) | 157.35 |
| Outstanding at December 31, 2022 | 229,787 | $138.92 |
| Exercisable at December 31, 2022 | 145,272 | $182.66 |

The weighted average remaining contractual term of outstanding and exercisable options as of December 31, 2022, is 6.5 years and 5.5 years, respectively. Total unrecognized share based compensation for options at December 31, 2022 is $2.9 million, which is expected to be recognized over a weighted average period of 2.1 years.

There was no intrinsic value of outstanding and exercisable options as of December 31, 2022

The following table summarizes the number of RSUs outstanding for the year ended December 31, 2022:

| | Number of RSUs |
|---|---|
| Outstanding at December 31, 2021 | 70,133 |
| Awarded | 40,339 |
| Vested | (13,375) |
| Forfeited | (13,481) |
| Outstanding at December 31, 2022 | 83,616 |

Total unrecognized compensation expense related to the unvested portion of the Company's RSUs at December 31, 2022 was $2.9 million, which is expected to be recognized over a weighted average period of 2.1 years.

Share-based compensation expenses:

The following table illustrates the effect of share-based compensation on the statements of operations:

| | Year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| Research and development expenses | 1,230 | 1,714 |
| Selling, general and administrative | 3,419 | 5,243 |
| Discontinued Operations* | (352) | 1,123 |
| | 4,297 | 8,080 |

* Income from stock-based compensation is related to forfeitures.

**NOTE 13 — INCOME TAX:**

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

| | Year ended December 31, | |
|---|---|---|
| (in thousands) | 2022 | 2021 |
| Income (loss) before income taxes: | | |
| Domestic | $(23,472) | $(69,196) |
| Foreign | 279 | (4,581) |
| Total loss before taxes | $(23,193) | $(73,777) |
| Current taxes: | | |
| Federal | $ — | $ (456) |
| State | 13 | 8 |
| Total current taxes | $ 13 | $ (448) |

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, | |
|---|---|---|
| | 2022 | 2021 |
| Federal income tax provision at statutory rate | 21.00% | 21.00% |
| State income tax provision, net of federal benefit | (0.04)% | (0.01)% |
| Permanent differences | (1.52)% | —% |
| Change in valuation allowances | (19.49)% | (20.27)% |
| Other | —% | (0.11)% |
| Effective income tax rate | (0.05)% | 0.61% |

The income tax expense for the years ended December 31, 2022 and 2021 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 FASB 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 $2.9 million and $2.8 million as of December 31, 2022 and 2021, 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 2018 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)** | **2022** | **2021** |
| Deferred tax assets: | | |
| Net operating loss carry forward | $ 72,903 | $ 73,259 |
| Tax credit carryforwards | 7,794 | 7,905 |
| Section 174 expenses | 3,529 | — |
| Share based compensation | 2,061 | 3,281 |
| Accrued expenses and other | 586 | 1,226 |
| Total gross deferred tax assets | 86,873 | 85,671 |
| Less – valuation allowance | (86,873) | (85,555) |
| Total deferred tax assets, net of valuation allowance | | |
| Deferred tax liabilities: | | |
| Other | — | (40) |
| Right of use assets | — | (76) |
| Total gross deferred tax liabilities | — | (116) |
| 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, 2022 and 2021, the Company recorded a valuation allowance against its net deferred tax assets of approximately $86.9 million and $85.6 million, respectively. The change in the valuation allowance during the years ended December 31, 2022 and 2021 was an increase of approximately $1.3 million and $15.8 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, 2022, the Company had federal and state pre-tax net operating loss carryforwards of approximately $318.3 million and $90.4 million, respectively.

As of December 31, 2022, research and development credit carryforwards for federal and state purposes are approximately $6.6 million and $1.2 million, respectively. 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 may have undergone ownership changes and therefore 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 unrecognized tax benefits (in thousands):

| | |
|---|---|
| Balance at January 1, 2021 | $3,083 |
| Additions for prior year positions | — |
| Additions for current year positions | 172 |
| Reductions related to expiration of statute of limitations | (456) |
| Balance at December 31, 2021 | $2,799 |
| Additions for prior year positions | — |
| Additions for current year positions | 55 |
| Reductions related to expiration of statute of limitations | — |
| Balance at December 31, 2022 | $2,854 |

## 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, 2022. Based on such evaluation, those officers have concluded that, as of December 31, 2022, 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 fourth quarter ended December 31, 2022 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 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, 2022. 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, 2022, our internal control over financial reporting was effective based on these criteria.

## ITEM 9B — OTHER INFORMATION

On March 9, 2023, the compensation committee (the "Compensation Committee") of our board of directors approved cash retention payments for the ten employees remaining at the Company as of the date of this report. In making its decision, the Compensation Committee considered (i) the limited number of employees remaining at the Company and the increase in each employee's responsibilities; (ii) the impact of the loss of any employee, especially members of management, on our ability to execute corporate objectives for 2023; and (iii) the limited number of shares available under our existing equity incentive plans following our 1-for-18 reverse stock split. After considering the foregoing, the Compensation Committee approved a cash retention plan with the goal of encouraging the retention of employees through milestone events in 2023.

Each of our employees, including David Domzalski, our President and Chief Executive Officer, Tyler Zeronda, our Chief Financial Officer, Iain Stuart, our Chief Scientific Officer, and Mutya Harsch, our General Counsel and Chief Legal Officer, is eligible to receive 100% of their target annual bonus (the "Retention Payment") over a period of time to maintain the continuity of business operations. Per the approved plan, one-third of the Retention Payment will be paid only upon the achievement of each of the following milestones, subject to the individual's remaining in our continuous service through each payment date: (i) the receipt of positive results from our Phase 1b clinical trial for VYN201; and (ii) the achievement of certain financing objectives. The remaining one-third of the Retention Payment will be paid if the employee has remained in our continuous service through December 31, 2023. Notwithstanding the foregoing, any then-unpaid portion of the Retention Payment will be paid if an employee experiences a termination of employment in connection with a change of control.

## 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 December 31, 2022:

| Name | Age | Position(s) |
|---|---|---|
| **Executive Officers and Employee Director** | | |
| David Domzalski | 56 | President, Chief Executive Officer and Director |
| Tyler Zeronda | 37 | Chief Financial Officer and Treasurer |
| Iain Stuart, Ph.D. | 50 | Chief Scientific Officer |
| Mutya Harsch | 48 | Chief Legal Officer, General Counsel and Secretary |
| **Non-Employee Directors** | | |
| Sharon Barbari | 68 | Director |
| Steven Basta | 57 | Director |
| Anthony Bruno | 66 | Director |
| Patrick LePore | 67 | Lead Independent Director |
| Elisabeth Sandoval | 61 | Director |

### Executive Officers

***David Domzalski*** has served as the Company's President and Chief Executive Officer and as a director since March 9, 2020, the closing date of the merger between Menlo and Foamix (the "Closing Date"). From

July 2017 until the Closing Date, Mr. Domzalski served as the Chief Executive Officer of Foamix. He also served as a director of Foamix beginning in January 2018. Mr. Domzalski's tenure with Foamix began in April 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 the Company and Foamix, and his extensive experience in operating and leadership roles in the pharmaceutical industry.

***Tyler Zeronda*** was appointed as the Company's Chief Financial Officer and Treasurer in March 2022 and previously served as Interim Chief Financial Officer and Treasurer since June 2021. Mr. Zeronda previously served as Vice President of Finance of the Company from the Closing Date until his appointment as Interim CFO. Mr. Zeronda joined Foamix in April 2019 and has been responsible for all finance activities related to the commercial operations, financial planning, treasury, risk management and supply chain matters of VYNE. From April 2013 until April 2019, Mr. Zeronda held positions of increasing responsibility in finance at Aerie Pharmaceuticals Inc. ("Aerie"), a Nasdaq listed company, culminating in his role as Director of Finance. While at Aerie, Mr. Zeronda supported the company's IPO and helped lead his department's growth and transition from that of a pre-IPO, development-stage entity to a fully integrated commercial finance organization supporting the launch of multiple drugs. Prior to joining Aerie, Mr. Zeronda was employed at Ernst & Young, LLP where he focused on assurance services in the healthcare industry. Mr. Zeronda received his Master of Science in accounting from the University of Virginia, holds a Bachelor of Arts in economics and business from Lafayette College and is a licensed CPA.

***Iain Stuart, Ph.D.*** has served as the Company's Chief Scientific Officer since the Closing Date. From January 2019 until the Closing Date, Dr. Stuart served as the Chief Scientific Officer of Foamix. Dr. Stuart previously served as Foamix's Senior Vice President of Research & Development from August 2017 to January 2019 and as Vice President of Clinical Development from October 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 the Company's Chief Legal Officer, General Counsel and Secretary since the Closing Date. From January 2019 until the Closing Date, Ms. Harsch served as the General Counsel and Chief Legal Officer of Foamix. She previously served as Foamix's General Counsel and Senior Vice President of Legal Affairs from January 2018 to January 2019. In addition, Ms. Harsch has served on the board of directors of Satsuma Pharmaceuticals Inc. since October 2021. Ms. Harsch has over 20 years of legal experience, previously holding 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. 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 Date and previously served as a director of Foamix from January 2019 until the Closing Date. Ms. Barbari previously served as Chief Financial Officer at Cytokinetics from 2004 to 2017 and as CFO at Gilead Sciences, where she served in senior financial roles from 1998 to 2002. Ms. Barbari also served as CFO and Senior Vice President of Finance and Administration at InterMune, and Vice President of Strategic Planning at Foote, Cone & Belding Healthcare. From 1972 to 1990, Ms. Barbari served in various roles of increasing responsibility at Syntex Corporation/ Roche Pharmaceuticals. Ms. Barbari currently serves on the board of directors of Agile Therapeutics. She previously served on the board of directors of Foamix from January 2019 until the Closing Date, Sonoma Pharmaceuticals, Phytogen Life Sciences and the Association of Bioscience Finance Officers. In 2017, Ms. Barbari was a recipient of the YWCA Silicon Valley Tribute to Women Awards. She received her BS in accounting from San Jose State University. The Board believes that Ms. Barbari's long career as a senior financial executive and her leadership roles in various biotechnology and pharmaceutical companies provides broad experience and knowledge of the global pharmaceutical business and industry, as well as extensive accounting expertise, to the Board and to the Company.

***Steven Basta*** served as our President and Chief Executive Officer from September 2015 until the Closing Date and has served as a member of our Board since September 2015. From December 2020 until

October 2022, Mr. Basta served as the Chief Executive Officer of Mahana Therapeutics, a privately-held digital therapeutics company. From October 2011 until August 2015, Mr. Basta served as Chief Executive Officer of AlterG, a privately held medical device company. From November 2002 to February 2010, Mr. Basta served as Chief Executive Officer of BioForm Medical, a publicly listed medical aesthetics company acquired by Merz, and from February 2010 to September 2011 served as Chief Executive Officer of Merz Aesthetics, the successor to BioForm Medical. He has served on the board of DermBiont, Inc., a privately held pharmaceutical company, since March 2020. Mr. Basta previously served as a board member of Viveve Medical from September 2018 until March 2023, including as Chairman of the Board from January 2019 until March 2023. Mr. Basta also previously served on the board of Carbylan Therapeutics from September 2009 to November 2016 when it was acquired by KalVista Pharmaceuticals. Mr. Basta served on the board of RF Surgical (acquired by Medtronic) from December 2013 to August 2015. 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.

***Anthony Bruno*** has served on our Board since the Closing Date and previously served as a director of Foamix from November 2018 until the Closing Date. Mr. Bruno is currently retired. He previously served as a strategic consultant to Foamix from 2014 until August 2018, and to various healthcare-focused investment funds from 2011 to January 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 legal career as an associate with 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 within the industry, as well as significant experience in product licensing and M&A transactions.

***Patrick LePore*** has served on our Board since September 2020 and was appointed as the lead independent director in February 2021. Mr. LePore previously served as Chairman, Chief Executive Officer and President of Par Pharmaceutical Companies, Inc. from September 2006 until its sale to affiliates of TPG Capital in 2012. He remained as chairman of Par Pharmaceutical through its sale to Endo International 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 was eventually sold to Cardinal Health in 2002. Mr. LePore is currently Chairman of the Board of Lannett Co. Inc. He previously served on the boards of Matinas BioPharma, PharMerica and Innoviva, and previously served as a trustee of Villanova University. Mr. LePore earned a bachelor's degree from Villanova University and 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*** has served as a member of our Board since March 2019. Ms. Sandoval currently serves as a consultant to the pharmaceutical industry. Previously, from 2016 to 2019, she served as the Chief Commercial Officer and Executive Vice President of Corporate Strategy for Alder Biopharmaceuticals, a clinical stage company focused on developing novel therapeutic antibodies for the treatment of migraine. Prior to this, Ms. Sandoval was Chief Commercial Officer for KYTHERA Biopharmaceuticals until KYTHERA's acquisition by Allergan. Before KYTHERA, Ms. Sandoval 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 23 years at Allergan in sales and marketing leadership roles in the specialties of dermatology, neurology, and aesthetics. Ms. Sandoval began her career in research and development at Johnson & Johnson's Ethicon division. Ms. Sandoval serves on the board of directors for Satsuma Pharmaceuticals and Procept BioRobotics. She holds an MBA from Pepperdine University and a B.S. in biology from the University of California, Irvine. We believe that Ms. Sandoval 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 may be viewed at http://https://vynetherapeutics.com/investors-media/corporate-goverance/.

**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.

Our Nominating and Corporate Governance Committee evaluated our leadership structure in 2021 and subsequently recommended that the Board appoint a lead independent director. Following such recommendation and a discussion by the full Board, our Board appointed Patrick LePore as lead independent director in February 2021. The Board determined that the appointment of a lead independent director is in the best interests of the Company and its 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 | X |
| Steven Basta | — | — | — |
| Anthony Bruno | — | X | X* |
| Patrick LePore | X | — | X |
| Elisabeth Sandoval | 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 and Mr. LePore, 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 Ms. Barbari is an audit committee financial expert as defined 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 and Mr. LePore are independent under the applicable rules of the SEC and Nasdaq.

The Audit Committee operates under a written charter that satisfies the applicable standards of the rules of the SEC and Nasdaq. A copy of the Audit Committee charter is available to security holders on our website at https://vynetherapeutics.com/investors-media/corporate-goverance/.

***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 Mr. Bruno and Mses. Barbari and Sandoval, with Ms. Sandoval serving as the chairperson of the committee. Our Board has determined that

each of Mr. Bruno and Mses. Barbari and Sandoval 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 outside advisors, including outside compensation advisor and legal counsel, considering the independence factors specified in the listing requirements of Nasdaq and concluded their work for the Compensation Committee does not raise any conflicts of interest.

The Compensation Committee operates under a written charter that satisfies the applicable standards of the rules of the SEC and Nasdaq. A copy of the Compensation Committee charter is available to security holders on our website at https://vynetherapeutics.com/investors-media/corporate-goverance/.

***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 Messrs. Bruno and LePore and Ms. Barbari, with Mr. Bruno serving as the chairperson of the committee. Our Board has determined that each of Messrs. Bruno and LePore and Ms. Barbari 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 that satisfies the applicable standards of the SEC and Nasdaq. A copy of the Nominating and Corporate Governance Committee charter is available to security holders on our website at https://vynetherapeutics.com/investors-media/corporate-goverance/.

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 but not limited to the following:

- 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 the Company's 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 our website at https://vynetherapeutics.com/investors-media/corporate-goverance/. 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.

**Prohibition on Margin Accounts and Hedging and Similar Transactions**

Our employees and directors are subject to an insider trading policy that, among other things, prohibits them 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.

## ITEM 11 — EXECUTIVE COMPENSATION

The following is a discussion of compensation arrangements of our named executive officers ("NEOs"). As an "emerging growth company" as defined in the JOBS Act, we have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

Our NEOs for the year ended December 31, 2022 were:

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

**Summary Compensation Table**

The following table sets forth the compensation information for our NEOs for the years ended December 31, 2022 and 2021.

| Name and Principal Position | Year | Salary ($) | Non-equity Incentive Compensation ($)[1] | Stock Awards ($)[2] | Option Awards ($)[2] | All Other Compensation ($)[3] | Total Compensation ($) |
|---|---|---|---|---|---|---|---|
| **David Domzalski** | 2022 | 637,560 | 325,156 | 190,504 | 128,044 | 12,200 | 1,293,464 |
| *President and Chief Executive Officer* | 2021 | 637,560 | 242,910 | 1,818,861[4] | 2,141,994[4] | 11,600 | 4,852,925 |
| **Mutya Harsch** | 2022 | 422,172 | 143,538 | 45,750 | 30,750 | 12,200 | 654,410 |
| *Chief Legal Officer, General Counsel and Secretary* | 2021 | 405,936 | 142,007 | 345,587[4] | 406,976[4] | 11,600 | 1,312,106 |
| **Iain Stuart** | 2022 | 421,811 | 143,415 | 45,750 | 30,750 | 12,200 | 653,926 |
| *Chief Scientific Officer* | 2021 | 405,576 | 117,620 | 345,587[4] | 406,976[4] | 11,600 | 1,287,359 |

(1) The amounts reported in this column reflect cash bonuses awarded pursuant to the achievement of our 2022 and 2021 corporate objectives.

(2) Represents the grant date fair value of the restricted stock units and stock options granted by the Company to our named executive officers during 2022 and 2021as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value are set forth in Note 12 to the financial statements included in this report.

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

(4) For stock and option awards granted in 2021, see "— Retention Compensation" for additional discussion regarding retention awards issued in September 2021.

**Non-Equity Incentive Plan Compensation**

Mr. Domzalski's eligibility to receive his target bonus is based 100% on the achievement of corporate performance objectives. Seventy-five percent of Ms. Harsch's and Dr. Stuart's target bonus is based on the achievement of corporate performance objectives and the remaining 25% is based on the achievement of individual performance objectives. For the 2022 bonuses, these corporate performance objectives included: (i) the advancement of our biotech strategy and the development of our pipeline; (ii) the achievement of certain research and development objectives, including receiving successful results in the Phase 2a trial for FMX114, and the advancement of our BET inhibitor programs; (iii) the execution of certain business development initiatives; (iv) and the achievement of certain financial objectives (the "2022 Corporate Assessment"). Based on the 2022 Corporate Assessment, Mr. Domzalski, Ms. Harsch and Dr. Stuart were awarded the bonuses reflected in the table above, which represents 85% of each individual's 2022 target bonus.

**Outstanding Equity Awards at Fiscal Year End**

The following table sets forth all outstanding equity awards held by each of the named executive officers as of December 31, 2022. The number of shares and, where applicable, exercise price per share, in the table and narrative that follow reflect the reverse stock split the became effective on February 10, 2023.

| Name | Vesting Commencement Date[1] | Option Awards | | | | Share Awards | |
|---|---|---|---|---|---|---|---|
| | | Number of Securities Underlying Unexercised Options Exercisable | Number of Securities Underlying Unexercised Options Unexercisable | Option Exercise Price ($) | Option Expiration Date | Number of Shares or Units of Shares That Have Not Vested (#) | Market Value of Shares or Units of Shares That Have Not Vested[2] ($) |
| David Domzalski | 6/9/2014 | 468 | — | 319.68 | 6/9/2024 | — | — |
| | 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 | — | 203.40 | 5/8/2028 | — | — |
| | 1/1/2019 | 4,009 | 267 | 151.20 | 1/1/2029 | 114 | 308 |
| | 2/24/2020 | 4,144 | 1,880 | 161.28 | 2/24/2030 | 805 | 2,174 |
| | 5/6/2020 | 5,904 | 3,539 | 140.40 | 5/6/2030 | 3,540 | 9,558 |
| | 2/22/2021 | 8,721 | 11,208 | 149.94 | 2/22/2031 | 4,803 | 12,968 |
| | 9/2/2021[3] | 11,123 | 6,672 | 30.24 | 9/2/2031 | 17,795 | 48,047 |
| | 3/17/2022 | — | 17,349 | 10.98 | 3/17/2032 | 17,350 | 46,845 |
| Mutya Harsch | 2/27/2018 | 1,250 | — | 254.16 | 2/27/2028 | — | — |
| | 1/1/2019 | 1,649 | 109 | 151.20 | 1/1/2029 | 46 | 124 |
| | 2/24/2020 | 1,659 | 750 | 161.28 | 2/24/2030 | 320 | 864 |
| | 5/6/2020 | 1,303 | 779 | 140.40 | 5/6/2030 | 780 | 2,106 |
| | 2/22/2021 | 1,658 | 2,127 | 149.94 | 2/22/2031 | 910 | 2,457 |
| | 9/2/2021[3] | 2,114 | 1,266 | 30.24 | 9/2/2031 | 3,381 | 9,129 |
| | 3/17/2022 | — | 4,165 | 10.98 | 3/17/2032 | 4,166 | 11,248 |
| 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 | — | — |
| | 1/01/2019 | 1,782 | 118 | 151.20 | 1/1/2029 | 50 | 135 |
| | 2/24/2020 | 1,659 | 750 | 161.28 | 2/24/2030 | 320 | 864 |
| | 5/06/2020 | 979 | 582 | 140.40 | 5/6/2030 | 583 | 1,574 |
| | 2/22/2021 | 1,658 | 2,127 | 149.94 | 2/22/2031 | 910 | 2,457 |
| | 9/2/2021[3] | 2,114 | 1,266 | 30.24 | 9/2/2031 | 3,381 | 9,129 |
| | 3/17/2022 | — | 4,166 | 10.98 | 3/17/2032 | 4,166 | 11,248 |

(1) Except as set forth in footnote 3 below, 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% every quarter thereafter.

(2) The market value is based on the closing price of our common stock on December 31, 2022.

(3) Awards granted pursuant to the Company's retention initiatives in September 2021. See "— Retention Compensation" for additional details, including vesting terms.

**Retention Compensation**

***September 2021 Retention Awards***

In August 2021, the Company announced that it would be divesting its commercial business and transitioning to a biotech strategy focused on drug development. In connection with such decision, on September 2, 2021, the Compensation Committee approved the grant of an aggregate of 66,939 shares subject to restricted stock unit and stock option awards to all continuing employees of the Company, including members of management. The awards were issued in accordance with the terms and conditions of the Company's 2019 Equity Incentive Plan and the 2018 Omnibus Incentive Plan and the underlying award agreements. The Compensation Committee determined such grants were appropriate to address the need to adequately retain the Company's employees through this period of strategic change and incentivize employees to effectively execute the Company's new strategic operating plan and closely align the interests of employees with the Company's stockholders over the long term.

Mr. Domzalski was awarded 17,795 restricted stock unit awards and employee stock options to purchase 17,795 shares. Dr. Stuart and Ms. Harsch were each awarded 3,381 restricted stock unit awards and employee stock options to purchase 3,381 shares. All of the shares subject to restricted stock unit awards will vest on September 30, 2023, and 50% of the shares subject to stock option awards vested on September 30, 2022, with the remaining 50% of the shares vesting thereafter in equal, quarterly installments through September 30, 2023, in each case, subject to the recipient's continued service to the Company through the vesting date. The exercise price for each stock option granted is $30.24 per share, which represents the closing price for the Company's common stock on the date of grant.

***2023 Retention Payments***

On March 9, 2023, the Compensation Committee approved cash retention payments for the ten employees remaining at the Company as of the date of this report. In making its decision, the Compensation Committee considered (i) the limited number of employees remaining at the company and the increase in each employee's responsibilities; (ii) the impact of the loss of any employee, especially members of management, on our ability to execute corporate objectives for 2023; and (iii) the limited number of shares available under our existing equity incentive plans following our 1-for-18 reverse stock split. After considering the foregoing, the Compensation Committee approved a cash retention plan with the goal of encouraging the retention of employees through milestone events in 2023.

Each of our employees, including each of our NEOs, is eligible to receive 100% of their target annual bonus (the "Retention Payment") over a period of time to maintain the continuity of business operations. Per the approved plan, one-third of the Retention Payment will be paid only upon the achievement of each of the following milestones, subject to the individual's remaining in our continuous service through each payment date: (i) the receipt of positive results from our Phase 1b clinical trial for VYN201; and (ii) the achievement of certain financing objectives. The remaining one-third of the Retention Payment will be paid if the employee has remained in our continuous service through December 31, 2023. Notwithstanding the foregoing, any then-unpaid portion of the Retention Payment will be paid if an employee experiences a termination of employment in connection with a change of control.

**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. Under his Offer Letter, Mr. Domzalski's annualized base salary for 2020 was $616,000, which was

increased to $637,560 in February 2021 by the Compensation Committee. Mr. Domzalski's salary remained unchanged for 2022 and will remain unchanged in 2023. 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 the Company 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 the Company without Cause or he resigns for Good Reason, in each case, within 12 months following a Change in Control (as defined in the 2019 Equity Incentive 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 hereunder; (2) the executive's indictment, conviction or entering of a plea of *nolo contendere* for a crime constituting a felony; (3) the executive's gross negligence or willful misconduct in connection with his employment; (4) the executive's willful and continued failure to substantially perform his duties; (5) the executive's 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 the executive and the Company or any of its subsidiaries and affiliates or any policy of the Company or any of its subsidiaries and affiliates by the executive.

"Good Reason" means (i) a material diminution in the executive's 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 the executive's position, responsibilities, duties or authorities from those in effect as of the effective date; (iii) any change in reporting structure such that the executive is required to report to someone other than the Board; (iv) any material breach by the Company of its obligations under this agreement; or (v) a change in the executive's primary work location that increases the executive's commute by more than 50 miles, in each case subject to certain notice and cure periods.

The Company must provide Mr. Domzalski with 30 days' notice prior to a termination without Cause, and he must provide the Company 30 days' notice prior to any resignation.

***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 base salary for 2022 was $422,172 and will be unchanged for 2023. Ms. Harsch is also eligible to receive an annual target bonus of 40% of her annual base salary. 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 performance targets and milestone criteria, as determined by the Chief Executive Officer, in accordance with our current general bonus plan.

The Offer Letter provides that, in the event of a termination of her employment without Cause (as defined in the 2019 Equity Incentive 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 (9) months following the date of termination, provided that the Company's 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 the Company 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 Equity Incentive Plan), she will be entitled to receive a change of control payment equal to (i) one times (1.0x) 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 twelve (12) months following the date of termination, provided that the Company's 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 base salary; (ii) a material reduction in target annual bonus opportunity; (iii) a relocation of principal place of employment by more than twenty-five (25) miles provided that such relocation increases the daily commute; or (iv) an adverse change in position, including title, reporting relationship(s), authority, duties or responsibilities; all of the above without consent., in each case subject to certain notice and cure periods.

The Company must provide Ms. Harsch with 30 days' notice prior to a termination without Cause, and she must provide the Company 30 days' notice prior to any resignation.

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

***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 base salary for 2022 was $421,811 and will be unchanged for 2023. Dr. Stuart is also eligible to receive an annual target bonus of 40% of his annual base salary. His eligibility for such annual target bonus, and the amount of such annual target bonus, is subject to his achievement of performance targets and milestone criteria, as determined by the Chief Executive Officer, in accordance with our current general bonus plan.

In the event of a termination of his employment without Cause (as defined in the 2019 Equity Incentive 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 (9) months following the date of termination, provided that the Company's 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 the Company 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 (1.0x) 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 twelve (12) months following the date of termination, provided that the Company's 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 base salary; (ii) a material reduction in target annual bonus opportunity; (iii) a relocation of principal place of

employment by more than twenty-five (25) miles provided that such relocation increases the daily commute; or (iv) an adverse change in position, including title, reporting relationship(s), authority, duties or responsibilities; all of the above without consent, in each case subject to certain notice and cure periods.

The Company must provide Dr. Stuart with 30 days' notice prior to a termination without Cause, and he must provide the Company 30 days' notice prior to any resignation.

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

***Terms and Conditions of 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.

**Director Compensation**

Set forth below is a summary of the compensation paid to the non-executive members of the Board during 2022. .

*Initial Equity Grants.* Each non-employee director who joins the Board will receive, upon appointment, options to purchase 2,278 shares of our common stock, representing two times (2x) the annual grant described below. The options will vest and become exercisable as to 1/3rd of the shares on each anniversary of the date of grant, subject to the director's continued service through each applicable vesting date.

*Annual Retainers.* Each of our non-employee directors receives an annual cash retainer of $40,000, payable quarterly. Each non-executive director who has served as a director on our Board for at least six months will be granted options to purchase 1,138 shares of our common stock on the date of our annual meeting of stockholders. The options vest over a 12 month period in equal, monthly installments. In addition to the annual cash retainer set forth above, 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:

| 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) | Member | Chair |
|---|---|---|
| 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 a non-employee chair or $25,000 for a lead independent director.

The exercise price per share of each option granted under this policy 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. Cash retainers will be paid on a quarterly basis in arrears, pro-rated based on the days served in the applicable fiscal quarter. In addition, none of our non-employee directors shall in any event be permitted to receive cash and equity-based compensation (calculated based on grant date fair value) exceeding, in the aggregate, $500,000 in any calendar year.

We also reimburse all of our non-employee directors for all reasonable and customary business expenses in accordance with company policy.

***Director Compensation Table***

The following table sets forth information for the fiscal year ended December 31, 2022 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 | 72,500 | 4,100 | 76,600 |
| Steven Basta | 40,000 | 4,100 | 44,100 |
| Anthony Bruno | 57,500 | 4,100 | 61,600 |
| Patrick LePore | 80,000 | 4,100 | 84,100 |
| Elisabeth Sandoval | 65,000 | 4,100 | 69,100 |

(1) Represent the grant date fair value of the stock options granted by the Company to our directors during 2022 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value are set forth in Note 12 to the financial statements included in this report.

(2) Each of our non-employee directors was granted an option to purchase 1,138 shares of our common stock on August 10, 2022 at an exercise price of $5.62.

As of December 31, 2022, our non-employee directors held the following equity awards:

| Name | Shares Underlying Outstanding Options |
|---|---|
| Sharon Barbari | 3,409 |
| Steven Basta | 14,546 |
| Anthony Bruno | 3,215 |
| Patrick LePore | 2,903 |
| Elisabeth Sandoval | 3,840 |

## ITEM 12 — SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The following table sets forth information relating to the beneficial ownership of our common stock as of February 15, 2023, 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 15, 2023 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 3,251,872 shares of our common stock outstanding as of February 15, 2023. Shares of our common stock that a person has the right to acquire within 60 days after February 15, 2023 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:** | | |
| — | — | —% |
| **Named Executive Officers and Directors:** | | |
| David Domzalski[(1)] | 83,017 | 2.5% |
| Mutya Harsch[(2)] | 16,228 | * |
| Iain Stuart[(3)] | 16,507 | * |
| Steven Basta[(4)] | 21,357 | * |
| Sharon Barbari[(5)] | 4,070 | * |
| Anthony Bruno[(6)] | 4,710 | * |
| Patrick LePore[(7)] | 5,787 | * |
| Elisabeth Sandoval[(8)] | 3,459 | * |
| All current directors and executive officers as a group (9 persons)[(9)] | 163,178 | 4.8% |

* Indicates beneficial ownership of less than 1% of the total outstanding common stock.

(1) Includes 14,713 shares of common stock and 68,304 shares of common stock underlying options and restricted stock units that have vested or will vest within 60 days of February 15, 2023.

(2) Includes 3,118 shares of common stock and 13,110 shares of common stock underlying options and restricted stock units that have vested or will vest within 60 days of February 15, 2023.

(3) Includes 2,816 shares of common stock and 13,691 shares of common stock underlying options and restricted stock units that have vested or will vest within 60 days of February 15, 2023.

(4) 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) 13,907 shares of common stock underlying options that have vested or will vest within 60 days of February 15, 2023. 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.

(5) Includes 1,041 shares of common stock and 3,029 shares of common stock underlying options that have vested or will vest within 60 days of February 15, 2023.

(6) Includes 1,875 shares of common stock and 2,835 shares of common stock underlying options that have vested or will vest within 60 days of February 15, 2023.

(7) Includes 3,472 shares of common stock and 2,315 shares of common stock underlying options that have vested or will vest within 60 days of February 15, 2023.

(8) Includes 3,459 shares of common stock underlying options that have vested or will vest within 60 days of February 15, 2023.

(9) Includes 127,110 shares of common stock underlying options or restricted stock units that have vested or will vest within 60 days of February 15, 2023.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table contains information about our equity compensation plans as of December 31, 2022.

**Equity Compensation Plan Information**

| 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 and weighted-average grant date price of RSUs | Number of securities remaining available for future issuance under equity compensation plans[3] |
|---|---|---|---|
| Equity compensation plans approved by security holders[1][2] | 340,912 | $110.46 | 188,611 |
| Equity compensation plans not approved by security holders | — | $ — | — |
| Total | 340,912 | $110.46 | 188,611 |

(1) Includes the 2018 Omnibus Incentive Plan, the 2019 Equity Incentive Plan and the 2019 Employee Share Purchase Plan (the "2019 ESPP").

(2) The 2018 Omnibus Incentive Plan contains an "evergreen" provision pursuant to which the number of shares of common stock reserved for issuance or transfer pursuant to awards under the plan shall be increased on January 1st of each year by a number equal to the least of (x) 41,666 shares, (y) four percent of the number of shares outstanding as of the last day of the immediately preceding calendar year, or (z) a lesser number of shares determined by the plan administrator.

(3) Includes 8,197 shares under the 2018 Omnibus Incentive Plan, 54,433 shares under the 2019 Equity Incentive Plan and 124,012 shares available under the 2019 ESPP. As of January 1, 2023, 41,666 shares have been added to the 2018 Omnibus Inventive Plan pursuant to the terms thereof.

## 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 during our last fiscal year and the year preceding our last fiscal year 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 capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest.

*Credit Agreement*

The Company was a party to the Amended and Restated Credit Agreement and Guaranty (the "Credit Agreement"), dated as of March 9, 2020, by and among the Company and its subsidiaries, the lenders party thereto and Perceptive Credit Holdings II, LP ("Perceptive"), as administrative agent for the lenders. As of August 11, 2021, the date of the prepayment of the total amount outstanding under the Credit Agreement, affiliates of Perceptive were holders of more than 5% of the Company's outstanding common stock. In connection with the prepayment of the Company's indebtedness, Perceptive received $18.3 million, representing their portion of the principal amount, interest and prepayment premium. Perceptive received an additional $1.1 million in interest payments from January 1, 2021 through July 2021.

*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 Messrs. Basta and Domzalski, are an "independent director" as defined under the applicable rules and regulations of the SEC, and the listing requirements and rules of Nasdaq. In addition, the Board determined that Mr. Bright, who served as a director until his death on January 11, 2022, was independent.

## ITEM 14 — PRINCIPAL ACCOUNTANT FEES AND SERVICES

PricewaterhouseCoopers LLP ("PwC") served as our principal independent registered public accounting firm for the year ended December 31, 2021. Baker Tilly US, LLP was appointed as our independent registered public accounting firm for the year ended December 31, 2022 in April 2022. The following table provides information regarding fees paid by us to PwC and Baker Tilly for the years ended December 31, 2022 and 2021:

| | Fiscal year ended December 31, | |
|---|---|---|
| | 2022 | 2021 |
| | (in thousands of U.S. dollars) | |
| Audit fees[1] | $409 | $1,050 |
| All other fees | — | 4 |
| Total Fees | $409 | $1,054 |

(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 and comfort letters.

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company 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 the Company during year.

## 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, 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 Designation of Preferences, Rights, and Limitations of Series A Convertible Preferred Stock. | 10-Q | 001-38356 | 3.1(b) | November 14, 2022 | |
| 3.1(c) | Certificate of Elimination of Series A Convertible Preferred Stock. | 8-K | 001-38356 | 3.1 | January 17, 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 | | | | | X |
| 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 | |
| 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†* | Evaluation and Option Agreement, dated as of April 30, 2021, by and between In4Derm Limited and VYNE Therapeutics Inc. | 10-Q | 001-38356 | 10.2 | November, 10, 2021 | |

| Exhibit Number | Description Of Document | Incorporation by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date | |
| 10.2(a)* | Letter Agreement, dated as of June 15, 2022, by and between Tay Therapeutics and VYNE Therapeutics Inc. | 10-Q | 001-38356 | 10.1 | August 12, 2022 | |
| 10.3 | Controlled Equity Offering Sales Agreement[SM], dated August 12, 2021, by and between VYNE Therapeutics Inc. and Cantor Fitzgerald & Co. | 8-K | 001-38356 | 1.1 | August 12, 2021 | |
| 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 | |

| Exhibit Number | Description Of Document | Incorporation by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date | |
| 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 | |
| 10.14 | Purchase Agreement, dated as of March 15, 2022, by and between VYNE Therapeutics Inc. and Lincoln Park Capital Fund, LLC. | 8-K | 001-38356 | 10.1 | March 15, 2022 | |
| 10.15 | Registration Rights Agreement, dated as of March 15, 2022, by and between VYNE Therapeutics Inc. and Lincoln Park Capital Funds, LLC. | 8-K | 001-38356 | 10.2 | March 15, 2022 | |
| 16.1 | Letter from PricewaterhouseCoopers LLP, dated April 6, 2022. | 8-K | 001-38356 | 16.1 | April 7, 2022 | |
| 21.1 | List of Subsidiaries of VYNE Therapeutics Inc. | | | | | X |
| 23.1 | Consent of independent registered public accounting firm. | | | | | X |
| 23.2 | Consent of former independent registered public accounting firm. | | | | | 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 |
| 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 |
| 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 |

| Exhibit Number | Description Of Document | Incorporation by Reference | | | | Filed Herewith |
|---|---|---|---|---|---|---|
| | | Form | SEC File No. | Exhibit | Filing Date | |
| 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) | | | | | |

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* 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.

# 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 14, 2023

**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 and Tyler Zeronda, 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<br>David Domzalski | Director and Chief Executive Officer (*Principal Executive Officer*) | March 14, 2023 |
| /s/ Tyler Zeronda<br>Tyler Zeronda | Chief Financial Officer (*Principal Financial Officer* and *Principal Accounting Officer*) | March 14, 2023 |
| /s/ Sharon Barbari<br>Sharon Barbari | Director | March 14, 2023 |
| /s/ Steven Basta<br>Steven Basta | Director | March 14, 2023 |
| /s/ Anthony Bruno<br>Anthony Bruno | Director | March 14, 2023 |
| /s/ Patrick LePore<br>Patrick LePore | Director | March 14, 2023 |
| /s/ Elisabeth Sandoval<br>Elisabeth Sandoval | Director | March 14, 2023 |