EXHIBIT 1048

Anagen LLC v. Veradermics, Inc.
Post-Grant Review of U.S. Patent No. 12,491,184

Veradermics, Inc. · Prospectus (Form 424B4)

Filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(4)
Registration Nos. 333-292657 and 333-293180

Source: SEC EDGAR, Accession No. 0001628280-26-005505
https://www.sec.gov/Archives/edgar/data/1827635/000162828026005505/veradermicsinc424b4.htm
Retrieved and rendered to PDF: August 19, 2026
Complete document as publicly filed (337 rendered pages follow).

Filed pursuant to Rule 424(b)(4)
Registration Nos. 333-292657 and 333-293180

PROSPECTUS

15,077,647 Shares



Common Stock

We are offering 15,077,647 shares of our common stock. This is our initial public offering, and no public market currently exists for our common stock. The initial public offering price is $17.00 per share of our common stock. Our common stock has been approved for listing on the New York Stock Exchange under the symbol "MANE."

We are an "emerging growth company" and a "smaller reporting company" as defined under federal securities laws and, as such, have elected to comply with certain reduced reporting requirements in this prospectus and may elect to do so in future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 14 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Initial Public Offering Price	$ 17.00	$ 256,319,999
Underwriting Discounts and Commissions(1)	1.19	17,942,400
Proceeds, Before Expenses, to Veradermics, Incorporated	15.81	238,377,599

(1) See the section titled "Underwriting" for additional disclosure regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about February 5, 2026.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 2,261,647 shares of common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $20,633,760, and the total proceeds to us, before expenses, will be $274,134,238.

Eli Lilly and Company, or Eli Lilly, has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount up to 4.9% of the number of shares of common stock issued and outstanding after this offering. The shares of common stock to be purchased by Eli Lilly will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, Eli Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Eli Lilly. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by Eli Lilly as it will from any other shares of common stock sold to the public in this offering. The number of shares of common stock available for sale to the public will be reduced to the extent that Eli Lilly purchases shares of common stock in the offering.

Wellington Management, or the cornerstone investor, also has indicated an interest in purchasing up to $30.0 million in shares of common stock in this offering at the initial public offering price. The shares of common stock to be purchased by the cornerstone investor will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, the cornerstone investor may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to the cornerstone investor. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by the cornerstone investor as they will from any other shares of common stock sold to the public in this offering. The number of shares of common stock available for sale to the public will be reduced to the extent that the cornerstone investor purchases shares of common stock in the offering.

Jefferies **Leerink Partners** **Citigroup** **Cantor**

Prospectus dated February 3, 2026.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

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TRADEMARKS

This prospectus contains references to our trademarks and those trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research and studies conducted by third parties. We believe that the information from these third-party publications, research and studies included in this prospectus is reliable. However, we have not separately verified this data. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable; however, such research has not been verified by any third party. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and "Special Note Regarding Forward-Looking Statements." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

PROSPECTUS SUMMARY

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in the prospectus, before making any investment decision. Except where the context otherwise requires or where otherwise indicated, the terms "Veradermics," "we," "us," "our," "the Company," and "our business" refer to Veradermics, Incorporated and its consolidated subsidiaries.

Overview

We are a dermatologist-founded, late clinical-stage biopharmaceutical company focused on developing innovative therapeutics to address pervasive treatment challenges in highly prevalent aesthetic and dermatological conditions. Our initial focus is developing better treatments for pattern hair loss, or PHL, a condition affecting approximately 50 million men and 30 million women in the United States. Current PHL treatment options are limited and therefore are consistently plagued with high rates of treatment failure, patient dissatisfaction and treatment discontinuation. Patients and healthcare providers routinely identify the following shortcomings with currently available treatment options:

- Slow onset of hair growth
- Inconsistent results
- Insufficient density of hair growth for patient satisfaction
- Tolerability issues related to hormonal, mood and cardiac side effects
- Inconvenient administration
- Limited U.S. Food and Drug Administration, or FDA, approved treatment options, and no FDA-approved oral options for women

We are developing VDPHL01 as an oral, non-hormonal treatment for men and women with PHL to reduce the barriers to wide adoption of chronic hair loss therapy and potentially transform PHL treatment. We believe that a marketing application could initially seek approval in male patients, followed by a supplemental new drug application, or sNDA, for female patients, or could alternatively pursue approval in both male and female patients simultaneously depending on the timing of the completion of our clinical trials.

VDPHL01 is an oral, extended-release, or ER, formulation of minoxidil, a proven hair growth agent, designed to maximize minoxidil's impact on hair restoration while minimizing the risk of cardiac activity. Though immediate-release, or IR, oral minoxidil was originally designed to treat resistant hypertension, it has been used off label as a treatment for PHL after hair growth was observed as a side effect. However, IR oral minoxidil's release profile was not designed for hair growth as its short duration of circulation allows less time for follicular saturation and must be used at lower doses to reduce the likelihood of reaching off target cardiac stimulative levels. VDPHL01 builds on minoxidil's validated hair growth biology via a novel and proprietary ER formulation designed to maximize the total plasma concentrations of minoxidil known to grow hair without inducing changes in cardiac activity. We believe that our efforts mark the first attempt to bring an ER formulation of minoxidil to patients with these optimized pharmacokinetic, or PK, and pharmacodynamic, or PD, qualities that raise the ceiling of hair growth.

We are currently dosing patients with VDPHL01 in our registration-directed clinical program consisting of three pivotal, multi-center, randomized, double-blind, placebo-controlled clinical trials: two in male patients and one in female patients with PHL. These trials are designed to support our planned submissions to the FDA for regulatory approval across both male and female patient populations through a 505(b)(2) New Drug Application, or NDA. We have fully enrolled the first of these registration-directed clinical trials, a Phase 2/3 trial evaluating

VDPHL01 in 519 male patients with mild-to-moderate PHL. This first trial assesses two dose regimens of VDPHL01 over 52 weeks of treatment. The co-primary endpoints are change in non-vellus hair count per square

centimeter and patient self-assessment of hair coverage benefit after 24 weeks from treatment initiation. We anticipate topline data from this clinical trial in the first half of 2026.

We have also initiated our confirmatory registration-directed Phase 3 trial targeting the enrollment of 498 male patients with mild-to-moderate PHL and our registrational-directed Phase 2/3 trial targeting the enrollment of 552 female patients with mild-to-moderate PHL. We expect to report data from this male Phase 3 trial in the second half of 2026. Enrollment in the female Phase 2/3 trial is ongoing and our projected time to topline data will be determined as the trial progresses. The clinical trials designated as Phase 2/3 are designed and conducted as registration-directed Phase 3 trials to support the planned marketing application, or NDA, for VDPHL01 for the treatment of PHL. The Phase 2/3 trials include a parallel Phase 2 component intended to further assess proprietary patient-reported outcome, or PRO, measures used as endpoints in all three registration-directed trials.

In a Phase 1 clinical trial, which we refer to as Study QSC300720, we studied VDPHL01 prototypes in doses up to 10 mg against a single reference dose of commercially available 2.5 mg IR oral minoxidil. When comparing the results of VDPHL01 8.5 mg with 2.5 mg IR oral minoxidil in male patients who were administered both dosage forms in this study, we found that VDPHL01 8.5 mg:

- delivered nearly twice the total amount of minoxidil in plasma over 12 hours than the total amount delivered by the 2.5 mg IR oral minoxidil tablet;
- sustained plasma concentrations above minoxidil's hair growth threshold two times longer than a 2.5 mg IR oral minoxidil tablet;
- maintained peak concentrations below the threshold at which signs of cardiac activity are typically observed; and
- was generally well tolerated with no serious adverse events, or SAEs, observed.

As this study was exploratory, no formal sample size calculation was made related to statistical power. The data presented above are reflective of the study's per-protocol primary objective, namely, to evaluate the PK profile and determine the relative bioavailability of VDPHL01 following single oral dosing of VDPHL01 versus the reference IR oral minoxidil formulation in healthy subjects.

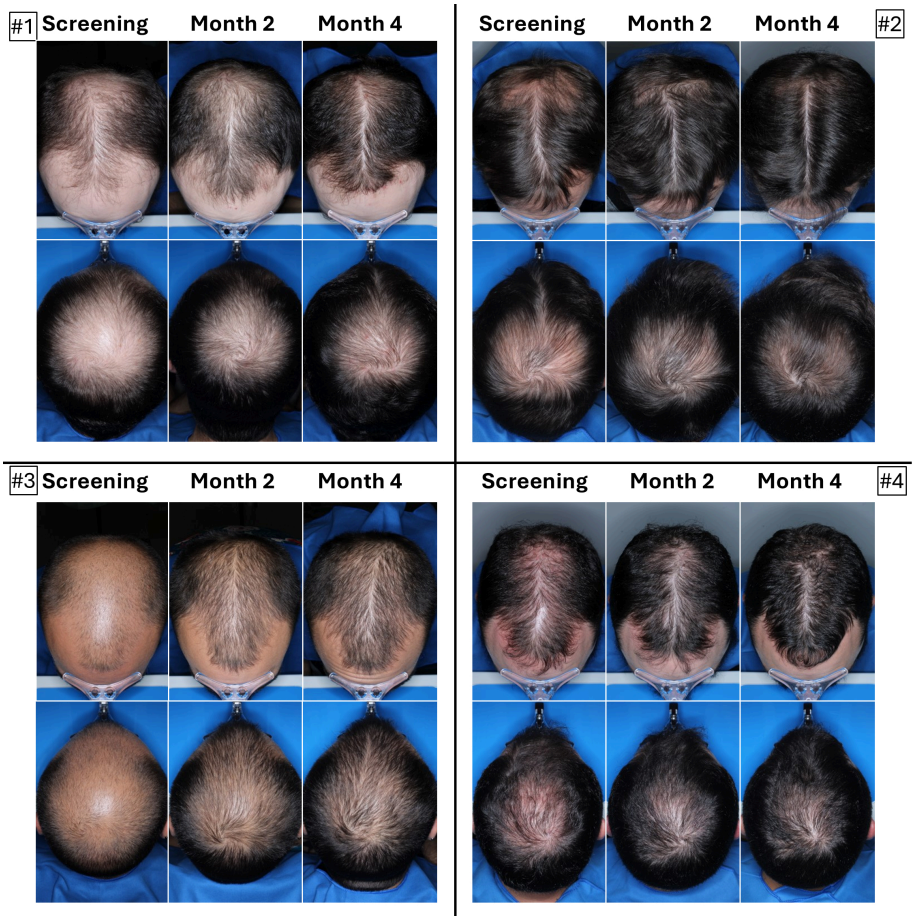
We are currently conducting a Phase 2 clinical trial evaluating VDPHL01 in male patients and female patients with mild-to-moderate PHL. As this trial is exploratory, no formal sample size calculation was made related to statistical power. Therefore, all trial endpoints, including objective hair count measures and subjective patient and investigator assessments, are exploratory and are planned to be reported as descriptive statistics. In October 2025, we announced preliminary data from the male cohort for those who had completed four months of treatment in this trial (n=21; the female cohort, currently with 22 subjects dosing, initiated enrollment in this trial later than males, and similar data is not yet available).

The preliminary data show that VDPHL01 drove favorable outcomes, which we believe underscores its potential to deliver a convenient, oral treatment that provides visible hair regrowth to the majority of users as early as two months, while maintaining a favorable tolerability profile. We believe that the results of this trial support the emerging product profile for VDPHL01 with the following key attributes:

- **Speed:** Visibly noticeable hair growth as early as two months after treatment in a majority of patients based on PRO, and an Investigator Global Assessment, or an IGA.
- **Consistency:** 90.5% treatment response at four months based on PRO of participants reporting “improved” or “much improved” hair coverage.
- **Intensity:** Average non-vellus (greater than 30 microns) hair count change of 47.3 hairs per cm^2, with double digit absolute non-vellus hair count changes in greater than 90% of patients completing four months of treatment.
- **Safety:** Generally well tolerated, with no treatment-related SAEs, including no cardiac or hormonal-related issues to date.

- **Convenience:** Preference for oral over topical administration supported by third-party research.
- **Marketability:** Potential to be the first oral, non-hormonal FDA-approved therapy for PHL.

The below images are of the four patients, of 20 patients in the cohort as of August 2025, the time at which a blinded image analysis study was conducted. These patients were observed to have the highest average hair growth improvement scores as determined by expert graders using images from our Phase 2 clinical trial in male patients at month four. This blinded, retrospective image assessment study used image files containing before-and-after (in randomized order) scalp photographs from both the vertex and frontal view. These image files were reviewed independently by three U.S. board certified dermatologists who were blinded to treatment group and asked to identify the baseline image before assigning an IGA score for improvement using a 7-point Likert scale, a commonly used tool for assessing change in hair growth ranging from greatly decreased (-3) to greatly increased (+3) with intermediate categories of no change (0), slightly decreased/increased (-1/+1) and moderately decreased/increased (-2/+2). Images for patients from screening, month two and month four are presented in order (highest to lowest) of the average improvement scores at month four. Average IGA improvement scores shown represent average improvement scores as assessed by the blinded expert graders ranging from +2.7 (patient #4) to +3.0 (patient #1). See "—Our Solution for PHL: VDPHL01—Ongoing Studies—Study 207: Our Phase 2 Open Label Proof of Concept Trial" for the full set of images from the study (images are excluded for patients (n=1) with improvement scores less than or equal to the 5th percentile or greater than or equal to the 95th percentile in both image views at month four).



This blinded, retrospective image assessment study used image files containing before-and-after (in randomized order) scalp photographs of each treatment from both the vertex and frontal view. These image files were reviewed independently by three U.S. board certified dermatologists who were blinded to treatment group and asked to identify the baseline image before assigning an IGA score for improvement using a 7-point Likert scale (–3 to +3), a commonly used tool for assessing hair growth, measuring whether scalp hair growth has "slightly," "moderately," or "greatly" increased or decreased or no change has occurred.

Our Phase 2 trial evaluating VDPHL01 in male patients and female patients with PHL is ongoing, and we have initiated three registration-directed trials evaluating VDPHL01, two in male patients with PHL and one in female

patients with PHL. If approved, we believe VDPHL01's commercial potential would be substantial, as we estimate that the current U.S. commercial opportunity for PHL treatments for men and women is valued at

approximately $9 billion annually, despite low patient engagement and high levels of dissatisfaction with current options reported. We believe that VDPHL01 could gain a meaningful share of this existing opportunity while also catalyzing substantial growth by offering a previously unavailable, transformative product profile to patients in an area of high unmet need. Our proprietary research indicates that 93% of patients would like to address their PHL yet only 9% are satisfied with their current treatment. Based on the initial product profile we have established for VDPHL01, we believe it could drive significant adoption in this large, motivated but underserved PHL patient population.

In anticipation of a potential NDA submission for VDPHL01 leveraging data from our registration-directed Phase 3 trials, we are developing a comprehensive multi-channel commercialization plan that will integrate patient identification, physician education, direct-to-consumer, or DTC, advertising, social media and telehealth engagement and customer care. This commercialization strategy will be designed to drive patient awareness of VDPHL01's differentiated profile and demand for hair loss treatment. We believe that the success of analog therapies highlights both the unmet need and motivation among patients and reinforces the potential for VDPHL01 to create demand in a cash-pay market, convert over-the-counter, or OTC, patients to prescribed therapies and activate a population of untreated patients. We plan to focus commercial efforts at launch on establishing a dermatology-focused field force and conducting DTC advertising. We believe these commercial pillars will drive significant VDPHL01 adoption, if approved.

We maintain a broad library of patents and patent applications related to the key innovations of VDPHL01, including its method of utilizing an oral route of administration, ER formulation to stimulate hair growth as well as its optimized PK and PD qualities and profile. The earliest expiring patent term is 2043.

Our Pipeline

Our goal is to develop a focused portfolio of aesthetic dermatology product candidates targeting high-prevalence dermatologic conditions, with potential selective development of medical dermatology product candidates. We are advancing our lead product candidate, VDPHL01, in clinical trials as depicted below.

PROGRAM	STUDY	OVERVIEW	PATIENT POPULATION	STATUS	NEAR-TERM MILESTONES
VDPHL01 (ER Oral Minoxidil for Pattern Hair Loss)	**Study 302**	• Phase 2/3 trial evaluating VDPHL01 in males • Includes a parallel in-trial Phase 2 component to further assess PRO measures used as endpoints in the male registration-directed trials	519 male patients with mild-to-moderate PHL	*Fully Enrolled*	6-month topline Phase 2/3 readout anticipated in H1 2026
	Study 304	• Confirmatory Phase 3 trial in males	498 male patients with mild-to-moderate PHL	*Enrollment Ongoing*	6-month topline Phase 3 readout anticipated in H2 2026
	Study 306	• Phase 2/3 trial evaluating VDPHL01 in females • Includes a parallel in-trial Phase 2 component to further assess PRO measures used as endpoints in the female registration-directed trial	552 female patients with mild-to-moderate PHL	*Enrollment Ongoing*	

Our Team and Investors

Our team comprises a seasoned management team with deep connections in the dermatology physician and patient communities and expertise spanning dermatology, clinical development, regulatory affairs, operations, manufacturing and commercialization. The company is led by dermatologists who are well-regarded within the

community, which we believe provides important credibility among physicians and insight into patient needs. Our corporate management team includes industry veterans with significant experience in both entrepreneurial

biotechnology and global pharmaceutical companies, and collectively, have authored more than 100 peer-reviewed publications. Our team has extensive late-stage clinical trial experience, having been involved in the successful development and approval of more than forty products. We are further supported by a board of directors comprised of thought-leading dermatologists, biotechnology industry leaders and corporate executives with collective decades of experience.

Since inception, we have raised $263.0 million from a broad syndicate of investors, including several leading investment advisers and life sciences funds, such as Longitude Capital, SR One, Surveyor Capital (a Citadel company), Suvretta Capital and Viking Global. Potential investors should not consider investments made by our existing investors when making a decision to purchase shares in this offering since our existing investors may have had different risk tolerances and paid less per share than the price at which the shares are being offered in this offering.

Our Competitive Strengths

We believe the following strengths will enable us to achieve our goal of becoming the leader in hair loss treatment:

- Potentially transformative late-stage lead product candidate, VDPHL01, innovating on validated science to address the millions of men and women suffering from PHL in the United States.
- Clinical data to date supports a potentially differentiated profile for VDPHL01, with topline data from our initial registration-directed trial anticipated to read out in the first half of 2026.
- Dermatology-rooted leadership with deep understanding of needs of PHL patients and physicians.
- Comprehensive commercialization strategy to educate and engage physicians and patients.
- Robust intellectual property portfolio designed to protect the key innovations that drive VDPHL01's therapeutic differentiation.

Our Strategy

Our goal is to develop a leading aesthetics- and dermatology-focused biopharmaceutical company that advances therapies to address significant unmet needs for large, underserved patient populations. In order to achieve this goal, we are currently advancing our lead candidate, VDPHL01, for the treatment of PHL. Our strategy involves the following key elements:

- Efficiently develop VDPHL01 through registration-directed trials to be the leading treatment of PHL for both men and women.
- Build a sales and marketing organization focused on prescribers and dedicated to increasing patient awareness and activation.
- Position for early and wide adoption through the cash-pay model.
- Deliver and commercialize VDPHL01, if approved, as the first FDA-approved oral treatment for female PHL.
- Evaluate strategic collaboration to maximize the value of our product candidates and deliver meaningful benefits to patients.
- Identify additional solutions to pervasive unmet needs in dermatology.

Summary of Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks could materially and adversely impact our business, financial condition and results of operations, which could cause the trading price of our common stock to decline and could result in a loss of all or part of your investment. Additional risks, beyond those summarized below or discussed elsewhere in this prospectus, may apply to our business, activities or operations as currently

conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate. These risks include the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future;
- Even if this offering is successful, we will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development or commercialization efforts;
- We currently anticipate that our success will depend on the approval and successful commercialization of VDPHL01, which is our lead product candidate. If we are unable to obtain regulatory approval for, and successfully commercialize, VDPHL01, or any of our other current or future product candidates, or experience significant delays in doing so, our business will be materially harmed;
- Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future preclinical studies or clinical trial results. We may encounter substantial delays in preclinical and clinical trials, or may not be able to conduct or complete preclinical or clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate;
- If the FDA does not conclude that VDPHL01 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for VDPHL01 under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful;
- Any significant AEs or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any. Additionally, the clinical profile of VDPHL01 in female patients may differ from the clinical profile in male patients, and the outcomes observed to date in male patients may not be reflective or predictive of future outcomes for female patients;
- We operate in highly competitive markets and face competition from large, well-established companies with significant resources as well as other entities, and, as a result, we may not be able to compete effectively;
- We currently have limited marketing, sales or distribution infrastructure. If we are unable to fully develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we may not be successful in commercializing our product candidates;
- Even if we obtain regulatory approval for VDPHL01 or any other product candidates, such products may fail to achieve market acceptance which would adversely affect our efforts to commercialize any such product successfully;
- The commercial opportunity for VDPHL01 and any of our other current or future product candidates we may develop may be smaller than we expect;
- Our strategy of focusing on the cash-pay healthcare market for VDPHL01 may limit our ability to increase sales or achieve profitability;
- If we fail to effectively maintain, promote, and enhance our reputation and VDPHL01 brand recognition in a cost-effective manner, our business and competitive advantage may be harmed;
- We are dependent on the services of our senior management and other key personnel, and if we are not able to retain these individuals or recruit additional management or key personnel, our business will suffer;
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business;
- Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for VDPHL01 and our other current and any future product candidates and other proprietary technologies;

- If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;

- We may not be able to protect our intellectual property rights throughout the world;
- The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. regulatory approval and, as a result, unable to commercialize our product candidates or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy;
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates;
- We currently rely on third parties for the manufacture of drug or biological substances for our preclinical studies and clinical trials and expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. Our reliance on third parties may increase the risk that we will not have sufficient quantities of such drug substance, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts;
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates;
- An active and liquid trading market for our common stock may not develop, and you may not be able to resell your shares of common stock at or above the public offering price, if at all; and
- The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see "Risk Factors."

Our Corporate Information

We were originally incorporated on October 5, 2019, as VeraDermics, Incorporated, a Texas corporation. On September 15, 2021, we converted to a Delaware corporation. Our principal executive offices are located at 470 James St., New Haven, Connecticut 06513, and our telephone number is (228) 372-3376. Our corporate website address is www.veradermics.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including reduced disclosure about our executive compensation arrangements, exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments and exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one Annual Report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to

other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We may continue to be a smaller reporting company until the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

THE OFFERING

Common stock offered by us	15,077,647 shares.
Common stock to be outstanding after this offering	35,077,084 shares (37,338,731 shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares of common stock from us	We have granted the underwriters an option to purchase up to an aggregate of 2,261,647 additional shares of common stock from us at the initial public offering price, less the estimated underwriting discounts and commissions, for a period of 30 days after the date of this prospectus.
Use of proceeds	We estimate that our net proceeds from the sale of our common stock in this offering will be approximately $234.0 million, based on the initial public offering price of $17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, to advance VDPHL01 through NDA approval and initial commercialization in the United States, if approved. These funds will support physician education, brand awareness initiatives, marketing, pre-commercial and commercial launch activities, including building our commercialization infrastructure and manufacture of commercial supply, with any remaining proceeds for business development activities and other general corporate purposes. See "Use of Proceeds."

Indications of interest	Eli Lilly has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount up to 4.9% of the number of shares of common stock issued and outstanding after this offering. The shares of common stock to be purchased by Eli Lilly will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, Eli Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Eli Lilly. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by Eli Lilly as it will from any other shares of common stock sold to the public in this offering. The number of shares of common stock available for sale to the public will be reduced to the extent that Eli Lilly purchases shares of common stock in the offering. The cornerstone investor also has indicated an interest in purchasing up to $30.0 million in shares of common stock in this offering at the initial public offering price. The shares of common stock to be purchased by the cornerstone investor will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, the cornerstone investor may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to the cornerstone investor. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by the cornerstone investor as they will from any other shares of common stock sold to the public in this offering. The number of shares of common stock available for sale to the public will be reduced to the extent that the cornerstone investor purchases shares of common stock in the offering.
Risk factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
New York Stock Exchange symbol	"MANE"

The number of shares of our common stock to be outstanding immediately following the consummation of this offering is based on 19,999,437 shares outstanding as of September 30, 2025, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock and (ii) the automatic conversion of all outstanding shares of Series C Convertible Preferred Stock, or Series C Preferred Stock, issued after September 30, 2025 into an aggregate of 11,789,280 shares of our common stock, in each case immediately prior to the consummation of this offering. These amounts exclude:

- 739,331 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2025, with a weighted average exercise price of $12.19 per share;
- 2,974,637 shares of our common stock issuable upon the exercise of stock options granted after September 30, 2025, with a weighted average exercise price of $12.77 per share;
- 685,080 shares of our common stock reserved for issuance under the VeraDermics, Incorporated 2021 Equity Incentive Plan, as amended, or the 2021 Plan, as of December 31, 2025, which ceased to be

available for issuance at the time the Veradermics, Incorporated 2026 Incentive Plan, or the 2026 Plan, became effective and were added to, and became available for issuance under, the 2026 Plan;

- a number of shares of our common stock equal to 10.8% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 4,518,426 shares) reserved for issuance under the 2026 Plan, which became effective in connection with this offering (which includes up to 1,768,254 shares of common stock underlying stock option awards to be granted to certain of our directors, executive officers and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 316,668 shares of our common stock reserved for issuance under the Verademics, Incorporated 2026 Employee Stock Purchase Plan, or the ESPP, which became effective in connection with this offering.

Except as otherwise noted, all information in this prospectus assumes or gives effect to:

- a 1-for-10.067 reverse stock split of our common stock, which was effected on January 27, 2026;
- (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock and (ii) the automatic conversion of all outstanding shares of Series C Preferred Stock issued after September 30, 2025 into an aggregate of 11,789,280 shares of our common stock, in each case immediately prior to the consummation of this offering;
- no exercise by the underwriters of their option to purchase up to an additional 2,261,647 shares of our common stock from us;
- the filing and effectiveness of our restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the consummation of this offering; and
- no vesting or exercise of the outstanding stock options described above.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this prospectus and our financial statements and the related notes included elsewhere in this prospectus. The statements of operations for the years ended December 31, 2024 and 2023 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations and comprehensive loss data for the nine months ended September 30, 2025 and 2024 and our balance sheet data as of September 30, 2025 have been derived from our unaudited financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of such financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The summary financial date in this section are not intended to replace the financial statements and the related notes thereto included elsewhere in this prospectus and are qualified in their entirety by those financial statements and the related notes.

(in thousands, except share and per share amounts)	Year Ended December 31,		Nine Months ended September 30,	
	2024	2023	2025	2024
Operating Expenses:				
Research and development	$ 23,283	$ 14,971	$ 43,873	$ 18,333
General and administrative	3,495	2,353	5,463	2,474
Total operating expenses	26,778	17,324	49,336	20,807
Loss from operations	(26,778)	(17,324)	(49,336)	(20,807)
Other income (expenses):				
Interest income	481	870	656	272
Other income	394	—	532	—
Interest expense	(585)	(36)	—	(293)
Total other income (expense), net	290	834	1,188	(21)
Loss before income taxes	(26,488)	(16,490)	(48,148)	(20,828)
Income tax benefit	—	—	—	—
Net loss	$ (26,488)	$ (16,490)	$ (48,148)	$ (20,828)
Net loss attributable to common stock	$ (27,303)	$ (16,490)	$ (55,166)	$ (20,828)
Net loss per share of common stock, basic and diluted[1]	$ (37.05)	$ (22.38)	$ (74.21)	$ (28.26)
Weighted average common stock outstanding, basic and diluted[1]	736,933	736,933	743,401	736,933
Pro forma net loss per share of common stock, basic and diluted[2]	$ (1.85)	$ (1.21)	$ (2.42)	$ (1.51)
Pro forma weighted average common stock outstanding, basic and diluted[2]	14,351,418	13,648,780	19,906,853	13,804,188

(1) See Note 7 to our unaudited condensed consolidated financial statements and Note 7 to our audited consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to holders of our common stock and the weighted-average number of shares of common stock used in the computation of the per share amounts.

(2) Pro forma basic and diluted net loss per share of common stock has been prepared to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock and (ii) the automatic conversion of all outstanding shares of Series C Preferred Stock issued after September 30, 2025 into an aggregate of 11,789,280 shares of our common stock, in each case as if such conversion had occurred at the beginning

of the period presented or the issuance dates of the respective preferred stock, if later, and (iii) the filing and effectiveness of our restated certificate of incorporation, which will be effective immediately prior to the consummation of this offering.

	As of December 31,	
(in thousands)	2024	2023
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 53,084	$ 16,296
Working capital	50,817	14,510
Total assets	55,535	17,562
Total liabilities	4,718	3,838
Redeemable convertible preferred stock	99,297	35,966
Accumulated deficit	(49,231)	(22,743)
Total stockholders' deficit	$ (48,480)	$ (22,242)

	As of September 30, 2025		
(in thousands)	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
Consolidated Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 15,139	$ 165,702	$ 399,680
Working capital[3]	13,019	163,582	397,560
Total assets	18,797	169,360	403,338
Total liabilities	5,710	5,710	5,710
Redeemable convertible preferred stock	109,102	—	—
Accumulated deficit	(97,379)	(97,379)	(97,379)
Total stockholders' deficit	(96,015)	163,649	397,627

(1) The pro forma balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock immediately prior to the consummation of this offering, (ii) the issuance and sale of 118,682,683 shares of Series C Preferred Stock, including the net proceeds from such sale, which occurred subsequent to September 30, 2025, and the automatic conversion of all outstanding shares of Series C Preferred Stock into an aggregate of 11,789,280 shares of our common stock immediately prior to the consummation of this offering, and (iii) the filing and effectiveness of our restated certificate of incorporation and amended and restated bylaws, which will be effective immediately prior to the consummation of this offering.

(2) The pro forma as adjusted balance sheet data give further effect to our issuance and sale of shares of our common stock in this offering at the initial public offering price of $17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this prospectus, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our audited financial statements and the related notes. The events discussed below may occur and adversely impact our business, financial condition, results of operations and prospects, which may cause the trading price of our common stock to decline, resulting in you losing all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company with a limited operating history on which to base your investment decision. We were formed in 2019 and our operations to date have been limited to organizing, staffing, and financing our company, conducting research and development activities, conducting clinical trials for our product candidates and establishing our intellectual property portfolio. We have never obtained regulatory approval for, or commercialized, a pharmaceutical product. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. We have financed our operations with $263.0 million in gross proceeds from equity financings to date. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization.

We have incurred, and will continue to incur, significant expenses related to the clinical development of VDPHL01 and our other current and any future product candidates and ongoing operations. Our net losses for the nine months ended September 30, 2025 and 2024 were $48.1 million and $20.8 million, respectively. Our net losses for the years ended December 31, 2024 and 2023 were $26.5 million and $16.5 million, respectively. As of September 30, 2025, we had an accumulated deficit of $97.4 million. Substantially all of our operating losses have resulted from expenses incurred in connection with development of VDPHL01 and our other product candidates and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we advance VDPHL01 in our ongoing Phase 3 trials and, if results are positive, prepare for the commercialization of VDPHL01, if approved.

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

- continue development of VDPHL01 and our other current product candidates, including preclinical development and conducting clinical trials;
- seek marketing regulatory approvals for VDPHL01 and for any of our other current or any future product candidates that successfully complete clinical trials;
- take steps toward supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- increase marketing in connection with the potential commercialization of VDPHL01, if approved;
- advance additional product candidates through preclinical development and clinical trials;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or acquisitions and conduct development activities, including preclinical studies and clinical trials;
- make royalty, milestone or other payments under any current or future license or collaboration agreements;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any future product candidates;

- establish agreements with contract research organizations, or CROs, and contract manufacturing organizations, or CMOs;
- attract, hire and retain additional qualified clinical, scientific, operations and management personnel;
- seek to continue to develop, maintain and defend our intellectual property portfolio, including against third-party interference, infringement and other intellectual property claims, if any;
- add and maintain operational, financial and information management systems;
- attempt to address any competing therapies and market developments;
- experience delays in our preclinical studies, clinical trials or regulatory approval for our current or any future product candidates, including with respect to failed studies, inconclusive results, safety issues or other regulatory challenges; and
- incur additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and the Securities and Exchange Commission, or the SEC, requirements, director and officer insurance premiums and investor relations costs.

We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability. Even if we succeed in commercializing VDPHL01 or one or more of our other product candidates, we will incur substantial expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays and other events that adversely affect our business. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. The size of our future net losses will depend, in part, on the rate that our expenses increase and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Even if this offering is successful, we will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development or commercialization efforts.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. We expect our expenses to substantially increase in connection with our ongoing and future activities, specifically as we advance development of VDPHL01 in our ongoing Phase 3 trials and prepare for potential commercialization of VDPHL01, if approved. In addition, because the outcome of any clinical trial or preclinical study is uncertain, we cannot reliably estimate the actual amount of capital necessary to successfully complete the development and commercialization of our other product candidates, and if we obtain regulatory approval for our other current or any future product candidates we also expect to incur significant commercialization expenses of such products. Furthermore, following the completion of this offering, we expect to incur additional costs associated with operating as a public company including significant legal, accounting, investor relations, and other expenses that we did not incur as a private company.

Subsequent to December 31, 2024, we completed the second funding of our Series B Preferred Stock financing of $8.4 million in the first quarter of 2025, followed by a Series C Preferred Stock financing in the fourth quarter of 2025, from which we received gross proceeds of $151.0 million. As of September 30, 2025, we had $15.1 million in cash, cash equivalents and marketable securities, which did not include the proceeds from the Series C Preferred Stock financing. We expect the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements for more than twelve months from the date of this prospectus. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. We expect to attempt to raise additional cash in advance of exhausting our available capital resources.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we may never generate significant revenue or profits. If we obtain regulatory approval for VDPHL01 or any of our other current or any future product candidates, and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. We also may require additional capital to pursue in-licenses or acquisitions of other product candidates. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, and other expenses that we did not incur as a private company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements, both near and long-term, will depend on, and could increase significantly as a result of, many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including our ongoing clinical trials for VDPHL01 and the development of our other current and any future product candidates;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the timing of and successful patient enrollment in, and the initiation and completion of, clinical trials;
- the outcome, timing and costs of meeting regulatory requirements established by the FDA or any comparable foreign regulatory authority, including any additional clinical trials required by the FDA or any comparable foreign regulatory authority;
- the willingness of the FDA or any comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of VDPHL01 and any other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for VDPHL01 or any other product candidates, including design, manufacturing and regulatory approval;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercialization;
- the cost of filing, prosecuting and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;

- our ability to hire additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, chemistry, manufacturing and controls, quality and commercial personnel;
- our ability to develop and commercialize products that are considered by physicians, patients and payors as medically and/or financially differentiated as compared to competitive products;
- our ability to establish arrangements with third-party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the cost of making royalty, milestone or other payments under any future in-license agreements;
- the extent to which we in-license or acquire additional product candidates or technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- the initiation, progress and timing of our commercialization of VDPHL01, if approved, or any other product candidates;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors, if applicable, and adequate market share and revenue;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the costs of operating as a public company.

We expect that our commercial revenue, if any, will initially be derived from sales of VDPHL01, which we do not expect to be commercially available in the near-term, if ever. Accordingly, we will need to rely on additional financing to achieve our business objectives until such time as we can generate sufficient commercial revenue. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, including as a result of tariffs, fluctuations in inflation rates and concerns of a recession in the United States or other major markets, market-wide liquidity shortages, geopolitical events or otherwise. Weakness and volatility in the capital markets and the economy in general could also increase our costs of borrowing. If we are unable to raise sufficient additional capital, we would be forced to curtail our planned operations and the pursuit of our growth strategy.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, imposing restrictions on our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, that we generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other 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 or other preferences that adversely affect your rights as a holder of our common stock. Any future debt or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other arrangements, we likely would relinquish valuable rights to our potential future revenue streams or product candidates. We also may grant licenses on terms that may not be favorable to us or that reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, or on acceptable terms, we would be required to delay, limit, reduce or terminate our product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, we may not be able to access a portion of our existing cash due to market conditions. If banks and financial institutions with whom we hold accounts enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to the Development of Our Product Candidates

We currently anticipate that our success will substantially depend on the approval and successful commercialization of VDPHL01, which is our lead product candidate. If we are unable to obtain regulatory approval for, and successfully commercialize, VDPHL01, or any of our other current or future product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have never obtained regulatory approval for, or commercialized, a pharmaceutical product. With respect to VDPHL01 in PHL, we may pursue a marketing application to initially seek approval in male patients followed by an sNDA for female patients, or could alternatively pursue approval in both male and female patients simultaneously. The FDA may require us to conduct additional trials to support approval if it does not think our existing data are sufficient to support approval. We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, VDPHL01, for the treatment of PHL in male patients and female patients. Our business substantially depends on the successful development and commercialization of our product candidates, and in particular, VDPHL01, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. We do not expect to generate significant revenue, if any, unless and until we are able to obtain regulatory approval for, and successfully commercialize, VDPHL01, or for any of our other current or future product candidates. Successful commercialization of a product candidate requires achievement of many key milestones, including obtaining regulatory approval. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We are not permitted to market or promote any of our product candidates, including VDPHL01, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Even if VDPHL01 or any of our other current or future product candidates is approved, they may be subject to limitations on the indicated uses for which they may be marketed, distribution restrictions, or to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that VDPHL01 or any other of our current or future product candidates will be successful in clinical trials or receive regulatory approval. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve its primary endpoints in subsequent clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

The future regulatory and commercial success of VDPHL01 and any of our other current or future product candidates is subject to a number of risks, including the following:

- effective Investigational New Drug, or IND, applications from the FDA that allow commencement of our planned or future clinical trials for our product candidates;
- timely and successful completion of preclinical studies and clinical trials;
- successful patient enrollment in clinical trials;
- successful data from our preclinical studies and clinical trials that support an acceptable risk-benefit profile of VDPHL01 and any of our other current or future product candidates in the intended populations and indications;
- satisfaction of applicable regulatory requirements;
- potential unforeseen safety issues or adverse side effects, either in clinical trials or following approval;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- remaining in compliance with post-marketing regulatory requirements;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for VDPHL01 and any of our other current or future product candidates;

- making arrangements or maintaining existing arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of VDPHL01 and any of our other current or future product candidates;
- entry into collaborations for the commercialization of VDPHL01 or to further the development of any of our other current or future product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of any approved products, whether alone or in collaboration with others;
- successfully launching commercial sales of VDPHL01 and any of our other current or future product candidates, if and when approved;
- successfully creating market demand for VDPHL01 and any of our other current or future product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- manufacturing VDPHL01 and any of our other current or future product candidates in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch, if approved, and thereafter;
- acceptance of VDPHL01 and any of our other current or future product candidates, if and when approved, by patients, the medical community and third-party payors;
- products, following approval, maintaining a continued acceptable safety profile;
- effectively competing with other therapies;
- ensuring that we promote and distribute our products consistent with all applicable healthcare laws; and
- enforcing and defending intellectual property rights and claims.

If we are unable to develop, receive regulatory approval for, or successfully commercialize VDPHL01 for the indications we are developing it for, or if we experience delays as a result of any of these risks or otherwise, our business and financial condition will be materially harmed.

In addition, of the large number of products in development in the pharmaceutical industry, only a small percentage result in the submission of an NDA to the FDA, and even fewer are approved for marketing and commercialization. Furthermore, even if we receive regulatory approval to market VDPHL01 for any indication, any such approval may be subject to limitations on the indications or uses or the patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development activities, we may not be able to successfully develop or commercialize VDPHL01 for any indication. If we or any of our current or licensing and collaboration partners are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize VDPHL01 for its initial indication or potential additional indications, we may not be able to generate sufficient revenue to continue our business.

We also are preparing to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition, and we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors that delay, impair or prevent us from achieving our business objectives. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations.

Preclinical and clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future preclinical studies or clinical trial results. We may encounter substantial delays in preclinical and clinical trials, or may not be able to conduct or complete preclinical or clinical trials on the expected timelines, if at all. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Our ongoing, planned or future clinical trials may not ultimately be successful or support further clinical development or regulatory approval of VDPHL01 or any of our other current or future product candidates. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the

safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials even after achieving promising results in earlier stage clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Our preclinical studies and future clinical trials may not be successful.

We may experience delays in initiating or completing preclinical studies or clinical trials, including as a result of delays in obtaining or failure to obtain the FDA's clearance to initiate clinical trials under INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, enroll an adequate number of subjects on time, or be completed on schedule, if at all. We may experience adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or terminate our trials, or delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials, including our ability to commence a clinical trial;
- we may fail or be delayed in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- we may be unable to or delayed in adding a sufficient number of clinical trial sites and obtaining Institutional Review Board, or IRB, or independent ethics committee approval at each clinical trial site;
- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our research efforts for our other product candidates;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of our clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- we may experience difficulties in having subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites may deviate from clinical trial protocol or drop out of a clinical trial;
- we may be unable or delayed in obtaining sufficient product supply of product candidate for use in preclinical studies or clinical trials from third-party suppliers;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- regulators may not consider the endpoints of our clinical trials to provide clinically meaningful results if, for example, we cannot establish that the PRO measures used in our registration-directed trials are fit-for-purpose; and

- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these studies, trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We would also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs, or ethics committees of the institutions in which such clinical trials are being conducted, by the Data Safety Monitoring Board, if any, for such clinical trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our current and future clinical trials who serve as scientific advisors or consultants to us from time to time receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If VDPHL01, or any of our other current or future product candidates, generally prove to be ineffective, unsafe or commercially unviable, our entire pipeline may have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

If the FDA does not conclude that VDPHL01 satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for VDPHL01 under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

While we believe that we will have the necessary supporting data to submit to the FDA a marketing application under the Federal Food, Drug and Cosmetic Act, or the FDCA, Section 505(b)(2) regulatory pathway for VDPHL01 for the treatment of patients with PHL upon completion of our ongoing registration-directed clinical trials of VDPHL01, the FDA may not agree that the Section 505(b)(2) pathway is appropriate and may not approve any such application or any future application for additional indication or future product candidates.

The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if available to us, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our future product candidates by potentially decreasing the amount of preclinical and/or clinical data that we would need to generate in order to obtain FDA approval. This pathway does not, however, expedite the FDA review process timelines.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional preclinical studies and/or clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for VDPHL01 or any of our other current or future product candidates, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates we develop, which could adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot be certain that VDPHL01 or any of our other current or future product candidates we develop will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products.

Any significant AEs or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any. Additionally, the clinical profile of VDPHL01 in female patients may differ from the clinical profile in male patients, and the outcomes observed to date in male patients may not be reflective or predictive of future outcomes for female patients.

Unacceptable, undesirable or clinically unmanageable side effects, caused by any of our product candidates, could cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities.

AEs, SAEs or other side effects in clinical trials often make it difficult to recruit participants to clinical trials and results in participants dropping out of trials. While certain side effects may be reversible following discontinuation of the product candidate with sufficient recovery periods, we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide, or be required, to perform additional studies or to halt or delay further clinical development of our product candidates.

We have observed certain AEs in our clinical trials of VDPHL01, including viral upper respiratory tract infection and headache. The occurrence of AEs, side effects or other safety or tolerability concerns, could limit our opportunity to disrupt the current standard of care, particularly if AEs and SAEs are deemed to be related to VDPHL01 or any of our other current or future product candidates. Such a determination may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market or maintain approval of our product candidates. In addition, unwanted hair growth on non-scalp parts of the body where hair is already naturally growing has been observed as a side effect of VDPHL01, which could deter adoption and continued use of VDPHL01 by those who find such additional hair growth to be undesirable. Additionally, although we are developing VDPHL01 in both male patients and female patients, we have less clinical experience to date with VDPHL01 in female patients and the tolerability profile of VDPHL01 in female patients may differ from the profile in male patients. The clinical profile of VDPHL01 in female patients may differ from the clinical profile in male patients, and the outcomes observed to date in male patients may not be reflective or predictive of future outcomes for female patients.

We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Many potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development and approval. Even if side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance.

Even if we successfully develop a product candidate and it receives marketing approval, the FDA could require additional precautions, including requiring us to adopt a REMS to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. Additionally, the FDA has required the inclusion of a boxed warning on the labeling for FDA-approved IR oral minoxidil for treatment of blood pressure and cardiovascular indications due to serious heart-related adverse effects. Although we have designed VDPHL01 to prevent the peak minoxidil concentrations from exceeding the drug's known cardiac activity threshold, and to date we have not observed any cardiac AEs in our clinical trials of VDPHL01, we do not know at this stage whether FDA is likely to require inclusion of a boxed warning for VDPHL01, if approved. Additionally, concerns about cardiac risks associated with minoxidil may impact the perception of tolerability of VDPHL01.

Although the clinical trial process is designed to identify and assess potential side effects and AEs, clinical development does not always fully characterize the safety and efficacy profile of a new drug, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. AEs or side effects during clinical trials or after approval expose us to several potential negative consequences, including:

- regulatory authorities may limit, suspend or withdraw approvals of such product, or may refuse to approve supplemental applications for such product;
- regulatory authorities may require additional warnings on the label, such as a boxed warning, contraindications or precautions, or otherwise limit the approved use of such product;
- regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product, including requiring a REMS;
- we may be required to recall the product or change the way it is administered in patients;
- we may be required to conduct additional clinical trials;
- we may decide to remove such product from the market;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from obtaining or maintaining regulatory approvals or achieving or maintaining market acceptance of our current and future product candidates or could substantially increase the costs and expenses of commercializing the affected product, which in turn could significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We operate in highly competitive markets and face competition from large, well-established companies with significant resources as well as other entities, and, as a result, we may not be able to compete effectively.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. While we believe our deep scientific knowledge of dermatology paired with our differentiated lead product candidate, VDPHL01, provides a strong competitive advantage, we face competition from many different sources, including pharmaceutical and biotechnology companies, generic drug companies, compounding pharmacies and consumer health companies as well as from academic institutions, governmental agencies and public and private research institutions. If our competitors develop technologies or product candidates more rapidly than we do, or if their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize VDPHL01 or any of our future product candidates may be adversely affected.

Our competitors may have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors' products may be more effective, safer, or more effectively marketed and sold, than any product candidate we may commercialize and may render VDPHL01 or any future product candidates obsolete or non-competitive before we can recover development and commercialization expenses. In addition, our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than VDPHL01 or any future product candidates that we may develop, which could render such product candidates obsolete and noncompetitive. They may also compete in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for, our product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity can be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly or earlier than us, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing our product candidates against competitors.

Further, our current or potential competitors may be acquired by third-parties with greater available resources, which has recently occurred in our industry. As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements and may have the ability to initiate or withstand substantial price competition. In addition, our competitors have established, and may in the future establish, cooperative relationships with vendors of complementary products, technologies or services to increase the availability of their solutions in the marketplace.

If approved, we anticipate that VDPHL01 will compete primarily against existing treatment options for PHL, including oral finasteride and topical minoxidil, off label IR oral minoxidil, low light laser therapy, or LLLT, and fractional laser non-ablative therapy as well as non-FDA approved non-prescription options such as "nutraceutical" supplements and shampoos. In particular, VDPHL01, if approved, will need to compete with an established OTC market and will require potential patients to consult with a doctor and receive a prescription, which may detract potential patients. Further, OTC products may be more competitively priced than VDPHL01, which may impact our ability to attract potential patients. We may also face competition from compounding pharmacies producing oral minoxidil formulations. Although FDA rules would not permit compounding pharmacies to prepare formulations that are essentially copies of VDPHL01 regularly or in inordinate amounts, FDA may not adequately regulate or enforce its requirements with respect to such compounding pharmacies, which could in turn lead to consumer confusion in the marketplace or result in potential VDPHL01 sales being diverted to compounding pharmacies.

There are several product candidates in clinical development which could potentially pose a direct competitive threat to VDPHL01 in the future for the treatment of PHL. To our knowledge, the only other late-stage product candidate that is currently under evaluation in a Phase 3 study in the U.S. for the treatment of PHL is Breezula, a topical androgen receptor antagonist by Cosmo Pharmaceuticals NV. We are also aware of other product candidates in clinical development, including: KX-826, a topical androgen receptor antagonist by Kintor Pharmaceutical Limited, PP405, a topical mitochondrial pyruvate carrier inhibitor by Pelage Pharmaceuticals, Inc., TDM-105795, topical thyromimetic by TechnoDerma Medicines Inc. and ET-02, a topical treatment of undisclosed mechanism by Eirion Therapeutics, Inc. We are also aware of other companies with programs for hair loss, including Hope Medicine Inc, Samson Clinical Pty Ltd, Amplifica Holdings Group Inc., Dermaliq Therapeutics, Inc. and Absci Corporation.

Our ability to compete effectively depends on our ability to distinguish our company and our offerings from our competitors and their products, and includes factors such as:

- efficacy, safety and tolerability of our products;
- timing and scope of regulatory approvals for these products;
- availability and cost of manufacturing;
- patent position;
- accessibility, ease of use and convenience;
- price and affordability;
- reimbursement coverage;
- brand recognition;
- long-term outcomes;
- breadth and efficacy of offerings;
- market penetration;
- marketing and sales capabilities;
- partnerships and alliances;
- relationships with providers, suppliers and partners; and
- regulatory compliance recourses.

If we are unable to successfully compete with existing and potential competitors, our business, financial condition, and results of operations could be adversely affected.

Delays or difficulties in the enrollment and dosing of patients in clinical trials may delay or prevent receipt of necessary regulatory approvals.

The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow-up periods. Participant enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the number and location of clinical sites, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, challenges in obtaining and maintaining participant consents, enrolled participants dropping out, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications being investigated by us.

In addition, clinical trials commonly compete with other clinical trials for product candidates that address the same diseases or conditions, and this competition reduces the number and types of participants available to us, because some participants who might have opted to enroll in our trials instead opt to enroll in a trial conducted by a competitor or elect to use a marketed therapy. We also could encounter delays if doctors face ethical challenges associated with enrolling participants in a clinical trial rather than prescribing an existing treatment with an established safety and efficacy profile.

If we or our collaborators, if any, are unable to enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate, continue or complete clinical trials for our product candidates. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment may result in increased costs, delay completion or adversely impact the outcome of the trial.

Participants, including in any control groups, frequently withdraw from a clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience adverse side effects or other issues. Withdrawal of participants from our clinical trials may compromise the quality of our data.

Difficulties enrolling a sufficient number of patients to conduct our clinical trials as planned may require us to delay, limit or terminate clinical trials for our product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company. Failure to successfully conduct our clinical trials as planned, would have an adverse effect on our business, financial condition, results of operations and prospects.

As an organization, we have only recently initiated registrational-directed clinical trials, and may be unable to complete such trials for any product candidates we may develop, including VDPHL01.

We will need to successfully complete our ongoing and planned clinical trials, including registrational clinical trials, in order to obtain FDA approval to market our product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have initiated Phase 2 and Phase 3 clinical trials, but we have not previously completed such later stage or registrational clinical trials and have not previously submitted an NDA for any product candidate. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to NDA submission and approval of any product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, including trials of VDPHL01 for men or for women could prevent us from or delay us in commercializing our product candidates, including VDPHL01.

Interim, initial, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time are subject to audit and verification procedures and may differ materially from final data as more patient data become available.

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

From time to time, we also may disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as participant enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. For example, in October 2025, we reported preliminary data in male patients from our Phase 2 trial of VDPHL01 in mild-to-moderate PHL; however, these results may not ultimately be reproducible or durable.

Furthermore, third parties, including regulatory authorities, 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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to disclose.

If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock after the completion of this offering.

We intend to expend our resources to pursue VDPHL01 and therefore may fail to capitalize on, or identify product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are currently focusing our development efforts on our lead product candidate, VDPHL01, for the treatment of PHL. As a result, we may forgo or delay pursuit of opportunities with other existing or potential product candidates or other indications for our existing product candidates that later prove to have greater commercial potential. Our resource allocation decisions may result in our failure to capitalize on viable commercial products or profitable commercial opportunities. Our spending on VDPHL01 and other current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. 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 collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development activities and PHL, which is the indication VDPHL01 is being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts of VDPHL01, if approved. For example, we have engaged in social media campaigns to increase awareness of VDPHL01 and to attract potential patients our clinical trials. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing, promotion of an unapproved new drug, false or misleading advertising, or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission, or FTC, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or adverse event, or AE. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable AE reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive, personal or confidential information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding us, our management, VDPHL01 or any of our other current or future product candidates. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, suffers reputational harm or incur other harm to our business.

We may not be successful in our efforts to build a pipeline of additional product candidates.

Our goal is to develop a focused portfolio of aesthetic dermatology product candidates targeting high-prevalence dermatologic conditions, with potential selective development of medical dermatology product candidates. We may not be able to continue to identify and develop new product candidates in addition to the pipeline of product candidates that we have established. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND and NDA submissions. From time to time, we may publicly announce the expected timing of such milestones. The

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achievement of these milestones is, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

Product liability lawsuits against us or any of our licensing and collaboration partners could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of VDPHL01 or any of our other current or future product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of VDPHL01 or any of our other current or future product candidates by us and any current and licensing and collaboration partners in clinical trials, and the sale of VDPHL01 or any of our other current or future product candidates, if approved, in the future, may expose us to liability claims. Product liability claims may be brought against us or our partners by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our current and licensing and collaboration partners or others using, administering or selling any of our future approved products. If we cannot successfully defend ourself against any such claims, we may incur substantial liabilities or be required to cease or limit commercialization of VDPHL01 or any of our other current or future product candidates if approved. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs, including with respect to potential class action lawsuits;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize VDPHL01 or any of our other current or future product candidates.

Although we maintain product liability insurance coverage of up to $5 million in the aggregate, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize VDPHL01 or any of our other current or future product candidates that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. Failure to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, could prevent or inhibit the development and commercial production and sale of VDPHL01 or any of our other current or future product candidates, which could harm our business, financial condition, results of operations and prospects. Furthermore, if any of our current or future product candidates, including VDPHL01, are approved for marketing and commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Risks Related to Commercialization of Our Product Candidates

We currently have limited marketing, sales or distribution infrastructure. If we are unable to fully develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we may not be successful in commercializing our product candidates.

We are currently building our marketing, sales or distribution capabilities. As a company we have not commercialized or marketed any products to date. If VDPHL01 is approved for the treatment of PHL or if any of our other current or future product candidate is approved, we will need to expand our sales and marketing

organization, on our own or in collaboration with third parties, and add further technical expertise and supporting distribution capabilities to commercialize the approved product in key territories, which will require substantial additional resources. We anticipate that a large portion of these costs will be incurred in advance of any approval of VDPHL01. There are risks involved with both establishing our own sales, marketing and distribution capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a commercial organization is expensive and time consuming and could delay any product launch. If the commercial launch of VDPHL01 or any other product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of VDPHL01 and any other product candidates.

Factors that may inhibit our efforts to commercialize VDPHL01 or any of our other current or future product candidates on its own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or our failure to educate adequate numbers of dermatologists or other physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with building out an independent sales and marketing organization.

We may enter into licensing and collaboration agreements in foreign territories for the commercialization of VDPHL01 or any of our other current or future product candidates, however, we may be unable to enter into such agreements on favorable terms, if at all. Our product revenue may be lower than if we directly marketed or sold our products, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

We also will compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts of VDPHL01 or any of our other current or future product candidates, if approved. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we do not expand our sales and marketing capabilities successfully, on our own or in collaboration with third parties, we will not be successful in commercializing VDPHL01, if approved, or any of our other current or future product candidates. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

Furthermore, our efforts to educate patients, dermatologists and other physicians, on the benefits of VDPHL01 or any of our other or future product candidates may require more resources than we anticipate and may never be successful. Even if VDPHL01 or any of our other or future product candidates is approved, if we are unable to market our products successfully we will not be able to generate significant revenues from such products.

Even if we obtain regulatory approval for VDPHL01 or any other product candidates, such products may fail to achieve market acceptance which would adversely affect our efforts to commercialize any such product successfully.

Our current business strategy is highly dependent on the successful development and commercialization of VDPHL01, if approved, and achieving and maintaining market acceptance of VDPHL01. VDPHL01, if approved as a hair loss treatment, may not be covered by government health benefit programs or private insurance as such treatments are generally not considered medically necessary. Lack of insurance coverage may adversely affect

our ability to successfully commercialize VDPHL01 if health care practitioners are unwilling to prescribe products that are not covered and consumers are unwilling to pay the full cost of such products.

If we are not successful in demonstrating to existing and potential customers the benefits of VDPHL01 or any of our other current or future product candidates, if approved, our business will be adversely affected. We have never commercialized a product, and even if VDPHL01, or any of our other current or future product candidates, is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients and others in the medical community. The rate of adoption by health care practitioners of any products for which we may receive marketing approval and consumer demand for such products will likely depend on several factors, including:

- the safety and effectiveness of the product;
- the prevalence and severity of any side effects;
- the convenience and ease of use of the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- changes in the standard of care for the targeted indications for the product;
- our ability to offer the product for sale at competitive prices;
- the cost, availability, and effectiveness of competitor therapies, including OTC drugs;
- changes in pricing and promotional efforts by competitors;
- the cost of the product for consumers;
- the willingness of consumers to try the product;
- consumer satisfaction with the results of the product;
- the extent to which health care practitioners recommend the product to their patients;
- the willingness of consumers to pay for products indicated for aesthetic purposes;
- the success of efforts to educate potential prescribers and consumers regarding the benefits of our product as compared to those of other treatments;
- the strength of sales, marketing, and distribution support; and
- the success of any DTC marketing efforts for the product, which may depend on current and future restrictions on any DTC advertising.

If we fail to generate sufficient market acceptance of our product candidates, if approved, our ability to obtain an appropriate return on investment on such products will be impacted.

Additionally, in order to attract new customers and incentivize existing customers to purchase more of our offerings, we plan to use social media, emails, text messages, celebrity influencers, and other marketing strategies, including DTC marketing strategies, to reach new and existing customers. In September 2025, the FDA stated that it intends to more aggressively enforce requirements for DTC drug advertising, as well as expand its oversight of digital and social media advertising. In connection with this announcement, the FDA sent more than 100 warnings or untitled letters to companies for allegedly deceptive prescription drug advertising, which represents a dramatic increase in FDA actions as compared to prior years. The administration has also announced plans to propose a rulemaking that would call for drug companies to disclose additional safety information in DTC broadcast advertisements. The nature and extent of changes to FDA regulations and enforcement approach is unclear but may impact pharmaceutical marketing efforts industry-wide, which could in turn impact our potential future sales and operations.

The commercial opportunity for VDPHL01 and any of our other current or future product candidates we may develop may be smaller than we expect.

We have focused our development of VDPHL01 for the treatment of PHL. We base our commercial opportunity estimates on a variety of factors, including our estimates of the number of people who have experienced PHL and the number of those we expect would use VDPHL01, if approved, including those who currently do not treat their PHL, have discontinued use of past treatment for PHL or currently use other OTC products or off-label therapies. These estimates are based on many assumptions and may prove incorrect, and new studies or market

research may reduce our estimated patient population and potential sales. The number of patients in the United States may turn out to be lower than expected or may not be otherwise amenable to treatment with VDPHL01. Further, while our regulatory strategy is to seek approval of VDPHL01 in male patients and female patients with PHL, we may only receive a more limited approval, which would impact our estimated commercial opportunity. If we are unable to advance VDPHL01, or any of our other current or future product candidates with attractive commercial opportunities or if our commercial opportunities are smaller than we expected, our future product revenues will be smaller than anticipated, which would adversely affect our business, financial condition, results of operations and prospects.

The total addressable commercial opportunity for VDPHL01 candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and, to the extent applicable, reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this prospectus should be viewed with caution. Further, the data and statistical information used in this prospectus, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Our strategy of focusing on the cash-pay healthcare market for VDPHL01 may limit our ability to increase sales or achieve profitability

Our strategy is to focus on the cash-pay healthcare market for VDPHL01, if approved. This focus may limit our ability to increase sales or achieve profitability. For example, to maintain our business model, we will not offer products or services available in the broader healthcare market that are reimbursed by third-party payors such as Medicare, Medicaid or commercial insurance. We believe pursuing cash-pay non-reimbursed product strategy allows for meaningful strategic advantages in the United States, including pricing and marketing flexibility and which we believe makes the market less sensitive to changes in insurance coverage and reimbursement. However, our business strategy was developed based on a number of important assumptions about the cash-pay healthcare market for VDPHL01. For example, we believe that the use of cash-pay for VDPHL01 will be attractive to patients as compared to traditional insurance models. Our expectations could be incorrect and sales of VDPHL01 or any of our current or future product candidates could differ materially from our projections. In addition, companies offering competitive products, whether they pursue a non-reimbursed product strategy or not, may nonetheless try to compete with VDPHL01 on price both directly through rebates, promotional programs and coupons and indirectly through attractive product bundling and customer loyalty programs. Further, changes in healthcare legislation and healthcare cost containment measures, as discussed in greater detail below, could impact the pricing of other products and procedures that compete with VDPHL01, which can indirectly impact our pricing strategy and profitability. If a competitor treatment is covered by third-party payors or has more favorable pricing for consumers, the pricing of VDPHL01 may be negatively impacted, which could have a material adverse effect on our ability to generate revenue and to attain profitability. Additionally, the out-of-pocket, cash-pay market for our patient population may be negatively impacted by other price increases and market conditions, including rising costs of other consumer goods, which patients may prioritize over any product candidates we may commercialize. Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient consumer demand for VDPHL01, if approved.

If we fail to effectively maintain, promote, and enhance our reputation and VDPHL01 brand recognition in a cost-effective manner, our business and competitive advantage may be harmed.

We believe that maintaining and enhancing our reputation and brand recognition for VDPHL01 will be critical to our relationships with customers, physicians and other partners, and to our ability to attract new customers, physicians and other partners. The promotion of VDPHL01 will require us to make substantial investments. Brand promotion and marketing activities may not be successful or yield increased revenue, and to the extent that these activities yield increased revenue, the increased revenue may not offset the expenses we incur and our results of operations could be harmed. In addition, any factor that diminishes our reputation or that of our management, including failing to meet the expectations of our customers, physicians and other partners, would

make it substantially more difficult for us to attract new customers, physicians and other partners. If we do not successfully maintain and enhance our reputation and brand recognition in a cost-effective manner, our business may not grow and we could lose our relationships with customers, physicians and other partners, which could harm our business, financial condition and results of operations.

Our products rely on consumer discretionary spending and the purchasing decisions of our customers, both of which are sensitive to difficult to predict global economic conditions, including the imposition of tariffs, or changes in consumer or customer sentiment.

We do not expect VDPHL01, if approved, to be reimbursed by any government or third-party payor and therefore VDPHL01 will continue to be paid for directly by the consumer. As a result, demand for VDPHL01 will be tied to the discretionary spending levels of our targeted consumer population. Sales of VDPHL01, if approved, may depend on short-term purchasing decisions made by our customers in response to consumer demand, aesthetics trends, our competitor's sales tactics, inventory management, seasonality, and other factors affecting consumer and customer purchasing behavior. As a result, it will be difficult to forecast demand for VDPHL01, if approved, and our revenues in a given period may be subject to volatility based on any of these factors.

Recent macroeconomic events, including inflationary pressures and threatened and imposed tariffs have negatively impacted consumer sentiment, resulted in decreased procedural volume for cash-pay medical aesthetics treatments, especially in the United States, and have impacted consumer purchasing behaviors. If these or similar conditions persist or worsen, our business, financial condition, and results of operations could be materially harmed.

Coverage and reimbursement by third-party payors may not be available or may be difficult to obtain for any product candidates for which we receive marketing approval. Failure to obtain or maintain coverage and adequate reimbursement for any such approved products could limit our ability to market those products and would decrease our ability to generate revenue.

While our commercialization plan for VDPHL01 is currently focused solely on cash-pay sales to patients outside private health insurance and government healthcare programs, such as the Medicare and Medicaid programs, we may in the future seek coverage and reimbursement from third-party payors for VDPHL01 or other product candidates if approved for marketing.

We cannot be sure that coverage will be available for any product that we commercialize and, if coverage is available, that the level of reimbursement will be adequate. Specifically, prescription drug products used for cosmetic purposes will generally not be covered by third-party payors because they are not considered medically necessary. And the availability of coverage and the adequacy of the reimbursement of prescription drugs used for medical purposes is uncertain. Without adequate coverage and reimbursement, commercial success for any such product may be adversely affected.

Third-party payors may limit coverage or otherwise seek to control the utilization and cost of drug products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Some third-party payors may impose coverage restrictions through medical policies or manage utilization of a particular product by requiring pre-approval, known as "prior authorization," for coverage of particular prescriptions, which allows the payor to assess medical necessity. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain net price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for drug products can differ significantly from payor to payor. One third-party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the drug product or will provide coverage at an adequate reimbursement rate.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of new products and services in addition to their safety and efficacy. Factors considered by these payors in determining

whether to cover drug products and what reimbursement to provide include product efficacy, cost-effectiveness, and safety, as well as the availability of other treatments, including generic prescription drugs or OTC drugs. To obtain or maintain coverage and reimbursement for any approved drug product, we may need to collect real-world evidence and conduct pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product candidates, if approved. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product or, if they do, the level of payment may not be sufficient to allow sale of a product at a profit. Thus, obtaining and maintaining coverage and adequate reimbursement status is complex, costly, and uncertain.

Federal and state initiatives to control healthcare costs, including measures to lower prescription drug pricing or reduce prescription reimbursement, may result in more restricted coverage and put additional downward pressure on pharmaceutical pricings, which could negatively impact coverage and reimbursement for our product candidates, if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development.

We may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicare and Medicaid or to sell products to government purchasers. More generally, we may need to offer price concessions to third-party payors to obtain favorable coverage or to purchasers to achieve sales.

We expect to experience coverage challenges and pricing pressures for any of our product candidates that may be approved and for which we seek coverage and reimbursement by third-party payors. Pricing pressures and healthcare reform efforts have become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

We are dependent on the services of our senior management and other key personnel, and if we are not able to retain these individuals or recruit additional management or key personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and other key personnel. We are highly dependent upon our co-founders, Chief Executive Officer, Reid Waldman, M.D., and President, Tim Durso, M.D., as well as our Chief Financial Officer, Dominic Carrano, CPA and other members of our senior management and clinical development teams. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates, if approved. Although we have executed employment agreements or offer letters with certain members of our management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We must expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater New England area. If we are not able to attract, integrate, retain and motivate personnel necessary to accomplish our business objectives, we may experience constraints that significantly impede the achievement of our commercial and development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of September 30, 2025, we had 19 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and

sales, marketing and distribution, as well as to support our public company operations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and we may not be able to implement improvements in an efficient or timely manner or may discover deficiencies in existing systems and controls. Our management may need to devote a significant amount of our attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth, in particular in connection with the potential commercial launch of VDPHL01, if approved, will also require significant capital expenditures and may divert financial resources from other product candidates or business initiatives. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of VDPHL01 or any other current or future product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Misconduct or other improper actions, including noncompliance with regulatory standards and requirements, by our employees, independent contractors, consultants, commercial partners and vendors exposes us to potential noncompliance with regulatory standards and requirements.

Employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and vendors exposes us to liability. Misconduct by these parties could be intentional, reckless and/or negligent conduct, including failure to comply with FDA or other regulations, provide true, complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, as will our costs associated with compliance. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials or creation of fraudulent data in preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, a person could allege fraud or other misconduct even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Any such actions instituted against us could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal or administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or, collectively, process, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, and financial information, or, collectively, sensitive data.

We and the third parties with whom we work face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. 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, rogue 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 and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, which could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks credential stuffing attacks, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, attacks enhanced or facilitated by AI, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. 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.

Remote work has increased risks to our information technology systems and data, as our personnel utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, 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.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, information technology, data hosting, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption,

disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

We may expend significant resources or modify our business activities (including clinical trials) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems, but we may not be able to detect and remediate all vulnerabilities including in a timely manner. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Applicable data privacy and security obligations may require us to notify data subjects, customers, partners, regulators and the media relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverages (if any) will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnels', or vendors' use of generative artificial intelligence, or AI, technologies.

Risks Related to Our Intellectual Property

Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for VDPHL01 and our other current and any future product candidates and other proprietary technologies.

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to VDPHL01 and our other current and any future product candidates. If we are unable to obtain or maintain patent protection with respect to VDPHL01 or any of our other current or any future product candidates and their uses, our business, financial condition, results of operations and prospects could be materially harmed.

We generally seek to protect our proprietary position by filing patents or patent applications in the United States and abroad related to VDPHL01 and our other current and any future product candidates that are important to our business, as appropriate. Our pending and future patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. Our patent applications may not result in patents being issued and issued patents may not afford sufficient protection against competitors with similar technology. Furthermore any issued patents may be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. The failure to obtain meaningful protection from the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and we or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. Obtaining and enforcing patents is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection.

Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek adequate patent protection.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including U.S. Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

Further, we may not be aware of all third-party intellectual property rights potentially relating to our research programs and product candidates, or their intended uses, and as a result the potential impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the potential impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to any product candidates or technologies. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There may be prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Our patents or pending patent applications, or the patents or pending patent applications that we license, may be challenged in the courts or patent offices in the United States and foreign jurisdictions. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. An adverse determination in any such challenge may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights.

Our success depends on a market that is observant of intellectual property rights and regulatory requirements. Developments that undermine that landscape can significantly impact our business and reputation. For example, inadequately regulated sales of unapproved compounded versions of our product candidates or approved products could materially impact our business by exposing patients to significant risk, diverting sales of any approved products and harming our reputation. Our actions intended to stop or prevent illegal sales of such medicines also may be costly or ineffective.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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.

Further, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product

candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents, all of which could adversely affect our business, financial condition, results of operations and prospects. Patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, redefined prior art and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates and other proprietary technologies or (ii) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense

of our future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology, products and enforce our intellectual property rights. Subsequent rulings could adversely impact our patents or patent applications. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. For example, the U.S. Supreme Court, in the case Amgen v. Sanofi, held that broad functional antibody claims are invalid for lack of enablement.

Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package, or the EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or the UPC, for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt out under the UPC, said European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke European patents, and allow for the possibility of a competitor to obtain a pan-European injunction in UPC member states. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects in Europe. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and patent applications. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We may, in some cases, be dependent on our licensors to take the necessary action to comply with these requirements with respect to licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Patent rights relating to inventions described and claimed in our pending patent applications may not issue and patents based on our patent applications may be challenged and rendered invalid and/or unenforceable.

We own patents and patent applications in our portfolio relating to VDPHL01 that are pending at the patent offices in the United States, Europe, Japan, and other foreign jurisdictions, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether our patent applications will result in issued patents with claims that cover VDPHL01 or any of our other current and any future product candidates or uses thereof; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our pending patent applications directed to VDPHL01 or any of our other current and any future product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business, or prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. Minoxidil, the ingredient in VDPHL01, was previously known, and thus our patents and patent applications are not to this ingredient itself as a chemical compound, but rather, to other aspects of VDPHL01, including its formulation and dosage form. Even if the patents do issue based on the patent applications we own, co-own or exclusively license, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. In the event of litigation or administrative

proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

Issued patents covering our product candidates, or the method of use of our product candidates, could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

After initiation of legal proceedings against a third party to enforce a patent covering a our product candidates or other proprietary technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In addition to such counterclaims, third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patent rights in such a way that they no longer cover our product candidates, therapeutic programs, and other proprietary technologies we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection provided to our product candidates, proprietary technologies, or other components of our therapeutic programs, as applicable. Even if a third party does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Such a loss of patent protection could have a material adverse impact on our business, financial condition, results of operations, and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market VDPHL01 or any of our other current and any future product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Our operations may, or may in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our operations or necessary for the commercialization of our product candidates in any jurisdiction.

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

or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents that will prevent, limit or otherwise interfere with our ability to make, use or sell VDPHL01 or any of our other current and any future product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market VDPHL01 or any of our other current and any future product candidates. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market VDPHL01 or any of our other current and any future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market VDPHL01 or any of our other current and any future product candidates.

Third-party patents may exist that might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, and manufacture thereof, which could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing VDPHL01 or any of our other current and any future product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell VDPHL01 or any of our other current and any future product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biopharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to VDPHL01 or any of our other current and any future product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, or of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity of third-party patents may be difficult and uncertain. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in defending our rights in these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product.

Alternatively, we may be required, or may choose, to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners may file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under a safe harbor to patent infringement. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, business, financial condition, results of operations or prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

VDPHL01, or any of our other current or future product candidates, may face competition sooner than expected, and our patents may be challenged.

Our success will depend in part on our ability to obtain and maintain patent protection for VDPHL01 and our other current and any future product candidates and technologies and to prevent third parties from infringing upon our proprietary rights. We must also operate without infringing upon patents and proprietary rights of

others, including by obtaining appropriate licenses to patents or other proprietary rights held by third parties, if necessary. However, the patent applications we have filed or may file in the future may never yield patents that protect our inventions and intellectual property assets. Failure to obtain patents that sufficiently cover our formulations and technologies would limit our protection against generic drug manufacturers, pharmaceutical companies and other parties who may seek to copy our products, produce substantially similar products or use technologies substantially similar to those we own, co-own, or exclusively license.

In the United States, when an NDA is approved under Section 505(b)(2), such NDA may be eligible for a period of non-patent exclusivity. When an NDA is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of Abbreviated New Drug Applications, or ANDAs, in the United States. In support of an ANDA a generic manufacturer generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration, and adequate labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning, in part, that it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Moreover, third-party insurers require, and many states allow or require, substitution of therapeutically equivalent generic drugs at the pharmacy level even if the branded drug is prescribed. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug may be lost to the generic product.

The FDA may not finally approve an ANDA for a generic product or a Section 505(b)(2) NDA of a competitor until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of three years of non-patent exclusivity for a drug product that contains an active moiety that has been previously approved by FDA, when the application contains reports of new clinical investigations conducted or sponsored by the sponsor that were essential to the application. For example, the changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the application containing those changes. In such an instance, FDA may not for a period of three years after the date of approval of the NDA approve another 505(b)(2) application or an ANDA for the conditions of approval of the NDA, or an ANDA submitted pursuant to an approved petition under that relies on the information supporting the conditions of approval of an original NDA. While VDPHL01 does not qualify for the five-year non-patent exclusivity provision under Section 505(b)(2), VDPHL01 may qualify for three years of non-patent exclusivity; if FDA does not grant VDPHL01 or other product candidates appropriate periods of non-patent exclusivity before approving generic versions of such products, the sales of such products could be adversely affected.

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to

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

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidates. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other confidential proprietary information could be disclosed or competitors could otherwise gain access to our trade

secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

These risks are heightened due to our reliance on third parties, including third party CROs and CMOs, for certain aspects of our business. The activities conducted by our third party vendors require us to share our trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

License agreements that we currently or in the future are party to impose and may impose various obligations on us. If we fail to comply with our obligations under our licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of our license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our business, financial condition, results of operations and prospects. Moreover, license agreements may be complex and subject to interpretation, and there may be disputes between us and our licensors about the scope or interpretation of the license agreement. Disputes related to license agreement could be distracting, time consuming and, if determined adversely, adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to third party patents for our product candidates through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license, or use third-party intellectual property and proprietary rights. Other pharmaceutical companies and academic institutions may own patents or may have filed, or be planning to file, patent applications potentially relevant to our business. In order to avoid infringing such patent rights, we may find it necessary or prudent to obtain licenses to such patent rights from such third parties. For example, we may be required by the FDA or comparable foreign regulatory authorities to provide a specific companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use patents or know-how owned or controlled by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties in the future, we may require licenses to such co-owners' interest to such patent or other intellectual property rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party

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intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate, or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property related to the products or product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer.

Certain intellectual property which we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Certain intellectual property rights we have or may license have been generated through the use of U.S. government funding and may therefore be subject to certain federal laws and regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, which are commonly referred to as "march-in rights." The U.S. government also has the right to take title to these inventions if the applicable licensor, fails to disclose the invention to the government and fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could adversely affect our competitive position, business, financial condition, results of operations and prospects.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by our patents;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by our patents or pending patent application;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. regulatory approval and, as a result, unable to commercialize our product candidates or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

Our current product candidates are, and any future product candidates will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing,

approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. Any analysis we perform of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of VDPHL01 or any of our other product candidates or any future product candidates.

Further, the FDA may respond to any NDA that we may submit by requesting additional data or studies that we do not anticipate. Such responses could delay clinical development of our product candidates or any future product candidates. The FDA also may consider its approvals of competing products, which may alter the treatment landscape, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate withdrawal of our NDA submissions.

Any delay or failure in obtaining required approvals would adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We also may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing

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regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, or to require the inclusion of a boxed warning, which highlights a specific life-threatening safety risk. FDA has required the inclusion of a boxed warning on the labeling for FDA-approved IR oral minoxidil for treatment of blood pressure and cardiovascular indications due to serious heart-related adverse effects. It is unclear at this stage whether FDA is likely to require inclusion of a boxed warning for our VDPHL01, as an ER oral minoxidil product. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with Current Good Manufacturing Practices, or cGMPs. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market.

Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products. If we promote our products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. The failure by us or our collaborators to comply with applicable regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates may result in, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Disruptions at the FDA, SEC or comparable foreign regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel necessary for the review, approval and commercialization of new products in a timely manner or otherwise prevent those authorities from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products is affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the regulatory authority's ability to perform routine functions. Average review times at the FDA and other regulatory authorities have fluctuated in recent years. In addition, government funding of other authorities and agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including in 2025, and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities.

If any future prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

The marketing of pharmaceutical products and related arrangements with healthcare providers, third-party payors, patients, and other third parties in the healthcare industry are subject to a wide range of federal and state healthcare laws and regulations that may constrain our business and/or financial arrangements. Some of these laws apply to us now, while other laws may apply to us only if and when we have marketed products or have marketed products that are covered by government health benefit programs or private health care insurance. These laws include:

- the federal Anti-Kickback Statute, which 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 under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower, or qui tam actions, as well as civil monetary penalty laws can impose criminal and civil penalties, assessment, and exclusion from participation for various forms of fraud and abuse involving the federal healthcare programs, such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also establishes requirements related to the privacy, security, and transmission of individually identifiable health information which apply to many healthcare providers, physicians, and third-party payors with whom we interact;
- the federal Food, Drug, and Cosmetic Act, or FDCA, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report, and certify certain complex product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the so-called federal “sunshine law” or Open Payments which requires manufacturers of drugs, devices, biologics, and medical supplies covered under certain government health benefit programs to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to teaching hospitals, physicians, and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state laws and regulations analogous to federal laws, including anti-kickback or related laws, some of which apply regardless of whether products or services are covered by government health benefit programs or private insurance, false claims laws, laws prohibiting consumer protection and unfair competition laws, and laws governing privacy, security, and breaches of health (and other personal) information in certain circumstances, many of which differ in significant ways from federal laws and across states and are often not preempted by federal law, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures, and/or require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

To the extent that we implement a telehealth platform, activities undertaken and arrangements implemented in connection with such a platform may implicate other laws such as state physician, pharmacy and telehealth licensure laws, corporate practice of medicine, and fee-splitting laws.

Efforts to ensure that our activities comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations, and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with such laws. For example, we have engaged physicians to serve as investigators and/or consultants, including service on advisory boards, and our commercialization plan may include significant physician outreach and education. Federal and state enforcement agencies scrutinize interactions between pharmaceutical companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from participation in federal health care programs such as Medicare and Medicaid, the curtailment or restructuring of our operations, and other actions. Further, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including FDA and CMS, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Legislative, regulatory, and executive healthcare and other reform initiatives aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Legislative, regulatory, and executive healthcare and other reform initiatives in the United States, including those aimed at containing or lowering the cost of healthcare, may adversely impact our business, operations, and financial condition.

A number of the healthcare reform initiatives have focused on pricing and payment for prescription drugs, including some recent initiatives that address pricing in DTC offerings. For example, the Inflation Reduction Act of 2022, or the IRA, which is having a significant and ongoing impact on the pharmaceutical industry, includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D, such as caps on Medicare Part D out-of-pocket costs and a drug price negotiation program for certain high-spend Medicare Part B and D drugs.

More recently, the Trump Administration has taken action intended to reduce the cost of prescription drugs, including drugs purchased directly by consumers. The administration issued two Executive Orders aimed at lowering drug prices through multiple directives, including directives to government agencies and officials to identify most-favored-nation pricing targets for prescription drugs (and looking to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients), to facilitate DTC purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price, to enhance competition for high-cost prescription drugs by accelerating approval of generics and biosimilars, facilitating the

process for re-classifying prescription drugs as OTC drugs, and increasing drug importation. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced new or expanded DTC offerings with discounted prices and/or reached agreement with the federal government regarding discounted pricing for drugs, including prices for Medicaid drugs and newly launched products. TrumpRx, a website sponsored by the federal government that is anticipated to offer pharmaceutical DTC channels, has also been announced. Federal agencies are also developing and proposing new drug pricing and payment pilot programs based on international pricing metrics under Medicare Parts B and D as well as Medicaid.

Other healthcare reform efforts or actions under the Trump Administration may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, will increase the number of uninsured.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge, which increases uncertainty. For example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups.

At the state level, legislatures have increasingly passed legislation and implemented 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, encourage importation from other countries and bulk purchasing. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations, and prospects.

Other recent government actions also may affect prices or payments for prescription drugs. For example, the Trump Administration's recently announced tariff on branded or patented drugs for manufacturers that do not invest in manufacturing plants in the United States or reach a drug pricing agreement with the Trump Administration may adversely impact our ability to realize an adequate return on the sale of any drug products imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken.

The nature and extent of future healthcare or other reforms cannot be predicted. There is significant uncertainty regarding the nature or impact of any drug pricing or broader healthcare reform implemented by the current presidential administration through executive action or by Congress and the extent to which such action may be subject to litigation or other challenges. Reform at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing, or effect of any federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results.

We are or may become subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, industry standards and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of

the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information.

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

For example, the California Consumer Privacy Act, or CCPA, provides for civil penalties per violation as well as a private right of action with statutory damages for certain data breaches. The CCPA also exempts some data processed in the context of clinical trials. These laws may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

There are many other federal and state-based data privacy and security laws and regulations, such as the Federal Communications Act, the Electronic Communications Privacy Act, the Telephone Consumer Protection Act, or the TCPA, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003, or the CAN-SPAM Act, and similar state consumer protection and communication privacy laws, such as California's Invasion of Privacy Act, or the CIPA. For example, the CAN-SPAM Act and the TCPA impose specific requirements on communications with consumers. The TCPA and analogous state laws impose various consumer consent requirements and other requirements on certain communications with consumers by phone or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission, or the FCC, or statutory damages of up to $1,500 per violation imposed through private litigation or by state authorities. The TCPA provides for substantial penalties and statutory damages and has generated significant class action activity. The costs of litigating and/or settling a TCPA or similar legal claim could be significant. There has also been a noticeable uptick in class action litigation wherein plaintiffs have utilized a variety of laws, including state wiretapping laws such as the CIPA, in relation to companies' use of certain tracking technologies, such as cookies and pixels. Actual or perceived failure to comply with these laws and regulations could subject us to legal proceedings (such as class action litigation and mass arbitration demands), which could result in adverse publicity, substantial monetary damages and legal defense costs, injunctive relief and fines or penalties.

We are or may become subject to laws governing the privacy of consumer health data, including reproductive, sexual orientation, and gender identity privacy rights. For example, Washington's My Health My Data Act, or MHMD, as applicable to our operations, broadly defines consumer health data, places restrictions on the processing of consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states have passed, are considering, and may adopt similar laws.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Our employees and personnel use or may in the future use generative AI and/or automated decision-making technologies to perform their work, and the disclosure and use of personal data in AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating AI and/or automated decision-making technologies. Our use of this technology could result in

additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI and/or automated decision-making technologies, it could make our business less efficient and result in competitive disadvantages.

The U.S. Department of Justice, or the DOJ, issued a rule entitled Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

We also publicly post certain of our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third-parties with whom we work may fail to comply with such obligations. Any actual or perceived failure by us or the third parties with whom we work to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we process as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or

commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department's Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Recently the SEC and the DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer VDPHL01 or any future product candidates in one or more countries and could materially damage our reputation, brand, international activities, ability to attract and retain employees, and business, prospects, operating results and financial condition.

In addition, VDPHL01 or any of our other current or future product candidates and activities may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of VDPHL01 or any of our other current or future product candidates, or our failure to obtain any required import or export authorization for VDPHL01 or any of our other current or future product candidates, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of VDPHL01 or any of our other current or future product candidates may create delays in the introduction of our product candidates in international markets or, in some cases, prevent the export of our product candidates to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of VDPHL01 or any of our other current or future product candidates by, or in our decreased ability to export VDPHL01 or any of our other current or future product candidates to existing or potential customers with international operations. Any decreased use of VDPHL01 or any of our other current or future product candidates or limitation on our ability to export or sell access to VDPHL01 or any of our other current or future product candidates would likely adversely affect our business.

Risks Related to Our Dependence on Third Parties

We currently rely on third parties for the manufacture of drug or biological substances for our preclinical studies and clinical trials and expect to continue to do so for commercialization of any product candidates that we may develop that are approved for marketing. Our reliance on third parties may increase the risk that we will not have sufficient quantities of such drug substance, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing VDPHL01 or any other product candidate. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP-drug substance and drug product of VDPHL01 and any other product candidates we develop and, in the future, for commercial supply for any approved product candidates. Currently, we rely on one CMO for the supply of drug product of VDPHL01. Reliance on third parties may expose us to more risk than if we were to manufacture our product candidates ourselves. For example, should demand for our drug significantly exceed what is expected, we may experience supply shortages in trying to obtain or source material to meet such demand. Additionally, we do not have long-term supply contracts with any of our CMOs for preclinical or clinical supply, and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. We may be unsuccessful in negotiating and entering into long-term master supply agreements with certain of our current or future CMOs on favorable terms or at all, which would likely jeopardize our ability to provide any product candidates to participants in clinical trials and products to market, if approved.

We have entered into a commercial supply agreement with a third-party manufacturer for commercial supply of VDPHL01, if approved. We intend to rely on this manufacturer as the primary source for drug product manufacturing and final packaging for VDPHL01. Unless and until we can secure an alternative source for drug product manufacturing and final packaging, our dependence on one manufacturer will subject us to the possible risks of shortages, interruptions and price fluctuations if VDPHL01 is approved for commercialization. We may not be able to establish agreements with other third-party manufacturers if necessary for VDPHL01 or any other product candidate that receives marketing approval, on acceptable terms or at all.

Reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture VDPHL01 or any other current or future product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our products or product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the failure of the third party to manufacture VDPHL01 or any other current or future product candidates according to our specifications;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the possible breach of the manufacturing agreement by the third-party;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- the failure of third-party contractors to comply with applicable regulatory requirements, whether related to VDPHL01 or any other current or future product candidates or products;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales;
- the misappropriation of our proprietary information, including our trade secrets and know-how;
- reliance on the third-party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and

- the possible inability of third-party suppliers to supply and/or transport materials, components and products to us in a timely manner as a result of disruptions to the global supply chain.

The manufacturing process for our product candidates is subject to the FDA and comparable foreign regulatory authority review. We and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Moreover, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or therapies, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our therapies and harm our business, financial condition, results of operations, and prospects.

While we provide oversight of manufacturing activities, we have limited ability to control the execution of manufacturing activities by, and are or will be dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates by our CMOs. As a result, we are subject to the risk that our product candidates may have manufacturing defects or fail to comply with regulatory requirements, which we have limited ability to prevent. CMOs may also have competing obligations that prevent them from manufacturing our product candidates in a timely manner. If a CMO cannot successfully manufacture drug substance that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance, and qualified personnel, and we were not involved in developing our CMOs' policies and procedures.

The facilities and processes used to manufacture our product candidates are subject to inspection by the FDA and other comparable foreign authorities. If the FDA or other comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities or conduct additional studies, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers raw materials necessary to produce our product candidates. We have limited ability to control the process or timing of the acquisition of these raw materials by our CMOs. Supplies of raw materials could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable time frame, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to

assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates. Moreover, our product candidates utilize drug substances that are produced on a small scale, which could limit our ability to reach agreements with alternative suppliers.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for, or commercialize our product candidates, if approved.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Any interruption or delay in the supply of sole source or limited source components for our product candidates, including as a result of us needing to seek alternative sources, which may not be available at reasonable prices or at all, would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and delayed revenue, if our product candidates are approved, and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to continue to rely on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current and future product candidates. Currently, Therapeutics, Inc. is our exclusive provider of clinical trial management, regulatory affairs activities (including acting as our designated agent with the FDA), program support and other CRO services, and will continue to be our exclusive provider of such services through the completion of Phase 2 of VDMN (or, if later, the first Verademics product candidate to reach completion of Phase 2).

Because of this reliance, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than if we conduct them ourselves. Third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties have contractual relationships with other entities, some of which may be our competitors, which may divert time and resources from our programs.

Our reliance on third parties reduces our control over our development activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards. For example, we remain responsible for ensuring that each of our preclinical studies are conducted in accordance with GLPs and clinical trials are conducted in accordance with Good Clinical Practice, or GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties

violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If our third party contractors do not successfully carry out their contractual duties, meet deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding contractors involves cost, takes time and diverts management's attention. In addition, there is a natural transition period when a new third party commences work. Delays could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We may be required to report some of these relationships to the FDA, and the FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affects interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

If our third-party manufacturer of VDPHL01 is unable to increase the scale of its production or we are not able to qualify additional manufacturers, then commercialization may be delayed or interrupted.

In order to produce sufficient quantities to meet the commercial demand for VDPHL01, if approved, our third-party manufacturers may be required to increase their production and optimize their manufacturing processes while maintaining the quality of VDPHL01. The transition to larger scale production could prove difficult. In addition, if we are unable to qualify additional manufacturers or our third-party manufacturers are not able to produce increased amounts of our product candidates to meet demand while maintaining the same quality then we may not be able to meet market demand for VDPHL01, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

We depend on third-party suppliers for materials used in the manufacture of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.

We rely on third-party suppliers for certain materials and components required for the production of our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

The operations of our supplier for minoxidil API for VDPHL01 are located outside of the United States and are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, our supplier for minoxidil API for VDPHL01 primarily operates outside of the United States. As a result, we are subject to risks associated with doing business abroad, including:

- geopolitical tensions, political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured, particularly China;
- the imposition of new laws and regulations, including those relating to labor conditions and safety standards, information and data transfer, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trade secret protection, in some countries, particularly China;
- disruptions in operations due to global, regional, or local epidemics, pandemics and other public health crises, or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our supplier's production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all and inhibit our suppliers' ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations and prospects.

Risks associated with the in-licensing or acquisition of product candidates could cause substantial delays in the preclinical and clinical development of our product candidates.

We may acquire or in-license additional product candidates for preclinical or clinical development in the future as we continue to build our pipeline. The risks associated with acquiring or in-licensing product candidates could result in delays in the commencement or completion of our preclinical studies and clinical trials, if ever, and our ability to generate revenues from our product candidates may be delayed. Please see "—Risks Related to Our Intellectual Property—Our commercial success depends on our ability to obtain and maintain sufficient intellectual property protection for VDPHL01 and our other current and any future product candidates and other proprietary technologies." for additional information regarding such risks.

We may seek to enter into collaborations, licenses and other similar arrangements for VDPHL01 or any of our other current or future product candidates and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships.

We may seek to enter into collaborations, licenses and other similar arrangements for the development or commercialization of VDPHL01 outside of the United States or of any of our other current or future product candidates, due to capital costs required to develop or commercialize our product candidates or manufacturing constraints. Such collaborative efforts may not be profitable. We may not be successful in our efforts to establish or maintain collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is often time-consuming and complex. We likely would relinquish valuable rights to our future revenue streams, research programs or product candidates, or may grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements restrict us from entering into additional agreements with other potential licensing and collaboration partners. We may not achieve an economic benefit that justifies any such transaction.

The success of any collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

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

Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, the development or approval of VDPHL01 or any of our other current or future product candidates is delayed, the safety of VDPHL01 or any of our other current or future product candidates is questioned or the sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners often negotiate for certain rights to control decisions regarding the development and commercialization of product candidates and products, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to VDPHL01 or any of our other current or future product candidates, would delay the development and commercialization of such product or product candidate and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Our reliance on third parties requires us to share our trade secrets, know-how and other proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform other preclinical and clinical services, we must, at times, share our proprietary information, including trade secrets and know-how, with them. We seek to protect our proprietary information, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our CROs, CMOs, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our proprietary information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets, know-how and other proprietary information increases the risk

that such proprietary information become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. We rely, in part, on trade secrets, know-how and other proprietary information to develop and maintain our competitive position and a competitor's discovery of our proprietary information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such 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 materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval, or comparable foreign regulatory requirements. 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 commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates.

Risks Related to this Offering and Ownership of Our Common Stock

An active and liquid trading market for our common stock may not develop, and you may not be able to resell your shares of common stock at or above the public offering price, if at all.

Prior to this offering, no market for shares of our common stock existed. Our common stock has been approved for listing on NYSE under the symbol "MANE." After the consummation of this offering, an active or liquid trading market for our common stock may never develop or be sustained following the consummation of this offering. Moreover, the initial public offering price for our common stock was determined through negotiations with the underwriters, and may vary from the market price of our common stock following the consummation of this offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price or at a price that you consider reasonable. Furthermore, an inactive market may reduce the fair market value of your shares, impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- volatility in our operating results or the failure of our operating results to meet the expectations of investors or securities analysts;
- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical and clinical studies for any product candidates that we may develop or changes in the development status of any of these programs;
- any delay in our regulatory filings for VDPHL01 or our other current or any future product candidates;
- failure or discontinuation of any of our product development and research programs;
- our failure to commercialize VDPHL01 or our other current or any future product candidates;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;

- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales or perceived potential sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply shortages;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- press reports, whether or not true, about our business;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement or expectation of additional financing efforts;
- the inability to obtain additional funding;
- market conditions in the pharmaceutical and biotechnology sectors;
- general global economic, industry, political and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; and
- the other factors described in this "Risk Factors" section and elsewhere in this prospectus, including those which are outside of our control.

In recent years, the stock market in general, and the market for biopharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock shortly following the consummation of this offering. The market price of our common stock may decline below the initial public offering price, and you may lose some or all of your investment.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of VDPHL01 or future development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;

- our execution of any strategic transactions, including acquisitions, collaborations, licenses, or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference, or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidate receives regulatory approval in the future, the terms of such approval, and market acceptance and demand for such products;
- regulatory developments affecting our product candidate or those of our competitors;
- global or regional public health emergencies, including any health epidemics and their residual effects, natural disasters, or major catastrophic events;
- adverse macroeconomic conditions or geopolitical events, including the conflict between Ukraine and Russia, the conflict between Israel and Hamas, high levels of inflation, heightened interest rates, and bank failures;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

You will incur immediate and substantial dilution as a result of the consummation of this offering.

If you purchase common stock in this offering, you will incur immediate and substantial dilution of $5.66 per share, representing the difference between the initial public offering price of $17.00 per share and our pro forma as adjusted net tangible book value per share as of September 30, 2025 after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock, (ii) the issuance and sale of 118,682,683 shares of Series C Preferred Stock, including the net proceeds from such sale, which occurred subsequent to September 30, 2025, and the automatic conversion of all outstanding shares of Series C Preferred Stock into an aggregate of 11,789,280 shares of our common stock and (iii) the filing and effectiveness of our restated certificate of incorporation and amended and restated bylaws. To the extent that shares are issued upon the exercise of options or the underwriters exercise their over-allotment option, you will incur further dilution. For a further description of the dilution you will experience immediately after the consummation of this offering, see the section titled "Dilution."

To the extent that stock options are exercised, new equity awards are issued under our equity incentive plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of 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 capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales upon the expiration of the lock-up agreements (described in the "Underwriting" section of this prospectus), the early release of the lock-ups, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After the consummation of this offering, we will have 35,077,084 shares of common stock outstanding, or 37,338,731 shares if the underwriters exercise their over-allotment option in full, in each case based on the

shares of our common stock outstanding as of September 30, 2025. Of these shares, the 15,077,647 shares (or 17,339,294 shares if the underwriters exercise their over-allotment option in full) we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the consummation of this offering as described in the "Shares Eligible for Future Sale" section of this prospectus. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time in their sole discretion and without notice, except for directors and officers, which would allow for earlier sales of shares in the public market.

In addition, Eli Lilly has indicated an interest in purchasing at the initial public offering price shares of common stock in this offering in an amount up to 4.9% of the number of shares of common stock issued and outstanding after this offering. The shares of common stock to be purchased by Eli Lilly will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, Eli Lilly may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to Eli Lilly.

The cornerstone investor also has indicated an interest in purchasing up to $30.0 million in shares of common stock in this offering at the initial public offering price. The shares of common stock to be purchased by the cornerstone investor will not be subject to a lock-up agreement with the underwriters. Because this indication of interest is not a binding agreement or commitment to purchase, the cornerstone investor may determine to purchase more, less or no shares in this offering or the underwriters may determine to sell more, less or no shares to the cornerstone investor.

If Eli Lilly or the cornerstone investor is allocated all or a portion of the shares it has indicated an interest in purchasing in this offering or more, and purchases any such shares, such purchases could reduce the available public float for our shares of common stock if Eli Lilly or the cornerstone investor holds such shares long-term.

Moreover, after the consummation of this offering, holders of an aggregate of 19,250,410 shares of our common stock will have rights, subject to 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 also plan to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders will continue to have substantial influence over us after the consummation of this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.

After the consummation of this offering, our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, will beneficially own shares representing approximately 13,779,032 of our outstanding common stock (assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options and excluding any purchases that may be made in this offering). As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate

declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock in the foreseeable future. See the section titled "Dividend Policy" for additional information.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we may remain an emerging growth company until December 31, 2031. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, 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, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely 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 stock price may be more volatile.

Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and amended and restated bylaws, which will become effective prior to the consummation of this offering, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares.

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Our restated certificate of incorporation and amended and restated bylaws, which will become effective prior to the consummation of this offering, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our restated certificate of incorporation will designate specific courts as the sole and exclusive forum for certain claims or causes of action that may be brought by our stockholders, which could discourage lawsuits against us and our directors and officers.

Our restated certificate of incorporation will provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses a Covered Claim (as defined below) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the following types of claims: (i) any derivative claim brought in the right of the Company, (ii) any claim asserting a breach of a fiduciary duty to the Company or the Company's stockholders owed by any current or former director, officer or other employee or stockholder of the Company, (iii) any claim against the Company arising pursuant to any provision of the DGCL, our restated certificate of incorporation or amended and restated bylaws, (iv) any claim to interpret, apply, enforce or determine the validity of our restated certificate of incorporation or amended and restated bylaws, (v) any claim against the Company governed by the internal affairs doctrine, and (vi) any other claim, not subject to exclusive federal jurisdiction and not asserting a cause of action arising under the Securities Act of 1933, as amended, or the Securities Act, brought in any action asserting one or more of the claims specified in clauses (a) (i) through (v) herein above, or each a Covered Claim. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our restated certificate of incorporation will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our restated certificate of incorporation will provide that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions to be contained in our restated certificate of incorporation may make it more costly for a stockholder to bring a claim, and it may also limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions to be contained in our restated certificate of incorporation are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. The choice of forum provisions may also impose additional litigation costs on stockholders who assert that the provisions are not enforceable or invalid.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the "Use of Proceeds" section of this prospectus. Accordingly, you will have to rely upon the judgment of our management with respect to the use of the proceeds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, fluctuating inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, tariffs and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

After the completion of this offering, as a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing SOX Section 404 and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue

a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

As a private company, we do not currently have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include workers' compensation, clinical trials, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects. We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to be volatile. The stock market in general, and NYSE and biopharmaceutical companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

Our operations or those of the third parties upon whom we depend might be affected by the occurrence of a natural disaster, pandemic or other catastrophic event.

We depend on our employees, consultants, vendors, service providers, and other contractors (including CMOs and CROs), as well as regulatory agencies and other third parties, for the continued operation of our business. Despite any precautions we take for natural disasters or other catastrophic events, these events, including terrorist attack, pandemics, hurricanes, fire, floods and ice and snowstorms, could result in significant disruptions to our research and development, preclinical studies, clinical trials, and, ultimately, commercialization of our products. Long-term disruptions in infrastructure caused by events, such as natural disasters, the outbreak of war, the escalation of hostilities and acts of terrorism or other "acts of God," particularly involving those places in which we maintain office space or at our manufacturing or clinical trial sites, could adversely affect our businesses. Although we carry business interruption insurance policies and typically have provisions in our contracts that protect us in certain events, our coverage might not respond or be adequate to compensate us for all losses that may occur. Any natural disaster or catastrophic event affecting us, our consultants, vendors, service providers, and other contractors, regulatory agencies or other parties with which we are engaged could have a significant negative impact on our operations and financial performance.

We could be subject to changes in tax rates or new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.

Changes to tax laws or regulations, or to the interpretation of such laws or regulations, in the jurisdictions in which we operate could significantly increase our effective tax rate and materially affect our financial condition. In addition, other factors or events, including business combinations and investments, changes in our stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to our taxes upon finalization of any of our various tax returns or as a result of deficiencies asserted by taxing authorities against us, increases in any of our expenses that are not deductible for tax purposes, changes in our available tax credits, and changes in the apportionment of our income and our activities among tax jurisdictions, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service, or the IRS, and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations in respect of our tax liabilities are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit or other proceeding could harm our business.

Our ability to use certain net operating loss, or NOL, carryforwards and certain other tax attributes may be limited.

As of December 31, 2024, we had federal and state NOL carryforwards of approximately $29.3 million. Federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such taxable year, if any. It is uncertain if and to what extent various states will conform to federal law. There also may be periods during which the use of state NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Certain of the state NOL carryforwards will begin to expire in 2040.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. In general, an "ownership change" occurs if there is a cumulative change in ownership of the corporation by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. We have initiated but not yet completed a study under Section 382 of the Code to determine whether we have previously experienced an ownership change. We may also experience an ownership change upon future issuances of our stock or due to secondary trading of our stock which may be outside of our control. Any of these ownership changes and their resulting limitations on our ability to use NOL carryforwards and other tax attributes could adversely impact our business, financial condition, results of operations and cash flows.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- the initiation, timing, enrollment, progress, results, and cost of our research and development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation or completion of our clinical trials for VDPHL01 and our other product candidates, and related preparatory work, and the period during which the results of the trials will become available;
- our regulatory strategy and the timing of our planned NDA submission for VDPHL01;
- the success, cost and timing of our clinical development of VDPHL01 and our other product candidates;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- the timing of and our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently selling, marketing or engaged in the development of treatments for diseases that our product candidates are designed to target, including PHL;
- our reliance on third parties to conduct our clinical trials;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- our estimates regarding the size and growth potential of the commercial opportunity for VDPHL01 and our current product candidates or other product candidates we may identify and pursue, and our ability to serve those markets;
- our ability to expand our pipeline through collaborations, partnerships and other transactions with third parties;
- our ability to identify and advance through clinical development any additional product candidates;
- the commercialization of VDPHL01 and our other current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build commercial infrastructure or enter into collaborations with third parties to market our current product candidates and any other product candidates we may identify and pursue;
- the effectiveness of physician outreach and education, direct-to-consumer advertising, telehealth engagement and social media campaigns on physician and patient adoption rates;
- our ability to develop and commercialize products that are considered by physicians, patients and payors as medically and/or financially differentiated as compared to competitive products;
- our ability to retain and recruit key personnel;
- our ability to obtain. maintain and successfully enforce adequate intellectual property rights;
- our patent portfolio, including issued, allowed and pending applications, and plans for future applications;
- our expectations about patient willingness to pay, the effect of macroeconomic conditions on discretionary spending and implications of limited or no third-party payor coverage and reimbursement on VPHL01, if approved;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our expected uses of the net proceeds to us from this offering and our existing cash, cash equivalents and marketable securities and the sufficiency of such capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our financial performance;

- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

The forward-looking statements in this prospectus are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as guarantees of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and management cannot predict all risks and uncertainties. Except as required by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately $234.0 million (or approximately $269.7 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $17.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

As of September 30, 2025, we had cash, cash equivalents and marketable securities of $15.1 million. Subsequent to September 30, 2025, we completed our Series C Preferred Stock financing, from which we received gross proceeds of $151.0 million.

We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities:

- to advance VDPHL01 through NDA approval and initial commercialization in the United States, if approved. These funds will support physician education, brand awareness initiatives, marketing, pre-commercial and commercial launch activities, including building our commercialization infrastructure and manufacture of commercial supply, with
- any remaining proceeds for business development activities and other general corporate purposes.

The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our preclinical development efforts, our operating costs and other factors described under "Risk Factors" in this prospectus.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into 2029. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We do not anticipate that the expected net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient for us to fund VDPHL01, or any of our other product candidates, through regulatory approval and commercialization, and we will need to raise substantial additional capital in order to do so. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current plans, commitments, or obligations to do so.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the consummation of this offering or the actual amounts that we will spend on the uses set forth above.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including the anticipated growth of our business, and we may find it necessary or advisable to use the net proceeds for other purposes. Pending the uses described above, we plan to invest the net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any indebtedness we may incur.

CAPITALIZATION

The following table sets forth our cash and capitalization as of September 30, 2025:

- on an actual basis;
- on a pro forma basis, to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock, (ii) the issuance and sale of 118,682,683 shares of Series C Preferred Stock, including the net proceeds from such sale, which occurred subsequent to September 30, 2025, and the automatic conversion of all outstanding shares of Series C Preferred Stock into an aggregate of 11,789,280 shares of our common stock, (iii) the filing and effectiveness of our restated certificate of incorporation and amended and restated bylaws immediately prior to the consummation of this offering and (iv) the reclassification of our subscription receivable, associated with our historical Preferred Stock transactions, from temporary equity to permanent stockholders' equity upon automatic conversion of all outstanding Preferred Stock; and
- on a pro forma as adjusted basis, to give further effect to our issuance and sale of shares of our common stock in this offering at the initial public offering price of $17.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the consummation of this offering will change based on the initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with the financial statements and related notes as appearing at the end of this prospectus and the information set forth under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	AS OF SEPTEMBER 30, 2025		
(in thousands, except share and per share amounts)	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
Cash, cash equivalents and marketable securities	$ 15,139	$ 165,702	$ 399,680
Series A preferred stock, $0.00001 par value; 12,865,375 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	36,860	—	—
Series B preferred stock, $0.00001 par value; 62,245,806 shares authorized, 62,245,805 issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	74,708	—	—
Series C preferred stock, $0.00001 par value; no shares authorized, issued or outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Subscription receivable	(2,466)	—	—
Total stockholders' (deficit) equity			
Preferred stock, $0.00001 par value; no shares authorized, issued and outstanding, actual; 25,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.00001 par value; 98,774,582 shares authorized, 749,027 shares issued and outstanding, actual; 26,568,670 shares authorized, 19,999,437 issued and outstanding, pro forma; 200,000,000 shares authorized, 35,077,084 shares issued and outstanding, pro forma as adjusted	1	1	1
Additional paid-in capital	1,363	263,493	497,471
Subscription receivable	—	(2,466)	(2,466)

(in thousands, except share and per share amounts)	AS OF SEPTEMBER 30, 2025		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
Accumulated deficit	(97,379)	(97,379)	(97,379)
Total stockholders' (deficit) equity	(96,015)	163,649	397,627
Total capitalization	$ 13,087	$ 163,649	$ 397,627

The outstanding share information in the table above as of September 30, 2025 excludes:

- 739,331 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2025, with a weighted average exercise price of $12.19 per share;
- 2,974,637 shares of our common stock issuable upon the exercise of stock options granted after September 30, 2025, with a weighted average exercise price of $12.77 per share;
- 685,080 shares of our common stock reserved for issuance under the 2021 Plan, as of December 31, 2025, which ceased to be available for issuance at the time the 2026 Plan became effective and were added to, and became available for issuance under, the 2026 Plan;
- a number of shares of our common stock equal to 10.8% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 4,518,426 shares) reserved for issuance under the 2026 Plan, which became effective in connection with this offering (which includes up to 1,768,254 shares of common stock underlying stock option awards to be granted to our directors, executive officers and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 316,668 shares of our common stock reserved for issuance under the ESPP, which became effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2025 was $(96.0) million, or $(128.19) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our redeemable convertible preferred stock, which is not included within stockholders (deficit) equity. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 749,027 shares of common stock outstanding as of September 30, 2025.

Our pro forma net tangible book value as of September 30, 2025 was $163.6 million, or $8.18 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of September 30, 2025 into an aggregate of 7,461,130 shares of our common stock, (ii) the issuance and sale of 118,682,683 shares of Series C Preferred Stock, including the net proceeds from such sale, which occurred subsequent to September 30, 2025, and the automatic conversion of all outstanding shares of Series C Preferred Stock into an aggregate of 11,789,280 shares of our common stock and (iii) the filing and effectiveness of our restated certificate of incorporation and amended and restated bylaws. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 30, 2025 after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 15,077,647 shares of common stock in this offering at the initial public offering price of $17.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2025 would have been $397.6 million, or $11.34 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $3.16 per share to existing stockholders and an immediate dilution of $5.66 in pro forma as adjusted net tangible book value per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 17.00
Historical net tangible book value (deficit) per share as of September 30, 2025	$ (128.19)	
Increase per share attributable to pro forma adjustments as described above	136.37	
Pro forma net tangible book value per share of common stock as of September 30, 2025	8.18	
Increase in net tangible book value per share of common stock attributable to this offering	3.16	
Pro forma as adjusted net tangible book value per share of common stock after this offering		11.34
Dilution per share of common stock to new investors participating in this offering		$ 5.66

If the underwriters exercise in full their option to purchase 2,261,647 additional shares of common stock from us in this offering, our pro forma as adjusted net tangible book value per share after the offering would be $11.61, representing an immediate increase in pro forma as adjusted net tangible book value per share of $3.42 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per

share of approximately $5.39 to new investors purchasing common stock in this offering, based on the initial public offering price $17.00 per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2025, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration and the average price per share (1) paid by existing stockholders and (2) to be paid by new investors participating in this offering at the initial public offering price of $17.00 per share before deducting the underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT (in thousands)	PERCENT	
Existing stockholders	19,999,437	57.0 %	$ 263,387	50.7 %	$ 13.17
New investors	15,077,647	43.0 %	256,320	49.3 %	17.00
Total	35,077,084	100.0 %	$ 519,707	100.0 %	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase 2,261,647 additional shares is exercised in full, the number of shares of common stock held by existing stockholders would be reduced to 53.6% of the total number of shares of common stock to be outstanding upon consummation of this offering, and the number of shares of common stock held by new investors participating in this offering will be increased to 46.4% of the total number of shares of our common stock to be outstanding upon consummation of the offering.

The share information presented in the tables and discussions above as of September 30, 2025 excludes:

- 739,331 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2025, with a weighted average exercise price of $12.19 per share;
- 2,974,637 shares of our common stock issuable upon the exercise of stock options granted after September 30, 2025, with a weighted average exercise price of $12.77 per share;
- 685,080 shares of our common stock reserved for issuance under the 2021 Plan, as of December 31, 2025, which ceased to be available for issuance at the time the 2026 Plan became effective and were added to, and became available for issuance under, the 2026 Plan;
- a number of shares of our common stock equal to 10.8% of shares issued and outstanding as of immediately following the consummation of this offering (not to exceed 4,518,426 shares) reserved for issuance under the 2026 Plan, which became effective in connection with this offering (which includes up to 1,768,254, shares of common stock underlying stock option awards to be granted to certain of our directors, executive officers and other employees under the 2026 Plan upon the pricing of this offering with an exercise price per share equal to the initial public offering price per share), as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder; and
- 316,668 shares of our common stock reserved for issuance under the ESPP, which became effective in connection with this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance thereunder.

New investors participating in this offering will experience further dilution when any new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities for lower consideration per share than in this offering in the future. In addition, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Financial Data" section of this prospectus and our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a dermatologist-founded, late clinical-stage biopharmaceutical company focused on developing innovative therapeutics to address pervasive treatment challenges in highly prevalent aesthetic and dermatological conditions. Our initial focus is developing better treatments for PHL, a condition affecting approximately 50 million men and 30 million women in the United States. Current PHL treatment options are limited and therefore are consistently plagued with high rates of treatment failure, patient dissatisfaction and treatment discontinuation. Patients and healthcare providers routinely identify the following shortcomings with currently available treatment options:

- Slow onset of hair growth
- Inconsistent results
- Insufficient density of hair growth for patient satisfaction
- Tolerability issues related to hormonal, mood and cardiac side effects
- Inconvenient administration
- Limited FDA-approved treatment options, and no FDA-approved oral options for women

We are developing VDPHL01 as an oral, non-hormonal treatment for men and women with PHL to reduce the barriers to wide adoption of chronic hair loss therapy and potentially transform PHL treatment. We believe that a marketing application could initially seek approval in male patients, followed by an sNDA for female patients, or could alternatively pursue approval in both male and female patients simultaneously depending on the timing of the completion of our clinical trials.

VDPHL01 is an oral, ER formulation of minoxidil, a proven hair growth agent, designed to maximize minoxidil's impact on hair restoration while minimizing the risk of cardiac activity. Though IR oral minoxidil was originally designed to treat resistant hypertension, it has been used off label as a treatment for PHL after hair growth was observed as a side effect. However, IR oral minoxidil's release profile was not designed for hair growth as its short duration of circulation allows less time for follicular saturation and must be used at lower doses to reduce the likelihood of reaching off target cardiac stimulative levels. VDPHL01 builds on minoxidil's validated hair growth biology via a novel and proprietary ER formulation designed to maximize the total plasma concentrations of minoxidil known to grow hair without inducing changes in cardiac activity. We believe that our efforts mark the first attempt to bring an ER formulation of minoxidil to patients with these optimized PK and PD qualities that raise the ceiling of hair growth.

In the first half of 2024 we completed several PK studies of VDPHL01 and then initiated our Phase 2 trial evaluating VDPHL01 in male patients and female patients with mild-to-moderate PHL. In the fourth quarter of 2024 we started dosing patients in our first Phase 2/3 trial evaluating VDPHL01 in male patients with mild-to-moderate PHL subsequent to the first closing of our Series B Convertible Preferred Stock, or Series B Preferred Stock, financing. The following milestones have been achieved to date through 2025:

- the initiation of a confirmatory registration-directed Phase 3 trial in male patients with mild-to-moderate PHL and the initiation of a registration-directed Phase 2/3 trial in female patients with mild-to-moderate PHL;

- completion of enrollment in our lead Phase 2/3 trial in male patients with mild-to-moderate PHL initiated in the fourth quarter of 2024;
- announcement of preliminary data from our Phase 2 trial in male patients with PHL who had completed four months of treatment, in which VDPHL01 drove favorable outcomes, which we believe underscores its potential to deliver a convenient, oral treatment that provides visible hair regrowth to the majority of users as early as two months, while maintaining a favorable tolerability profile; and
- the completion of the second funding of Series B Preferred Stock of $8.4 million in the first quarter of 2025, followed by a Series C Preferred Stock financing in the fourth quarter of 2025, from which we received gross proceeds of $151.0 million.

Since our inception we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support our operations. We have never obtained regulatory approval for, or commercialized, a pharmaceutical product. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. To date, we have financed our operations primarily with proceeds from the sales of our redeemable convertible preferred stock.

We have incurred recurring net losses since inception, including net losses of $48.1 million and $20.8 million for the nine months ended September 30, 2025 and 2024, respectively, and net losses of $26.5 million and $16.5 million for the years ended December 31, 2024 and 2023, respectively. We have incurred negative cash flows from operations of $48.0 million and $20.1 million for the nine months ended September 30, 2025 and 2024, respectively, and negative cash flows from operations of $23.7 million and $13.5 million for the years ended December 31, 2024 and 2023, respectively. In addition, as of September 30, 2025, the Company had an accumulated deficit of $97.4 million. Substantially all of our operating losses have resulted from expenses incurred in connection with development of VDPHL01 and our other product candidates and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, as we advance VDPHL01 or any of our other current and future product candidates through clinical development, seek regulatory approval for such product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, conduct pre-commercial launch activities and infrastructure building, and operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities initially in the United States.

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

- continue development of VDPHL01 and our other current product candidates, including preclinical development and conducting clinical trials;
- seek marketing regulatory approvals for VDPHL01 and for any of our other current or any future product candidates that successfully complete clinical trials;
- take steps toward supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- increase marketing in connection with the potential commercialization of VDPHL01, if approved;
- advance additional product candidates through preclinical development and clinical trials;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or acquisitions and conduct development activities, including preclinical studies and clinical trials;
- make royalty, milestone or other payments under any current or future license or collaboration agreements;
- procure the manufacturing of preclinical, clinical and commercial supply of our current or any future product candidates;
- establish agreements with contract research organizations and CMOs;

- attract, hire and retain additional qualified clinical, scientific, operations and management personnel;
- seek to continue to develop, maintain and defend our intellectual property portfolio, including against third-party interference, infringement and other intellectual property claims, if any;
- add and maintain operational, financial and information management systems;
- attempt to address any competing therapies and market developments;
- experience delays in our preclinical studies, clinical trials or regulatory approval for our current or any future product candidates, including with respect to failed studies, inconclusive results, safety issues or other regulatory challenges; and
- incur additional costs associated with being a public company, including audit, legal, regulatory and tax-related services associated with maintaining compliance with an exchange listing and the SEC requirements, director and officer insurance premiums and investor relations costs.

We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability. Even if we succeed in commercializing VDPHL01 or one or more of our other product candidates, we will incur substantial expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays and other events that adversely affect our business. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

At this time, due to the inherently unpredictable nature of clinical development we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if at all. For the same reasons, we are also unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or sustain profitability on a continuing basis, then we may be unable to raise additional capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research and development activities, these can include drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under agreements with third parties, such as CROs, as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including fees paid to CMOs;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in research and development efforts;
- costs of outside consultants supporting research and development;
- the costs of acquiring and developing clinical trial materials;
- clinical trial recruitment costs;

- expenses to acquire technologies, such as intellectual property, to be used in research and development including in-process research and development, that has no alternative future use at the time of asset acquisitions;
- costs related to compliance with regulatory requirements; and
- other indirect costs.

Costs for certain activities are recognized based on an evaluation of the progress to completion of each specific contract using information and data provided to us by our vendors and analyzing the progress of our research studies or other services performed. Significant judgments and estimates are made in determining the expenses incurred balances at the end of any reporting period.

Our direct, external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. We track these external research and development costs on a program-by-program basis.

We do not allocate employee costs, costs associated with our development efforts and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and development activities as well as for managing our process development, manufacturing and clinical development activities.

The successful development of our product candidates is highly uncertain. We plan to substantially increase our research and development expenses in the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly with our ongoing clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

Any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates.

In addition, clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessment as to each product candidate's commercial potential. However, we may never succeed in achieving regulatory approval for any of

our product candidates and may obtain unexpected results from our clinical trials. As a result, we may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

We anticipate that our research and development expenses will continue to increase as we continue our current research programs, initiate new research programs, continue our preclinical development of product candidates and conduct future clinical trials for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation for our personnel in executive, legal, finance and accounting, and other administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters, professional fees paid for accounting, auditing, tax and consulting services, insurance costs, travel expenses and direct facility costs not otherwise included in research and development expenses.

We anticipate that our general and administrative expenses will increase as we increase headcount to provide additional administrative support to our research and development activities. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs, as well as investor and public relations expenses associated with operating as a public company. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of that product candidate.

Total Other Income, Net

Total other income, net, includes interest income earned on cash and cash equivalents, interest expense incurred on convertible and promissory notes payable, tax credits and other income and expense items.

Results of Operations

Comparison of the Nine months ended September 30, 2025 and 2024

The following table summarizes our results of operations:

	Nine Months Ended September 30,		
(in thousands)	**2025**	**2024**	**CHANGE**
Operating Expenses:			
Research and development	$ 43,873	$ 18,333	$ 25,540
General and administrative	5,463	2,474	2,989
Total operating expenses	49,336	20,807	28,529
Loss from operations	(49,336)	(20,807)	(28,529)
Total other income (expense), net	1,188	(21)	1,209
Income tax benefit	—	—	—
Net loss	$ (48,148)	$ (20,828)	$ (27,320)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented:

(in thousands)	Nine Months Ended September 30, 2025	2024	CHANGE
VDPHL01	$ 39,458	$ 11,395	$ 28,063
VDMN	978	3,100	(2,122)
VDMC	22	1,154	(1,132)
VDAA	9	439	(430)
Other program candidates and expenses	48	1,322	(1,274)
Other unallocated research and development costs			
Personnel expenses (including stock-based compensation)	3,012	830	2,182
Other expenses	346	93	253
Total research and development expenses	$ 43,873	$ 18,333	$ 25,540

Research and development expenses were $43.9 million for the nine months ended September 30, 2025, compared to $18.3 million for the nine months ended September 30, 2024. The increase of $25.5 million was primarily due to:

- a $28.1 million increase in costs related to VDPHL01 primarily due to a $22.6 million increase in clinical trial expenses, including investigator fees, pass-through costs, and program management fees resulting from expanded registrational and confirmatory study activity in 2025 compared to the prior period, as well as an additional $4.6 million increase in clinical trial recruitment costs. The remaining increase is related to chemistry, manufacturing and controls activities, including costs associated with GMP manufacturing and clinical materials to support ongoing and planned clinical studies as compared to the prior year; and
- a $2.2 million increase in personnel-related costs, including stock-based compensation expense, primarily due to an increase in research and development related headcount as compared to the same period in the nine months ended September 30, 2024.

These increases were partially offset by:

- a decrease in costs related to VDMN, VDMC, VDAA, and other program candidates of $2.1 million, $1.1 million, $0.4 million and $1.3 million respectively. These decreases were primarily related to decreases in chemistry, manufacturing and controls activities for VDMN and other program candidates, a decrease in clinical trial expenses for VDMN, and decreases in other research and development costs related across these programs.

General and Administrative Expenses

General and administrative expenses were $5.5 million for the nine months ended September 30, 2025, compared to $2.5 million for the nine months ended September 30, 2024. The increase of $3.0 million was primarily due to an increase in payroll and personnel-related costs, including stock-based compensation, primarily as a result of an increase in general and administrative related headcount and other professional fees associated with legal and intellectual property matters, operating activities, commercial readiness and preparations for becoming a public company.

Total Other Income, Net

Total other income, net, was $1.2 million for the nine months ended September 30, 2025, compared to net expense of less than $0.1 million for the nine months ended September 30, 2024. The increase of $1.2 million is primarily attributable to a $0.5 million increase in accretion income on investments, a $0.4 million increase in interest income reflecting higher yields on average cash and investment balances during the period, and a $0.3 million decrease in interest expense resulting from the repayment of convertible notes and promissory notes using proceeds from the Series B Preferred Stock financing in 2024.

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations:

	Year Ended December 31,		
(in thousands)	**2024**	**2023**	**CHANGE**
Operating Expenses:			
Research and development	$ 23,283	$ 14,971	$ 8,312
General and administrative	3,495	2,353	1,142
Total operating expenses	26,778	17,324	9,454
Loss from operations	(26,778)	(17,324)	(9,454)
Total other income, net	290	834	(544)
Income tax benefit	—	—	—
Net loss	$ (26,488)	$ (16,490)	$ (9,998)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented:

	Year Ended December 31,		
(in thousands)	**2024**	**2023**	**CHANGE**
VDPHL01	$ 14,641	$ 2,953	$ 11,688
VDMN	3,747	5,056	(1,309)
VDMC	1,329	3,648	(2,319)
VDAA	402	1,146	(744)
Other program candidates and expenses	1,370	1,036	334
Other unallocated research and development costs			
Personnel expenses (including stock-based compensation)	1,499	1,131	368
Other expenses	295	1	294
Total research and development expenses	$ 23,283	$ 14,971	$ 8,312

Research and development expenses were $23.3 million for the year ended December 31, 2024, compared to $15.0 million for the year ended December 31, 2023. The increase of $8.3 million was primarily due to:

- an $11.7 million increase in costs related to VDPHL01 primarily due a $9.0 million increase in clinical trial expenses, including investigator fees and pass-through costs. Remaining increase related to chemistry,

manufacturing and controls activities, including costs associated with GMP manufacturing and clinical materials to support ongoing and planned clinical studies as compared to the prior year;
- a $0.4 million increase in personnel-related costs, including stock-based compensation expense, primarily due to an increase in research and development related headcount as compared to the same period in the year ended December 31, 2023;

These increases were partially offset by:

- a decrease in costs related to VDMN, VDMC and VDAA of $1.3 million, $2.3 million and $0.7 million respectively. These decreases were primarily related to decreases in chemistry, manufacturing and controls activities for VDMN and VDMC and a decrease in other research and development costs related to VDAA;

General and Administrative Expenses

General and administrative expenses were $3.5 million for the year ended December 31, 2024, compared to $2.4 million for the year ended December 31, 2023. The increase of $1.1 million was primarily due to an increase in payroll and personnel-related costs, including stock-based compensation, primarily as a result of an increase in general and administrative related headcount and other professional fees associated with operating activities and the preparations for becoming a public company.

Total Other Income, Net

Total other income, net, was $0.3 million for the year ended December 31, 2024, compared to $0.8 million for the year ended December 31, 2023. The decrease of $0.5 million is primarily attributable to $0.4 million decrease in interest income, which reflected lower yields on average cash balances during the period, as well as a $0.5 million increase in interest expense related to convertible notes and promissory notes paid off with proceeds from the Series B Preferred Stock financing. These items were partially offset by a $0.4 million increase in other income resulting from the recognition of certain tax credits that we elected to exchange for cash.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through equity financings, and through September 30, 2025, had received proceeds of approximately $112.2 million, net of issuance costs of $0.7 million, from the sale of our Series A and B redeemable convertible preferred stock. As of September 30, 2025, we had $15.1 million of cash, cash equivalents and marketable securities.

Uses of Liquidity

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our manufacturing, licensing and lease obligations described further below.

Future Funding Requirements

Subsequent to September 30, 2025, we completed a Series C Preferred Stock financing in the fourth quarter of 2025, from which we received gross proceeds of $151.0 million. We expect the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements for more than twelve months from the date of this prospectus. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

We expect to incur significant expenses and operating losses in the foreseeable future as we advance VPHL01 or any of our other current or any future product candidates through clinical development, seek regulatory approval and pursue commercialization of any approved product candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements, both near and long-term, will depend on, and could increase significantly as a result of, many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our clinical trials through all phases of development, including our ongoing clinical trials for VDPHL01 and the development of our other current and any future product candidates;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the identification, assessment, acquisition and/or development of additional research programs and additional product candidates;
- the timing of and successful patient enrollment in, and the initiation and completion of, clinical trials;
- the outcome, timing and costs of meeting regulatory requirements established by the FDA or any comparable foreign regulatory authority, including any additional clinical trials required by the FDA or any comparable foreign regulatory authority;
- the willingness of the FDA or any comparable foreign regulatory authorities to accept our clinical trial designs, as well as data from our completed and planned preclinical studies and clinical trials, as the basis for review and approval of VDPHL01 and any other product candidates;
- the progress, timing and costs of the development by us or third parties of companion diagnostics, if required, for VDPHL01 or any other product candidates, including design, manufacturing and regulatory approval;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- development and timely delivery of commercial-grade drug formulations that can be used in our planned clinical trials and for commercialization;
- the cost of filing, prosecuting and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us;
- the costs associated with potential clinical trial liability or product liability claims, including the costs associated with obtaining insurance against such claims and with defending against such claims;
- the effect of competing technological and market developments;
- our ability to hire additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, chemistry, manufacturing and controls, quality and commercial personnel;
- our ability to develop and commercialize products that are considered by physicians, patients and payors as medically and/or financially differentiated as compared to competitive products;
- our ability to establish arrangements with third-party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the cost of making royalty, milestone or other payments under any future in-license agreements;
- the extent to which we in-license or acquire additional product candidates or technologies;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if approved;
- the initiation, progress and timing of our commercialization of VDPHL01, if approved, or any other product candidates;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors, if applicable, and adequate market share and revenue;
- maintaining a continued acceptable safety profile of the product candidates following approval; and
- the costs of operating as a public company.

A change in the outcome of any of these, or other variables with respect to the development of any of our product candidates, could significantly change the costs and timing associated with the development of that product candidate. We will need to continue to rely on additional financing to achieve our business objectives.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

Until such time, if ever, as we generate significant revenue from product sales, we expect to finance our operations through the sale of equity, debt financings, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or other sources. We currently have no credit facility or committed sources of capital. If we raise additional funds through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Nine Months Ended September 30,		Year Ended December 31,	
(in thousands)	**2025**	**2024**	**2024**	**2023**
Net cash used in operating activities	$ (47,974)	$ (20,056)	$ (23,688)	$ (13,510)
Net cash used in investing activities	(9,080)	—	—	—
Net cash provided by financing activities	9,630	10,170	60,476	13,895
Net increase in cash and cash equivalents	$ (47,424)	$ (9,886)	$ 36,788	$ 385

Operating Activities

Net cash used in operating activities was $48.0 million for the nine months ended September 30, 2025 as compared to $20.1 million for the nine months ended September 30, 2024. The increase in cash used in operations was primarily due to the increase of $25.5 million in research and development expense for the advancement of our lead asset VDPHL01 and $3.0 million in general and administrative expenses as compared to the same period the prior year. The increase in research and development spending reflects greater clinical trial activity, manufacturing scale-up, and personnel costs related to support the advancement of VDPHL01. The increase in general and administrative expenses was driven by higher external professional fees, including legal and intellectual property matters, accounting, and consulting costs to support our corporate activities including commercial readiness and preparations for becoming a public company.

Net cash used in operating activities was $23.7 million for the year ended December 31, 2024 as compared to $13.5 million for the year ended December 31, 2023. The increase in cash used in operations was primarily due to the increase of $8.3 million in research and development expense for the advancement of our lead asset VDPHL01 and $1.1 million in general and administrative expenses as compared to the same period the prior year. The increase in research and development spending reflects greater clinical trial activity, manufacturing scale-up, and personnel-related costs to support the advancement of VDPHL01. The increase in general and administrative expenses was driven by higher external professional fees, including legal, accounting, and consulting costs to support our corporate activities.

Investing Activities

Net cash used in investing activities was $9.1 million for the nine months ended September 30, 2025. The increase was primarily driven by the purchase of investment securities partially offset by maturities of short-term investments during the period.

Financing Activities

Net cash provided by financing activities was $9.6 million for the nine months ended September 30, 2025 as compared to $10.2 million for the nine months ended September 30, 2024. The decrease of $0.6 million was primarily attributable to lower proceeds from financing transactions driven primarily from the issuance of $8.4 million of preferred stock in connection with the Series B financing in 2025, compared to the issuance of $10.2 million of convertible notes in the prior period, partially offset by an increase of $1.1 million in pre-funded equity financing as compared to the prior period.

Net cash provided by financing activities was $60.5 million for the year ended December 31, 2024 as compared to $13.9 million for the year ended December 31, 2023. The increase was primarily attributable to higher proceeds from financing transactions, reflecting a net increase of $46.6 million from the issuance of preferred stock and convertible notes in connection with the Series B financing in 2024, compared to the proceeds from the issuance of preferred stock related to the Series A financing in the prior year.

Contractual Obligations

In February 2025, we entered into an office lease agreement in New Haven, Connecticut. We currently lease a total of 1,202 square feet, and the term of the lease extends to February 2027. We have the option to extend the lease for an additional two years after initial expiration. We believe our existing facilities are sufficient for our current needs. To meet the future needs of our business, we expect to lease additional or alternate office space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms. Remaining lease payments from September 30, 2025 through the end of the lease term are less than $0.1 million.

Purchase and Other Obligations

We enter contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments that may be due upon cancellation consist of payments for services provided or expenses incurred. As of September 30, 2025 and 2024 there were no amounts accrued related to termination charges.

Critical Accounting Policies and 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 and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: valuation of prepaid and accrued expenses related to certain research and development contracts, and stock-based compensation expense which includes estimating the fair value of its common stock.

Estimates related to research and development contract accruals and prepayments are reasonably likely to change in future periods as project scopes, timelines, and vendor billing patterns evolve. Similarly, estimates of stock-based compensation expense are sensitive to changes in assumptions such as the fair value of common stock, expected volatility, and the estimated term of awards. Management will continue to evaluate these estimates each reporting period and adjust them as additional information becomes available.

While our significant accounting policies are described in more detail in Note 2 "Summary of Significant Accounting Policies" to our audited consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

We estimate and expense research and development costs as incurred, which involves determining the expenses for personnel, stock-based compensation, external services, clinical trials, and other contracted activities. This estimation process requires reviewing open contracts, purchase orders, and communicating with personnel and vendors to assess the level of services performed, particularly when an invoice hasn't been received. We base our estimates on the progress to completion of each contract, using data from vendors and clinical sites. Depending on the timing of payments, we recognize either prepaid or accrued expenses, which are management's estimates based on work performed, milestones achieved, and experience with similar contracts. We monitor these factors and adjust the prepaid or accrual balances if the actual timing or effort differs from our initial estimate, including for non-refundable advance payments. While we expect our estimates to be materially accurate, any difference between the estimated and actual status and timing of services performed could cause research and development expenses to be overstated or understated in a given reporting period.

Stock-Based Compensation Expense

We measure stock-based compensation using the grant date fair value of the awards and recognize the expense on a straight-line basis over the requisite service period, which is typically the vesting period, classifying the expense according to the function to which the services relate. Forfeitures are recognized as they occur. Given the absence of a public market for our common stock, the fair value was determined by the Board of Directors, considering independent third-party valuation reports. These reports primarily used an Option Pricing Method (OPM), which treats common and preferred stock as call options on the company's total equity value and applies a discount for lack of marketability to value the common stock. Key inputs for this valuation, particularly the Black-Scholes model, involved significant estimates: expected volatility was based on historical volatility of publicly-traded peer companies; the expected term was estimated at 10 years (the full grant term) due to a lack of sufficient company history; and the risk-free interest rate was based on the U.S. Treasury yield curve. Because we don't expect to pay dividends, the expected dividend yield is zero. These valuations incorporate management's best estimates and significant judgments regarding future operating performance, product development, and the timing of a potential liquidity event; consequently, if different assumptions were used, the resulting expense could be materially different. Following a public offering, the fair value of our common stock will be determined by its quoted market price. Additional information regarding stock-based compensation expense is provided in Note 2 "Summary of Significant Accounting Policies" to our audited consolidated financial statements included elsewhere in this prospectus.

Common Stock Valuations

As there has been no public market for our common stock, the estimated fair value of our common stock has been determined by our Board of Directors after considering valuation reports provided by an independent third-party valuation firm and exercising reasonable judgment and considering numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each stock option grant date. In accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, a third-party valuation firm prepared valuations of our common stock using an OPM. The total equity value can be implied from the OPM, using the preferred stock financing price if transacted around each valuation date.

Given the absence of a public trading market, our Board of Directors, with input from management considered numerous objective and subjective factors to determine the fair value of our common stock. The factors included, but were not limited to:

- the prices at which we sold preferred stock and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development efforts, including the status of clinical development for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones; and
- the likelihood of achieving a liquidity event for the holders of our preferred stock and holders of our common stock, such as an initial public offering, or a sale of our company, given prevailing market conditions.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our Board of Directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Emerging Growth Company and Smaller Reporting Company

As an emerging growth company under the JOBS Act we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to SOX Section 404, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. Therefore, the reported results of operations contained in our consolidated financial statements may not be directly comparable to those of other public companies.

We may remain classified as an emerging growth company until the end of the fiscal year in which the fifth anniversary of this offering occurs, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we will cease to be an emerging growth company as of December 31 of the applicable year. We also will cease to be an emerging growth company if we issue more than $1.0 billion of non-convertible debt over a three-year period. We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act.

We are also a “smaller reporting company” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 “Summary of Significant Accounting Policies” to our audited consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a dermatologist-founded, late clinical-stage biopharmaceutical company focused on developing innovative therapeutics to address pervasive treatment challenges in highly prevalent aesthetic and dermatological conditions. Our initial focus is developing better treatments for PHL, a condition affecting approximately 50 million men and 30 million women in the United States. Current PHL treatment options are limited and therefore are consistently plagued with high rates of treatment failure, patient dissatisfaction and treatment discontinuation. Patients and healthcare providers routinely identify the following shortcomings with currently available treatment options:

- Slow onset of hair growth
- Inconsistent results
- Insufficient density of hair growth for patient satisfaction
- Tolerability issues related to hormonal, mood and cardiac side effects
- Inconvenient administration
- Limited FDA-approved treatment options and no FDA-approved oral options for women

We are developing VDPHL01 as an oral, non-hormonal treatment for men and women with PHL to reduce the barriers to wide adoption of chronic hair loss therapy and potentially transform PHL treatment. We believe that a marketing application could initially seek approval in male patients, followed by an sNDA for female patients, or could alternatively pursue approval in both male and female patients simultaneously depending on the timing of the completion of our clinical trials.

VDPHL01 is an oral, ER formulation of minoxidil, a proven hair growth agent, designed to maximize minoxidil's impact on hair restoration while minimizing the risk of cardiac activity. Though IR oral minoxidil was originally designed to treat resistant hypertension, it has been used off label as a treatment for PHL after hair growth was observed as a side effect. However, IR oral minoxidil's release profile was not designed for hair growth as its short duration of circulation allows less time for follicular saturation and must be used at lower doses to reduce the likelihood of reaching off target cardiac stimulative levels. VDPHL01 builds on minoxidil's validated hair growth biology via a novel and proprietary ER formulation designed to maximize the total plasma concentrations of minoxidil known to grow hair without inducing changes in cardiac activity. We believe that our efforts mark the first attempt to bring an ER formulation of minoxidil to patients with these optimized PK and PD qualities that raise the ceiling of hair growth.

We are currently dosing patients with VDPHL01 in our registration-directed clinical program consisting of three pivotal, multi-center, randomized, double-blind, placebo-controlled clinical trials: two in male patients and one in female patients with PHL. These trials are designed to support our planned submissions to the FDA for regulatory approval across both male and female patient populations through a 505(b)(2) NDA. We have fully enrolled the first of these registration-directed clinical trials, a Phase 2/3 trial evaluating VDPHL01 in 519 male patients with mild-to-moderate PHL. This first trial assesses two dose regimens of VDPHL01 over 52 weeks of treatment. The co-primary endpoints are change in non-vellus hair count per square centimeter and patient self-assessment of hair coverage benefit after 24 weeks from treatment initiation. We anticipate topline data from this clinical trial in the first half of 2026.

We have also initiated our confirmatory registration-directed Phase 3 trial targeting the enrollment of 498 male patients with mild-to-moderate PHL and our registrational-directed Phase 2/3 trial targeting the enrollment of 552 female patients with mild-to-moderate PHL. We expect to report data from this male Phase 3 trial in the second half of 2026. Enrollment in the female Phase 2/3 trial is ongoing and projected time to topline data will be determined as the trial progresses. The clinical trials designated as Phase 2/3 are designed and conducted as registration-directed Phase 3 trials to support the planned marketing application, or NDA, for VDPHL01 for the treatment of PHL. The Phase 2/3 trials include a parallel Phase 2 component intended to further assess proprietary patient-reported outcome, or PRO, measures used as endpoints in all three registration-directed trials.

In a Phase 1 clinical trial, which we refer to as Study QSC300720, we studied VDPHL01 prototypes in doses up to 10 mg against a single reference dose of commercially available 2.5 mg IR oral minoxidil. When comparing the results of VDPHL01 8.5 mg with 2.5 mg IR oral minoxidil in male patients who were administered both dosage forms in this study, we found that VDPHL01 8.5 mg:

- delivered nearly twice the total amount of minoxidil in plasma over 12 hours than the total amount delivered by the 2.5 mg IR oral minoxidil tablet;
- sustained plasma concentrations above minoxidil's hair growth threshold two times longer than a 2.5 mg IR oral minoxidil tablet;
- maintained peak concentrations below the threshold at which signs of cardiac activity are typically observed; and
- was generally well tolerated with no SAEs observed.

As this study was exploratory, no formal sample size calculation was made related to statistical power. The data presented above are reflective of the study's per-protocol primary objective, namely, to evaluate the PK profile and determine the relative bioavailability of VDPHL01 following single oral dosing of VDPHL01 versus the reference IR oral minoxidil formulation in healthy subjects.

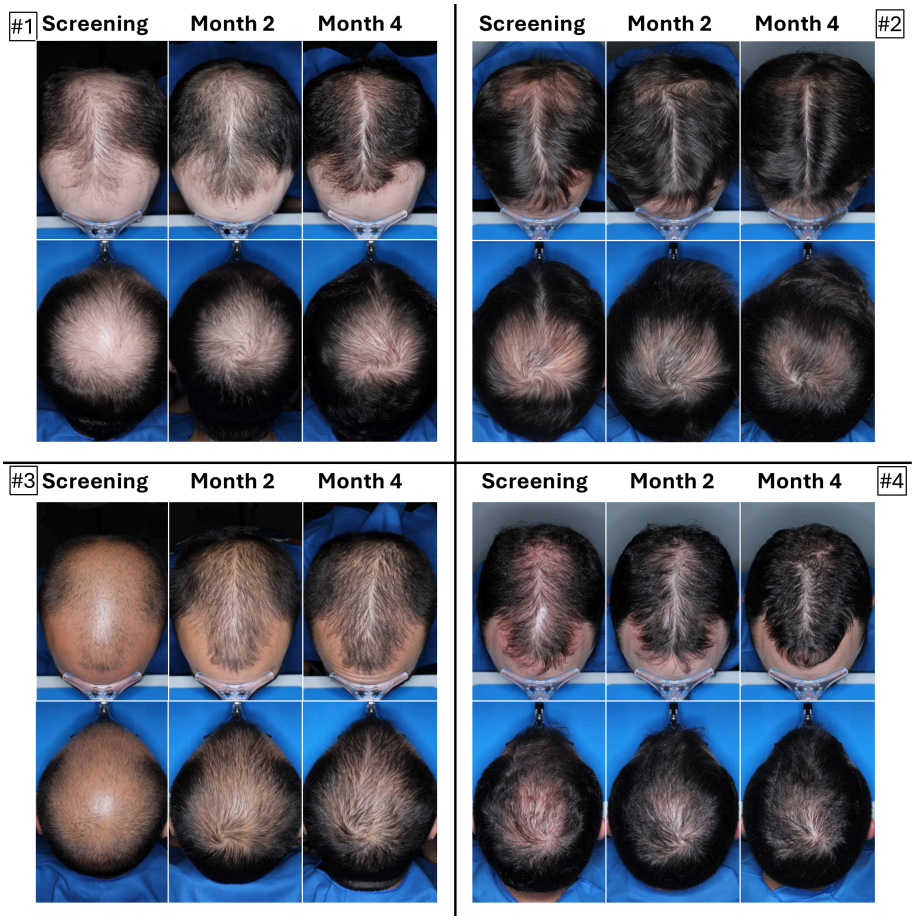
We are currently conducting a Phase 2 clinical trial evaluating VDPHL01 in male patients and female patients with mild-to-moderate PHL. As this trial is exploratory, no formal sample size calculation was made related to statistical power. Therefore, all trial endpoints, including objective hair count measures and subjective patient and investigator assessments, are exploratory and are planned to be reported as descriptive statistics. In October 2025, we announced preliminary data from the male cohort for those who had completed four months of treatment in this trial (n=21; the female cohort, currently with 22 subjects dosing, initiated enrollment in this trial later than males, and similar data is not yet available).

The preliminary data show that VDPHL01 drove favorable outcomes, which we believe underscores its potential to deliver a convenient, oral treatment that provides visible hair regrowth to the majority of users as early as two months, while maintaining a favorable tolerability profile. We believe that the results of this trial support the emerging product profile for VDPHL01 with the following key attributes:

- **Speed:** Visibly noticeable hair growth as early as two months after treatment in a majority of patients based on PRO and an IGA.
- **Consistency:** 90.5% treatment response at four months based on PRO of participants reporting "improved" or "much improved" hair coverage.
- **Intensity:** Average non-vellus (greater than 30 microns) hair count change of 47.3 hairs per cm^2, with double digit absolute non-vellus hair count changes in greater than 90% of patients completing four months of treatment.
- **Safety:** Generally well tolerated, with no treatment-related SAEs, including no cardiac or hormonal-related issues to date.
- **Convenience:** Preference for oral over topical administration supported by third-party research.
- **Marketability:** Potential to be the first oral, non-hormonal FDA-approved therapy for PHL.

The below images are of the four patients, of 20 patients in the cohort as of August 2025, the time at which a blinded image analysis study was conducted. These patients were observed to have the highest average hair growth improvement scores as determined by expert graders using images from our Phase 2 clinical trial in male patients at month four. This blinded, retrospective image assessment study used image files containing before-and-after (in randomized order) scalp photographs from both the vertex and frontal view. These image files were reviewed independently by three U.S. board certified dermatologists who were blinded to treatment group and asked to identify the baseline image before assigning an IGA score for improvement using a 7-point Likert scale, a commonly used tool for assessing change in hair growth ranging from greatly decreased (-3) to greatly increased (+3) with intermediate categories of no change (0), slightly decreased/increased (-1/+1) and moderately decreased/increased (-2/+2). Images for patients from screening, month two and month four are presented in order (highest to lowest) of the average improvement scores at month four. Average IGA improvement scores shown represent average improvement scores as assessed by the blinded expert graders

ranging from +2.7 (patient #4) to +3.0 (patient #1). See "—Our Solution for PHL: VDPHL01—Ongoing Studies—Study 207: Our Phase 2 Open Label Proof of Concept Trial" for the full set of images from the study (images are excluded for patients (n=1) with improvement scores less than or equal to the 5th percentile or greater than or equal to the 95th percentile in both image views at month four).



This blinded, retrospective image assessment study used image files containing before-and-after (in randomized order) scalp photographs of each treatment from both the vertex and frontal view. These image files were reviewed independently by three U.S. board certified dermatologists who were blinded to treatment group and asked to identify the baseline image before assigning an IGA score for improvement using a 7-point Likert scale (–3 to +3), a commonly used tool for assessing hair growth, measuring whether scalp hair growth has "slightly," "moderately," or "greatly" increased or decreased or no change has occurred.

Our Phase 2 trial evaluating VDPHL01 in male patients and female patients with PHL is ongoing, and we have initiated three registration-directed trials evaluating VDPHL01, two in male patients with PHL and one in female patients with PHL. If approved, we believe VDPHL01's commercial potential would be substantial, as we estimate that the current U.S. commercial opportunity for PHL treatments for men and women is valued at approximately $9 billion annually, despite low patient engagement and high levels of dissatisfaction with current options reported. We believe that VDPHL01 could gain a meaningful share of this existing opportunity while also catalyzing substantial growth by offering a previously unavailable, transformative product profile to patients in an area of high unmet need. Our proprietary research indicates that 93% of patients would like to address their PHL yet only 9% are satisfied with their current treatment. Based on the initial product profile we have established for VDPHL01, we believe it could drive significant adoption in this large, motivated but underserved PHL patient population.

In anticipation of a potential NDA submission for VDPHL01 leveraging data from our registration-directed Phase 3 trials, we are developing a comprehensive multi-channel commercialization plan that will integrate patient

identification, physician education, DTC, advertising, social media and telehealth engagement and customer care. This commercialization strategy will be designed to drive patient awareness of VDPHL01's differentiated profile and demand for hair loss treatment. We believe that the success of analog therapies highlights both the unmet need and motivation among patients and reinforces the potential for VDPHL01 to create demand in a cash-pay market, convert OTC patients to prescribed therapies and activate a population of untreated patients. We plan to focus commercial efforts at launch on establishing a dermatology-focused field force and conducting DTC advertising. We believe these commercial pillars will drive significant VDPHL01 adoption, if approved.

We maintain a broad library of patents and patent applications related to the key innovations of VDPHL01, including its method of utilizing an oral route of administration, ER formulation to stimulate hair growth as well as its optimized PK and PD qualities and profile. The earliest expiring patent term is 2043.

Our Pipeline

Our goal is to develop a focused portfolio of aesthetic dermatology product candidates targeting high-prevalence dermatologic conditions, with potential selective development of medical dermatology product candidates. We are advancing our lead product candidate, VDPHL01, in clinical trials as depicted below.

PROGRAM	STUDY	OVERVIEW	PATIENT POPULATION	STATUS	NEAR-TERM MILESTONES
VDPHL01 (ER Oral Minoxidil for Pattern Hair Loss)	**Study 302**	• Phase 2/3 trial evaluating VDPHL01 in males • Includes a parallel in-trial Phase 2 component to further assess PRO measures used as endpoints in the male registration-directed trials	**519 male patients** with mild-to-moderate PHL	*Fully Enrolled*	**6-month topline Phase 2/3 readout anticipated in H1 2026**
	Study 304	• Confirmatory Phase 3 trial in males	**498 male patients** with mild-to-moderate PHL	*Enrollment Ongoing*	**6-month topline Phase 3 readout anticipated in H2 2026**
	Study 306	• Phase 2/3 trial evaluating VDPHL01 in females • Includes a parallel in-trial Phase 2 component to further assess PRO measures used as endpoints in the female registration-directed trial	**552 female patients** with mild-to-moderate PHL	*Enrollment Ongoing*	

Our Team and Investors

Our team comprises a seasoned management team with deep connections in the dermatology physician and patient communities and expertise spanning dermatology, clinical development, regulatory affairs, operations, manufacturing and commercialization. The company is led by dermatologists who are well-regarded within the community, which we believe provides important credibility among physicians and insight into patient needs. Our corporate management team includes industry veterans with significant experience in both entrepreneurial biotechnology and global pharmaceutical companies, and collectively, have authored more than 100 peer-reviewed publications. Our team has extensive late-stage clinical trial experience, having been involved in the successful development and approval of more than forty products. We are further supported by a board of directors comprised of thought-leading dermatologists, biotechnology industry leaders and corporate executives with collective decades of experience.

Since inception, we have raised $263.0 million from a broad syndicate of investors, including several leading investment advisers and life sciences funds, such as Longitude Capital, SR One, Surveyor Capital (a Citadel company), Suvretta Capital and Viking Global. Potential investors should not consider investments made by our existing investors when making a decision to purchase shares in this offering since our existing investors may

have had different risk tolerances and paid less per share than the price at which the shares are being offered in this offering.

Our Competitive Strengths

We believe the following strengths will enable us to achieve our goal of becoming the leader in hair loss treatment:

- ***Potentially transformative late-stage lead product candidate, VDPHL01, innovating on validated science to address the millions of men and women suffering from PHL in the United States.*** PHL represents an attractive commercial opportunity. Existing treatments provide insufficient hair growth and have potential tolerability issues and/or inconvenient administration. To our knowledge, currently there is only one FDA-approved oral treatment (finasteride 1 mg tablet) in male patients and none in female patients. Topical minoxidil is FDA-approved for use in both male patients and female patients, but delivers only modest efficacy, variable response rates and a burdensome application to the scalp that results in 86% of patients discontinuing within a year. We designed VDPHL01 to build upon minoxidil's validated biology for stimulating hair growth to maximize the total amount of minoxidil that can be delivered to follicles over a 12- or 24-hour period without inciting spikes in peak plasma concentrations, or Cmax, of minoxidil known to induce changes in cardiac activity. We are currently in registration-directed trials and we believe VDPHL01 has the potential to be the first oral, non-hormonal FDA-approved therapy for PHL.
- ***Clinical data to date supports a potentially differentiated profile for VDPHL01, with topline data from our initial registration-directed trial anticipated to read out in the first half of 2026.*** We believe the preliminary data reported in October 2025 from our Phase 2 clinical trial in males support VDPHL01's differentiated clinical profile with the following key attributes:
  - ***Speed***: Visibly noticeable hair growth as early as two months after treatment in a majority of patients based on PRO and an IGA.
  - ***Consistency***: 90.5% treatment response at four months based on PRO of participants reporting "improved" or "much improved" hair coverage.
  - ***Intensity***: Average non-vellus (greater than 30 microns) hair count change of 47.3 hairs per cm^2, with double digit absolute non-vellus hair count changes in greater than 90% of patients completing four months of treatment.
  - ***Safety***: Generally well tolerated, with no treatment-related SAEs, including cardiac or hormonal-related issues to date.
  - ***Convenience***: Preference for oral over topical administration supported by third-party research.
  - ***Marketability***: Potential to be the first oral, non-hormonal FDA-approved therapy for PHL.
- ***Dermatology-rooted leadership with deep understanding of needs of PHL patients and physicians.*** Our founding dermatologists have direct experience with PHL patients, the impact of the disease and the lack of suitable treatment options, all of which inform our efforts to bring a novel solution to patients. With this base of first-hand knowledge, we have strategically built our network and connectivity with the major PHL stakeholders and opinion leaders, that has enhanced our deep understanding of approaches and challenges to treatment today and areas of unmet patient needs. These insights coupled with our own experiences as dermatologists benefit both our product development and commercialization planning as we strive to bring a potential solution to the millions of men and women suffering from PHL.
- ***Comprehensive commercialization strategy to educate and engage physicians and patients***. Our commercial strategy will be designed to establish VDPHL01, if approved, as the product of choice for the treatment of PHL. We are developing a comprehensive multi-channel commercialization plan that will integrate patient identification, physician education, DTC, advertising, social media and telehealth engagement and customer care. This commercialization strategy will be designed to drive patient awareness of VDPHL01's differentiated profile and demand for hair loss treatment. We believe that success of analog therapies highlights both the unmet need and motivation among patients and reinforces the potential for VDPHL01 to create demand in a cash-pay market, convert OTC patients to prescribed therapies and activate a population of untreated patients. We plan to focus commercial efforts at launch on establishing a dermatology-focused field force and conducting DTC advertising. We believe these commercial pillars will drive significant VDPHL01 adoption, if approved.

- ***Robust intellectual property portfolio designed to protect the key innovations that drive VDPHL01's therapeutic differentiation.*** We maintain a broad library of patents and patent applications related to the key innovations of VDPHL01, including its method of utilizing an oral route of administration, ER formulation to stimulate hair growth as well as its optimized PK and PD qualities and profile. We believe each of these elements contributes to a potentially differentiated therapeutic profile that patients may find compelling, if VDPHL01 is approved. This strategy has elements that have been successfully utilized to protect other pharmaceutical products approved under the 505(b)2 NDA pathway.

Our Strategy

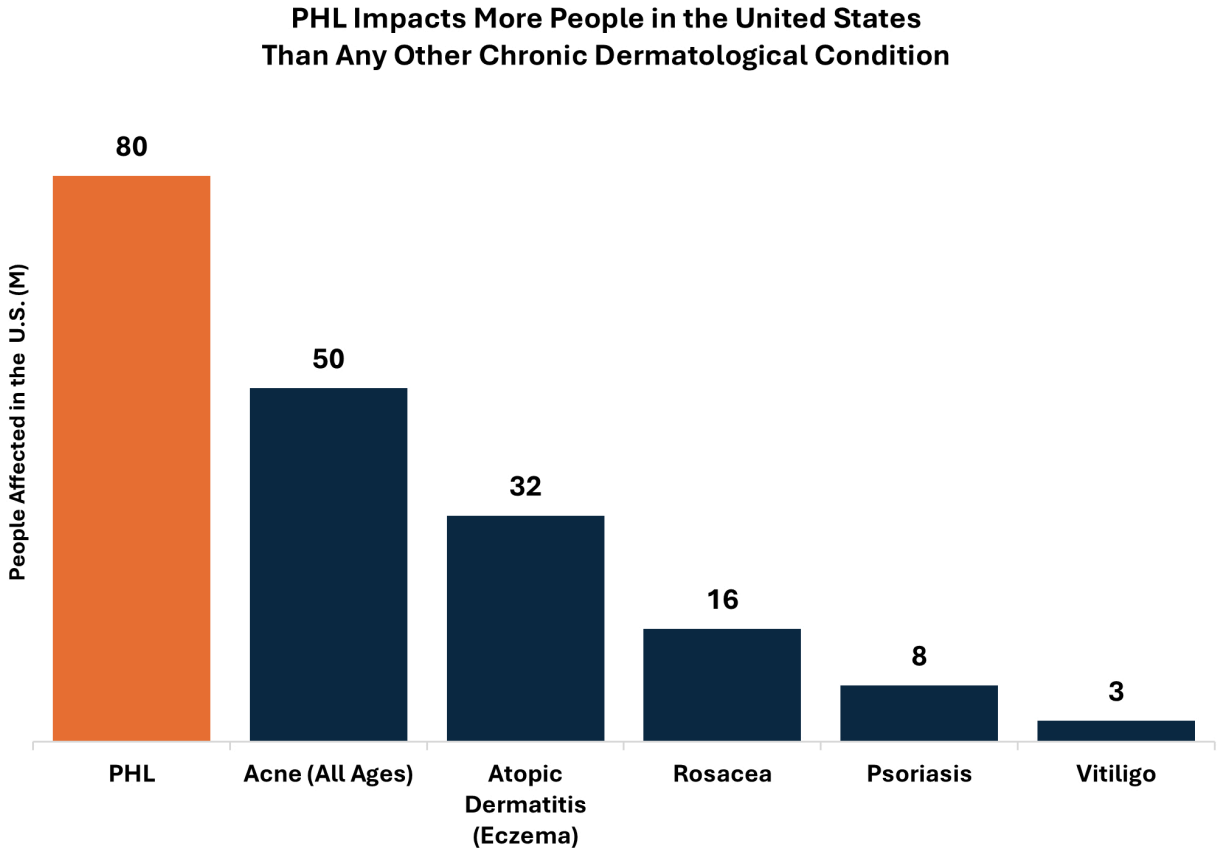
Our goal is to develop a leading aesthetics- and dermatology-focused biopharmaceutical company that advances therapies to address significant unmet needs for large, underserved patient populations. In order to achieve this goal, we are currently advancing our lead candidate, VDPHL01, for the treatment of PHL. Our strategy involves the following key elements:

- ***Efficiently develop VDPHL01 through registration-directed trials to be the leading treatment of PHL for both men and women.*** We believe that VDPHL01 has the potential to transform the treatment of PHL because of its encouraging preliminary Phase 2 clinical results with respect to fast, consistent and intense hair growth and its favorable tolerability profile as observed in our clinical trials to date. We are currently advancing VDPHL01 through late-stage clinical development in our registration-directed Phase 3 program consisting of three clinical trials: two in male patients and one in female patients with PHL. If approved, VDPHL01 would be the first FDA-approved oral minoxidil product for the treatment of PHL, the first FDA-approved oral product for the treatment of PHL in female patients, and we believe VDPHL01 would be the only FDA-approved branded product for the treatment of PHL that would be actively marketed in the United States at the anticipated time of product launch. We believe an FDA-approved ER oral minoxidil product for hair loss will drive broader prescriber adoption, particularly among those who currently prescribe infrequently or have never prescribed IR oral minoxidil for PHL. Furthermore, we believe that the ability to actively promote an approved product has the potential to enable widespread physician and patient awareness and adoption of VDPHL01.
- ***Build a sales and marketing organization focused on prescribers and dedicated to increasing patient awareness and activation.*** We are developing a targeted commercial infrastructure designed to educate dermatologists and patients about VDPHL01's differentiated clinical profile to maximize adoption upon potential approval. Our plan is to target based on detailed patient and prescriber segmentation to focus on those most likely to adopt VDPHL01. We will seek to raise awareness of VDPHL01 via expert voice and advertising and generate excitement and drive activation of patients to proactively seek treatment.
- ***Position for early and wide adoption through the cash-pay model.*** We plan to sell VDPHL01 directly to patients through the cash-pay model, which bypasses the pharmacy benefit managers and eliminates the inconvenience of dealing with insurance companies. Multiple analogs in PHL and other indications have demonstrated patient willingness to pay. We believe this cash pay model will facilitate product access and enable VDPHL01, if approved, to become widely available to patients.
- ***Deliver and commercialize VDPHL01, if approved, as the first FDA-approved oral treatment for female PHL.*** Women represent nearly 40% of PHL patients in the United States and experience a disproportionately higher psychological burden from the condition. Women represent approximately 85% of the U.S. aesthetics market and account for the majority of hair supplement purchases. If VDPHL01 is approved as the first oral therapy for women, we believe it could be especially well-received among the approximately 30 million female PHL patients in the United States.
- ***Evaluate strategic collaboration to maximize the value of our product candidates and deliver meaningful benefits to patients.*** Our goal is to be a premier aesthetic dermatology company and to maximize the number of patients who benefit from our product candidates. We retain exclusive worldwide rights to all of our product candidates, including VDPHL01. We aim to establish VDPHL01, if approved, as the product of choice for men and women experiencing PHL. We plan to establish partnerships with physicians and tele-dermatologists, helping them identify potential patients for VDPHL01, if approved, to accelerate consultation and prescription. We may selectively consider strategic collaboration opportunities to expand the reach and maximize the value of VDPHL01.
- ***Identify additional solutions to pervasive unmet needs in dermatology.*** We aim to utilize our deep experience in treating patients as practicing dermatologists to identify additional opportunities that could potentially

create paradigm shifts in aesthetic or potentially medical dermatology. We intend to focus on identifying innovative therapeutics that target highly prevalent and bothersome skin conditions. We also plan to continue to explore opportunities to internally develop or in-license assets to address unmet medical needs in dermatology.

PHL: The Largest Unmet Need in Aesthetic Dermatology

PHL is the largest unmet need in aesthetic dermatology. A genetically predetermined, progressive disorder, PHL impacts approximately 50 million men and 30 million women in the United States alone. For men, approximately two-thirds will experience some degree of noticeable hair loss by age 35, and by age 50, 85% will have experienced significant thinning. Approximately 40% of women will experience PHL by age 50. PHL demonstrates a lifetime prevalence of nearly 50%, significantly higher than psoriasis (2–3% of individuals) or atopic dermatitis (approximately 10% of adults). Approximately two times as many people in the United States actively treat their PHL each year than suffer from psoriasis. As demonstrated in the graphic below, PHL impacts more Americans than any other chronic dermatological condition, according to the American Academy of Dermatology:



The detrimental effect of PHL on quality of life rivals that of other skin diseases with obvious presentation, such as alopecia areata, or AA, or acne vulgaris. Hair loss negatively impacts the self-image and self-confidence of the affected individual and alters social behavior, causing health-related impairments in quality of life. A study investigating the detrimental psychosocial effects of PHL found that hair loss can increase negative socioemotional events, such as looking older or feeling less attractive, having lower self-esteem and decreased life satisfaction compared with the general population. Although PHL is more commonly associated with men, psychological studies of male and female PHL patients consistently reported that the negative impacts of the condition are felt more acutely by women, who remain an underserved community with no FDA–approved oral treatment options. The impact on the female PHL population is further demonstrated by women's willingness to

treat with topical minoxidil at higher rates than men, despite the inconvenience of topical application. Despite its large prevalence and associated quality of life impairments, the treatment landscape for PHL has experienced a lack of innovation and has remained fragmented, mostly dominated by products that have either limited efficacy, safety concerns, undesired topical administration or are costly and invasive surgical options.

Limitations of the Current PHL Treatment Landscape

While there are therapeutic as well as procedural and supplement-based treatments, outcomes for PHL patients continue to be very poor. Collectively, these options, whether used as a monotherapy or in combination, offer limited benefit, can be costly or burdensome and, in some cases, expose patients to serious, potentially life-threatening side effects. These incomplete therapeutic profiles are the primary reason that, despite the expressed desire of the vast majority of patients to address their PHL, only about 20% of PHL patients are actively engaged in treatment and only about 9% of those engaged are satisfied with their treatment outcomes, based on a proprietary commercial survey of 410 hair loss patients. Despite the low overall satisfaction with the outcomes offered by these treatments, patient willingness to pay remains high, often including significant upfront or recurring costs ranging from $700 up to $12,000 depending on the treatment. Current treatments for PHL can be categorized as follows:

- ***Therapeutics***
  - FDA-approved: oral finasteride (prescription, male patients only) and topical minoxidil (OTC).
  - Off-label: drugs that were FDA-approved for other indications and are used “off-label” for hair growth, such as IR oral minoxidil.
- ***Procedures and Other***
  - FDA-cleared laser-based procedures: LLLT and fractional laser non-ablative therapy.
  - Surgical procedures: platelet rich plasma therapy, or PRP, and hair transplant surgery.
  - Various non-FDA-approved, non-prescription options: such as “nutraceutical” supplements and shampoos.

Finasteride

Finasteride, sold under the brand name Propecia, is one of only two FDA-approved products for the treatment of PHL in men. The drug is an oral 5 alpha reductase inhibitor anti-androgenic that addresses the hormonally driven elements of PHL by decreasing the production of DHT and reducing the conversion of other forms of male hormones into DHT. We believe finasteride has several key limitations that have impacted adoption:

- ***Tolerability issues associated with hormonal AEs:*** Due to its anti-androgenic impact, finasteride is associated with multiple reproductive, psychological and hormonal side effects. Finasteride’s original warning label includes references to adverse reactions of decreased libido, erectile dysfunction and ejaculation disorder. In a 2012 label update, a warning for potential increased risk of high-grade prostate cancer was added as were notations of incidences of depression and gynecomastia. In 2022, the FDA updated the finasteride label to include reports of suicidality and suicidal behavior, and, in 2025, the European Medicine Agency confirmed that suicidal ideation is a potential side effect of treatment with finasteride. In 2025, the FDA also provided guidance recognizing potential irreversibility of certain finasteride-related AEs.
- ***Lack of female approval:*** Finasteride is not approved for the treatment of female PHL and studies of its efficacy in treating female PHL have been limited. Elevated DHT levels — a primary driver of PHL in men — play a less significant role in women, limiting the effectiveness of hormonal treatments such as finasteride.
- ***Modest hair growth benefit:*** In two pivotal trials of finasteride in male PHL, patients treated with finasteride achieved the following hair growth results following twelve months of treatment:
  - ***Non-vellus hair count:*** Growth of 16.9 hairs per cm^2 (86 hairs) at twelve months from baseline.

- ***PRO:*** Only 39% of finasteride-treated patients were satisfied with the overall appearance of their hair vs. 22% treated with placebo.
- ***Expert Grading:*** Trial investigators rated 65% of men treated with finasteride as having increased hair growth compared with 37% in the placebo group. Amongst the treatment group, however, only 18% were judged to have achieved more than slight improvement.

OTC Supplements

OTC supplements for PHL are widely available and utilized by many patients. As dietary supplements, these products are subject to far fewer requirements for transparency regarding safety, efficacy and composition as compared to FDA-approved treatments. Consequently, advertised results for supplements typically have not been validated through large, independent, peer-reviewed clinical trials.

The most widely used of these non-FDA-approved supplements, Nutrafol, is an oral nutraceutical supplement composed of phytoactive ingredients, vitamins and minerals that is used by 1.5 million people at an estimated average annual cost of $700 to $1,000. Nutrafol's small, manufacturer-sponsored studies are not required to be conducted pursuant to FDA review and oversight and have not, to date, been independently confirmed or reproduced.

Procedures

Procedural interventions for PHL include LLLT, fractional non-ablative laser therapy, PRP, injections and hair transplant surgery. While these approaches have expanded the treatment landscape for PHL patients, they remain constrained by limited efficacy, considerable invasiveness, high cost and high patient burden.

LLLT devices, which are FDA-cleared, use low-intensity light to stimulate hair follicles and promote regrowth. Although non-invasive, LLLT typically demonstrates modest clinical benefit and requires prolonged, time-intensive treatment regimens that impedes adherence. These devices also carry high upfront costs and are rarely reimbursed by insurance, limiting their practical utility.

Fractional non ablative laser therapy aims to induce controlled microthermal injury to the scalp to stimulate new hair growth. While also FDA-cleared, the clinical evidence supporting its benefit remains limited to small, often non controlled studies. The procedure can cause discomfort, erythema and post treatment irritation, further restricting adoption outside of cosmetic clinics.

PRP therapy, in which autologous plasma enriched with platelets and growth factors is injected into the scalp, has shown outcomes inferior to topical minoxidil and oral finasteride as monotherapy with mean hair count increase of approximately 10.4 per cm^2 after 6 months of treatment. However, PRP is not FDA-approved for hair loss, requires multiple treatment sessions and can cost several thousand dollars per year, with no insurance coverage. Clinical response is also highly variable, dependent on preparation technique and operator experience.

Hair transplantation, such as follicular unit extraction or follicular unit transplantation, is a procedure that offers permanent redistribution of hair follicles from a donor site at the back of the head to recipient sites at the front or vertex of the scalp. Despite technological advances, these surgeries remain invasive, costly (typically $8,000–$12,000 per procedure) and associated with post operative discomfort, potential scarring and downtime. Importantly, transplanted follicles and native hair both require adjunctive pharmacologic therapy before and after surgery to optimize graft survival and minimize ongoing hair loss. Based on utilization of topical minoxidil-based products in the pre- and post-transplant settings, we believe that, if approved, VDPHL01 could potentially capture a portion of both the pre- and post-transplant adjunctive populations.

Collectively, these procedural modalities offer limited or temporary benefit while often imposing high economic, time and recovery burdens

Minoxidil-based PHL Treatments

Minoxidil is a drug that, following conversion to its active metabolite minoxidil sulfate by the sulfotransferase enzymes, SULT1A1 or SULT2A1, acts as a peripheral vasodilator by opening potassium channels on smooth muscle, causing membrane hyperpolarization to ultimately reduce vascular resistance. This potent vasodilation

drives significant reductions in both systolic and diastolic blood pressure, which led to minoxidil's initial approval in 1979 for the treatment of resistant hypertension under the brand name Loniten. During its use for this indication in the 1980s, reports of hair growth among hypertensive patients emerged, sparking interest in its potential as a treatment for hair loss, consequently supporting eventual FDA approval as a topical solution. Oral formulations for hair loss, however, were not pursued due to concerns regarding potential adverse effects.

Minoxidil Topical Solution

Topical minoxidil, marketed as Rogaine, was first approved by the FDA in 1988 for men as a 2% prescription solution and in 1991 for women at the same concentration. These approvals were followed by subsequent clearance for nonprescription OTC use for both genders at either 2% or 5% concentrations. Despite its widespread availability and long-standing use, topical minoxidil has several limitations:

- ***Modest efficacy:*** Rogaine 5% Foam was cleared for female patients based on results showing hair count increase at week 24 of 13.4 hairs per cm^2 and achieved hair growth totals in male patients of 18.6 hairs per cm^2 at 48 weeks in clinical studies. Across multiple clinical trials, topical minoxidil's profile has remained consistent in both magnitude and speed of hair growth simulation, with 5% topical formulation consistently generating superior results to 2% topical formulation in head-to-head studies.
- ***Variable response:*** Self-administered and applied directly to the scalp, minoxidil is absorbed into hair follicles and converted to its active metabolite by SULT1A1. Clinical studies show that hair growth response to topical minoxidil correlates with follicular SULT1A1 expression, with up to 60% of patients potentially responding poorly to topical minoxidil therapy due to low baseline levels of SULT1A1 activity.
- ***Burdensome method of administration:*** For optimal results, minoxidil must be applied at least once daily to a dry scalp, with showering avoided for four hours post-application. Application can leave residue on the hair that can impact cosmetics and styling. This regimen is time-consuming, often leading to poor adherence and inconsistent drug exposure, which can diminish treatment results.

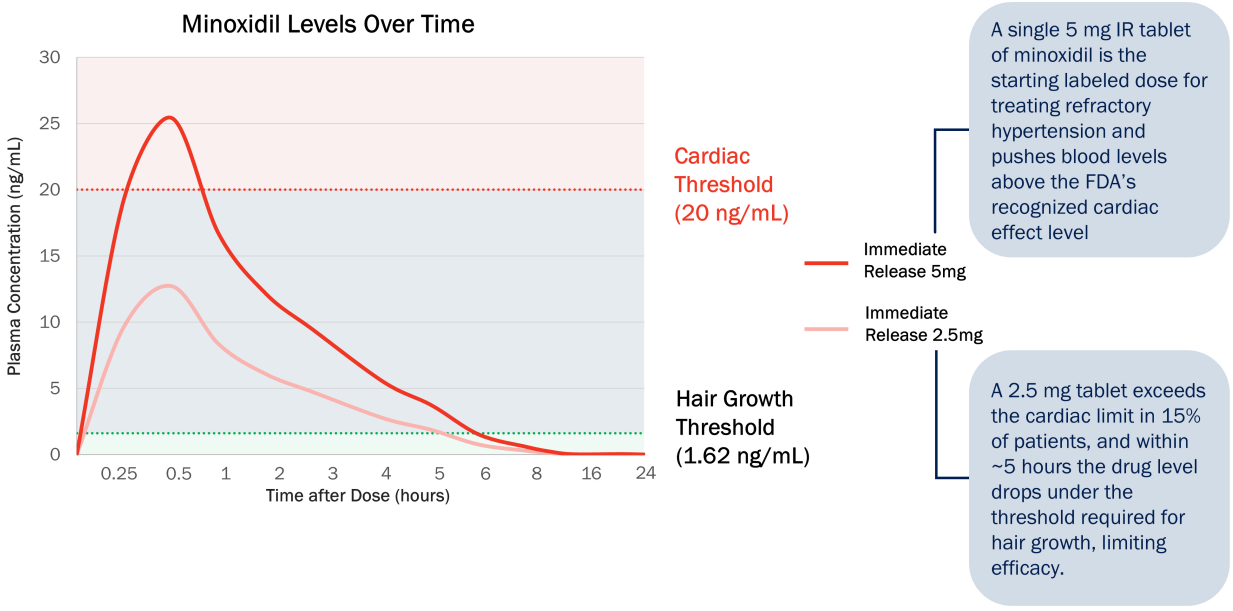
We believe there are approximately five million users of topical minoxidil in the United States annually, yet 86% discontinue within one year for the aforementioned reasons.

IR Oral Minoxidil Has Potential as a Hair Loss Treatment; However, Inherent Limitations of IR Oral Minoxidil Have Limited Adoption

IR oral minoxidil, an FDA-approved treatment for resistant hypertension at doses starting at 5 mg, is the most commonly prescribed hair loss treatment in the United States. Despite its label explicitly stating that it is not an approved treatment to promote hair growth, IR oral minoxidil has been prescribed approximately 3 million times in 2024, with its prescriptions surging approximately ten-fold following the 2022 publication of a *New York Times* article extolling its potential utility for PHL. This growth in IR oral minoxidil use points to strong underlying demand for a convenient non hormonal oral hair loss treatment, yet adoption remains limited to approximately 0.6% of the eligible population, with nearly 30% of all prescriptions written by fewer than 1,000 healthcare providers. While mechanistically promising, off-label IR oral minoxidil faces several widespread adoption barriers:

- **Hair growth ceiling:** We believe IR oral minoxidil has a mismatch between its PK profile and what hair follicles require for hair growth. IR oral minoxidil has a half-life of approximately 90 minutes, creating peaks and troughs in plasma concentration. During the peaks, IR oral minoxidil delivers a rapid antihypertensive effect, reaching Cmax within one hour and materially clearing within four hours. While this drug release profile is intentionally suited for blood pressure control, it is ill-suited for hair growth as the short exposure hinders follicular conversion of minoxidil to active metabolite minoxidil sulfate via local sulfotransferase enzymes, as this enzymatic conversion is capacity-limited and time-dependent. IR oral minoxidil's oscillating exposure pattern increases cardiac risk without added hair growth potential, as the majority of minoxidil exposure occurs within two hours of administration during a brief spike, rather than remaining below the threshold at which signs of cardiac activity are typically observed. In investigator-sponsored studies, off-label use of IR oral minoxidil has shown an efficacy ceiling demonstrating non-vellus hair count change on par with topical minoxidil.
- **Dose-dependent cardiac risk:** Doses producing the strongest hair growth also generate plasma concentrations that trigger adverse cardiac activity. The greatest hair regrowth for oral minoxidil occurs as the dose level

increases. However, for 5 mg IR oral minoxidil, which is the consensus maximum dose of IR oral minoxidil for hair growth treatment, peak plasma levels reach 37 ng/mL, which exceed the FDA threshold of 20 ng/mL for cardiac and vascular changes. Despite peak regrowth potential, these peak plasma levels exceed the FDA threshold of about 20 ng/mL for cardiac and vascular changes, as described further below. These spikes in plasma concentration are not required for hair growth and they may drive off-target effects. Trials have reported patients experiencing symptomatic hypotension, dizziness, tachycardia, palpitations, blood pressure and EKG changes after 5 mg of IR oral minoxidil, as well as rare, potentially life-threatening complications such as pericardial effusion. We believe that prescribers recognize the potential for AEs at the 5 mg IR level, as physicians currently prescribe the 2.5 mg IR dosage form for approximately 90% of patients, despite its inferior stimulation of hair growth. The below graph depicts the plasma concentration levels of minoxidil after oral dosing at both IR 2.5 mg and IR 5 mg, relative to the cardiac threshold and the threshold required for hair growth.



Minoxidil 2.5 mg IR data represent average plasma concentrations for all patients (n=15) from the relevant dosing period in Study QSC300720. Minoxidil 5 mg IR data represent average plasma concentrations estimates using dose linear PK of minoxidil 2.5 mg IR data for all patients (n=15) from the relevant dosing period in Study QSC300720.

- **Lack of FDA Approval:** We believe that lack of FDA approval for the treatment of PHL and other forms of hair loss limits prescriber willingness and patient awareness to adopt oral minoxidil. The absence of large-scale randomized trials and clinical data contributes to prescriber and patient hesitancy to adopt use and limited awareness of oral minoxidil for treating PHL and may contribute to variability in dosing of minoxidil that may further increase prescriber hesitancy and result in suboptimal outcomes. Furthermore, as IR oral minoxidil is not FDA-approved for any hair loss indication, it cannot be actively promoted for the treatment of hair loss, limiting awareness. In a proprietary commercial survey of 410 hair loss patients, the second most common reason why individuals using over the counter treatments for treating their hair loss do not opt for a prescription treatment is because they are unaware of prescription treatments for hair loss.

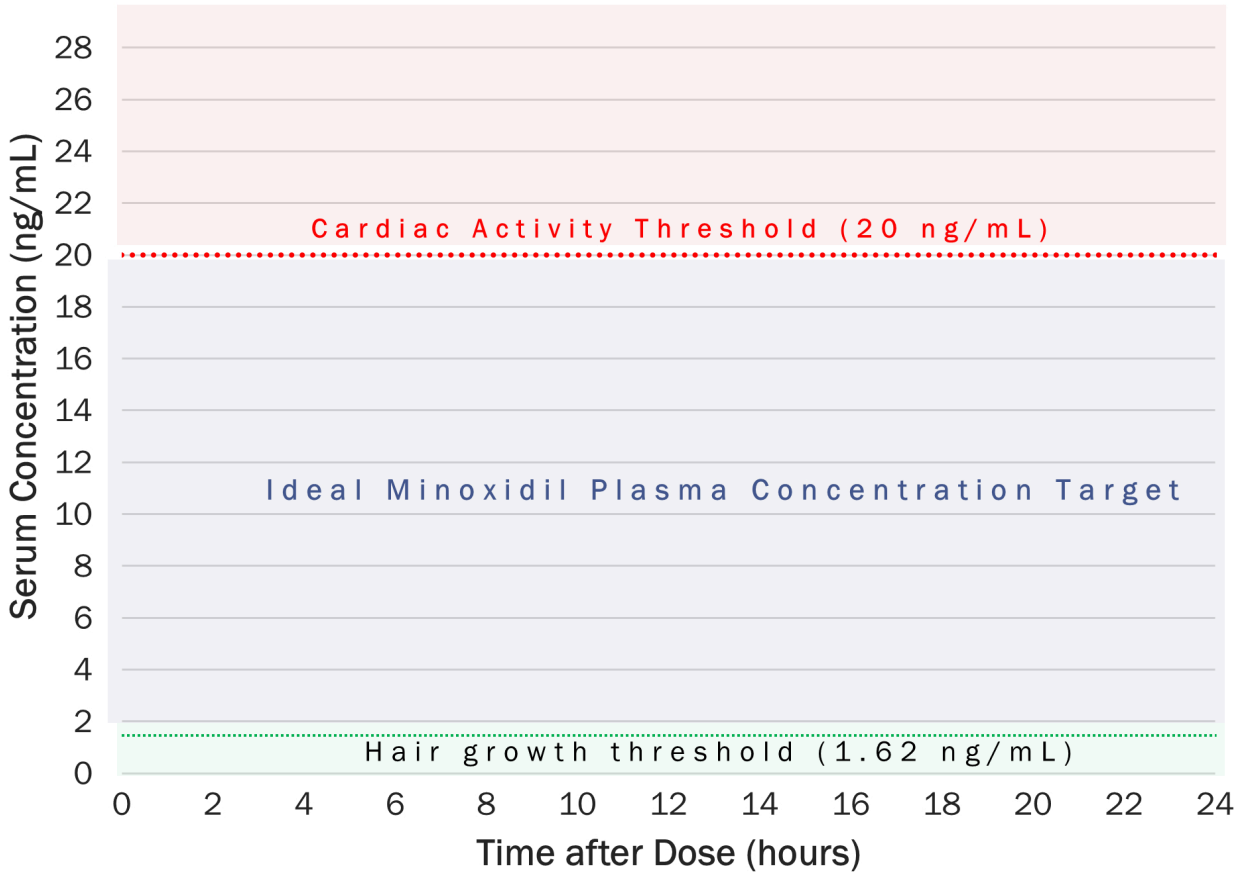
Our Solution for PHL: VDPHL01

VDPHL01's key innovation is its release profile, which is designed to maximize the total amount of drug that can be delivered to follicles over a 12- or 24-hour period without inciting spikes in Cmax of minoxidil known to induce changes in cardiac activity. VDPHL01 aims to provide long lasting concentrations of minoxidil above the drug's 'hair growth threshold' (i.e., 1.62 ng/mL, the minimally effective concentration needed to grow hair) while maintaining peak concentrations well below the drug's 'cardiac activity threshold' (i.e., about 20 ng/mL, the

threshold concentration level at which cardiac effects occur). The key innovation that enables VDPHL01's differentiated profile is the performance of the proprietary hydrogel tablet formulation, which is designed to:

- prevent Cmax from exceeding the 'cardiac activity threshold' to preserve the cardiac safety of minoxidil;
- maximize total drug exposure and duration of drug exposure above the 'hair growth threshold' to increase hair growth potential; and
- increase the metabolism of minoxidil to its active metabolite that is responsible for hair growth, minoxidil sulfate, by increasing amount and duration of drug exposure at the follicular level where the activating SULT1A1 enzyme is present.

The below graphic depicts the plasma concentration levels of minoxidil representing the cardiac activity threshold as compared to the hair growth threshold and the proposed target concentration range for hair growth.

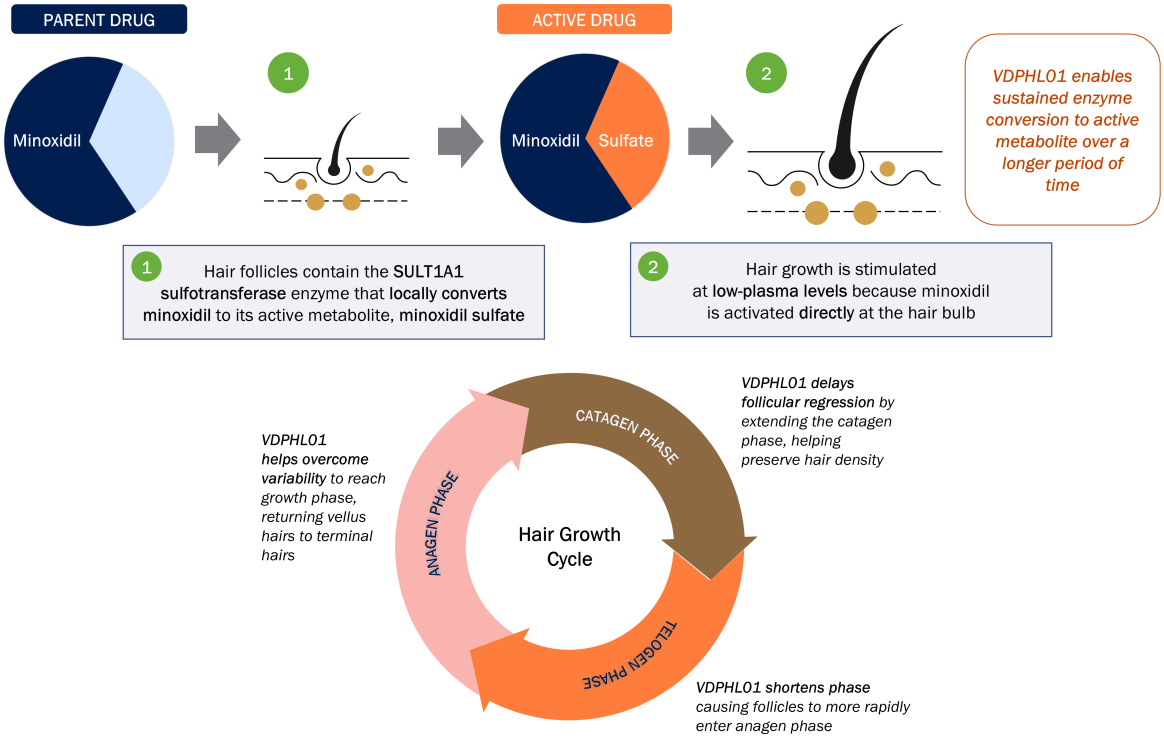


We designed VDPHL01's PK profile on the cardiac activity threshold established during the topical minoxidil OTC-switch process in the 1990s. This threshold was discovered via IV steady-state studies that identified the plasma concentration at which heart rate changes greater than 5 beats per minute can be detected. The cardiac activity threshold has been repeatedly recognized by the FDA in multiple subsequent approvals of topical minoxidil products. The hair growth threshold is the minimal Cmax concentration that must be reached to achieve hair growth, which was established based on the following data points:

- Prospective PK data tying systemic administration to hair growth — hair growth was observed at Cmax as low as 1.62 ng/mL.
- IR oral minoxidil data demonstrating hair growth at 0.25 mg daily — based on dose proportionality of minoxidil PKs, a 0.25 mg dose would be anticipated to have a Cmax of 1.4 ng/mL-1.6 ng/mL.

- Rogaine 5% data demonstrating distant site hair growth — the Cmax of Rogaine 5% foam is less than 2 ng/mL.

Furthermore, VDPHL01's ER formulation of minoxidil is designed to overcome high inter-individual variability in sulfation capacity by enabling sustained drug exposure and consistent local formation in the hair follicle of the active metabolite, minoxidil sulfate. The prolonged exposure from VDPHL01's ER tablet is designed to facilitate increased minoxidil sulfate formation, improving the likelihood of transitioning follicles into the anagen growth phase. This prolonged exposure is intended to avoid spiking systemic concentrations of minoxidil that otherwise could lead to enzymatic saturation (i.e., capacity-limited). We believe this key catalyzing interaction is enabled by VDPHL01, which increases the total amount of minoxidil available for conversion and extends the duration of engagement with the SULT1A1 sulfotransferase enzyme responsible for producing minoxidil sulfate (i.e., time dependent).



The ability of VDPHL01 to drive a differentiated metabolite profile is demonstrated by Phase 1 data in healthy volunteers, which showed a higher than anticipated ratio of minoxidil glucuronide to minoxidil, demonstrating an ability to increase metabolism of minoxidil to its most common metabolite. The ability to potentially increase sulfation of minoxidil is important since approximately 40% of individuals exhibit low SULT1A1 enzyme activity that has been shown to have a greater than 90% negative predictive value related to topical minoxidil response. We believe VDPHL01 has the potential to improve positive outcomes among individuals that exhibit low SULT1A1 enzyme activity due to prolonged exposure to minoxidil at concentrations above the hair growth threshold.

VDPHL01 has the potential to address inherent limitations in the current PHL treatment landscape

We believe that VDPHL01 could transform the PHL treatment paradigm and reduce the high levels of dissatisfaction and frustration associated with the current patient journey. VDPHL01 may deliver improved outcomes versus existing treatment options across the product attributes most desired by patients. In particular, we believe VDPHL01 will raise the hair growth ceiling with improved speed, consistency and intensity of effect by enabling greater sustained exposures to minoxidil throughout the day, without driving peak concentrations of systemic minoxidil associated with known cardiac effects. Many experts believe that variability in the response to

minoxidil as a treatment for hair loss is due to variability in hair follicle sulfation of minoxidil to active minoxidil sulfate. We believe that increasing the duration of exposure of minoxidil above levels that have been shown to grow hair may increase the percentage of individuals that respond and the intensity of response to a minoxidil treatment by driving capacity-limited and time-dependent conversion of minoxidil to active minoxidil sulfate. Supported by the preliminary data reported in October 2025 from our Phase 2 clinical trial data in male patients with PHL, VDPHL01's emerging profile has following potential benefits:

- **Speed.** In our proprietary market surveys of Americans with PHL, survey respondents cited more rapid onset of growth as a primary desire in a treatment for PHL. In our Phase 2 open-label trial, the majority of male patients receiving VDPHL01 8.5 mg twice daily reported that their hair coverage was "improved" or "much improved" after only two months of treatment.
- **Consistency.** Survey respondents seek hair growth responses consistent in magnitude and rapidity. Studies on the efficacy of finasteride in male patients showed slight improvement at month 12 according to expert grader review. In our Phase 2 open-label trial, 90.5% of male patients receiving VDPHL01 8.5 mg twice daily for four months of treatment reported that their hair coverage was "improved" or "much improved."
- **Intensity.** Survey respondents identified more robust density and total hair growth as a critical attribute for a hair growth product. In our Phase 2 open-label trial, males receiving VDPHL01 8.5 mg BID for four months of treatment had an average non-vellus (greater than 30 microns) hair count change of 47.3 hairs per cm^2, with double digit absolute non-vellus hair count changes in greater than 90% of patients.
- **Safety**. Both patients and physicians prioritize a safety profile devoid of hormonal and mood or psychological side effects, with minimized cardiac side effects associated with currently available treatment.
- **Cardiac.** IV minoxidil steady-state work has supported that cardiac effects are driven by a Cmax threshold of about 20 ng/mL. VDPHL01 is designed to enable dosing of higher amounts of minoxidil than would be otherwise achievable with maintained cardiac tolerability by reducing peak-to-trough variability of minoxidil exposure and overall reducing peak levels of minoxidil.
- **Hormonal and Psychological.** Minoxidil is non-hormonal and minoxidil treatments are not typically associated with hormonal and psychological side effects.
- **Convenience.** Patient respondents to surveys regarding their preferred route of administration for any medicine consistently cite an oral tablet as their top choice given its ease of use.
- **Marketability.** VDPHL01 has the potential to be the first oral, non-hormonal FDA-approved therapy for PHL. We believe an FDA-approved oral minoxidil product for hair loss will drive broader prescriber adoption, particularly among those who currently prescribe infrequently or have never prescribed oral minoxidil for PHL. Furthermore, we believe that the ability to actively promote an approved product has the potential to enable widespread physician and patient awareness and adoption of VDPHL01. Our proprietary market research identified that the second most common reason that current OTC users are not using a prescription product is lack of awareness of prescription offerings.

If approved, VDPHL01 could provide an attractive treatment option by combining these attributes in a way not currently available. We believe VDPHL01's commercial potential could be substantial, as we estimate that the current commercial opportunity for PHL treatments for men and women in the United States is approximately $9 billion, based on publicly available industry data and patient surveys to determine the number of PHL patients using prescription and OTC therapies in the United States in 2024, our proprietary third-party market research of estimates of duration of therapy and our analysis of pricing for prescription and OTC treatments. We believe that VDPHL01 could not only gain a meaningful share of this existing commercial opportunity, but also capture patients previously deterred by inadequate treatments and expand the addressable commercial opportunity.

Summary of our clinical trials and data generated to date

Our belief in VDPHL01's ability to deliver a differentiated, target PK profile relative to other forms of minoxidil is bolstered by data from our Phase 1 PK studies. The first was a dose ranging Phase 1 clinical trial of VDPHL01 prototypes in doses up to 10 mg against a single reference dose of commercially available 2.5 mg IR oral minoxidil administered to the same cohort of healthy male patients and female patients in sequential dosing periods. As this study was exploratory, no formal sample size calculation was made related to statistical power. The data presented below are reflective of the study's per-protocol primary objective, namely, to evaluate the PK profile and determine the relative bioavailability of VDPHL01 following single oral dosing of VDPHL01 versus the

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reference IR oral minoxidil formulation in healthy subjects. The study demonstrated the substantially different Cmaxs and total drug exposure levels achieved by the multiple prototype ER doses and 2.5 mg IR, the most prescribed off-label dose form. In the study, fasted administration of all dose levels from 5 mg up to 10 mg ER achieved both higher total exposures and lower Cmaxs than 2.5 mg IR. The 8.5 mg dose, which we expect would be VDPHL01's commercially available dose for male patients and is the dose we are evaluating in Study 302, our first registration-directed clinical trial in male patients, specifically achieved an average total drug exposure, or AUC, of 42.5 ng/mL and average peak Cmax, of 8.32 ng/mL versus 25.3 ng/mL and 13.90 ng/mL respective levels for 2.5 mg IR. In addition, no patients dosed with VDPHL01 8.5 mg ER Tablet achieved a Cmax that exceeded the reported threshold for cardiac effects, which are seen at concentrations exceeding 20 ng/mL, whereas 13.3% of patients dosed with 2.5 mg IR oral minoxidil achieved a Cmax greater than 20 ng/mL. Additional details related to this PK study are outlined below in "— Completed Study QSC300720: A Phase 1, Single-Part, Open-Label, Six Period Sequential Crossover Study Designed to Evaluate the Pharmacokinetic Profile of VDPHL01 in Male and Female Subjects."

In our second PK study, a Phase 1 clinical trial in healthy male patients, we assessed the potential for twice daily dosing to further boost overall minoxidil exposure. In this study, VDPHL01 8.5 mg was given either once or twice daily to twelve healthy male volunteers, and results showed consistent profiles in blunting Cmax irrespective of dosage frequency. The results of this PK study are summarized below in "— Study 250-13951-105: A Two-Period Randomized Crossover Design Study to Evaluate the Pharmacokinetic Profile of VDPHL01 In Healthy Male Subjects."

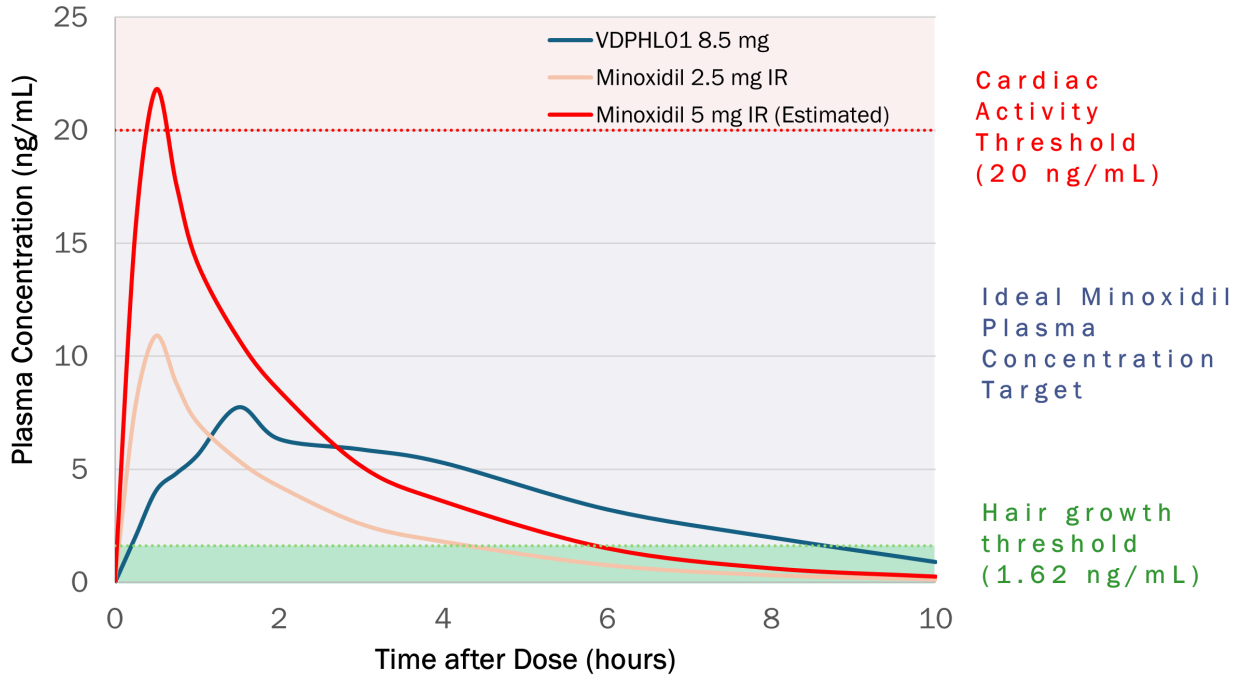
Based on these results, VDPHL01 8.5 mg maintained plasma levels of minoxidil that fell between the thresholds for promoting hair growth and inducing cardiac activity for more than 7.5 to 12 hours if given once daily or 15 to 24 hours if given twice daily. In this same study, VDPHL01 8.5 mg was generally well tolerated in both arms, and we saw no signs of cardiac activity or drug-related severe AEs and had no patient withdrawals for drug-related AEs.

Completed Study QSC300720: A Phase 1, Single-Part, Open-Label, Six Period Sequential Crossover Study Designed to Evaluate the Pharmacokinetic Profile of VDPHL01 in Male and Female Subjects

Study QSC300720 was a single center, open-label, six-period sequential crossover single dose Phase 1 clinical trial in 16 healthy male and female patients to establish and assess the PK and safety of VDPHL01 prototype formulations at a range of potential doses and release rates in comparison to a reference 2.5 mg IR oral minoxidil tablet formulation. A summary of relevant PK parameters from this study are as outlined above.

The VDPHL01 prototype formulations were generally well tolerated at all doses and release rates. We observed no SAEs, and no patients were withdrawn for treatment-related AEs. Overall, seven patients reported a total of eight mild AEs across the six treatment periods. The only AE reported by more than one patient was viral upper respiratory tract infection, reported by two patients. Importantly, there were no clinically significant observations or changes from baseline on vital signs, ECG, physical examinations or clinical laboratory safety tests.

We reviewed the results of Study QSC300720 to compare the head-to-head PK profile of VDPHL01 8.5 mg with the PK profile of 2.5 mg IR oral minoxidil for male patients who were administered both dosage forms, as well as the estimated PK profile of 5 mg IR oral minoxidil using published dose linear PK in the same male subjects. Based on this comparison, we observed that the PK profile of VDPHL01 8.5 mg demonstrated a differentiated systemic delivery profile as compared to both 2.5 mg observed and 5 mg estimated IR oral minoxidil. The below graphic illustrates representative average plasma concentration levels of minoxidil for VDPHL01 8.5 mg compared to those for IR oral minoxidil in the same male subjects relative to the cardiac activity threshold, the hair growth threshold and the proposed target concentration range for hair growth.



- VDPHL01 8.5 mg curve represents average plasma concentrations for male patients (n=10) from Study QSC300720.
- Minoxidil 2.5 mg IR data represent average plasma concentrations for male patients (n=10) from Study QSC300720.
- Minoxidil 5 mg IR data represent average plasma concentrations estimates using dose linear PK of minoxidil 2.5 mg IR data for male patients (n=10) from Study QSC300720.

Representative average plasma concentration levels for VDPHL01 8.5 mg demonstrated blunting of Cmax below the cardiac threshold and lengthening of time above the hair growth threshold as compared to IR oral minoxidil (2.5 mg observed head-to-head, 5 mg estimated) of male subjects from Study QSC300720.

Study 250-13951-105: A Two-Period Randomized Crossover Design Study to Evaluate the Pharmacokinetic Profile of VDPHL01 In Healthy Male Subjects

Study 250-13951-105, or Study 105, was a multi-dose PK Phase 1 study in 12 healthy male volunteers to evaluate the safety and PK profile of 8.5 mg of VDPHL01 either once (QPM) or twice (BID) daily, to determine the PK profile of expected registrational dosing.

Both dosing regimens, 8.5 mg once daily and 8.5 mg twice daily, were generally well tolerated over an 8-day dosing period. No SAEs and/or cardiac-related AEs were reported, and no patients were withdrawn for treatment-related AEs. One patient reported AEs (intermittent headache and nasal congestion), all of which resolved.

Consistent with previous results, no individual Cmax value exceeded the cardiac threshold concentration of 20 ng/mL following single and multiple dosing of VDPHL01 once or twice daily. Consistent with the short half-life of minoxidil, minimal accumulation of minoxidil was observed following either once or twice daily administration of

minoxidil. The below graphic illustrates our Cmax, AUC24 and AUC12 findings for both dosing regimens on Day 8 in this trial:

Dosing Regimen	Cmax (ng/mL)	AUC12 (h*ng/mL)	AUC24 (h*ng/mL)
VDPHL01 8.5 mg QPM	8.219	NA	40.81
VDPHL01 8.5 mg BID	8.014	37.27	74.54*

*Select respective PK parameters (Cmax, AUC24 and AUC12) are presented from Study 105 after the last dose of VDPHL01 8.5 mg on Day 8 of dosing following preceding administration either once daily or twice daily. Cmax = Maximum observed concentration; AUC12 = Area under the curve from time 0 to 12 hours; AUC24 = Area under the curve from time 0 to 24 hours *estimated based on anticipated doubling of AUC upon twice daily administration.*

Study 250-13951--109: PK Study of VDPHL01 4.5 mg of ER Oral Minoxidil and 20 mg of IR Oral Minoxidil in Female Patients

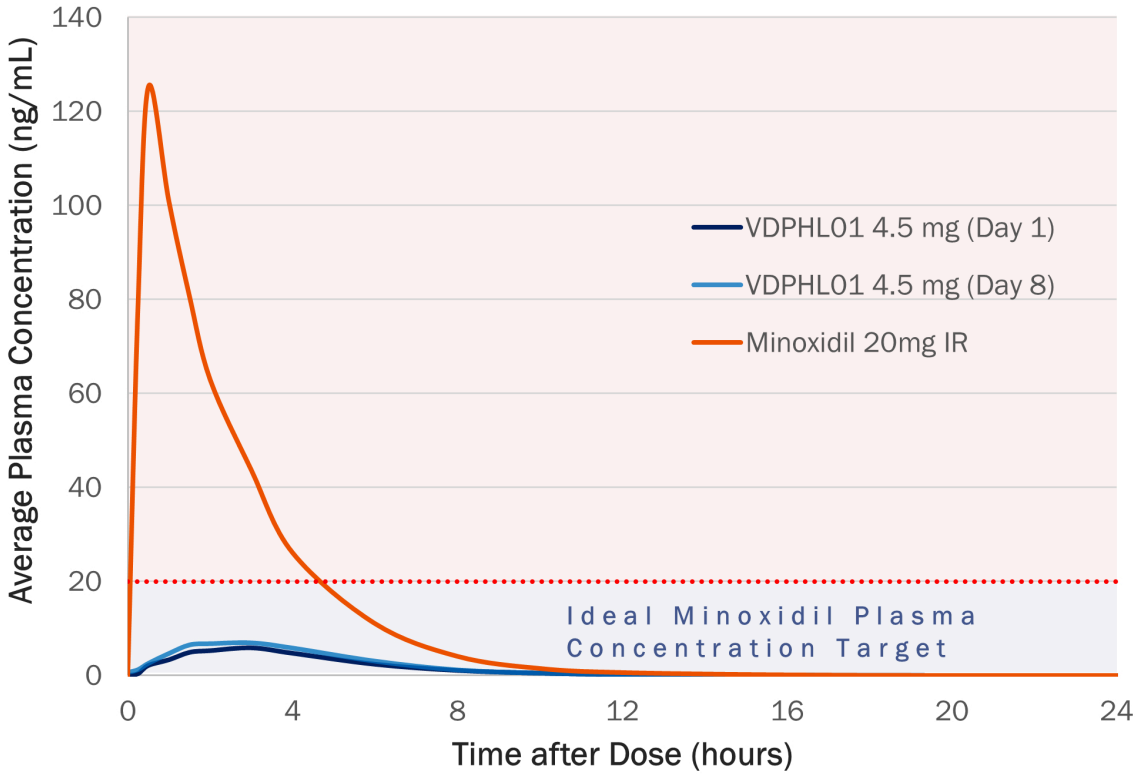
To establish VDPHL01 4.5 mg (ER oral minoxidil) as an appropriate dose for female PHL patients and establish a PK bridge to the reference to IR oral tablet, we conducted Study 250-13951-109, or Study 109, a Phase 1 study of 24 healthy female patients who were administered VDPHL01 4.5 mg as a single dose on day one, a twice daily dose on days two through seven and a single morning dose on day eight. After a washout period, the same patients were administered 20 mg of IR oral minoxidil on the morning of day eleven. The below graphic illustrates our geometric mean AUC, geometric mean Cmax and maximum observed Cmax findings for VDPHL01 4.5 mg and 20 mg IR oral minoxidil in this trial:

Dosing Regimen	Cmax (ng/mL) (n=24)	Maximum Observed Cmax (h*ng/mL) (n=1)	AUC24 (h*ng/mL) (n=24)
VDPHL01 4.5 mg - Day 1	6.417	12.3	27.84
VDPHL01 4.5 mg - Day 8	7.735	13.4	36.94
IR Oral Minoxidil 20 mg - Day 11	135.1	250	315.3

Select respective PK parameters (geometric mean AUC24, geometric mean Cmax and peak Cmax) are presented from Study 109 for VDPHL01 4.5 mg after the initial dose on Day 1 and after the last dose on Day 8 following preceding administration twice daily. These same parameters are presented for 20 mg IR oral minoxidil administered on Day 11 after washout from VDPHL01.Cmax = Maximum observed concentration; AUC24 = Area under the curve from time 0 to 24 hours

We observed the comparative bioavailability of PK profile of VDPHL01 4.5 mg to that of IR oral minoxidil 20 mg in the Study 109. The below graphic illustrates average plasma concentration levels of minoxidil for VDPHL01 4.5 mg at Day 1 and Day 8 compared to those for IR oral minoxidil 20 mg at Day 11 in Study 109 relative to

the cardiac activity threshold, the hair growth threshold and the proposed target concentration range for hair growth.



Average plasma concentration levels for VDPHL01 4.5 mg from Study 109 demonstrated significant blunting of Cmax below the cardiac threshold as compared to IR oral minoxidil while preserving time above the hair growth threshold.

Adverse Events (AEs)

The AE summary presented in the graphic below from Study 109 illustrates the AE profile of VDPHL01 4.5 mg as compared to that of IR oral minoxidil. After multiple-day dosing of VDPHL01 4.5 mg, only 5 of the 23 total reported AEs were classified as "possibly related" or "probably related" to VDPHL01, and no cardiac AEs were reported. After single dose administration of IR oral minoxidil in these same patients, 42 of the 43 total reported

AEs were classified as “possibly related” or “probably related” to the drug, and cardiac effects (palpitations, heart rate increase) were reported. No SAEs were reported in any dosing cohort in this study.

Dosing Period 1: VDPHL01 4.5 mg (Day 1-8, n=24 subjects)		Dosing Break Day 9-10	Dosing Period 2: Minoxidil 20 mg IR (Day 11, n=24 subjects)	
23 total Adverse Events			**43 total Adverse Events**	
10 most frequent adverse events			**10 most frequent adverse events**	
Headache	4		Headache	8
Myalgia	2		Heart Rate Increased	5
Bruising Due to Venipuncture Site	1		Palpitations	4
Constipation	1		Orthostatic Tachycardia	2
Sore Throat	1		Dizziness, Postural	2
Abdominal Discomfort	1		Fatigue	2
Burning with Urination	1		Nausea	2
Dry Lips	1		Vomiting	2
Labia Irritation	1		Hyperhidrosis	2
White Discharge, Vaginal	1		Blurred Vision	1

AEs and relation to VDPHL01		AEs and relation to Minoxidl IR	
Not Related	11	Not Related	0
Unlikely Related	7	Unlikely Related	1
Possibly Related	3	Possibly Related	18
Probably Related	2	Probably Related	24

AEs from Study 109 are summarized by dosing regimen (VDPHL01 4.5 mg and 20 mg IR oral minoxidil) with listing of the most common AEs reported for each group. Relatedness of all AEs is also summarized by group. Overall, the AE summary demonstrates that VDPHL01 was generally well tolerated.

Study 108: PK Study of VDPHL01 8.5 mg (ER Oral Minoxidil) and 20 mg of IR Oral Minoxidil in Male Patients

A similar study has been conducted for VDPHL01 8.5 mg, the male dose form, with a nearly identical study design that is intended to establish a PK bridge to the reference IR oral tablet. In September 2025, 24 men were administered VDPHL01 8.5 mg as a single dose on day one, a twice daily dose on days two through seven and a single morning dose on day eight. After a three-day washout period, the same patients were administered 20 mg of IR oral minoxidil. Data from this study is anticipated in the first half of 2026.

Preliminary Phase 2 Data Demonstrated VDPHL01’s Differentiated Impact on Hair Growth at Four Months

We are currently conducting an ongoing Phase 2 open-label trial of VDPHL01 in 21 adult male patients and 22 adult female patients with PHL. Preliminary data from 21 male patients dosed with VDPHL01, 8.5 mg twice daily, in the Phase 2 clinical trial demonstrated consistent hair growth responses at 2 and 4 months, improved PRO and that VDPHL01 was generally well tolerated. Preliminary data showed male patients receiving VDPHL01 achieved restoration of 37.5 hairs per cm^2 and 47.3 hairs per cm^2 from baseline after two and four months of therapy, respectively. We believe these preliminary data results support our belief that VDPHL01 possesses a differentiated profile.

The degree of visible aesthetic improvement resulting from both this magnitude and speed of change in hair count was identified by both patients and trial investigators. 50% and 90.5% of male patients indicated an improvement in hair coverage at two months and four months, respectively. 80% and 90.5% of physicians indicated an improvement in hair coverage on the IGA, at 8 weeks and 16 weeks, respectively. Importantly,

these outcomes were captured at or before the 16-week mark from initial treatment, with the initial observation of visibly noticeable improvements as early as 8 weeks.

As this trial is exploratory, no formal sample size calculation will be made related to statistical power. Therefore, all trial endpoints, including objective hair count measures and subjective patient and investigator assessments, are exploratory and are planned to be reported as descriptive statistics.

Blinded Review Presented at 2025 Congress of the European Academy of Dermatology and Venerology Indicated VDPHL01's Encouraging Results and Rapid Onset of Benefit

We sponsored a blinded, retrospective grader imaging analysis that was presented at the 2025 Congress of the European Academy of Dermatology and Venerology. This study compared outcomes via IGA, from the 20 male patients who completed four months of treatment with VDPHL01 8.5 mg twice daily in our Phase 2 clinical trial with completed and published trial dataset from a double-blind, randomized controlled study of 33 male patients receiving 5 mg IR oral minoxidil once daily over 6 months and 34 male patients receiving 5% minoxidil solution twice daily over 6 months. Subjects across both our trial and the published trial data set demonstrated similar baseline hair loss characteristics as measured by Norwood Hamilton subtypes. The physical assessment of a person with PHL involves measuring the pattern and extent of hair loss. The Norwood-Hamilton scale is commonly used to classify male-pattern baldness. On this scale, the stages of hair loss are described with a number from 1 (least severe) to 7 (most severe).

This blinded, retrospective image assessment study used image files containing before-and-after (in randomized order) scalp photographs of each treatment from both the vertex and frontal view. These image files were reviewed independently by three U.S. board certified dermatologists who were blinded to treatment group and asked to identify the baseline image before assigning an IGA score for improvement using a 7-point Likert scale, a commonly used tool for assessing change in hair growth ranging from greatly decreased (-3) to greatly increased (+3) with intermediate categories of no change (0), slightly decreased/increased (-1/+1) and moderately increased/decreased (-2/+2).

Mean IGA Improvement

In cases where the grader incorrectly selected the baseline photo (i.e., they selected the follow-up image as being the baseline image and assigned an IGA improvement score based on that perception), they would in reality have perceived a worsening in scalp hair growth. Therefore, after completion of blinded grading, scores were corrected for baseline misidentification by reversing score direction. After correction for mis-sequencing, mean IGA improvement scores (mean ± standard deviation) for the frontal and vertex views, respectively, were: 2.02 ± 0.75 and 2.05 ± 0.79 for VDPHL01, 0.29 ± 1.32 and 0.02 ± 1.03 for topical minoxidil, and 0.59 ± 1.28 and 0.53 ± 1.15 for IR oral minoxidil. As illustrated in the graphic below, the mean improvement for VDPHL01 was superior and as compared to both topical minoxidil and IR oral minoxidil. Additionally, there was