UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2026

OR

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

For the transition period from _____ to _____

Commission file number: 001-43097

Veradermics, Incorporated
(Exact name of registrant as specified in its charter)

Delaware	**84-3304423**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
470 James St., New Haven, CT	**06513**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(228) 372 3376**

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.00001 per share	MANE	New York Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated

filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The number of shares of Registrant's Common Stock outstanding as of May 07, 2026 was 41,778,687.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 VDPHL01, 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 our existing cash, cash equivalents and marketable securities, including the net proceeds to us from this offering and our IPO, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report on Form 10-Q titled “Risk Factors” and the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q. 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 Quarterly Report on From 10-Q 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.

Risk Factor Summary

Our business is subject to a number of risks that are discussed more fully in the “Risk Factors” section of this Quarterly Report on Form 10-Q. 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;
- 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 be sustained; and
- The market price of our common stock may be volatile, which could result in substantial losses for investors.

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.”

PART I - FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

VERADERMICS, INCORPORATED

Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share and per share amounts)	As of March 31, 2026	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 168,412	$ 21,766
Marketable securities at fair value	222,385	120,096
Prepaid expenses and other current assets	6,272	10,632
Total current assets	397,069	152,494
Long-term assets:		
Property, plant and equipment, net	21	22
Right-of-use asset and other long-term assets	266	103
Total non-current assets	287	125
Total assets	$ 397,356	$ 152,619
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,071	$ 2,126
Accrued expenses	5,606	6,979
Other current liabilities and lease liabilities	39	47
Total current liabilities	6,716	9,152
Lease liabilities - non-current	—	4
Total liabilities	6,716	9,156
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock:		
Series A preferred stock, $0.00001 par value, 12,865,375 shares authorized, issued and outstanding with an aggregate liquidation preference of $37,238 as of December 31, 2025, net of issuance costs	—	36,860
Series B preferred stock, $0.00001 par value, 62,245,805 shares authorized, issued and outstanding with an aggregate liquidation preference of $85,376 as of December 31, 2025, net of issuance costs	—	78,903
Series C preferred stock, $0.00001 par value, 118,682,683 shares authorized, issued and outstanding with an aggregate liquidation preference of $154,815 as of December 31, 2025, net of issuance costs	—	150,563
Subscription receivable	—	(1,849)
Stockholders' equity (deficit)		
Preferred stock, $0.00001 par value, 25,000,000 and 0 shares authorized as of March 31, 2026 and December 31, 2025, respectively and 0 shares issued or outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—

(in thousands, except share and per share amounts)	As of March 31, 2026	As of December 31, 2025
Common stock, $0.00001 par value, 200,000,000 and 267,466,797 shares authorized as of March 31, 2026 and December 31, 2025, respectively and 37,340,290 and 749,760 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	543,044	2,346
Subscription receivable	(1,228)	—
Accumulated other comprehensive income	(524)	60
Accumulated deficit	(150,653)	(123,421)
Total stockholders' equity (deficit)	390,640	(121,014)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 397,356	$ 152,619

See accompanying notes to the financial statements

VERADERMICS, INCORPORATED

Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

(in thousands, except share and per share amounts)	Three Months Ended March 31, 2026	2025
Operating expenses:		
Research and development	$ 20,925	$ 11,447
General and administrative	8,937	1,468
Total operating expenses	29,862	12,915
Loss from operations	(29,862)	(12,915)
Other income:		
Interest income	2,481	482
Other income	149	33
Total other income, net	2,630	515
Loss before income taxes	(27,232)	(12,400)
Income tax benefit	—	—
Net loss	$ (27,232)	$ (12,400)
Net loss attributable to common stock	$ (30,011)	$ (14,582)
Net loss per share of common stock, basic and diluted	$ (1.32)	$ (19.79)
Weighted average common stock outstanding, basic and diluted	22,704,124	736,933
Other comprehensive loss:		
Net unrealized losses on marketable securities	(584)	—
Total other comprehensive loss	(584)	—
Total comprehensive loss	$ (27,816)	$ (12,400)

See accompanying notes to the financial statements

VERADERMICS, INCORPORATED

Condensed Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

(in thousands, except share amounts)	Redeemable Convertible Preferred Stock							Stockholders' Equity (Deficit)					
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock			Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Subscription Receivable	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2024	12,865,375	$ 36,860	55,246,971	$ 66,285	—	$ —	$ (3,848)	736,933	$ 1	$ 750	$ —	$ (49,231)	$ (48,480)
Issuance of Series B Redeemable Convertible Preferred Stock, net of issuance costs of $10	—	—	6,998,834	8,423	—	—	—	—	—	—	—	—	—
Subscription receivable settled through research and development services received	—	—	—	—	—	—	357	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	213	—	—	213
Net loss	—	—	—	—	—	—	—	—	—	—	—	(12,400)	(12,400)
Balance, March 31, 2025	12,865,375	$ 36,860	62,245,805	$ 74,708	—	$ —	$ (3,491)	736,933	$ 1	$ 963	$ —	$ (61,631)	$ (60,667)

(in thousands, except share amounts)	Redeemable Convertible Preferred Stock							Stockholders' Equity (Deficit)						
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock			Common Stock						
	Shares	Amount	Shares	Amount	Shares	Amount	Subscription Receivable	Shares	Amount	Additional Paid-In Capital	Subscription Receivable	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2025	12,865,375	$36,860	62,245,805	$78,903	118,682,683	$150,563	$ (1,849)	749,760	$ 1	$ 2,346	$ —	$ 60	$ (123,421)	$ (121,014)
Issuance of common stock in connection with initial public offering, net of issuance costs of $25,666	—	—	—	—	—	—	—	17,339,294	—	269,102	—	—	—	269,102
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(12,865,375)	(36,860)	(62,245,805)	(78,903)	(118,682,683)	(150,563)	1,849	19,250,410	—	266,326	(1,849)	—	—	264,477
Subscription receivable settled through research and development services received	—	—	—	—	—	—	—	—	—	—	621	—	—	621
Stock-based compensation	—	—	—	—	—	—	—	—	—	5,259	—	—	—	5,259
Stock option exercises	—	—	—	—	—	—	—	826	—	11	—	—	—	11
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(584)	—	(584)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(27,232)	(27,232)
Balance, March 31, 2026	—	$ —	—	$ —	—	$ —	$ —	37,340,290	$ 1	$543,044	$ (1,228)	$ (524)	$ (150,653)	$ 390,640

See accompanying notes to the financial statements

VERADERMICS, INCORPORATED

Condensed Consolidated Statements of Cash Flows
(unaudited)

(in thousands)	Three Months Ended March 31, 2026	2025
Cash flows from operating activities:		
Net loss	$ (27,232)	$ (12,400)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,259	213
Non-cash research and development services	621	357
Net accretion of discount/premium on debt securities	(73)	(13)
Other	6	2
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	4,360	79
Interest receivable on marketable securities	(1,499)	—
Accounts payable	(1,055)	(686)
Accrued expenses	(1,373)	(862)
Other long term assets	(174)	—
Other current liabilities and lease liabilities	(8)	(7)
Net cash used in operating activities	(21,168)	(13,317)
Cash flows from investing activities:		
Purchase of property, plant and equipment	—	(19)
Purchases of marketable securities	(122,988)	(15,731)
Maturities of marketable securities	21,689	—
Net cash used in investing activities	(101,299)	(15,750)
Cash flows from financing activities:		
Issuance of Series B preferred stock, net of issuance costs paid	—	8,423
Initial public offering, net of issuance costs paid	269,102	—
Exercise of stock options	11	—
Net cash provided by financing activities	269,113	8,423
Net increase (decrease) in cash and cash equivalents	146,646	(20,644)
Cash and cash equivalents—beginning of period	21,766	53,084
Cash and cash equivalents—end of period	$ 168,412	$ 32,440
Supplemental schedule of noncash activities:		
Unrealized loss on marketable securities	$ (584)	$ —
Right-of-use asset exchanged for lease liabilities	$ —	$ 90

See accompanying notes to the financial statements

VERADERMICS, INCORPORATED

Notes to Financial Statements (unaudited)

1. Nature of the Business

Veradermics, Incorporated and its wholly-owned subsidiary (collectively, the "Company" or "Veradermics") is 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. The Company's initial focus is developing better treatments for pattern hair loss, or PHL, a condition affecting approximately 50 million men and approximately 30 million women in the United States. Beyond VDPHL01, the Company has created a portfolio utilizing its real-world experience as dermatologists to generate compelling pipeline assets, including VDMN for the treatment of common warts, VDAA for the treatment of alopecia areata, and VDMC for the treatment of molluscum contagiosum.

Veradermics began its operations in 2019 as a company incorporated under the laws of the State of Texas. Effective on September 14, 2021, the Company was converted into a company incorporated under the laws of the State of Delaware. The Company is headquartered in New Haven, Connecticut.

On February 5, 2026, the Company completed its initial public offering ("IPO") of 17,339,294 shares of common stock at a public offering price of $17.00 per share, including 2,261,647 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. The Company raised gross proceeds of approximately $294.8 million and net proceeds of approximately $269.1 million after deducting underwriting discounts, commissions, and offering expenses. Upon completion of the IPO, all outstanding shares of convertible preferred stock automatically converted into 19,250,410 shares of common stock. The Company's common stock is listed on the New York Stock Exchange under the ticker symbol "MANE."

In May 2026, the Company completed its underwritten public offering (the "Follow-On Public Offering") of 4,420,358 shares of the Company's common stock, par value $0.00001 per share (the "Common Stock"), at a public offering price of $100.00 per share, including 576,568 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The gross proceeds from the Follow-On Public Offering were approximately $442.0 million, before deducting underwriting fees and discounts.

In May 2026, the Company closed a private placement (the "Private Placement") pursuant to a Securities Purchase Agreement (the "Purchase Agreement"), dated April 29, 2026, among the Company and certain entities affiliated with Suvretta Capital (each, an "Investor" and collectively, the "Investors"), in which the Company sold to the Investors pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 300,000 shares of Common Stock, at an offering price of $99.99999 per Pre-Funded Warrant. The gross proceeds of the Private Placement were approximately $30.0 million, before deducting placement agent fees and other expenses.

The exercise price of each Pre-Funded Warrant equals $0.00001 per underlying share of Common Stock. The exercise price and the number of shares of Common Stock issuable upon exercise of each Pre-Funded Warrant is subject to appropriate adjustment in the event of certain stock dividends, stock splits, stock combinations, or similar events affecting the Common Stock. The Pre-Funded Warrants are exercisable in cash or by means of a cashless exercise and will not expire until the date the Pre-Funded Warrants are fully exercised. The Pre-Funded Warrants may not be exercised if the aggregate number of shares of Common Stock beneficially owned by the holder thereof (together with its affiliates) immediately following such exercise would exceed 9.99% of the Company's Common Stock; provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving written notice to the Company, but not to any percentage in excess of 19.99% and any such increase will not be effective until the 61st day after such notice is delivered to the Company.

Liquidity and Ability to Continue as a Going Concern

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company has incurred recurring losses since its inception, including net losses of $27.2 million and $12.4 million for the three months ended March 31, 2026 and 2025, as well as incurred negative cash flows from operations of $21.2 million and $13.3 million, respectively. In addition, as of March 31, 2026, the Company had an accumulated deficit of $150.7 million. The Company expects to continue to generate operating losses for the foreseeable future. Through March 31, 2026, the Company has financed its operations primarily from the sale of equity securities. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital to fund its operations.

The Company completed its IPO in the first quarter of 2026, from which it received gross proceeds of $294.8 million. In May 2026, the Company completed the Follow-On Public Offering and the Private Placement, from which it received gross proceeds of $472.0 million, before deducting underwriting discounts, placement agent fees and other expenses. The net proceeds from the IPO, the Follow-On Public Offering and the Private Placement, together with existing cash on hand, will enable the Company to meet its obligations for at least the twelve-month period from the date the financial statements are available to be issued.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the pharmaceutical industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and those specific to the pharmaceutical industry such as the U.S. Food and Drug Administration (“FDA”), and the ability to secure additional capital to fund operations. Products currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance and reporting capabilities. The Company’s future clinical trials require significant compliance and monitoring by government agencies and there can be no assurances that such agencies will approve procedures followed in the Company’s trials. Another likely scenario is that such agencies would require additional procedures to be performed which would push out commercialization timing. Further, even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

If the Company’s product development efforts are successful, they are subject to significant risks and uncertainties related to product commercialization and launch, including being unable to secure additional funding to make support to Company’s commercial launch efforts. Additionally, the Company’s potential product would compete in the market of medical dermatology. The industry is subject to technology advancements as well as being affected by political conditions which could impact the market’s reimbursement and regulatory policy, and by economic conditions surrounding availability and affordability of health insurance and access to health services. The pharmaceutical industry is heavily regulated by the need for approval in order to sell a product, to reimbursement policy for use of the product, and how companies can and cannot interact and sell to physicians or hospitals.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted (“U.S. GAAP”) in the United States. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and ASUs promulgated by the Financial Accounting Standards Board (“FASB”).

In the opinion of management, the unaudited interim condensed consolidated financial statements reflect all normal recurring adjustments considered necessary for a fair presentation of the Company’s financial position and the results of its operations for the interim periods presented.

On January 27, 2026, the Company effected a 1-for-10.067 reverse stock split of the Company’s issued and outstanding common stock and adjusted the conversion ratio of the Company’s outstanding convertible preferred stock. Accordingly, all share and per share amounts for all common stock in the periods presented have been retroactively adjusted, where applicable, to reflect the reverse stock split and the adjustment of the preferred stock conversion ratios.

Principles of Consolidation

The accompanying financial statements include the accounts of the Company and the Company’s subsidiary, which the Company controls. Accordingly, all intercompany balances and transactions between these entities have been eliminated within the financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities 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 share-based compensation expense which includes estimating the fair value of its common stock.

Significant accounting policies

The significant accounting policies used in preparation of these condensed consolidated financial statements are consistent with those discussed in Note 2, *Summary of Significant Accounting Policies,* to the consolidated financial statements for the year ended December 31, 2025 included in the Company's 2025 annual report on Form 10-K (the "Annual Report"), except for the following:

Stock-Based Compensation Expense

Prior to the IPO, the Company did not meet the criteria to apply the simplified method for determining the expected term of stock option grants under the Black-Scholes option pricing model. Following the completion of its IPO in the first quarter of 2026, the Company elected to adopt the simplified method for stock option grants issued subsequent to the IPO. Under this method, the expected term is calculated as the midpoint between the vesting term and the contractual term of the award.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, ("ASU 2024-03"). ASU 2024-03 requires disclosure of additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. The standard is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with prospective or retrospective application and early adoption permitted. The Company is currently evaluating the impact ASU 2024-03 will have on its financial statements.

3. Prepaid Expenses, Other Current Assets, and Accrued Expenses

Prepaid expenses and other current assets consist of the following:

(in thousands)	As of March 31, 2026	As of December 31, 2025
Prepaid research and development	$ 3,260	$ 5,609
Tax credit receivable	1,213	1,255
Prepaid insurance	759	31
Deferred IPO costs	—	3,387
Interest receivable on cash equivalents	438	43
Other	602	307
	$ 6,272	$ 10,632

Accrued expenses consists of the following:

(in thousands)	As of March 31, 2026	As of December 31, 2025
Professional fees	$ 3,024	$ 4,338
Research and development	2,019	702
Bonus	563	1,939
	$ 5,606	$ 6,979

4. Marketable Securities

The amortized cost and fair value of our marketable securities by type of security as of March 31, 2026 are as follows:

(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	Level 1	$ 17,298	$ —	$ —	$ 17,298
U.S. treasury securities	Level 1	334,695	1	(458)	334,238
U.S. government agency securities	Level 2	38,138	—	(66)	38,072

The amortized cost and fair value of our marketable securities by type of security as of December 31, 2025 are as follows:

(in thousands)	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	Level 1	$ 12,204	$ —	$ —	$ 12,204
U.S. treasury securities	Level 1	78,268	46	—	78,314
U.S. government agency securities	Level 2	49,767	15	(1)	49,781

The fair values of marketable securities, by classification, included in the condensed consolidated balance sheets as of March 31, 2026 and December 31, 2025 are as follows:

(in thousands)	As of March 31, 2026	As of December 31, 2025
Cash and cash equivalents	$ 167,223	$ 20,203
Marketable securities	222,385	120,097

As of March 31, 2026 and December 31, 2025, the amounts shown for marketable securities are inclusive of $1.9 million and $0.9 million of earned interest receivable, respectively.

The fair value of available-for-sale debt securities as of March 31, 2026 and December 31, 2025, by contractual maturity, are summarized as follows:

	As of March 31, 2026		As of December 31, 2025	
(in thousands)	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in one year or less	$ 289,398	$ 289,301	$ 114,003	$ 114,047
Due in one year through five years	100,733	100,307	26,237	26,253
Due in five years through ten years	—	—	—	—
Due after ten years	—	—	—	—
Total	$ 390,131	$ 389,608	$ 140,240	$ 140,300

The aggregate fair value of available-for-sale debt securities in an unrealized loss position as of March 31, 2026 and December 31, 2025 was $267.4 million and $9.6 million, respectively. The Company had no realized gains or losses during the three months ended March 31, 2026 or 2025. As of March 31, 2026 and December 31, 2025, the Company believes that the cost basis of our marketable securities is recoverable and no allowance for credit losses was recorded.

5. Stockholders' Equity – Common and Preferred Stock

Common Stock

On December 22, 2025, the Company amended its certificate of incorporation, whereby the Company increased shares of common stock it was authorized to issue to 267.5 million shares of common stock, par value $0.00001 per share, of which 253.4 million were designated as voting common stock and 14.1 million were designated as non-voting common stock. Each share of non-voting common stock was convertible, at the option of the holder thereof, at any time, and without the payment of additional consideration by the holder thereof, into one fully paid and nonassessable share of voting common stock. The Company had no outstanding shares of non-voting common stock as of December 31, 2025. Upon the consummation of the IPO, the Company restated its certificate of incorporation, and as of February 5, 2026, the Company was authorized to issue 200.0 million shares of common stock, par value $0.00001 per share, of which no shares were designated as non-voting common stock and 25.0 million shares of preferred stock, par value $0.00001 per share. The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, power, and preferences of the preferred stockholders.

As of March 31, 2026 and December 31, 2025, a total of 37,340,290 and 749,760 shares of common stock were issued and outstanding, respectively. An aggregate of 2,269,048 shares and 316,668 shares of common stock were reserved for the granting of stock-based compensation under the Company's 2026 Equity Incentive Plan (the"2026 Plan") and 2026 Employee Stock Purchase Plan (the "2026 ESPP"), respectively, as of March 31, 2026. In addition, the Company has reserved sufficient shares of common stock for issuance upon conversion of convertible preferred stock.

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are no cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of common stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Fifth Amended and Restated Certificate of Incorporation.

Preferred Stock

Preferred stock outstanding as of December 31, 2025 consisted of the following:

Preferred Series Shares	Date Sold	Shares Sold	Par Value	Sales Price/Share	Total Proceeds (in millions)	Liquidation Preference as of December 31, 2025 (in millions)
Series A-1	September 2021	6,515,849	$ 0.00001	$ 2.8770	$ 18.7	$ 18.7
Series A-2	September 2021	680,479	0.00001	2.1578	1.5	1.5
Series A-3	September 2021	703,475	0.00001	2.8770	2.0	2.0
Series A-4	April 2023	4,965,572	0.00001	3.0208	15.0	15.0
Series B	November 2024 - February 2025	62,245,805	0.00001	1.2049	75.0	85.4
Series C	October 2025 - November 2025	118,682,683	0.00001	1.2723	151.0	154.8

In connection with the Series A4 Preferred Stock Purchase Agreement, the Company increased the number of shares of common stock authorized from 18,000,000 to 25,500,000 under the Second Amended and Restated Certificate of Incorporation dated as of April 13, 2023.

In connection with the Series B Preferred Stock Purchase Agreement, the Company increased the number of shares of common stock authorized from 25,500,000 to 98,774,582 under the Third Amended and Restated Certificate of Incorporation dated as of November 22, 2024.

In connection with the Series C Preferred Stock Purchase Agreement, the Company increased the number of shares of common stock authorized from 98,774,582 to 267,466,797 under the Fourth Amended and Restated Certificate of Incorporation dated as of December 22, 2025.

Immediately prior to the completion of the IPO on February 5, 2026, all outstanding shares of the Company's Series A1, A2, A3, A4, B and C preferred stock automatically converted into an aggregate of 19,250,410 shares of common stock.

Collectively, the shares of Series A1, A2, A3 and A4 preferred stock are referred to as "Series A preferred stock." The Series B and C preferred stock are referred to as "Senior preferred stock." The following terms detailed below for the Series A, B and C preferred stock are documented in the Company's Fourth Amended and Restated Certificate of Incorporation dated as of December 22, 2025 and other equity-related documents and reflect the rights, preferences and privileges of holders of preferred stock prior to conversion into common stock upon the closing of the IPO:

Conversion

Each share of Series A, Series B and Series C preferred stock, at the option of the holder, was convertible into a number of fully paid and non-assessable common shares as determined by multiplying the number of shares of Series A, Series B and Series C preferred stock being converted by the applicable conversion rate. The conversion rate in effect at any time was determined by dividing the preferred stock issue price by the conversion price in effect at that time. The conversion price applicable (all adjusted for the reverse stock split) to the Series A1 preferred stock was equal to $28.963 per share, the conversion price applicable to the Series A2 preferred stock was equal to $21.7226 per share, the conversion price applicable to the Series A3 preferred stock was equal to $28.963 per share, the conversion price applicable to the Series A4 preferred stock was equal to $30.4104 per share, the conversion price applicable to the Series B preferred stock was equal to $12.1297 per share and the conversion price applicable to the Series C preferred stock was equal to $12.8082 per share. Such initial conversion price, and the rate at which shares of preferred stock may be converted into common stock, was subject to adjustment. See Note 2 for information on the reverse stock split that adjusted the preferred stock conversion ratio.

The Series A, Series B and Series C preferred stock would automatically convert to common stock either upon the closing of a public offering of the Company's common stock at a price of at least 1.2 times the conversion price, noted above, resulting in aggregate proceeds of at least $100.0 million, or upon the written election of a majority of the holders of Senior preferred stock.

Dividends

The Series B and Series C preferred stock contained cumulative dividend rights at the annual rate of 12%, if and when declared by the board of directors (the "Board"), such that the Series B and Series C preferred stockholders, acting as one class, shall first receive, or simultaneously receive, preferential dividends as calculated under the terms of the Company's Third Amended and Restated Certificate of Incorporation prior to Series A and common stockholders receiving any declared dividend. Since inception, no dividends have been declared or paid on the Series B or Series C preferred stock. In connection with the IPO, all outstanding preferred stock converted into common stock. As a result of the conversion, approximately $17.0 million of cumulative undeclared dividends were extinguished.

The Series A preferred stock contained non-cumulative dividend rights at the annual rate of 8%, if and when declared by the Board, such that the holders of the preferred stock, acting as one class, shall receive, or simultaneously receive, preferential dividends as calculated under the terms of the Company's certificate of incorporation prior to common stockholders receiving any declared dividend. As of December 31, 2025, no dividends had been declared by the Board.

Deemed Liquidation Event

Certain transactions were defined as Deemed Liquidation Events, unless waived by the holders of a majority of the outstanding preferred stock. These events generally include a merger or consolidation involving the Company, the sale or disposition of all or substantially all of the Company's assets, a SPAC transaction, or a merger or other business combination with a public company. Transactions in which existing stockholders retain a majority of the voting power of the surviving entity are not considered Deemed Liquidation Events.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of the Company, the Senior preferred stockholders were entitled to receive prior to, and in preference to, any distribution to the Series A preferred and common stockholders, an amount equal to the greater of the applicable Original Issue Price per share plus accrued but unpaid dividends whether or not declared, or such amount per share as would have been payable had all shares of Senior preferred stock been converted to shares of common stock immediately prior to such event of liquidation, dissolution or winding up. In the event that upon liquidation or dissolution, if the assets and funds of the Company were insufficient to permit the payment to preferred stockholders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution would be distributed ratably among the Senior preferred stockholders in proportion to the full preferential amount each was otherwise entitled to receive.

Following the completion of the distributions to the Senior preferred stockholders, the Series A preferred stockholders were entitled to receive prior to, and in preference to, any distribution to the common stockholders, an amount equal to the greater of the applicable Original Issue Price per share plus accrued but unpaid dividends declared, or such amount per share as would have been payable had all shares of Series A preferred stock been converted to shares of common stock immediately prior to such event of liquidation, dissolution or winding up. In the event that upon liquidation or dissolution, if the assets and funds of the Company were insufficient to permit the payment to preferred stockholders of the full preferential amounts, then the entire assets and funds of the Company legally available for distribution were to be distributed ratably among the Series A preferred stockholders in proportion to the full preferential amount each was otherwise entitled to receive. After the distributions described above had been paid in full, the remaining assets of the Company available for distribution would be distributed pro-rata to the common stockholders.

Voting Rights

Each Series A, Series B and Series C preferred stockholder was entitled to the number of votes equal to the number of shares of voting common stock into which such holder's shares were convertible.

Series B Preferred Stock Modification

In connection with the closing of the Company’s Series C preferred stock financing in the fourth quarter of 2025, the Company amended the terms of its Series B convertible preferred stock pursuant to the amended and restated certificate of incorporation. The amendment decreased the liquidation preference of the Series B preferred stock from two to one times the original issuance price per share.

The change in liquidation preference represented a modification of the economic rights associated with the Series B preferred stock. The Company determined that the modification was substantive, and accounted for the transaction as an extinguishment and new issuance of the Series B preferred stock at fair value as of the modification date which resulted in an adjustment of approximately $4.2 million. In accordance with ASC 718-20, the Company recorded this amount as a non-cash adjustment to Series B preferred stock within mezzanine equity and retained earnings. The modification did not involve the issuance of additional shares or the receipt or payment of cash by the Company.

Because the modification represented a reallocation of value among the Company’s preferred shareholders and did not represent a distribution to or from common stockholders, the adjustment did not affect net loss attributable to common shareholders. Accordingly, the modification had no impact on basic or diluted net loss per share for the year ended December 31, 2025.

6. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated as follows:

	Three Months Ended March 31,	
(in thousands except for share and per share amounts)	**2026**	**2025**
Net loss	$ (27,232)	$ (12,400)
Less: Cumulative dividends on Series B preferred stock	988	2,182
Less: Cumulative dividends on Series C preferred stock	1,791	—
Net loss attributable to common stock	(30,011)	(14,582)
Weighted-average number of shares of common stock outstanding, basic and diluted	22,704,124	736,933
Net loss per common share, basic and diluted	$ (1.32)	$ (19.79)

Basic net loss per common share is calculated by dividing the net loss, adjusted for the unpaid cumulative Series B and Series C preferred stock dividends, by the weighted-average number of shares of common stock outstanding during the period. Diluted loss per share is computed by dividing net loss for the period by the weighted-average number of shares of common stock and common stock equivalents outstanding (unless their effect is anti-dilutive) for the period. Common share equivalents include shares issuable upon the exercise of stock options and the conversion of preferred stock. During the three months ended March 31, 2026 and 2025, convertible preferred stock on an as if converted basis and unexercised options have been excluded as their effect is antidilutive. There were no other potentially dilutive, unissued shares of common stock for the three months ended March 31, 2026 and 2025. The Company had no outstanding non-voting common stock as of March 31, 2026 and 2025.

The Company reported net losses for each of the three months ended March 31, 2026 and 2025 and therefore excluded all options and convertible preferred stock from the computation of diluted net loss per common share as their inclusion would have had an antidilutive effect, as summarized below:

	Three Months Ended March 31,	
	2026	2025
Stock options	5,476,081	720,560
Convertible preferred stock	—	7,461,125
Total potentially dilutive shares	5,476,081	8,181,685

7. Stock-Based Compensation

The Company adopted the 2021 Equity Incentive Plan (the “2021 Plan”) to grant option awards to its officers, directors and employees as compensation for their services to the Company. In the fourth quarter of 2025, the Board approved increases to the aggregate shares of common stock available for issuance under the 2021 Plan from 771,832 shares to 4,411,143 shares.

Stock option awards under the 2021 Plan were to be issued at an exercise price of not less than 100% of the fair market value of the voting common stock at the date of the grant. The 2021 Plan was administered by the Board, which had the authority to grant awards, interpret the plan and related agreements, establish rules and regulations, and make all other determinations necessary for its administration. The Board could delegate these powers to a committee. Stock option awards granted under the 2021 Plan generally vest over 36 or 48 months, with 33.3% or 25% vesting one year after the grant date and the remainder vesting in equal monthly installments over the following 24 or 36 months, respectively.

In connection with the IPO in the first quarter of 2026, the Board adopted, and the stockholders approved, the 2026 Plan, which superseded the 2021 Plan. The 2026 Plan had an initial share pool of 4,032,751 shares available to be granted. Additionally, in connection with the IPO, the Board adopted, and the stockholders approved, the 2026 ESPP with an initial share pool of 316,668 shares available to be granted.

During the three months ended March 31, 2026 and 2025, the Company recognized stock-based compensation expense of $5.3 million and $0.2 million, respectively. Stock-based compensation expense for the three months ended March 31, 2026 and 2025 was allocated as follows:

	Three Months Ended March 31,	
(in thousands)	2026	2025
Research and development	$ 1,974	$ 120
General and administrative	3,285	93
	$ 5,259	$ 213

Stock option awards grants in 2025 included 543,635 performance-based stock option awards with both a market condition and a performance condition made in the fourth quarter of 2025. The performance-based stock option awards were earned based upon achievement of specified corporate milestones, including a performance condition related to the completion of the Company's initial public offering and a market condition related to attainment of certain post-IPO market capitalization levels. The weighted average grant date fair value of awards subject to both a market condition and a performance condition was $5.13. The Company achieved these milestones in the first quarter of 2026, resulting in the full vesting of the awards and recognition of $2.8 million in stock-based compensation in the first quarter of 2026.

In connection with the IPO in the first quarter of 2026, stock option awards to purchase an aggregate of 1,705,791 shares of Common Stock with time-based vesting conditions were granted to employees and members of the Company's Board with a weighted average grant date fair value of $12.58.

8. Commitments and Contingencies

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of March 31, 2026 and December 31, 2025, there were no matters which would have a material impact on the Company's financial results.

In July 2022, the Company entered into a license agreement to which the Company was granted intellectual property rights in certain technology, to develop, manufacture and commercialize such technology related to the advancement of its VDMC asset. The Company is required to make development and regulatory milestone payments up to $3.3 million and commercial and sales milestone up to $16.0 million. The Company is also required to pay annual single-digit royalties on net product sales over the term of the license agreement. As of March 31, 2026, it is not practicable to estimate the future payments of any such milestone payments or royalties that may arise due to the clinical stage of development of VDMC.

9. Development and Manufacturing Agreement and Master Service Agreement

Master Service Agreement

In September 2020, the Company entered into a Master Service Agreement (the "MSA"). The MSA provides the terms and conditions upon which the Company may engage for the purpose of managing the preclinical and clinical development of its products in the field of dermatology, and other related services or projects, by executing work orders specifying the details of the service and the related terms and conditions. The MSA automatically renews for additional 1-year terms until the MSA is terminated upon written notice. Either party may terminate a work order for material breach (subject to a cure period) and the Company may terminate any work order for any reason on 90 days' written notice, subject to payment of fees earned and expenses payable, in addition to a termination fee equal to a low-double-digit percentage of the remaining work order budget. As of March 31, 2026, there are no outstanding work order cancellation fees.

During the three months ended March 31, 2026 and 2025, the Company recognized research and development expense of $10.5 million and $8.6 million, respectively, in connection with the MSA. As of March 31, 2026 and December 31, 2025, the Company has deposits with the counterparty of $1.9 million and $4.1 million, respectively, which is included in prepaid expenses on its condensed consolidated balance sheets.

Collaboration Agreement

In September 2020, the Company entered into a Collaboration Agreement, pursuant to which the counterparty serves as the exclusive provider of certain clinical trial management, regulatory, and related CRO services through completion of Work Order Number One of the MSA noted herein. In connection with the agreement, the Company issued the counterparty an unsecured convertible promissory note with a principal amount of approximately $0.5 million, which was converted into 238,008 shares of Series A-2 Preferred Stock in September 2021. The agreement may be terminated by the Company upon payment of a mid-six-figure liquidated damages amount, subject to reduction based on completed in-human clinical studies. As of March 31, 2026, there are no outstanding termination fees.

10. Related Party Transaction

Agreements with Green Line Talent Group LLC

In December 2024, the Company entered into certain talent search agreements with Green Line Talent Group LLC, or Green Line, a related party in accordance with ASC 850, *Related Party Disclosures,* pursuant to which the Company retained Green Line on an exclusive basis to provide end-to-end recruitment services for various roles. The agreements are considered related party transactions as a Partner at Green Line is the spouse of the Company's Chief Financial Officer. During the three months ended March 31, 2026 and 2025, the Company paid Green Line $0.2 million and less than $0.1 million, respectively, pursuant to the talent search agreements.

11. Segments

The Company defines its segments on the basis of the way in which internally reported financial information is regularly reviewed by the Chief Operating Decision Maker, or CODM, to analyze financial performance, make decisions, and allocate resources. The Company's CODM is the Chief Executive Officer. The Company manages its operations as a single operating and reportable segment and the measure of segment profit or loss is net loss. The CODM uses net loss in the budget and forecasting process and considers budget-to-actual variances on a quarterly basis when making decisions about the allocation of operating and capital resources. The following table summarizes the significant segment expenses presented on the Company's condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended March 31,	
(in thousands)	**2026**	**2025**
Direct research and development by program		
VDPHL01	17,188	9,278
VDMN	149	1,118
VDMC	26	7
VDAA	1	1
Other program candidates and expenses	—	80
Other unallocated research and development costs		
Personnel expenses (including share-based compensation)	3,476	879
Other expenses	85	84
General and administrative, excluding personnel expenses	4,608	1,050
General and administrative, personnel expenses (including share-based compensation)	4,329	418
Other segment items[(1)]	(2,630)	(515)
Segment net loss	(27,232)	(12,400)

(1) For the three months ended March 31, 2026 other segment items include interest income of $2.5 million and investment accretion of $0.1 million. For the three months ended March 31, 2025, other segment items include interest income of $0.5 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes included in our Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, 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 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 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, 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 pharmacokinetics and pharmacodynamics qualities that raise the ceiling of hair growth.

The following milestones have been achieved to date through the first quarter of 2026:

- completion of enrollment in our confirmatory registration-directed Phase 3 trial in male patients with mild-to-moderate PHL; and
- completion of our initial public offering, or IPO, pursuant to which we issued and sold an aggregate of 17,339,294 shares of common stock at a price to the public of $17.00 per share, including 2,261,647 shares issued upon the exercise in full of the underwriters' over-allotment option to purchase additional shares. We received aggregate net proceeds of $269.1 million after deducting underwriting discounts, commissions and offering expenses.

Subsequent to the first quarter of 2026, the following milestones have been achieved:

- In May 2026, we completed our underwritten public offering, or the Follow-On Public Offering, of 4,420,358 shares of our common stock, par value $0.00001 per share, or Common Stock, at a public offering price of $100.00 per share, including 576,568 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The gross proceeds from the Follow-On Public Offering were approximately $442.0 million,

before deducting underwriting fees and discounts. Concurrently with the Follow On Public Offering, on May 1, 2026, we closed a private placement, or the Private Placement, pursuant to a Securities Purchase Agreement, or the Purchase Agreement, dated April 29, 2026, among us and certain entities affiliated with Suvretta Capital, or each, an Investor, and collectively, the Investors, in which we sold to the Investors pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 300,000 shares of Common Stock, at an offering price of $99.99999 per Pre-Funded Warrant. The gross proceeds of the Private Placement were approximately $30.0 million, before deducting placement agent fees and other expenses.

Recent Developments

Study '302' Data

On April 27, 2026, we announced positive topline data from the Phase 2/3 clinical trial, or Study '302', evaluating VDPHL01 in males with mild-to-moderate PHL. Study '302' is a multi-center, randomized, placebo-controlled study evaluating the clinical efficacy, safety, and tolerability in 519 enrolled patients who were randomized to receive either VDPHL01 8.5mg once daily, or QD, VDPHL01 8.5mg twice daily, or BID, or placebo. The trial met all primary and all key secondary endpoints with statistical significance, demonstrating a potentially differentiated clinical profile defined by rapid onset of activity, consistent response across patients, and robust increases in hair count while being generally well tolerated with no treatment-related serious adverse events, or SAEs, and no adverse events of special interest, or AESIs, of cardiac origin.

In the study, VDPHL01 achieved superior hair growth compared with placebo ($p<0.0001$) on the co-primary endpoints of non-vellus Target Area Hair Count, or TAHC, and patient reported outcome, or PRO, benefit of 'improved' or 'much improved' on the Androgenetic Alopecia Impact Rating Scale, or AAIRS, at Month 6. Patients achieved an average increase in non-vellus TAHC of 30.3 hairs/cm² ($p<0.0001$) and 33.0 hairs/cm² ($p<0.0001$) in QD and BID VDPHL01 treatment arms, respectively. Those receiving placebo only showed a 7.3 hairs/cm² increase from baseline at Month 6.

Following 6 months of treatment with VDPHL01, 79.3% of patients in the QD dose arm ($p<0.0001$) and 86.0% of patients in the BID dose arm ($p<0.0001$) reported improvement in hair coverage on the AAIRS versus 35.6% of placebo patients. Additionally, 48.4% of patients in the QD dose arm ($p<0.0001$) and 62.9% of patients in the BID dose arm ($p<0.0001$) achieved 'improved' or 'much improved' hair coverage on the AAIRS compared to only 13.4% of placebo patients.

In addition to meeting the co-primary endpoints, the study also met the key secondary endpoints. Investigator perception was measured with investigators grading 72.0% (QD; $p<0.0001$) and 84.4% (BID; $p<0.0001$) of male patients as having improved hair coverage at Month 6 ($p<0.0001$). Rapid onset of hair growth was also observed at the earliest measured time point measured in the trial, with statistically significant separation from placebo on TAHC and IGA as early as Month 2.

Treatment with VDPHL01 was generally well tolerated through Month 6 with overall treatment-emergent adverse events, or TEAEs, rates similar between VDPHL01 and placebo, and with an overall safety profile consistent with Phase 2. VDPHL01 demonstrated lower discontinuation rates than placebo, and the adverse event-related discontinuation rate was similar between active and placebo. No treatment-related SAEs and no AESIs of cardiac origin were observed in the study. The most common TEAEs occurring in greater than 5% of patients vs. placebo included peripheral edema (5.3% QD, 6.3% BID) and hypertrichosis (3.5% QD, 6.3% BID). These TEAEs resulted in approximately 1% discontinuation for both QD and BID dosing groups for peripheral edema and no discontinuations occurred related to hypertrichosis in either the QD or the BID dosing groups.

Other Updates

Following the receipt of the Study '302' topline data, we fielded a double-blind proprietary market research survey with 153 health care providers, or HCPs, and 190 male patients to gauge early reactions to the male Study '302' topline data. The results of this proprietary market research survey indicated robust intent to prescribe and use VDPHL01 among HCPs and male patients if approved by the FDA:

- 91% of surveyed HCPs viewed VDPHL01 as being positively differentiated versus the currently available treatment options for PHL and 63% of HCPs say VDPHL01 is very or extremely differentiated. 73% of HCPs also indicated they would be either very or extremely likely to prescribe VDPHL01 once approved. HCPs in the study also indicated that they would expect to treat 52% of their male PHL patients with VDPHL01.

- 95% of surveyed patients viewed VDPHL01 as being positively differentiated versus the currently available treatment options for PHL and 71% of patients said VDPHL01 is very or extremely positively differentiated. 71% of patients also indicated they would be highly likely to talk to their doctor about VDPHL01.

Additionally, the Company expects to release 12-month data from this 302 study and additional Phase 2 data in 2026.

Overview of the Company's Financial Condition and Results of Operations

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 and proceeds from our IPO.

We have incurred recurring net losses since inception, including net losses of $27.2 million and $12.4 million for the three months ended March 31, 2026 and 2025, respectively. We have incurred negative cash flows from operations of $21.2 million and $13.3 million for the three months ended March 31, 2026 and 2025, respectively. In addition, as of March 31, 2026, the Company had an accumulated deficit of $150.7 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 U.S. Securities and Exchange Commission, or 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 and other income and expense items.

Results of Operations

Comparison of the three months ended March 31, 2026 and 2025

The following table summarizes our results of operations:

(in thousands)	Three Months Ended March 31, 2026	2025	CHANGE
Operating Expenses:			
Research and development	$ 20,925	$ 11,447	$ 9,478
General and administrative	8,937	1,468	7,469
Total operating expenses	29,862	12,915	16,947
Loss from operations	(29,862)	(12,915)	(16,947)
Total other income, net	2,630	515	2,115
Income tax benefit	—	—	—
Net loss	$ (27,232)	$ (12,400)	$ (14,832)

Operating Expenses

Research and Development Expenses

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

(in thousands)	Three Months Ended March 31, 2026	2025	CHANGE
VDPHL01	$ 17,188	$ 9,278	$ 7,910
VDMN	149	1,118	(969)
VDMC	26	7	19
VDAA	1	1	—
Other program candidates and expenses	—	80	(80)
Other unallocated research and development costs			
Personnel expenses (including stock-based compensation)	3,476	879	2,597
Other expenses	85	84	1
Total research and development expenses	$ 20,925	$ 11,447	$ 9,478

Research and development expenses were $20.9 million for the three months ended March 31, 2026, compared to $11.4 million for the three months ended March 31, 2025. The increase of $9.5 million was primarily due to:

- a $7.9 million increase in costs related to VDPHL01 primarily due to a $2.4 million increase in clinical trial expenses, including investigator fees, pass-through costs, and program management fees which resulted from expanded registration-directed and confirmatory clinical trial activity in the first quarter of 2026 compared to the prior period, as well as a $1.7 million increase in clinical trial recruitment costs. The increase in VDPHL01 costs also include additional medical education activities as compared to the prior year. The remaining increase in VDPHL01 costs 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 $2.6 million increase in personnel-related costs, including stock-based compensation expense, primarily due to expense recognized on performance stock options in the first quarter of 2026 as well as an increase in research and development related headcount as compared to the same period in the prior year;

These increases were partially offset by:

- a decrease in costs related to VDMN and other program candidates and expenses of $1.0 million and $0.1 million respectively. These decreases were primarily attributable to the Company's decision to pause activities related to these programs to focus efforts on VDPHL01, which resulted in decreases in chemistry, manufacturing, and control activities as well as clinical trial expenses for VDMN and other program candidates.

General and Administrative Expenses

General and administrative expenses were $8.9 million for the three months ended March 31, 2026, compared to $1.5 million for the three months ended March 31, 2025. The increase of $7.5 million was primarily due to:

- a $3.9 million increase in payroll and personnel-related costs, including stock-based compensation, as a result of expense recognized on performance stock options in the first quarter of 2026 as well as an increase in general and administrative related headcount;
- a $2.3 million increase in commercial readiness costs related to VDPHL01; and
- a $0.8 million increase in other professional fees associated with preparations for becoming a public company and operating as a public company subsequent to our IPO.

Total Other Income, Net

Total other income, net, was $2.6 million for the three months ended March 31, 2026, compared to $0.5 million for the three months ended March 31, 2025. The increase of $2.1 million is primarily attributable to a $2.0 million increase in interest income on greater average cash and investment balances during the period.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through equity financings. Through March 31, 2026, we had received proceeds of approximately $263.2 million, net of issuance costs of $1.1 million, from the sale of our Series A, Series B and Series C redeemable convertible preferred stock and proceeds of approximately $269.1 million, net of issuance costs of $25.7 million, from our IPO. In May 2026, we completed the Public Offering and the Private Placement, from which we received gross proceeds of $472.0 million. As of March 31, 2026, we had $390.8 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

We completed our IPO in the first quarter of 2026, from which we received gross proceeds of $294.8 million. In May 2026, we completed the Public Offering and the Private Placement, from which we received gross proceeds of $472.0 million. The net proceeds from the IPO, the Public Offering and the Private Placement, together with our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2030, based on our current operating plans. 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 VDPHL01 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.

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:

(in thousands)	Three Months Ended March 31, 2026	Three Months Ended March 31, 2025
Net cash used in operating activities	$ (21,168)	$ (13,317)
Net cash used in investing activities	(101,299)	(15,750)
Net cash provided by financing activities	269,113	8,423
Net increase (decrease) in cash and cash equivalents	$ 146,646	$ (20,644)

Operating Activities

Net cash used in operating activities was $21.2 million for the three months ended March 31, 2026 and primarily consisted of a net loss of $27.2 million adjusted for non-cash items, including stock-based compensation expense of $5.3 million, non-cash research and development services of $0.6 million, and net accretion on discount/premium of debt securities of $0.1 million, as well as the change in our net working capital.

Net cash used in operating activities $13.3 million for the three months ended March 31, 2025, and primarily consisted of a net loss of $12.4 million adjusted for non-cash items, including stock-based compensation expense of $0.2 million and non-cash research and development services of $0.4 million, as well as the change in our net working capital.

Investing Activities

Net cash used in investing activities was $101.3 million for the three months ended March 31, 2026 as compared to $15.8 million for the three months ended March 31, 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 $269.1 million for the three months ended March 31, 2026 as compared to $8.4 million for the three months ended March 31, 2025. The increase was primarily attributable to proceeds of $269.1 million from our initial public offering, compared to proceeds of $8.4 million from the issuance of our Series B financing in the prior year.

Contractual Obligations

In February 2025, we entered into an office lease agreement in New Haven, Connecticut for a total of 1,202 square feet. This lease agreement provided the option to move to a larger space within the building during the term of the lease agreement, which we chose to do in April 2026. The new leased space is 6,336 square feet and the revised lease agreement expires in April 2029, with an 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 March 31, 2026 through the end of the lease term are approximately $0.6 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 March 31, 2026 and December 31, 2025 there were no amounts accrued related to termination charges.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or 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 the consolidated financial statements for the year ended December 31, 2025 included in the Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our condensed 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 has not 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. Prior to the completion of our IPO, the fair value was determined by our Board, 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. Subsequent to the completion of our IPO, we continue to use the Black-Scholes model to determine the fair value of awards but now utilize our closing market price of our common stock on the date of grant as an input to the model and have adopted the use of the simplified method for expected term, which calculates the term as the midpoint between the vesting term and contractual term of the grant.

We estimate the fair value of awards subject to both a market condition and a performance condition on the grant date using a Monte Carlo simulation model. For awards with vesting subject to the fulfillment of both market and performance conditions, stock-based compensation expense is recognized using the accelerated attribution method beginning when the achievement of the performance condition becomes probable over the applicable service period. The amount of stock-based compensation expense is dependent on our periodic assessment of the probability of the performance condition being satisfied and our estimate, which may vary over time, of the number of shares that will ultimately be issued. If the performance condition is not met, no compensation expense is recognized, and any previously recognized compensation cost is reversed. The Monte Carlo simulation model requires various subjective assumptions that represent management's best estimates of the fair value of common stock, expected equity volatility, risk-free interest rate, discount period, expected dividend yield, and expected time to achievement of a performance condition. Expected volatility was based on historical volatility of publicly-traded peer companies; 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. Expected time to achieve performance condition is based on our best estimate of the period of time it will take to achieve the specified performance condition.

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 our IPO, 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 the consolidated financial statements for the year ended December 31, 2025 included in the Annual Report.

Common Stock Valuations

Prior to our IPO there was no public market for our common stock, and therefore, the estimated fair value of our common stock had been determined by our Board 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, 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 IPO, 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.

A public trading market for our common stock was established in connection with our IPO in the first quarter of 2026; therefore, it will no longer be necessary for our Board 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.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We qualify as an "emerging growth company" as defined in 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 nonbinding 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 remain classified as an emerging growth company until December 31, 2031, 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.

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 following our IPO is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company 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.

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 condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Not Applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company on the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including, our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There has been no change in our internal control over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources, negative publicity and reputational harm and other factors.

Item 1A. Risk Factors

Investors should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our condensed consolidated financial statements and 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 $1,029.8 million in gross proceeds from equity financings to date, including $294.8 million of gross proceeds from our IPO and $472.0 million from the Public Offering and the Private Placement. 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 three months ended March 31, 2026 and 2025 were $27.2 million and $12.4 million, respectively. As of March 31, 2026, we had an accumulated deficit of $150.7 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 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.

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, 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 prior to our IPO.

We completed our IPO for gross proceeds of $294.8 million in the first quarter of 2026. As of March 31, 2026, we had $390.8 million in cash, cash equivalents and marketable securities. Subsequent to March 31, 2026, we completed the Follow-On Public Offering and the Private Placement, from which we received gross proceeds of $472.0 million, before deducting underwriting fees and discounts, and placement agent fees and other expenses. We expect our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2030, based on our current operating plans. 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, 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 prior to our IPO. 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 which may impose 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 registration-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 April 2026, we reported topline data in male patients from Study '302'; 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.

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, suffer 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 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 our Annual Report on Form 10-K should be viewed with caution. Further, the data and statistical information used in our Annual Report on Form 10-K, 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, our Chief Commercial and Strategy Officer, Mark Neumann, 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 March 31, 2026, we had 24 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”. 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 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 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 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, 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 TCPA, the CAN-SPAM Act, and similar state consumer protection and communication privacy laws, such as 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 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 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 is 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 Ownership of Our Common Stock

An active and liquid trading market for our common stock may not be sustained.

Our common stock is listed on NYSE under the symbol "MANE." If an active or liquid trading market is not sustained, our stockholders may be unable to resell shares of our common stock at a price that a stockholder considers reasonable. Furthermore, an inactive market may reduce the fair market value of your shares, impact 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.

Since shares of our common stock were sold in our IPO in February 2026 at a price of $17.00 per share and through May 1, 2026, the per share price of our common stock has ranged from $17.00 to $114.50. 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 Quarterly Report, 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.

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 United States and Israeli military actions against Iran, 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.

A significant portion of our total outstanding shares are, as of the date of filing this Quarterly Report on Form 10-Q, restricted from immediate resale but may be sold into the market upon expiration of the lock-up agreement entered into in connection with our IPO, 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 entered into by holders of substantially all of our common stock outstanding immediately prior to our IPO, 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. As of May 7, 2026, we had 41,778,687 shares of common stock outstanding. Of these shares, 17,339,294 shares sold in our IPO and 4,420,358 shares sold in the Public Offering may be resold in the public market immediately, unless held by our affiliates. The remaining shares are currently restricted under securities laws or other agreements, subject in some cases to applicable volume limitations under Rule 144 beginning after the close of trading on August 2, 2026.

Additionally, holders of an aggregate of approximately 23,594,826 shares of our common stock, excluding shares purchased by non-affiliates in or after the IPO, 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 have registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares 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 entered into in connection with our IPO. 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 have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, beneficially own shares representing approximately 43% of our outstanding common stock as of May 7, 2026. 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 our Annual Report on Form 10-K, we did not include 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 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 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 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. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our Board 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;
- 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 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 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 designates 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 provides 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 further provides 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 provides 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 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.

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.

We will not receive significant additional funds upon the exercise of the Pre-Funded Warrants sold in the Private Placement.

Each Pre-Funded Warrant sold in the Private Placement may be exercised by way of a cashless exercise, meaning that the holder may choose not to pay a cash purchase price upon exercise, and instead would receive, upon such exercise, the net number of shares of common stock determined according to the formula set forth in the Pre-Funded Warrant. Accordingly, we may not receive any additional funds upon the exercise of the Pre-Funded Warrants. In addition, the Pre-Funded Warrants have an exercise price of $0.00001 per pre-funded warrant, and as a result we will not receive significant additional funds upon their exercise, even if exercised for cash.

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 United States and Israeli military action against Iran and 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 have incurred, and 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.

As a public company, we have incurred, 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, 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, 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.

We are 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 March 31, 2026, we had federal and state NOL carryforwards of approximately $180.3 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

From January 1, 2026 to February 5, 2026 (the date of the filing of our registration statement on Form S-8, File No. 333-293238), we issued and sold to an employee an aggregate of 8,319 shares of Common Stock, before giving effect to the reverse stock split as part of our IPO, or 826 shares of Common Stock, after giving effect to the reverse stock split as part of our IPO, upon the exercise of stock options under our 2021 Stock Plan at an exercise price of $1.27 per share, for an aggregate purchase price of $10,565.13.

Use of Proceeds

On January 30, 2026, the Company's registration statement on Form S-1 (File No. 333-292657), or the IPO Prospectus, related to our IPO became effective.

There has been no material change in the planned use of proceeds from our IPO from that described in the IPO prospectus.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During our fiscal quarter ended March 31, 2026, certain of our directors or "officers," (as defined in Rule 16a-1(f) under the Exchange Act) entered into a contract, instruction or written plan for the purchase or sale of our securities that is intended to satisfy the conditions specified in Rule 10b5-1(c) under the Exchange Act for an affirmative defense against liability for trading in securities on the basis of material nonpublic information. We refer to these contracts, instructions, and written plans as "Rule 10b5-1 trading plans" and each one as a "Rule 10b5-1 trading plan."

We describe the material terms of these Rule 10b5-1 trading plans in the table below.

Rule 10b5-1 Trading Plans

Director/Officer	Action and Date of Action	Commencement of Trading Period	Scheduled Termination of Trading Period (1)	Security Covered	Maximum Number of Securities to be Purchased or Sold Pursuant to the Rule 10b5-1 Trading Plan (2)	Covers Purchase or Sale
Reid Waldman	Adoption 03/05/2026	08/17/2026	08/18/2027	Common Stock	135,000	Sale
Timothy Durso	Adoption 03/05/2026	08/17/2026	08/18/2027	Common Stock	87,000	Sale

(1) The plan is subject to earlier termination under certain circumstances specified in the plan, including upon the sale or purchase (as applicable) of all shares subject to the plan and upon either party to a plan giving notice of termination within the time prescribed under the plan.
(2) Subject to adjustments for stock splits, stock combinations, stock dividends and other similar changes to our common stock.

Item 6. Exhibits

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
3.1	Restated Certificate of Incorporation of the Company, (incorporated by reference to Exhibit 3.1 to the Form 8-K filed on February 5, 2026).
3.2	Amended and Restated Bylaws of the Company, (incorporated by reference to Exhibit 3.2 to the Form 8-K filed on February 5, 2026).
4.1	Specimen stock certificate evidencing shares of common stock, (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on January 28, 2026).
4.2	Third Amended and Restated Investors' Rights Agreement, dated as of October 14, 2025 among the Company and certain of its stockholders, (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.1#	Veradermics, Incorporated 2026 Employee Stock Purchase Plan, (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.2#	Form of Veradermics, Incorporated 2026 Equity Incentive Plan, (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8 filed on February 5, 2026).
10.3#	Form of Non-Statutory Stock Option Agreement under the 2026 Equity Incentive Plan, (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.4#	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under the 2026 Equity Incentive Plan, (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.5#	Form of Incentive Stock Option Agreement under the 2026 Equity Incentive Plan, (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.6#	Veradermics, Incorporated 2026 Cash Incentive Plan, (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.7#	Amended and Restated Employment Agreement between the Company and Reid Waldman, (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.8#	Amended and Restated Employment Agreement between the Company and Timothy Durso, (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.9#	Employment Agreement between the Company and Dominic Carrano, (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed on January 28, 2026).
10.10#	Form of Indemnification Agreement between the Company and each of its directors and executive officers, (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed on January 28, 2026).

31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Filed herewith.

# Indicates management contract or compensatory plan.

† This certification will not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 12, 2026

VERADERMICS, INCORPORATED

By: /s/ Reid Waldman, M.D.
Name: Reid Waldman, M.D.
Title: Chief Executive Officer
(Principal Executive Officer)

By: /s/ Dominic Carrano, CPA
Name: Dominic Carrano, CPA
Title: Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Reid Waldman, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Veradermics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2026

/s/ Reid Waldman, M.D.
Reid Waldman, M.D.
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
PURSUANT TO 17 CFR 240.13a-14
PROMULGATED UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dominic Carrano, CPA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Veradermics Incorporated;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2026

/s/ Dominic Carrano, CPA
Dominic Carrano, CPA
Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Veradermics Incorporated (the "Company") on Form 10-Q for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Reid Waldman, M.D., Chief Executive Officer and Director of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"); and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Reid Waldman, M.D.

Reid Waldman, M.D.
Chief Executive Officer (Principal Executive Officer)
May 12, 2026

This certification accompanies each Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

A signed original of this written statement required by Section 906 has been provided by the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Veradermics Incorporated (the "Company") on Form 10-Q for the quarter ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dominic Carrano, CPA, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"); and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dominic Carrano, CPA

Dominic Carrano, CPA
Chief Financial Officer and Treasurer (Principal Financial Officer)
May 12, 2026

This certification accompanies each Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

A signed original of this written statement required by Section 906 has been provided by the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

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